User/Operator Manual

English Non-USA

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Tempus Pro

Patient Monitor

Software versions 4.40 & 7.40

PHILIPS

Manufacturer's address

Tempus Pro is designed and manufactured by:

Remote Diagnostic Technologies Ltd.
Ascent 1
Farnborough Aerospace Centre
Aerospace Boulevard
Farnborough
Hampshire
GU14 6XW
United Kingdom

Tel: +44 (0) 1256 362 400
Email: rdt_info@philips.com
www.philips.com

CE
0413

EC REP Philips Medical Systems Nederland B.V.
Veenpluis 6
5684PC Best
The Netherlands

Australian TGA sponsor:
Philips Electronics Australia Ltd
65 Epping Road
North Ryde
NSW Australia 2113

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About this manual

This manual is for the Tempus Pro patient monitor with printer, hardware versions 00-1024-R and 00-1026-R, and non-printer models 00-1007-R. All Tempus Pro versions with software versions 4.40 & 7.40 installed.

References to i2i Reachbak Telemedicine have been removed from this manual as it has been discontinued for sale and will no longer be supported as of February 28th, 2027. To access information on i2i, including the exclusive voice and video functions, please refer to your current or previous versions of the IFU.

All Tempus Pro® monitors have a standard configuration that provides ECG monitoring, non-invasive blood pressure (NIBP), pulse oximetry (SpO_2) and impedance respiration. Additional functions are available depending on Tempus Pro part number:

- 00-1007-R: standard configuration with IBP (2 channels), $EtCO_2$, contact temperature (1 or 2 channels)
- 00-1004-R is no longer available for purchase
- 00-1024-R: standard configuration with printer, $EtCO_2$ and contact temperature (1 or 2 channels).
- 00-1026-R: standard configuration with printer, Invasive Blood Pressure (IBP)(2 channels), $EtCO_2$ and contact temperature (1 or 2 channels).

Tempus Pro pulse oximetry provides the standard SpO_2, pulse rate and perfusion index (PI) measurements but also has the capability to monitor carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), total oxygen content (SpOC) and pleth variability index (PVI).

The Tempus Pro is supplied in different configurations depending on the customer's requirements. This manual is written to cover all Tempus Pro features and therefore details regarding optional features will not be applicable to all units.

Important
If any serious incident has occurred in relation to the device it should be reported to Remote Diagnostic Technologies Limited and the competent authority of the Member State in which the user and/or patient is established.

Document library

Consult the instructions for use. These are provided in electronic format in the Philips Document Library.

Important
Please check the Philips Document Library regularly for new versions of this document.

A paper copy of this document may be requested from the Philips Document Library or by sending a request to RDT_Customerservice@philips.com.

Use of this manual

The instructions and safety precautions provided in this manual must be observed during all phases of the operation, usage, service or repair of the Tempus Pro and its accessories.

Failure to comply with the information contained in this manual e.g. warnings, precautions, instructions etc. will violate the safety standards of design, manufacture and intended use of the products. Remote Diagnostic Technologies Ltd. ('RDT') assumes no liability for customer failure to comply with the information contained in this manual.

For a list of accessories with RDT part numbers, refer to the spares list in "Accessories list".

Important
If any cable or sensor is damaged or does not work, it should be unplugged and replaced. The part numbers of the various probes and cables are given in "Accessories list". Replacement parts can be ordered from RDT, see "Manufacturer's address".

WARNING
The Tempus Pro is intended to be operated by clinically qualified personnel only. This manual, as well as accessory directions for use and all precautionary information and specifications should be read before use.

CAUTION
Separate manuals are provided for the set up and maintenance of the Tempus Pro. These manuals are intended for the communications engineers and bio-medical engineers responsible for such activities.

Safety and note icons

The following icons are used to indicate safety, caution and warning messages (per ISO 3864-2):

DANGER
Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION
Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

The note icon is used for important and helpful information:

Indicates a condition that may lead to equipment damage or malfunction.

A point of particular interest or emphasis intended to provide more effective or convenient operation.

CapnoLine®, Smart CapnoLine® O2, Smart CapnoLine® Plus, Smart CapnoLine® Plus O2, Smart CapnoLine® H Plus, Smart CapnoLine® H Plus O) and Integrated Pulmonary Index™ (IPI).

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Inseego™ and the Inseego logo are trademarks of Inseego Corp.

CE statement

Marking by the 0413 symbol indicates compliance of this medical device to the Medical Devices Directive (MDD) 93/42/EEC (as amended) and the Radio Equipment Directive (RED) 2014/53/EU (as amended). The CE mark is accompanied by the number 0413 which is the reference number for the MDD 93/42/EEC Notified Body who certify RDT's quality system.

The Tempus Pro is a class IIb device under the MDD and is a class I device (harmonized frequencies) under the Radio Equipment Directive (RED) 2014/53/EU.

A Declaration of Conformity in accordance with the above regulations has been made and is on file with RDT at the "Manufacturer's address". The wireless portion of this equipment may be operated in GB, France, Italy, Switzerland, Germany, Holland, Portugal, Spain, Sweden, Norway, Denmark and Finland.

FDA prescription statement

Federal law (USA) restricts the use or sale of this device by, or on the order of, a physician.

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1 Introduction to the Tempus Pro

This chapter contains the following topics:

1.1 Intended purpose

WARNING
Access to the device must be limited to authorized users. It is important that you consider physical security measures to ensure that unauthorized users cannot gain access.

The Tempus Pro is a portable vital signs monitor for clinical and pre-hospital care applications. It is for the attended or unattended monitoring of single or multiple vital signs. Users must be clinicians or medically qualified personnel.

The Tempus Pro is a transportable medical device that can be used in rotary and fixed wing aircraft as well as land based ambulances.

1.1.1 Indications for use

The device is indicated for: 3- and 5-lead ECG monitoring; 12-lead ECG recording with interpretation; real-time arrhythmia detection / alarming; QT measurement / alarming and ST measurements / alarming; impedance pneumography; non-invasive blood pressure (NIBP); end-tidal CO_2 ($EtCO_2$) and respiration rate; pulse oximetry (SpO_2); contact temperature; and Invasive Blood Pressure (IBP) and extended pulse oximetry capability including; carboxyhemoglobin (SpCO), methemoglobin (SpMet), total hemoglobin (SpHb) and total oxygen content (SpOC) measurements.

The Tempus Pro does not replace a physician’s care. The device is not an apnea monitor.

The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).

The monitor can be used to display images from Interson 3.5 MHz General Purpose (GP) and 7.5 MHz Small Parts / Vascular (SR) USB ultrasound probes or a Karl Storz C-MAC S USB video laryngoscope. The monitor can also be used to display the following readings from a Masimo ISA OR+ gas module(*): end-tidal and fractionally inspired CO2, O2, N2O, Halothane, Isoflurane, Enflurane, Sevoflurane, and Desflurane. These optional accessories are to be used in accordance with their indications for use.

(*) Anesthetic agent monitoring is not cleared for use with the Tempus Pro in Canada, the USA or Singapore.

1.1.2 Contraindications

The Tempus Pro is not intended to be used in strong magnetic or electro-magnetic fields which are generated by MRI, electrocautery equipment, diathermy equipment, and other sources of EM disturbances for medical purposes

1.1.3 Patient target populations

The patient target groups for use of the Tempus Pro are adults, pediatrics and neonates.

1.1.4 Intended users

RDT assumes that users of the product are clinically trained in how to take and interpret a patient's vital signs.

While the Tempus Pro has been designed as a good quality monitor; RDT reminds users that no monitor can replace good clinical judgement or the care and attention of a clinician. Before attempting to work with this equipment, the user must read, understand, note, and strictly observe all warnings, cautions and safety markings in this manual and labels on the equipment.

RDT recommend users complete an approved training course in the use of Tempus Pro and familiarizes themselves with the product before use.

1.1.5 Clinical benefits

The use of the Tempus Pro, a portable vital signs monitor, is associated with the following clinical benefits:

- Provides multiple, simultaneous clinical parameters measurement.
- Provides these measurements in real time, before hospital admission.
- Enables detection of changes (or absence of changes) in the clinical status of a patient.
- Increases likelihood of early and accurate diagnosis. This leads to the most appropriate patient treatment and management.

1.1.6 Undesirable side-effects

Our reports show that no undesirable side-effects occur when the Tempus Pro user obeys the correct instructions. The user must follow the instructions in this manual.

1.2 General warnings, cautions and notes

The use of the  or the  symbols indicate that the user must read the user manual before using the product.

Before you unpack, use, maintain or dispose of the Tempus Pro you must read and understand the following:

DANGER
ELECTRICAL SHOCK HAZARD when covers are removed. Do not remove covers. Refer servicing to qualified personnel authorized by RDT

DANGER
Explosion Hazard: DO NOT use the Tempus Pro in the presence of flammable gases such as fuels. Use of the Tempus Pro in such environments may present an explosion hazard.

WARNING
The FilterLine may ignite in the presence of O_2. when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent flammability of the FilterLine or surrounding surgical drapes.

WARNING
When used with the Tempus Pro AC/DC adapter, to avoid the risk of electric shock, the power supply must be connected to a mains supply with a protective earth.

WARNING
Do not connect the Tempus Pro to an electrical outlet controlled by a dimmer.

WARNING
To ensure patient electrical isolation, only connect the Tempus Pro to other systems that are compliant with the relevant IEC standard, such as 62368-60950, and which employ electronically isolated circuits.

Electrical isolation can be achieved through either removal of the electrical mains plug or through an isolation switch which switches both poles simultaneously. Reference IEC 60601-1.

Signal input and output connectors are only for the connection of equipment that complies with the relevant IEC safety standards and must be configured to comply with IEC 60601-1 3.1, 60601-1-1 or IEC 60601-1.

WARNING
It is recommended that the Tempus Pro operates on batteries when in an emergency medical service environment.

WARNING
Attaching different medical systems together can cause increases in leakage currents. If the Tempus Pro is connected to other medical devices, or if the patient has multiple devices attached to them at the same time, the cumulative effect of leakage currents must be considered.

WARNING
Do not touch the patient at the same time as touching the body or contacts of any of the medical or communications or power connectors.

WARNING
Many environmental variables, including patient physiology and clinical application, can affect the accuracy and performance of the monitor. The clinician must verify all vital-signs information prior to patient intervention.

WARNING
Do not autoclave, ethylene oxide sterilize, or immerse in liquid the Tempus Pro or any of its cables or accessories as this may cause sensor damage which may result in inaccurate readings.

WARNING
Attention should be paid to the EMC information in this manual prior to installing or using the device.

WARNING
The Tempus Pro should not be stacked next to other equipment. If this is necessary verify normal operation before utilizing device adjacent to or stacked with other electrical equipment.

WARNING
Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of the device.

WARNING
Computers, cables and accessories not tested to IEC/EN 60601-1-2 or equivalent IEC standards may result in increased emissions or decreased immunity of the device.

WARNING
Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.

WARNING
Only use the Tempus Pro with the relevant cables and peripherals provided by RDT. Use of any other accessories could result in inaccurate measurements. Use of any other cables or accessories could affect defibrillator protection.

WARNING
The wireless communication features of the Tempus Pro or its accessories may be interfered with by other devices which operate at the same frequencies.

WARNING
The sensors of the Tempus Pro are only for contact with intact and undamaged skin.

WARNING
Operating high frequency electrosurgical equipment in the vicinity of the monitor can produce interference in the monitor and cause incorrect measurements.

WARNING
Do not use the monitor with nuclear spin tomography (MRT, NMR, NMT) as the function of the monitor may be disturbed.

WARNING
This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Tempus Pro or shielding the location.

WARNING
Any device or accessory that has been dropped, damaged or subjected to harsh usage or extreme environmental conditions should be inspected by qualified service personnel prior to use to ensure proper operation.

WARNING
The ECG device is not intended for use in a sterile environment. Do not use for direct cardiac application.

WARNING
Do not attempt to insert the ECG device (including patient cables) into an electrical outlet.

WARNING
The ECG recorder and monitoring functions are for resting ECG and should not be used in stress testing environments.

WARNING
Though false positive errors will intentionally outnumber false negative errors, both will occur, thus the necessity for over reading by a qualified physician of any computer-interpreted ECG. The computer interpretation does not produce a definitive diagnosis.

WARNING
Ensure electrodes are connected only to the patient.

WARNING
Conductive parts of electrodes and connectors, including neutral electrode, should not contact other conductive parts including earth.

WARNING
Always keep motion to a minimum. Motion artifact can potentially affect the accuracy of patient readings.

WARNING
Do not connect more than one patient to a monitor. Do not connect more than one monitor to a patient.

WARNING
Do not use the Tempus Pro in a Magnetic Resonance Imaging (MRI) suite or a hyperbaric chamber.

WARNING
Do not place the monitor or its accessories in locations where they could fall onto the patient. When moving the product take care that any connected leads and sensors are not jerked so that they become detached or damaged.

WARNING
The Tempus Pro is protected against defibrillator discharge. However, rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.

WARNING
During defibrillation, keep the defibrillator’s paddles or electrodes away from the monitor’s ECG wires, electrodes and any other sensors or conductive parts of the monitor.

WARNING
There is no defibrillator synchronization output on the device.

WARNING
Pacemaker signals can differ from one pacemaker to the next. The Association for Advancement of Medical Instrumentation (AAMI) cautions “in some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. All pacemaker patients should be kept under close or constant observation.” See "Tempus Pro medical specifications" for details of the pacemaker pulse rejection capability of the Tempus Pro.

WARNING
Device may not operate effectively on patients who are experiencing convulsions or tremors.

WARNING
Misuse or improper handling of the device or its sensors or cables can cause damage which may lead to equipment failure or inaccurate readings.

WARNING
Do not apply excessive tension to any cable. Using a damaged patient sensor may cause inaccurate readings, possibly resulting in patient injury or death. Inspect each sensor. If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair center for help.

WARNING
The Tempus Pro, all its cables and accessories should be inspected frequently to check for damage. Any worn or damaged items should be replaced. Failing to thoroughly and regularly inspect and maintain the product could result in hazards to patients or equipment failure.

WARNING
Using a damaged patient cable may cause inaccurate readings, possibly resulting in injury or death. Inspect the patient cable. If the patient cable appears damaged, do not use it. Contact your authorized repair center for help.

WARNING
Ensure that close attention is paid to the alarm configuration settings of the product. If alarm volumes are turned down or if the product is used in noisy environments then the alarm may not be audible. If alarms are muted this will be indicated on the screen. Always ensure the screen of the Tempus Pro can be seen in case the audible alarms cannot be heard or are turned off.

WARNING
Do not attempt to charge a non-rechargeable battery. Never over charge, crush, heat or incinerate, short-circuit, deform, puncture, dismantle or immerse the batteries in any liquid.

WARNING
Only use rechargeable batteries and battery chargers specified by RDT.

WARNING
Ensure patient cabling or tubing is carefully routed on device to reduce the possibility of patient entanglement or strangulation.

WARNING
All numerical, graphical and interpretive data should be evaluated with respect to the patient's clinical and historical picture.

WARNING
Do not attempt to insert any connections from the Tempus Pro (including patient cables) directly into an electrical outlet. (IEC60601-2-34)

WARNING
Failure of Operation: If the Tempus Pro fails to respond as described in this user guide; DO NOT use it until approved for use by qualified personnel.

WARNING
Reuse, disassembly, cleaning, disinfecting or sterilizing of any single use items (such as the capnometer cannula) may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labelled as single patient use is reused.

WARNING
The USB connection must only be connected to non-mains powered peripherals (such as a mouse or keyboard) or to interface accessories provided by RDT (such as the USB-Serial Cable part number 01-1022). Any connections made to the USB port must be to medical or IT peripherals or communications systems which comply with the applicable IEC safety standard (i.e. IEC 62368-160601-1 or IEC60950). Any connection arrangements must be made in a manner compliant with IEC 60601-1 3.1, 60601-1-1 or IEC60601-1.

WARNING
The alarm functions of the Tempus Pro are intended to be used by the attendant user only. If the device is connected to an alternate location this is for the purpose of sharing vital signs data in real time, between two users for the purpose of obtaining additional clinical support. The system is not a distributed alarm system (e.g. nurse monitoring station system) in the terms of IEC60601-1-8.

When using Corsium, the Tempus Pro alarm system does not send or receive alarm conditions; as per IEC 60601-1-8 Tempus Pro it is not a distributed alarm system or a distributed information system. If using Corsium to assist with the Clinical management of patients be aware that system delays may occur (e.g. communication, internet delays) between vital signs displayed on Tempus and displayed at Corsium. Further more Tempus Pro as a distributed information system does not comply to IEC 60601-1-8 section 6.4.2 for signal output to any other system

WARNING
When connected to a PC at an alternate location, streamed data, such as the waveforms displayed on the Tempus Pro, will be transmitted and displayed automatically on that PC's display. Users are advised that streamed data is transmitted using the UDP protocol. The UDP protocol includes error checking but does not retransmit data. Therefore any data that is dropped, lost or delayed during the streaming process will not be retransmitted. In the event that packets of waveform data are lost, they will appear as gaps in the waveform that is displayed on the PC.

Medical data (vital signs data, photos, ECG recordings, patient details, TCCC cards etc.) are transmitted using TCP/IP, this includes error checking and retransmission so missing or dropped packets are retransmitted.

WARNING
Do not disassemble the device. The device must only be serviced by trained and authorized biomedical engineers following RDT approved procedures and using parts provided by RDT. Any other changes or processes are unauthorized and should not be performed. No other modifications are allowed. Unauthorized processes, repairs, modifications, reworks or service not expressly approved by RDT could void any guarantees and warranty and could be hazardous. Do not modify this device without authorization from RDT. If the device is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the device.

WARNING
To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, such as rain.

WARNING
To get the best possible readings from Tempus Pro, the user must prevent shocks and vibrations. During patient vehicular transport, the user must attach the Tempus Pro with one of:

- Tempus Pro Litter Mount (part number 01-2035)
- Tempus Pro SMART Mount (part number 01-2244)

WARNING
ECG interpretation done by software is not an alternative for review and diagnosis of ECG recordings by an approved clinician.

WARNING
The user must not use only the arrhythmia analysis tool (ECG monitor) to check the patient. The user must manually check the patient at all times.

WARNING
An approved clinician must make decisions about the clinical significance of Tempus Pro arrhythmia events or alarms.

WARNING
There are different default alarm values for adult, pediatric, and neonate patients. For each new patient, the user must make sure that the alarm limits are applicable for the patient's age.

WARNING
The user must make sure that the display and alarm bar are always visible. The handle and rear alarm light must stay clean and clear. The alarm speaker must stay clear. The user must set the alarm volume to a level applicable to the level of background noise.

WARNING
The optional Tactical Switch is for military users in positions where light and sound levels must be low. When the optional Tactical Switch is on, the device will not give visual or audible alarms. It can also give a display that is too dim to see. Users must make sure that they use the optional Tactical Switch only when necessary. Users must manually check the patient more carefully when the Tactical Switch is on.

WARNING
When the user discards Tempus Pro batteries, they must obey the local regulations. Users must not break or burn batteries, as they could cause fire or explosion. Users must give batteries to an organization that can and will obey the local regulations.

WARNING
The user must not repair the battery or fit an incorrect battery, as this causes a danger of explosion.

WARNING
When Tempus Pro receives patient data from a device, the user must select the correct patient record. The user must identify the record by patient name (last and first), identification number, or incident start time. If the user is not sure which is the correct patient record, they must select **Admit as new patient**. If the user mixes different patient records, this could lead to misdiagnosis.

WARNING
Tempus Pro's Wi-Fi, Bluetooth and cell phone functions give out radio frequency (RF) power (maximum 63 mW). This can prevent the correct operation of implantable devices such as pacemakers. If the patient has an implantable device, the user must stop all wireless while they record patient data. After this, they must move the device a minimum of 2.3 m from the patient and then start wireless communications. If the implantable device has an immunity level more than 10 V/m, the separation must be more than 2.3 m (7.5 ft).

WARNING
Do not use the device where oxygen levels are high.

WARNING
The Tempus Pro is suitable for use in the presence of electrosurgery. Burn hazard protection is provided via a 1K current-limiting resistor contained in each ECG lead wire. Proper lead placement, avoiding the site of the electrosurgery, is important to reduce burn hazards in the event of a defect in the electrosurgical equipment.

Do not entangle the ECG cables with the electrosurgical equipment wires; do not place the ECG cabling near the electrosurgical equipment's grounding plate.

WARNING
Access to the device must be limited to authorized users. It is important that you consider physical security measures to ensure that unauthorized users cannot gain access.

WARNING
DO NOT connect the video laryngoscope USB probe to the Tempus Pro during device boot-up. Once ‘Patient Details’ dialog appears, enter patient data then plug in the video laryngoscope USB probe

CAUTION
The Tempus Pro has been tested in a “heavy” wireless environment consisting of different wireless technologies (Bluetooth, WiFi 802.11 b and cellular communications) with multiple transmitters used simultaneously. Users deploying the Tempus Pro in environments where other wireless technologies are being used should evaluate the potential risk of interference and aggregate spectrum usage.

CAUTION
The Tempus Pro may be used on ambulances or on vehicles using radios. It has been tested to determine operation in field strengths greater than 3 V/m (as detailed in "10.4 Electromagnetic compatibility (EMC)"). Users are advised to maintain the best distance possible between radio antennas and the Tempus Pro as best practice.

CAUTION
Make sure that there is sufficient clearance on the back of the Tempus Pro Non Printer when docked within the Tempus Mount Smart mount.

The external IP module can be detached from the RapidPak if more clearance is required.

CAUTION
Use of the Tempus AC-DC adapter without a stable and verified earth connection can cause interference when monitoring a patients ECG.

CAUTION
The Tempus Pro will present results in a different layout depending on whether the device is set to ECG monitoring or Diagnosis ECG. The alarm function will be the same in either case.

CAUTION
Certain line-isolation monitors may cause interference on the ECG display and may inhibit heart rate alarms. Users should make sure that electrodes are correctly placed and that the skin is prepared as instructed in advance.

CAUTION
The Tempus Pro is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.

CAUTION
The Tempus Pro may not operate correctly if used or stored outside the relevant temperature or humidity ranges described in the performance specifications of this manual.

CAUTION
Only use only approved accessories supplied by RDT. Conventional 4 mm snap-on, pre-gelled ECG electrodes may be used so long as they comply with AAMI EC12. Users are reminded to read and adhere to the instructions for such electrodes including noting single use only status, maximum usage times and patient indications.

CAUTION
Do not clean the Tempus Pro or its accessories except as directed in this guide.

CAUTION
In the event that the device displays an error that is not described within this manual, for example an application error, turn the device off and then on again. This should clear the error and allow normal operation to resume. Do not continue to use the device if such an error is displayed. If symptoms persist, please contact RDT.

CAUTION
The Tempus Pro records data that it measures. In order to ensure that data from different patients is not confused, the device must be switched off between taking readings from different patients or the patient discharge function used.

CAUTION
Should the Tempus Pro become wet, wipe off all moisture and allow sufficient time for drying before operating. Take care to ensure that water or liquids are not spilt over the device or into its ventilation holes in the side corners.

CAUTION
If the accuracy of any measurement is in question, verify the patient's vital sign(s) by an alternative method and then check the monitor for proper functioning.

CAUTION
Follow local government regulations and recycling instructions regarding disposal and recycling of device and device components.

CAUTION
The Tempus Pro and its accessories use different types of battery which include rechargeable and non-rechargeable types. If any battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly. Dispose of batteries in accordance with applicable regulations which vary from country to country.

(In most countries, the disposal of used batteries is forbidden in general domestic and commercial waste and the end-users are invited to dispose them properly, typically through not-for-profit organizations, mandated by local governments or organized on a voluntary basis by professionals).

CAUTION
Pressing buttons on the touchscreen with sharp or pointed instruments may cause permanent damage. Only fingers should be used to press these keys.

CAUTION
Do not charge the BT headset on the Tempus Pro when the main battery is very low or flat (less than 10% charge – as represented by a single flashing LED on the battery charge indicator). Doing this could reduce the battery charge into a “deep discharge” state (where no battery lights come on).

CAUTION
Use of monitoring during continuous nebulized medication delivery will result in damage to the device which is not covered by the warranty. Disconnect the capnometer sample line from the device, or switch off the device, during medication delivery.

CAUTION
Observe proper battery polarity (direction) when replacing batteries. The batteries slide easily into place when correctly oriented and should not be forced.

CAUTION
The mobile RF communications equipment contained within the device and its accessories can affect other medical devices that are in close proximity to the device.

CAUTION
Use of the RF communications equipment contained in the device and its accessories may be prohibited in a number of areas. These include: on aircraft in-flight (including during take-off and landing), near defibrillators (that are in use), near other electronic medical devices and in hospitals.

CAUTION
Before switching on the Tempus Pro, ensure that the battery is correctly installed and the battery contacts are in good condition.

CAUTION
The optional Tactical Switch is intended for use by military users for scenarios where low emitted light and low emitted sound is required or desired. Users are reminded that while these functions are enabled, the device will not emit visual alarms from the alarm bar, will not emit audible alarms from the speaker and will present a display that may be too dim to see in daylight conditions. Users should therefore ensure that they use these features only when required and recognize that greater levels of patient care and supervision will be required.

CAUTION
When using the Tempus Pro with portable satellite terminals such as Iridium handsets or BGAN terminals, ALWAYS ensure that the terminal is provided with any applicable data adaptors and is set up to support data calls. It is recommended that Users thoroughly familiarize themselves with the operation their satellite terminals and perform a test connection BEFORE going into the field with the equipment. Advice on this can be sought from RDT if required.

CAUTION
The use of the RF communications equipment contained in the device and its accessories may be prohibited in explosive atmospheres e.g. in fuelling areas, near fuel or chemical transfer or storage areas and in areas containing chemicals or particles such as grain, dust or metal powders.

CAUTION

When using the Tempus Pro with BGAN terminals, in order to avoid the risk of interference from the output beam from the antenna of the terminal with the operation of the device, ALWAYS ensure that the device is situated at least 6 m behind the face of the antenna. Since the power of the BGAN terminal's beam is high (25 W approx.), care should be taken to ensure that the antenna remains fixed and to maintain the device away from the face (and therefore the beam) of the antenna.

CAUTION

The use of the RF communications equipment contained in the device and its accessories may cause interference with some implanted pacemakers and other medically implanted equipment. A minimum distance of 2.3 m (7.5 feet) must be maintained between the device and its accessories (containing RF communications equipment) and other medical equipment (including implantable medical devices such as defibrillators and pacemakers). Note that if such medical equipment has an electromagnetic interference immunity level of less than 3 V/m (or 10 V/m for implantable devices), this distance should be increased in line with the requirements of IEC60601-1-2.

If you suspect interference is being caused, disconnect the connection to the alternate location. Examples of interference could include visible interference on equipment displays, audible interference e.g. buzzing, from speakers of other equipment, or equipment unexpectedly changing state e.g. functions starting or stopping.

- Example of a PC display with no interference:

- Example of a PC display with interference:

CAUTION
RF energy may affect some electronic systems in motor vehicles, such as car stereos, safety equipment, etc. Check with your vehicle manufacturer's representative to be sure that your product will not affect the electronic system in your vehicle.

CAUTION
Do not use the Tempus Pro's Bluetooth® or WiFi communications on-board any aircraft where its use is prohibited.

CAUTION
Take care to minimize the risk that trailing cables will be caught by passers by.

CAUTION
Prior to deployment of Tempus Pro there are settings that user organizations need to configure. Carefully check all the relevant settings on each Tempus Pro before it is deployed. For more information, see section "3.2 Before deployment".

CAUTION
Configuration needs to be carried out by a biomedical engineer or suitably qualified persons. Information is provided in the following:

- *Tempus Pro Maintenance Manual*
- *Tempus Pro Configuration Utility User Guide*

CAUTION
If you use mounting systems that are not supplied or approved by RDT, we cannot guarantee the performance of the Tempus Pro.

CAUTION
Do not attempt to calibrate the Tempus Pro or its accessories. If there is any indication that calibration is necessary, for example a warning message, contact RDT support.

CAUTION
Tempus Pro must only be used with the devices listed in this manual. Do not use it with any other devices or general purpose equipment.

CAUTION
The Tempus Pro software must always be updated when RDT issues a security update.

CAUTION
After a sudden drop in air pressure, the user must examine Tempus Pro to make sure it operates.

CAUTION
If there is damage to the paper roll, the user must replace it.

CAUTION
Patient age affects the settings applied in some medical modules.

CAUTION
User must not service parts during use of the Tempus Pro.

The Tempus Pro has been tested and found to comply with IEC/EN 60601-1-2.

If all the battery lights remain off when the battery button is pressed, the battery may be in a “deep discharge” state. The battery is not damaged when in this state but will require an extended period on charge (additional 24 hours) in order to restore normal operation.

The Tempus Pro is intended for use in the electromagnetic environment(s) specified in this manual. Users of this equipment should ensure that it is used in such environment(s).

After the life cycle of the Tempus Pro and its accessories have been met, disposal should be accomplished following national and/or local requirements.

Operation of the device may be adversely affected in the presence of conducted electrical transients or strong electromagnetic or radio frequency sources such as electrosurgery and electrocautery equipment, HF radio transmission antenna, x-ray machines and high intensity infra-red radiation.

All user and patient accessible materials are non-toxic and do not contain CMR substances or endocrine-disrupting substances.

Hazards arising from software errors have been minimized. Hazard analysis was performed to meet the requirements of EN ISO 14971 and 60601-1 3rd Edition and IEC 62304.

Each external connection and part of the device is electrically isolated.

Performance and safety test data are available on request from RDT.

Cell phone usage is restricted by the network availability, roaming agreements and local provision of circuit mode connections.

Users should not put the device into service until they fully understand its use and also (where appropriate) the device has been commissioned on their aircraft, vessel or other intended site of operation.

IBP sealing is not guaranteed if the device is subject to rough handling, impact, improper use or rapid decompression.

Device should be returned for service if it is subject to rough handling and IBP sealing is needed to be relied upon.

The device specifications are subject to change without notice.

It is recommended that the device is connected to the alternate location every month for a test patch.

The iAssist help processes on your Tempus Pro may differ from the example iAssist help process used in this manual; however the process always follows the same key elements.

Always ensure that you read the complete iAssist help process in order and do exactly what it requires.

For optimum performance of the wireless communications, please make sure that there is no metal surrounding the Tempus Pro.

Over bending the folding foot or RapidPak clip could cause them to be damaged. Do not over-bend these items.

Take care when repacking cables to ensure they cannot be snagged or damaged in the RapidPak clip and the folding foot.

The Tempus Pro should be repacked following the relevant instructions. Lost or damaged cables and accessories should be replaced with spares ordered from RDT.

The **Display Menu** offers different vital signs data views on the home screen. The user must refer to "The Display menu" for instructions.

The high contrast display is available for all Home screen modes.

To display ultrasound and video laryngoscopy on the Tempus Pro, the user can use third-party ultrasound and laryngoscopy accessories. The user must refer to *Tempus Pro Ultrasound Supplement Guide* and *Tempus Pro Laryngoscope Supplement Guide* for instructions.

When the user connects the laryngoscope, Tempus Pro automatically turns on pulse tones.

There are no known conditions that will affect the basic safety of the Tempus Pro either by:

- Electromagnetic interference
- Degraded or loose electrodes
- Lint, dust or light including sunlight

The Patient Monitor must be secured when im use. It is recommended that a RDT Philips SMARTMount is used to secure the monitor.

The user can get an ultrasound image during general and FAST exams. The user must refer to *Tempus Pro Ultrasound Supplement Guide* for instructions.

1.3 Features list

Not all features are supported in all territories.

All Tempus Pro monitors come with the following items:

- Lithium-ion battery
- Non-invasive blood pressure hose
- Non-invasive blood pressure cuff

- Masimo SpO_2 patient cable with either a reusable sensor or a disposable sensor starter pack
- Tempus Pro ECG cable
- Tempus Pro user manual set (CD-ROM)

If fitted with a capnometer, a filter line sample pack is also supplied.

All Tempus Pro monitors have the following features:

- 72 hour data storage for multiple patients
- Water and sand resistant to IP66
- Multiple ways of reviewing patient data, including 4 waveform color display
- Easy and quick switching between patients
- A daylight readable, NVG friendly, glove-operable touch driven screen
- Integral camera for recording images of the patient
- Wide operating & storage temperature range
- Trending and data capture
- iAssist system which gives additional information on how to use the Tempus Pro on screen

The following functionality is available with the Tempus Pro:

Items	**Provided as standard or optional**
Masimo SET pulse oximetry including pulse rate, SpO_2 , and PI	Standard
Masimo SET Pleth Variability Index (PVI)	Optional
Masimo rainbow SET measurements (SpHb, SpMet, SpCO and SpOC)	Optional
Non-invasive blood pressure	Standard
Electrocardiogram (ECG) monitoring (3-lead, 4-lead and 5-lead), real-time arrhythmia detection	Standard
Impedance respiration	Standard
ECG ST and QT monitoring and alarming	Optional
12-lead diagnostic ECG	Optional
Oridion Microstream capnography for intubated and non-intubated patients	Optional
Contact temperature, YSI series 400	Optional
Two channels for invasive pressure	Optional
Up to 4 channels for invasive pressure measurement	Optional
Corsium ReachBak, near real-time data	Optional
Corsium Crew extended display	Optional
Wireless communications	Optional
Bluetooth headset for voice communication	Optional

Items	Provided as standard or optional
Internal thermal printer	Optional
Ultrasound	Optional
Video laryngoscopy	Optional
Anesthetic agent monitoring	Optional
Glasgow 12-lead ECG interpretation with 12 lead ECG	With 12-lead ECG

The Tempus Pro is not supplied with contact temperature probes as standard.

Proprietary notice

The purpose of this document is to provide the user with adequately detailed information to efficiently install, operate, maintain and order spare parts for the Tempus Pro. Every effort has been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that the document is error free or that it is accurate with regard to any specification. RDT reserves the right to change specifications without notice.

NO IMPLIED LICENSE: Possession or purchase of this device does not convey any expressed or implied license to use the device with unauthorized sensors or cables that would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

1.4 Theory of operation

The Tempus Pro is a battery powered, fully featured, small, lightweight, vital signs monitor designed for use in pre-hospital and clinical environments. The monitor allows you to collect and share medical and patient data in near real-time and post event. In addition to providing conventional vital signs monitoring and alarm features, the Tempus Pro can provide Corsium ReachBak® capabilities. These allow you to transmit all data in real-time to an alternate location. The Tempus Pro is designed to be scalable. This enables the purchaser to select the most appropriate configuration for their immediate budget. It also allows integration with emerging technologies and future applications.

All measurements made by the Tempus Pro are displayed on-screen. Attaching a sensor to a patient will initiate measurements for that particular parameter. Monitoring will continue until the sensor is removed from the patient or the unit, and the consequent alarm is silenced. In the case of non-invasive blood pressure, measurements start once the user presses the measurement button. Measurements will continue on a regular basis until either the cycle is stopped by the user or the unit is unable to take a reading, e.g. the cuff is removed.

1.4.1 Electrocardiograph (ECG)

The ECG is intended to monitor patients of all ages in hospital and pre-hospital applications (including transport) for general cardiac monitoring. Electrical currents influenced by the cardiac impulse flow through the body tissue around the heart. The Tempus Pro uses:

- a 3-lead cable to monitor ECG leads I-III;
- a 4-lead cable is available to monitor ECG leads I-III, aVR, aVL and aVF;
- a 5-lead cable is available to monitor ECG leads I-III, aVR, aVL, aVF and a user-placeable V lead.

Twelve-lead diagnostic recording functionality is available as an option. To support this, use one of the standard or modular 12-lead cables (including precordial chest electrodes) available from RDT.

ECG cables can be used with conventional disposable pre-gelled electrodes (not supplied) for ECG monitoring and alarming.

Impedance pneumography

Impedance pneumography is an indirect method of measuring respiration. It works by continuously measuring changes in the impedance of the patient’s body. This is done using two or more ECG electrodes allowing the device to measure the patient’s impedance through the chest. Impedance is measured using a low-current, high frequency current signal. As the patient breathes, the chest expands and contracts giving a rising and falling impedance reading. The Tempus Pro measures the time between successive peaks and troughs of the impedance measurement and translates the time into an interval or rate of respiration.

The impedance method is subject to muscle noise and electrode placement and therefore is inferior to the respiration rate measurement (end tidal CO_2 analysis).

1.4.2 Non-invasive blood pressure

The Tempus Pro uses oscillometric technology to measure the patient's blood pressure noninvasively. A pump within Tempus Pro inflates the reusable blood pressure cuff around the patient's arm. Circulating blood within the arm causes slight changes (oscillations) in the cuff pressure, which can be detected and measured. As the inflation pressure changes, the systolic, diastolic and mean arterial pressure can be measured.

This method of blood pressure measurement provides accurate readings provided that the correct size of cuff is used, it is attached to the patient correctly and the specified operating precautions are observed.

1.4.3 Pulse rate and oxygen saturation (SpO_2)

Pulse oximetry measures functional oxygen saturation.

Pulse oximetry is based on the following:

- The difference in the absorption of red and infrared light, spectrophotometry, by oxyhemoglobin and deoxyhemoglobin
- Changes in the volume of arterial blood in tissue during the pulse cycle (plethysmography), and hence, light absorption by that blood.

A pulse oximeter determines Spot Oxygen Saturation (SpO_2) by passing red and infrared light into an arteriolar bed and measures changes in light absorption during the pulsatile cycle. Red and infrared low power light emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector.

Since oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow.

During systole, a new pulse of arterial blood enters the vascular bed. This means that blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point.

The monitor bases its SpO_2 measurements on the difference between the maximum and minimum absorption (measurements at systole and diastole). The focus of light absorption by pulsatile arterial blood eliminates the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Pulse rate and oxygen saturation are detected by a soft reusable finger probe which can be packed on the rear of the device (disposable sensors may also be used). It is important that the sensor is not used on the same arm as the blood pressure cuff, because false readings may occur when the cuff is inflated. Readings will not be obtainable or may be inaccurate from patients with some colors of nail varnish or polish.

Masimo rainbow SET measurements use a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide content and blood with oxidized hemoglobin. The sensors have various light emitting diodes (LEDs) that pass light through the site to a photodiode (photodetector). The maximum radiant power of the strongest light is rated at 22 mW. The photodetector receives the light and converts it into an electronic signal. Masimo rainbow SET signal extraction technology then calculates the measurement values.

1.4.4 Invasive pressure

Two channels of invasive pressure are measured using a socket on the Tempus Pro. An interface cable needs to be attached to this socket, the interface cable splits into two ends, each of which can be connected to a third-party pressure transducer, with a sensitivity of 5 µV/V/mmHg. A range of third-party transducers, both reusable and disposable, are available. A list of compatible sensors is provided in the "B.2 Invasive Blood Pressure accessories" section. A different interface cable is required to adapt the Tempus Pro's socket to the specific connectors of each type of transducer. The Tempus Pro takes a pressure reading by measuring the changing resistance in the transducer. When a transducer is correctly attached to the Tempus Pro, and to the patient's blood stream, e.g. in the pulmonary artery, it obtains a constant reading of resistance that equates to the systolic and diastolic pressure. Mean arterial pressure and heart rate are also calculated from this reading.

An additional two channels are available via an external module.

1.4.5 End tidal CO_2 ($EtCO_2$) and respiration rate

The Tempus Pro uses Microstream® non–dispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO_2 present at the end of exhalation ($EtCO_2$), and the Respiratory Rate.

Infrared spectroscopy is used to measure the concentration of molecules that absorb infrared light. Since absorption is proportional to the concentration of the absorbing molecule, CO_2 concentration can be determined by comparing its absorption to that of a known standard.

The Microstream® $EtCO_2$ consumables deliver a sample of the inhaled and exhaled gases from the ET tube adaptor, or directly from the patient via an oral/nasal cannula, into the monitor for CO_2 measurement. Moisture and patient secretions are extracted from the sample, while maintaining the shape of the CO2 waveform.

The 50 ml/min. sampling flow rate reduces liquid and secretion accumulation, decreasing the risk of obstruction in the sample pathway in humid ICU environments.

Once inside the Microstream® CO_2 sensor, the gas sample goes through a micro-sample cell (15 microlitres). This extremely small volume is quickly flushed, allowing for fast rise time and accurate CO_2 readings, even at high respiration rates.

The Micro Beam IR source illuminates the micro-sample cell and the reference cell. This proprietary IR light source generates only the specific wavelengths characteristic of the CO_2 absorption spectrum. No compensations are required when different concentrations of N_2O, O_2, anaesthetic agents and water vapour are present in the inhaled and exhaled breath. The IR that passes through the micro-sample cell and the IR that passes through the reference cell are measured by the IR detectors. The microprocessor in the monitor calculates the CO_2 concentration by comparing the signals from both detectors.

1.4.6 Temperature

Two channels of contact temperature are measured using the two sockets on the Tempus Pro.

These sockets are compatible with YSI type 400 probes only. A range of third-party YSI 400 series compatible transducers can also be used. These transducers can be re-usable or disposable.

The Tempus Pro takes a temperature reading by measuring the changing resistance in the tip of the transducer. When a transducer is correctly attached to the Tempus Pro, and to the patient e.g. in the rectum or axilla, it obtains a constant “direct” reading of resistance that equates to the temperature at that site. There is no offset or reference body site. The device contains a self-checking system which checks the thermometer against a known, internal, reference point every second. If this cross-check fails at any time the thermometer will be disabled and an error posted on the display.

The thermometer’s reading can be presented in °C or °F.

1.4.7 Controls and indicators

The controls and indicators are divided into three types, items on a touchscreen, membrane buttons and LED indicators. The Tempus Pro can be operated with or without gloves.

Touchscreen and membrane buttons should be pressed once. As with all touchscreens if your finger wavers or quivers, the Tempus Pro may register it as more than one press.

1.5 Patent and warranty

Patent claims

RDT has applied for patents covering the Tempus Pro and its communications technology in the following jurisdictions: Patents Pending (PCT/GB2018/051798, PCT/EP2019/079312 & other areas).

The capnography component of this product is covered by one or more of the following US patents: 6,428,483; 6,997,880; 6,437,316; 7,488,229; 7,726,954 and their foreign equivalents. Additional patent applications pending.

PATENT MARKING: This device is covered under one or more of the following U.S.A. patents: 6,157,850, 6,263,222, 6,501,975, 7,469,157 and other applicable patents listed at http://www.masimo.com/patents.htm.

Limited warranty

Remote Diagnostic Technologies Limited ('RDT') warrants each new Tempus Pro to be free from defects in workmanship and materials under normal conditions of use and service. For details please refer to the Terms and Conditions of Sale. Consumable items are expressly excluded from this Warranty. RDT's sole obligation under this warranty will be to repair or, at RDT's option, replace products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. Except as set forth herein, RDT makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. The warranty shall be void if the Tempus Pro is in any way modified or used with non-approved consumables, unless specifically authorized in writing by RDT, and RDT shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

Full terms and conditions of sale are available from RDT and are provided with your order confirmation.

All specifications quoted in this manual are nominal unless detailed otherwise.

Service support and returns

Repairs made under warranty to any new Tempus Pro must be made by the manufacturer. If the device requires repair or return for any reason, please contact your local distributor or Remote Diagnostic Technologies in order to first obtain a returns reference (RMA) number. RDT reserves the right not to accept returns which have not first been provided with an RMA number. When calling, please be ready to quote the serial number of the device.

The Tempus Pro is designed to be as maintenance free as possible. The only user replaceable and user serviceable parts are those listed in this manual.

In the event that the Tempus Pro device fails to operate correctly or in a way that is not described in this manual, stop using the device immediately and switch the device off immediately. Contact the manufacturer or distributor at once. Do not attempt any kind of corrective action and do not connect the device to a patient. If the device malfunctions and may have caused or contributed to a serious injury of a patient or user, RDT must be notified immediately by telephone, fax or written correspondence.

1.6 Disposal at end of life

The expected life of the Tempus Pro (excluding batteries) is 5 years.

The WEEE logo refers to the EU Directive on Waste Electrical and Electronic Equipment (WEEE). This Directive entered into force as European law on 13th February 2003; it resulted in a major change in the treatment of electrical equipment at end-of-life. The purpose of this Directive is, as a first priority, the prevention of WEEE, and in addition, to promote the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste.

The symbol indicates that this product must not be disposed of or dumped with household waste. The owner of the equipment is liable to dispose of all electronic or electrical waste equipment by delivering to the specified collection point for recycling of such hazardous waste, collection and proper recovery of electronic and electrical waste equipment at the time of disposal will allow the producer to help conserve natural resources. Recycling of the electronic and electrical waste equipment will ensure safety of human health and the environment. For more information about electronic and electrical waste equipment disposal, recovery and collection points, please contact your local, waste disposal service or producer / distributor of this equipment.

WARNING
Batteries should not be crushed or incinerated as they could present a risk of fire or explosion. Batteries should be handed to an appropriate organization that is competent in the disposal of such devices; this must be done in accordance with local regulations.

Disposal of single use devices

Any accessories that are designated as single-use devices must be discarded after use. No particular precautions are required when disposing of these items provided that they are not contaminated with bodily fluids. In case of such contamination, the items could present a bio-hazard and therefore should be disposed of in accordance with local regulations governing such matters.

2 Network Safety, Security and Privacy - Regulatory Controls

2.1 Customer Role in the Product Security Partnership

The security of Philips products needs to be an important part of your security-in-depth strategy. However, protection can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from internal and external threats.

Following industry-standard practice, your strategy should address:

- Physical security
- Operational security
- Procedural security
- Risk management
- Security policies
- Contingency planning

The practical implementation of technical security elements varies by site and may employ several technologies, configurations and software solutions.

As with any computer-based system, protection can include firewalls, network segmentation and/or other security devices between the medical system and your institution's network. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy. Any connection to an internal or external network should be done with appropriate risk management for product effectiveness and data and systems security. The USA Veterans Administration has developed a widely used Medical Device Isolation Architecture for this purpose.

WARNING

Only connect Tempus Pro to trusted networks with strong operational security controls, security monitoring, and governance.

Philips is not responsible or liable for security configuration or governance of upstream third-party systems that may process patient data originating from the Tempus Pro.

2.2 Security Risk Management

The confidentiality, integrity, and availability of the device and related data should be risk-assessed considering the following recommendations.

- Implement network and physical access controls to limit the likelihood of compromise.
- Monitor the manufacturer's product security recommendations as required by your information security policy.

The assessment should be repeated whenever changes are made to the network. Such changes include:

- Changes in the network configuration
- Connection of additional items to the network
- Disconnection of items from the network
- Updates or upgrades to items that are connected to the network

2.3 Protect Patient’s Health Information

One of the most important assets to protect with security measures is the patient's health related information. Many governments require maintaining the confidentiality of this information. Therefore, strict security measures must be taken to guard this protected information.

When a Tempus Pro device is returned for repair, disposed of, or removed from your facility for other reasons, prior to shipping you must make sure:

- All patient data is removed from the device.
- The Corsium ReachBak feature is disabled by an authorized Maintenance User.
- Authentication credentials for any upstream systems (Wi-Fi SSIDs and passwords, SMTPS servers and third-party ePCR systems) are deleted.

2.4 EU Directives

If applicable, your organization’s security strategy should include the practices set forth in the Directive on the protection of individuals regarding the processing of personal data and on the free movement of such data (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016). In addition, your facility should also consider any additional, more stringent standards put forward by any individual EU countries.

2.5 Philips Product Security Policy Statement

Review Philips product security policies in the “Product Security Policy Statement” and additional information sources available through this website. Security and privacy information can be found on the Philips product security web site at: www.philips.com/security

2.6 Manufacturer Disclosure Statement for Medical Device Security – MDS2

You can request a copy of the Tempus Pro Manufacturer Disclosure Statement for Medical Device Security (MDS2) from your local support representative.

2.7 Prevent Unauthorised Device Modification

Philips operate controls during the development and release of Tempus Pro software to mitigate against tampering and supply chain attacks.

Operators of this medical device must permit only Philips authorized changes to be made to the Tempus Pro, either by Philips' personnel or under Philips' explicit published direction.

2.8 Software Installation

WARNING

Do not install unauthorized software onto the Tempus Pro.

Tempus Pro software is updated regularly, and software updates will periodically include security patches, available from your local support representative. Users must install software updates as soon as they are available, as described in the Tempus Pro EULA.

2.9 Managing privileged Maintenance User passkeys

User organizations should adopt policies and procedures for managing and rotating privileged Maintenance User passkeys for their Tempus Pro device fleets. Philips strongly recommends using different passkeys for privileged users on different device families (Tempus Pro and Tempus LS).

2.10 Tempus Pro Security controls

Bluetooth Security and Authentication

Prior to pairing with a Tempus LS defibrillator, authentication keys must be generated and distributed 'out of band' for both Tempus Pro and Tempus LS, as an additional trust and authorization control.

Device Hardening

- Tempus Pro software update packages are encrypted.
- Tempus Pro software update packages are integrity checked prior to release and re-validated during the installation process.
- Only authorized Maintenance Users have access to the software update menu on Tempus Pro.
- There are no open ports broadcasting network services from Tempus Pro.
- Tempus Pro does not provide Users or Maintenance Users access to the operating system.
- Unnecessary services, applications and features have been removed from the Tempus Pro operating system platform build.
- Transfer of patient data from Tempus Pro is encrypted and restricted to known, trusted and authenticated 3rd party systems that must be configured by your organization's trained, authorized Maintenance User.
- USB ports may be disabled by a Maintenance User, should your local information security policy require.

Audit trail

Tempus Pro's intended use is for remote and mobile emergency medical response, it does not require Clinical Users to authenticate themselves. There are no audit trail capabilities for actions attributable to an individual identity..

Device Cybersecurity information

To ensure the proper functioning of the medical device, Philips may recommend specific customer or service actions, or issue service recommendations to update, alter, or even replace the equipment's protection mechanisms. The latest device cybersecurity information can be found on the following website: www.philips.com/security .

If a device is suspected to have been compromised, or when you notice that unfamiliar behavior or degraded performance occurs you should contact your local support representative for further investigation.

Detecting and handling security events

The system provides logging capabilities for local processes that support diagnostics and forensics. System failures are handled depending on the nature and severity of the failure and may result in changes to the workflow, error messages, logging, or audit events.

Incident reporting

Any serious incident that has occurred in relation to this device should be reported to Philips and the regulatory authority in which the user and/or patient is established.

Logging

Log files generated by Tempus Pro do not contain patient data.

Microsoft Security Updates

A Product Security Status Document for Tempus Pro is available to users on request and provides information about the patch level of the operating system and third-party software libraries included in the released software. Recommendations about compensating risk controls for user organisations may also be provided.

Network Time Synchronization (for Tempus Pro devices with an optional IntelliSpace Corsium subscription)

Each time Tempus Pro connects to IntelliSpace Corsium, the UTC clock on the device is synchronized to network time. This ensures that the Tempus Pro uses the same clock so that all relevant user actions and data transmissions can be checked in chronological order.

Network Security

Tempus Pro must be placed on a local network that has protection against unauthorized access. Make sure the device is connected to a local network that uses appropriate protection, including but not limited to firewalls, intrusion detection systems and network inspection for malicious traffic.

Network services

There are no open ports broadcasting network services from Tempus Pro. Outbound, dynamic network ports are only opened transiently, when authorized patient data transfer activity to a remote system is initiated by a clinical user. Patient data transfer from Tempus Pro to trusted, authenticated remote systems is always done over an encrypted channel and must be configured by trained, authorized Maintenance Users.

WARNING

Security governance and configuration of upstream, third-party systems is expressly the responsibility of user organizations.

Protection of patient identifiers at rest

Patient identification information stored on Tempus Pro is encrypted at rest.

Protection of authentication credentials at rest

User configurable credentials and authentication passkeys set on Tempus Pro are hashed or encrypted at rest.

Protection of patient data in transit

When patient data are transmitted over a network or exported to USB media, Tempus Pro is designed by default to encrypt the data to mitigate against unauthorized disclosure, access and modification.

Removable and Portable media

When using removable media such as USB storage devices, be aware of these security and privacy issues:

- Inserting removable media may introduce malware to the medical device.
- If removable media is used to store patient data, protect the information from media obsolescence by planning and performing data migrations to newer storage technologies.
- Make sure that the integrity of the removable media is in accordance with your data recovery planning.

WARNING

In some circumstances, USB ports on Tempus Pro may have been disabled by an organizational Maintenance User as a protection mechanism. Ensure that you are familiar with your organizations' USB device usage policy and how the policy impacts intended use in a clinical setting.

CAUTION

Before connecting USB storage devices to the Tempus Pro, scan them to check whether they have been exposed to malware.

CAUTION

Exported Tempus Pro device handover packages contain confidential patient data.

• Implement appropriate physical controls when handling USB handover packages, to reduce the likelihood of data loss and unauthorized access.

CAUTION

Removable media that contains patient data must be stored in a secure area that is not accessible by unauthorized individuals. If the removable media is to be discarded, it must be destroyed (or the contained data permanently deleted) so that the data stored on it can no longer be accessed.

Software and Security updates

Without proper cybersecurity maintenance, the effectiveness of existing controls may degrade over time because malware is continuously altered to target newly discovered vulnerabilities. The systematic analysis of cybersecurity vulnerabilities involves an assessment on the applicability and need for applying security updates, considering any mitigating circumstances in the intended use and design of this equipment.

Security updates alter the equipment's design and thus require proper validation and approval by Philips. Tempus Pro security updates are distributed by the Philips Service organization.

WiFi Security and Authentication

Only industry standard, recommended protocols are supported for communication over wireless networks. Deprecated protocols are not supported.

3 Getting started

This chapter explains the basic principles of operation, i.e. turning on, entering patient details etc..
This chapter contains the following topics:

3.1 Unpacking the Tempus Pro

The Tempus Pro is supplied from the factory in protective outer packaging. No special precautions are required when unpacking the Tempus Pro. RDT recommends that you keep the packaging.

RDT recommends that the equipment is inspected and tested on receipt to confirm that the unit has not been damaged and that all expected items and accessories have been received and are in working order. New batteries should be charged up for at least 4 hours on receipt.

As detailed in section "1.3 Features list"", the Tempus Pro is supplied in a number of configurations. Confirm that all items ordered have been received.

3.2 Before deployment

WARNING
Access to the device must be limited to authorized users. It is important that you consider physical security measures to ensure that unauthorized users cannot gain access.

CAUTION
When handling sensitive device data, do so in accordance with the security policies that apply in your healthcare environment.

CAUTION
When handling patient data, do so in accordance with the privacy policies that apply in your healthcare environment and privacy laws that apply in your region.

The Tempus Pro must be secured to a suitable mount, if a mount is not available:

- During normal use, to avoid overbalancing, only use the Tempus Pro laying on its back.
- When the Tempus Pro is in motion, to avoid overbalancing, only use the Tempus Pro laying on its back.

Carefully check all the relevant settings on each Tempus Pro before it is deployed.

When deploying multiple units, you may set up a single unit and export the configuration from one unit to the others (clone the settings).

Three types of configuration are exported and imported:

- events (summary record of care);
- new patient defaults;
- settings.

Summary record of care events include:

- summary record of care assessment, intervention, drug and fluid events;
- summary record of care injury and burns body map tags and dressings;
- summary record of care general screen events selection.

New patient defaults include:

- patient alarm limits for all parameters;
- default patient mode (adult, pediatric or neonate);
- alarm silence and suspend times;
- default NIBP settings (mode, auto-time and inflation pressures);
- default ECG settings (HR/PR source, ST/QT etc.);
- printer default settings.

Settings include:

- communications settings (e.g. IP address);
- email settings;
- ePCR settings;
- patient record type, language, passwords.

- Configuration needs to be carried out by a biomedical engineer or suitably qualified person following the instructions in the *Tempus Pro Configuration Utility User Guide*.
- The unit name is not cloned from one device to another.
- Licensed options and enabled features are not cloned from one device to another.

3.3 Overview of the Tempus Pro

The Tempus Pro has a series of membrane buttons, a touchscreen and various connectors for attaching patient applied parts or accessories.

WARNING
Do not touch the patient at the same time as touching the body or contacts of any of the medical, communications or power connectors. Normally the ECG, NIBP and SpO_2 connectors will have their sensor cables attached at all times.

WARNING
The 2 USB sockets are reserved ONLY for non-mains powered radios (or other communications devices), non-mains powered USB IT peripherals (such as mouse and keyboards) or non-mains powered medical accessories. Any accessory or peripheral attached to the Tempus Pro MUST be approved for use with the Tempus Pro by RDT.

Any connections made to the USB port must be to medical or IT peripherals or communications systems which comply with the applicable IEC safety standard (i.e. IEC60601-1 or IEC60950). Any connection arrangements must be made in a manner compliant with IEC60601-1. Users must ensure that they prevent the patient from coming into contact with the peripheral and also must ensure the user does not touch the peripheral while touching the patient. Alternatively a suitable isolation device can be used. RDT recommends using appropriate opto-isolation devices such as the Ulinx™ Model UH401 or the Baaske USB 1.1 isolator. Further details can be obtained from RDT upon request.

WARNING
Power socket - Only use the Tempus Pro approved power supply provided by RDT.

Headset socket - only use the Wired Headset part number 01-1019 supplied by RDT or the Tactical Headset Adaptor Cable part number 01-2041 supplied by RDT (this cable adapts to Peltor® or similar military-style headsets).

WARNING
Always use a Baaske MI 1005 isolation device when connecting from the Ethernet socket to any mains-powered communications device (e.g. router, access point, hub, communications terminal etc.)

WARNING
The Ethernet connection must only be connected to battery powered (non-mains-powered) communications devices such as laptop computers or satellite communications terminals such as BGAN or VSAT terminals. Any connections made to the Ethernet port must be to medical or IT peripherals or communications systems which comply with the applicable IEC safety standard (i.e. IEC60601-1 or IEC60950). Any connection arrangements must be made in a manner compliant with IEC60601-1 or IEC60601-1-1. Users must ensure that they maintain the communications device 1.5 m away from the patient and also must ensure the user does not touch the communications device while touching the patient. If such devices require mains power then the device must be powered using a power supply compliant with the electrical isolation requirements IEC60601-1.

WARNING
The audio connector must only be connected to unpowered microphone headsets or battery powered microphone headsets (such as Peltor® or Bose®). Further details can be obtained from RDT upon request.

WARNING
Optional Tactical switch – this switch allows the user to switch the Tempus Pro visual and audible outputs to a minimal setting and is described in section "3.4.2 Tactical mode (optional)".

CAUTION
Consideration needs to be made to the potential for leakage currents to be created if the Tempus Pro or its connectors are made wet or dusty. In the event that any connectors (but particularly patient leads i.e. ECG, IBP, SpO_2, contact temperature) or their respective sockets become wet or contaminated with sand or dust, they should be cleaned and dried before use, see section "Cleaning the connectors". Connectors and their immediate surrounding areas should be clean and dry at all times.

CAUTION
Do not use USB hubs (powered or unpowered) with the Tempus Pro. This could cause the USB sockets to cease operating.

CAUTION
Ensure the communications connectors are securely covered with their dust covers (if fitted) at all times.

CAUTION
Ingress protection of the 4G dongle might be compromised if the dongle kit or the dongle sleeve is damaged.

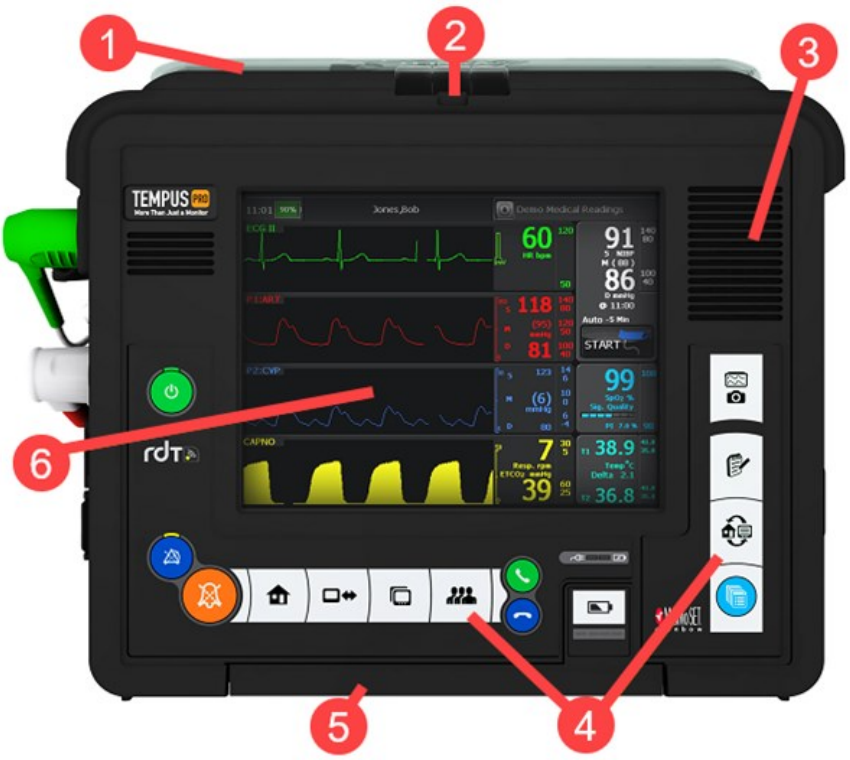
CAUTION
If the Capnometer cover is open it draws air into the enclosure, therefore the device does not conform to IP66. All other covers if open will still maintain the IP66 rating.

The Tempus Pro's connectors are rated IP66 in their own right and are therefore water proof and sand proof against ingress of water or particulate into the device's enclosure without the covers. The covers provide additional protection to prevent nuisance ingress of sand into the connectors in the event that a cable or sensor is not in place.

All Tempus Pro functions will work when the device is operating on battery power. Interruption of the mains power supply will not affect any functions, even if the mains power interruption exceeds 30 seconds.

3.3.1 Tempus Pro front

The front of the Tempus Pro has a large screen which is fitted with a touch-screen. The front panel houses two keypads which are graphically labelled with their function.



(1) Carry strap

(2) Alarm bar

(3) Speaker

(4) Membrane buttons

(5) Battery

(6) Touchscreen

3.3.2 Tempus Pro base

The base of the Tempus Pro houses the battery. The battery can be removed by pushing the latches at each end of the battery together. This will release the battery allowing it to be pulled out.

The battery includes a charge level button and four indicator lights.

(1) Battery

(2) Docking connector

3.3.3 Tempus Pro rear

Non-printer models

(1) Rear alarm light, behind the RapidPak

(2) Storage for the NIBP Cuff

(3) Storage for ECG cables

(4) 4G USB Dongle

(5) Camera

If the Tempus Pro is not fitted with an internal printer (part number 00-1007-R):

- The rear houses the RapidPak clip.
- Also on the rear is the aperture for the camera and backlight.
- The clip carries a general product label for regulatory purposes and also a label that helps to guide the user to repack the ECG cable.

If the Tempus Pro is equipped with a Bluetooth headset:

- The Bluetooth headset can be charged up automatically via a USB connector, ensuring that the headset is always ready to use.
- The Bluetooth headset is a Sennheiser Presence or Sennheiser VMX200.

Printer models

CAUTION

Ingress protection of the 4G dongle might be compromised if the dongle kit or the dongle sleeve is damaged.

Always store the Tempus Pro with a paper roll fitted in the printer.

If the Tempus Pro is a printer model (part number 00-1024-R or 00-1026-R):

- The rear houses the internal thermal printer.
- Also on the rear are the camera, backlight and moveable foot.

- The RapidPak clip is absent.
- The ECG cables and NIBP cuff are stored in the bag.

(1) Rear alarm light
(2) Printer
(3) Moveable foot
(4) Camera

3.3.3.1 Packing the RapidPak

The RapidPak is designed to hold the equipment that follows:

- Adult NIBP Cuff
- 3, 4 or 5 lead ECG cables.

The RapidPak is not designed to carry any other accessories including the modular or 12 lead ECG's

The RapidPak can be packed as follows.

1. Adult NIBP Cuff, containing:
   - the NIBP hose
2. ECG cable storage area

Storing the ECG cables

> **CAUTION**
> The 4-Lead modular device cannot be stored in the rapidpak.

Loop the 3, 4 or 5 lead ECG cables around your hand, before you push the cables into the ECG Cable storage area.

The 12 Lead ECG cable and the modular ECG cable cannot be stored in the ECG Cable storage area.

Storing the NIBP cuff

Use the Adult or Large Cuff to store cables and hoses.

Loop the NIBP hose around your hand before you position the NIBP hose, along with the SpO_2 cable, inside the NIBP Cuff.

You must use your finger to open the RapidPak clip before you insert the NIBP cuff into the RapidPak.

3.3.4 Tempus Pro left side

The left side of the device contains medical connectors.

The Tempus Pro connectors are rated IP66 in their own right and are therefore water proof and sand proof against ingress of water or particulate into the device's enclosure without the covers. The covers provide additional protection to prevent nuisance ingress of sand into the connectors in the event that a cable or sensor is not in place.

(1) ECG socket

(2) NIBP socket

(3) Pulse oximeter (SpO_2) socket

(4) Invasive pressure socket

(5) Capnometry socket

(6) Two contact temperature sockets

3.3.5 Tempus Pro right side

The right side of the Tempus Pro houses the data communication and power connections.

(1) DC in socket

(2) Audio jack

(3) Optional Tactical switch

(4) Ethernet RJ-45 socket

(5) Two USB A sockets

Power Supply Unit

WARNING
The user must connect the Tempus Pro to only approved power supply units, unapproved power supply units can compromise patient safety.

Only use a Tempus Pro approved power supply provided b y RDT, one of the following:

- Tempus Pro AC/DC adapter, part number 989803219271
- Tempus Pro Vehicle power supply, part number 989803219281.

Audio Jack

This is only for use with the Wired Headset (Part number 01-1019) supplied by RDT or for use with the Tactical Headset Adapter Cable (part number 01-2041) supplied by RDT (this cable adapts to Peltor or similar military-style headsets)

Tactical switch (Optional)

This switch allows the user to switch the visual and audible outputs to a minimal setting.
The tactical switch has a cover installed, illustrated below, for non military organizations.

Two USB 2.0 sockets

Whilst connected to a patient these are reserved ONLY for non-mains powered radios (or other communications devices), non-mains powered USB peripherals (such as mouse and keyboards) or non-mains powered medical accessories. Any accessory or peripheral attached to the Tempus Pro MUST be approved for use with the Tempus Pro by RDT.

3.4 Starting and stopping the Tempus Pro and selecting a patient

WARNING
Ensure the latches on both sides of the battery are fully engaged prior to using the Tempus Pro - an incorrectly fitted battery could result in the Tempus Pro losing power during use.

The Tempus Pro can be started in normal mode or tactical mode using the optional tactical mode switch.
See "3.3 Overview of the Tempus Pro" for the switch location.

3.4.1 Switching on

CAUTION

- With the optional tactical switch off, start the Termpus Pro and check that the alarm bar lights and the patient alarm sounds. This is to demonstrate that these functions are operational.
- Do not press any of the controls until the Tempus Pro has started.
- Check the battery charge level, replace or charge if necessary. If the battery is completely discharged during use the device will shut down immediately.
- Before use, check that the speaker and alarm LEDs are functioning correctly.

To switch on the Tempus Pro:

1. If your Tempus Pro has the optional Tactical switch installed, to start the Tempus Pro in Tactical mode, set the optional Tactical switch to the Tactical position.
2. Press and hold the  button on the front panel for 1 second.
3. The LED on the button will flash green.
4. If in normal mode the alarm bar will light and the alarm will sound.
5. The device is ready for use when the power button LED shines green constantly.

3.4.2 Tactical mode (optional)

WARNING
The optional Tactical switch is intended for use by military users for scenarios where low emitted light and low emitted sound is required or desired. Users are reminded that while these functions are enabled, the device will not emit visual alarms from the alarm bar, will not emit audible alarms from the speaker and will present a display that may be too dim to see in daylight conditions. Users should therefore ensure that they use these features only when required and recognize that greater levels of patient care and supervision will be required.

WARNING
To ensure that the Tempus Pro is safe to use when colleagues are using NVGs (night vision goggles), use only the settings in the green shaded **NVG** areas of the **Attention - NVG/Tactical Mode** menu: **LED Indicators** set to **off**, **Brightness** set to **Min**, **Low** or **Mid**.

WARNING
If the maintenance user has configured **Limited Tactical Mode**, the display will not be dimmed when the optional tactical mode is switched on.

- Changing between modes will immediately return the display settings to their previous configuration.
- The optional tactical switch disables the AC power and charging LEDs; these are only enabled using this switch.

Tactical mode is designed for use when low light and sound levels are a necessity. When in tactical mode, the device will not display visual alarms from the alarm bar, or audible alarms from the speaker. The display may be too dim to see in daylight conditions.

Only use tactical mode when necessary. Remember greater levels of patient care and supervision will be required than when using in normal mode.

In tactical mode the Tempus Pro will start in the following configuration:

- All alarm LEDs off
- All audible signals off
- Wireless functions off (*)
- Battery charging and mains power LEDs off
- Display set to mid brightness and standard contrast mode (*)
- Battery charge level LEDs on

(*) If the maintenance user has configured **Limited Tactical Mode**, the preconfigured wireless functions and brightness setting will persist in tactical mode.

Changing between tactical and normal modes

To change between modes:

1. Slide the optional Tactical switch  closer or further away from the tactical mode symbol.

When you turn the Tempus Pro on in tactical mode or change it to tactical mode, the **Attention - NVG/Tactical Mode** menu appears. Adjust the following settings as required:

- **Audio Alarm Sounds**
- **LED Indicators**
- Screen **Brightness**
- **High Contrast**
- **Wireless Enabled**

To toggle **High Contrast**, press and hold the  button on the front panel for 2 seconds.

3.4.3 Selecting or entering patient information

WARNING
Ensure that you select the correct patient record, mixing different patient's records could lead to confusion and misdiagnosis. Records can be identified by:

- Patient **Name** (**Last** and **First**)
- **ID** (4-9 digits)
- Incident start time

If you are not sure if the record you wish to select is the correct one then select **Admit new patient**.

WARNING
Ensure that the Tempus Pro is disconnected from the old patient before confirming that a new patient is being monitored. If this is not done, vital signs data from the old patient will be entered for the new patient.

CAUTION
Patient age group is an important factor for determining the correct initial inflation pressure (and maximum inflation pressure) for non-invasive blood pressure measurements in children of 12 years and under and also for neonates (28 days old or less). Failure to set the correct age group for these patients may result in them being subject to higher inflation pressures than is warranted. For new patients, the default settings are **Adult**/**Male**. Always check and enter the patient's **Age** or select the correct age group.

CAUTION
If the Tempus Pro is connected to an alternate location, discharging the old patient and starting to monitor a new one will create a new patient record at the alternate location. Ensure the alternate location understands who is being monitored.

CAUTION
Admitting a new patient will reset all alarm settings to the factory defaults. See section "5 Alarms" for further information.

Important

- Do not attempt to connect the Tempus Pro to other medical systems until the functionality is properly supported.
- If the sensors are removed from the patient, then the Tempus Pro will not detect the patient. If the Tempus Pro does not detect a patient, the option to select a new or an existing patient will be given.If patient signals are lost for more than 5 minutes, the Tempus will automatically give the user the option of switching to a new patient without having to press the **Patient** button.
- Weight and height are included in the patient report but do not affect any monitoring settings in the Tempus Pro medical parameters.

- The patient's **Age** (or age group) and **Sex** can be entered at any time. If the **Age** (in years) is entered by the user, the Tempus Pro calculates the age group. If the patient's age is not known or is less than 1 year, the user can select the patient's age group. The Tempus Pro uses the selected age group to update alarm limits.
- You can add patient information at any time, it does not need to be done when you first start monitoring the patient.
- If a connection has not been established to an alternate location, all data for the patient can be transmitted at a later time; so long as a new patient is not admitted. See "7 Connecting to IntelliSpace Corsium" for details of how to connect to an alternate location.

- If the patient has a TC3 card you will be able to review its content.
- If the Tempus Pro is powered up within 30 seconds of switching off (for example, when changing the battery) the monitoring will resume automatically and continue to monitor the patient. If you need to monitor a different patient, use the patient information button to discharge/admit patient.

When the Tempus Pro is switched on you can admit/discharge a patient in 4 different ways. These are:

- admit as a new patient
- continue monitoring the last patient
- continue monitoring a patient from the last 72 hours
- continue monitoring a patient whose details have been imported from another Tempus Pro.

If you specify a new patient, the Tempus Pro defaults to an adult. If your patient is not an adult, i.e. 13 years or older, enter their correct age. The monitoring functions and default alarm settings are affected by the age of the patient.

To set the type of patient:

a. Admit as a new patient:
    1. You can choose to enter details now or later. If you press **Enter details now**, the **Patient** details tab opens.
    2. Use the menu button and the touchscreen keyboard to enter the patients:
        - **Name** - **Last** and **First**
        - **Age/Sex**
        - **Weight/Height**
        - **ID**
        - **Allergies**

b. Continue monitoring the last patient:
    1. Press **Still monitoring**.

c. Continue monitoring a patient from the last 72 hours:
    1. Press **Switch to a previous patient**.
    2. Select the correct patient. The Tempus Pro always shows the last 20 patients, even if they were admitted more than 72 hours ago. This feature is useful for multi-casualty situations.
    3. Press **Confirm**.

d. Continue monitoring a patient whose details have been imported from another Tempus Pro:

1. Insert the USB memory device into the Tempus Pro. The Tempus Pro automatically opens the **Data Input / Output Menu** screen.
2. Press **Tempus to Tempus data handover**. The Tempus Pro opens the **Tempus to Tempus data handover** screen.
3. Press the **Import for handover** button.
4. Check that this patient has not been monitored using this Tempus Pro before.
5. Ensure you select the correct patient record. If you are already monitoring the patient you are asked if you want to **Merge the Data**. Select **OK**
6. Press the **Confirm** button.

3.4.4 Entering patient details

WARNING
Patient Details entered into the Tempus Pro either via the Enter Patient Details screen or the TC3 card are a medical record and should be kept in accordance with the standards for medical records in your country.

WARNING
Patient age is used to determine the correct initial and maximum inflation pressures for non-invasive blood pressure measurements in children of 12 years and under, and neonates. Failure to set the correct age for these patients will subject them to higher inflation pressures than is warranted.

To add additional information about the patient at any point:

1. Press the **Patient** button  .
2. Select **Patient details**.
3. Use the touchscreen keys to enter the following details about the patient:

- **Name**
- **Age/Sex**
- **Weight/Height**
- **ID**
- **Allergies**

3.4.5 Switching off

WARNING
Do not remove battery until the LED has gone off.

To power off quickly with no countdown or confirmation:

1. Ensure the Tempus Pro is not in use.
2. Press and hold the  button for 2 seconds.

To power off with countdown and confirmation:

1. Ensure the Tempus Pro is not in use.
2. Press and release the  button. The LED on the on/off button will start flashing.
3. The Tempus Pro displays a 10 second countdown timer.
   Press the **Confirm Power Off** button.

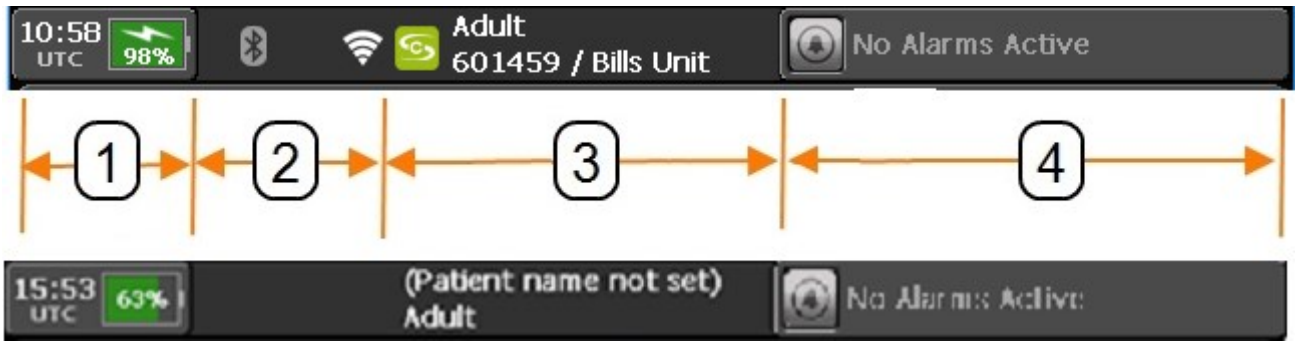
3.5 Home screen and status bar

The Home Screen has the following areas:

- Four parameter channels: these are labelled and color coded to the patient connectors on the sides of the Tempus Pro. In each parameter channel area it will either show the readings / trace or a message saying that the sensor has not been connected
- The vital signs are displayed with the alarm limits in smaller text to the right.
- The touchscreen in each parameter area works as a button. Use the button to access the parameter settings.

3.5.1 Status bar

The status bar across the top of the screen has the following areas:



1. The time and battery status which are always visible. Battery status displays the % charge left, and if the battery is being recharged:

Tempus Pro battery is not currently charging.

Tempus Pro battery is connected to mains power and charging is in progress.


Tempus Pro cannot communicate with the battery - check the following:

- Is the battery fitted?
- Are the battery clips fully engaged?
- Are the battery contacts clean and undamaged?
- Is the battery in deep discharge state?

For more information, see"9.4.3 Checking the charge"

2. Icons indicate which peripheral features are connected or running.
3. The Patient **Name**, which you entered into the **Patient** tab, and Type of patient. Patient Type defaults to **Adult**, i.e. 13 years or older. Connection status replaces the patient name.
4. Alarm status, which shows the active alarm or the last patient alarm time.

The battery charge can always be checked by pressing the **Battery Gas Gauge** button, even when the Tempus is switched off – see "9.4 Tempus Pro battery".

3.5.2 Touchscreen lock

The maintenance user can enable, disable and configure the Tempus Pro touchscreen timeout period.

When the home screen is displayed, if you do not press the touchscreen or membrane buttons and the timeout period expires, the touchscreen locks automatically. Tempus Pro continues to perform all monitoring and alarming functions when the touchscreen is locked.

You can control the touchscreen lock:

- To unlock the touchscreen, press any membrane button.
- To lock the touchscreen, press and hold the **Home** button  for two seconds.

If NIBP monitoring is in progress when the touchscreen is locked, the NIBP **STOP** button remains active as a safety feature.

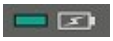
The timeout period and touchscreen lock only apply when the Tempus is on the home screen.

3.6 Membrane buttons and LED indicators

	The **On/Off** button. Press and hold it down to start or stop the Tempus Pro. See "3.4.1 Switching on".
	The **Alarm Suspend** button. Press it to prevent alarms for 2 minutes or for as long as is configured in the alarm settings. See "5.3 Silencing or suspending alarms".
	The **Alarm Silence** button. Press it to stop any audible alarm signals for 2 minutes or for as long as is configured in the **All Alarms Menu**. See "5.3 Silencing or suspending alarms".
	The **Home** button. Press it to make the touchscreen display the home screen. When the home screen is displayed, press and hold the **Home** button for 2 seconds to lock the touchscreen.
	The **Data Input / Output** button. Press it to access the **Data Input / Output Menu**. Press and hold it for 2 seconds to automatically open **Send Patient Data/Report**. See "3.7.4 Data Input / Output Menu".
	The **Display** button. Press it to access the **Display Menu** settings on the touchscreen. Press and hold it for 2 seconds to automatically set **High contrast** to **on** for use in strong daylight conditions. See "3.7.2 Display Menu"
	The **Patient** button. Press it to access the **Patient Menu**. Press and hold it for 2 seconds to automatically select the **Patient** details tab.
	The **Connect** button. See: "7 Connecting to IntelliSpace Corsium"
	The **Disconnect** button. See: "7 Connecting to IntelliSpace Corsium"

	The **Camera & Waveform Snapshot** button. Press and release to capture a waveform. Press and hold to start the **Camera & Video** screen. Certain events will cause the Tempus Pro to capture a waveform automatically. For devices with software revisions earlier than v4, this button will only perform the camera function. Please contact RDT for software updates. See: • "8.3 Using the digital camera". • "6.1 Event capture".
	The **Main Menu** button. Press and release to access the **Main Menu (Monitoring)**, **Main Menu (Communications)** and **Main Menu (Settings)** screens. See "3.7.1 Main Menu" .
	The **Event** button. Press it to access the Summary Record of Care (SRoC), trend graphs, trend tables and the TCCC card (if configured). See "6 Summary record of care".
	The **Previous Activity** button. Press it to return to whatever non-monitoring function was last performed. For example, if an alarm is raised when you are editing the **TC3** card, you can investigate the alarm and then use this button to return to the **TC3** card.
	The **Battery Gas Gauge** button. Press it to turn on the LEDs that display power status. See "9.4.3 Checking the charge".

The Tempus Pro has the following LED indicators:

	The mains power LED. It lights solid green when the mains charger is attached.
	The Battery Charger LED. It flashes green for up to 20 seconds when a battery is first connected and lights when the battery is charging.

3.7 Menus

3.7.1 Main Menu

> **CAUTION**
> The **Quick Start Guide** is intended to provide field-based users with summary information only. It does not replace the need to read this User Manual or any other Tempus Pro labelling, and does not replace proper training on the Tempus Pro.

Press the **Main Menu** button  to access the following features and controls:

- **All Alarms** menu - displayed in the right-hand column of the **Main Menu** screen - see "5 Alarms" section.
- **Trends** button - displayed in the right-hand column of the **Main Menu** screen - see "6.3 Trends" section.

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- **TDL Settings** - see "11 Linking Tempus LS to Tempus Pro".
- **Quick Start Guide** – pressing each numbered button will take you through a series of graphics which explain the features of the device.
- **Medical Parameter Settings** – provides access to the **Medical Parameter Settings** menu. Settings details are provided in section "4.1 Medical Functions - General". Each medical parameter setting can also be accessed by pressing the area of the home screen associated with the required parameter.
- **Summary Record of Care** - performs the same function as the **Event** membrane button.
- **Waveform Snapshot** - performs the same function as pressing and releasing the **Camera & Waveform Snapshot** membrane button.
- **Display Menu** – performs the same function as the **Display** membrane button.

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- **Patient Menu** – performs the same function as the **Patient** membrane button. See "3.4 Starting and stopping the Tempus Pro and selecting a patient" section.
- **Data Input / Output Menu** – performs the same function as the **Data Input / Output** membrane button. See "3.7.4 Data Input / Output Menu"section.
- **Previous Activity** - performs the same function as the **Previous Activity** membrane button.
- **Camera** - performs the same function as pressing and holding the **Camera & Waveform Snapshot** button. See "8.3 Using the digital camera" section.
- **Home** – performs the same function as the **Home** membrane button.
- **iAssist** on-off switch – see "3.8 iAssist processes" section.

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- **Communication Modes** - see section "8.4 Identifying your location (GPS)" .
- **Wireless Enabled** - allows all wireless communications to be disabled or enabled from a single control.

  If any of the wireless communication features are not enabled (either not purchased or disabled in the device's maintenance settings) then they will be greyed out.

- **Connect** – performs the same function as the **Connect** membrane button.
- **Manage Wi-Fi Networks** - provides access to the **Manage Wi-Fi Netwroks** menu. See "8.1 Managing Wi-Fi networks"
- **GPS Location** – allows the Tempus Pro's built-in GPS module to identify the unit's location. See"8.4 Identifying your location (GPS)" section.

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- **Power and Clock Settings** – provides access to screen **Power save mode**, **Brightness**, **Date** and **Time**. See "3.10 Changing the date and time (optional)" section.
- **Maintenance and Settings** – provides access to the **Maintenance and Settings** menu. Use this menu to change the unit name or mode network settings. See the *Tempus Pro Maintenance Manual* for more details.
- **Demonstration and Training** – provides access to the **Demonstration and Training** menu. See "8.7 Demonstration and training" section.
- **About Tempus Pro** – displays device identification data and a list of features installed on Tempus Pro.
- **Printer and Headset** - see "9.5 Wireless headset battery" and "8.5.2 Send patient report to an external printer".

3.7.2 Display Menu

WARNING
The low display settings are intended for use by military users for scenarios where low emitted light is required or desired. Users are reminded that while these functions are enabled, the device will present a display that may be too dim to see in daylight conditions. Users should therefore ensure that they use this feature only when required and recognize that greater levels of patient care and supervision will be required.

Press the **Display** button  to gain access to the following features and menus:

- Display mode icons - offers different ways to display the vital signs data on the Home Screen. Each Home Screen display option is shown as an icon. Select the option you need to use.

- When performing a diagnostic ECG, press the **Display** button to show the diagnostic view on the home screen. See "4.2.10 ECG settings" for more details.
- The second waveform in the large ECG view defaults to display the impedance pneumography (ECG respiration) if the capnometer is not plugged in.
- When switching between the 4 waveform and the large ECG views, the **ECG gain (mm/mV)** only changes if the gain is set to 1mm/mV or 2 mm/mV on the 4 channel view. When these gain settings are used, the ECG will be displayed as 4 mm/mV. See section "4.2.10 ECG settings" for details of how to adjust the gain settings to optimize the available waveform height.

- **High Contrast** - offers a high contrast view of the results screen - black on white. The high contrast display mode can be enabled automatically by pressing and holding the button for 2 seconds. This allows you to switch the high contrast display on by pressing a single button.

The high contrast display is available for all Home Screen display modes.

- **Waveform / Lead selection** - used to customize the selection of waveforms in the four-waveform home screen. See section "3.9 Waveform and lead selection".
- **Brightness** - the screen's brightness has five available settings as follows:
  - **Min** – 10%;
  - **Low** – 30%;
  - **Mid** (default) – 60%;
  - **High** – 80%;
  - **Max** – 100%.

- **Min**, **Low** and **Mid** are compatible with NVGs (night vision goggles).
- Using a lower brightness setting will improve battery life.
- Only use the **Max** setting in locations with strong sunlight.

- **Lock Touchscreen** - allows the touchscreen to be intentionally disabled. When pressed you are prompted to disable the touchscreen lock, by pressing the buttons marked "1" then "2" within 3 seconds of each other. If neither button is pressed, or the buttons are not pressed in the correct sequence, then the message will leave the screen after 5 seconds.
- **Power Save Mode** - If no controls are used and no alarms triggered, the display can be set to revert to the **Min** brightness setting after 15 minutes reducing power consumption. This setting does not persist after powering off the device.

3.7.3 Patient Menu

If the sensors are removed from the patient, then the Tempus Pro will not detect the patient.

If the Tempus Pro does not detect a patient, the option to select a new or an existing patient will be given..

If patient signals are lost for more than 5 minutes, the Tempus will automatically give the user the option of switching to a new patient without having to press the **Patient** button.

Press the **Patient** button  to gain access to the following features and menus:

- **TC3 card** – complete an electronic version of the military Tactical Combat Casualty Care (TCCC) card.

  The **TC3 card** option is only available on Tempus Pro units sold to military users.

- **Patient details** - allows you to complete the Summary Record of Care (SRoC).
- **Discharge/admit patient** - allows you to admit new or existing patients, and discharge them.
- **Switch to a previous patient** - allows you to switch between the current patient and any patient that has been monitored on the same Tempus Pro within the last 72 hours.
- **Medics** - allows you to enter details of medics.
- **End of shift** - allows you to clear the patient list. This means that you will not have access to previous patient incidents.

3.7.4 Data Input / Output Menu

Press the **Data Input / Output** button  to gain access to the following features and menus:

- **Send patient data/report** - see "8.5 Sending patient data/report" section.
- **Tempus to Tempus data handover** - see "8.6 Tempus to Tempus data handover" section.
- **Laryngoscope** - described in *Tempus Pro Laryngoscope Supplement Guide*.
- **Ultrasound** - described in *Tempus Pro Ultrasound Supplement Guide*.
- **Import Tempus LS data** - for use with the Tempus LS system.

3.8 iAssist processes

The iAssist mode on the Tempus Pro guides you through a series of processes. Every step is detailed in pictures with accompanying text instructions.

> Always ensure that you read the complete iAssist help process in order and do exactly what it requires.

iAssist Mode can be set by experienced Tempus Pro users so less experienced users are supported by on-screen instructions.

To start the iAssist mode:

1. Press **Main Menu** button  .
2. Press the **iAssist** button.

The second ECG lead waveform will be removed and the plethysmogram and capnogram will be moved up to make room for a row of graphical symbols. Press the symbol to get iAssist instructions for that area. The areas currently covered are:

 ECG monitoring

 Non-invasive blood pressure

 Blood oxygen

 Capnometry

 Temperature

There are instructions for everything you need to use the parameter the process is supporting.

3.9 Waveform and lead selection

Use the Waveform / Lead Selection screen to customize the display of waveforms in the four-waveform home screen. To access this screen, either press the **Display** button  and then press **Waveform / Lead selection**, or from the **ECG Settings** menu press **Waveform / Lead selection**.

(1) Waveform regions (the first is reserved for ECG)

(2) ECG leads (availability depends on the type of ECG cable connected)

(3) Plethysmogram or capnogram

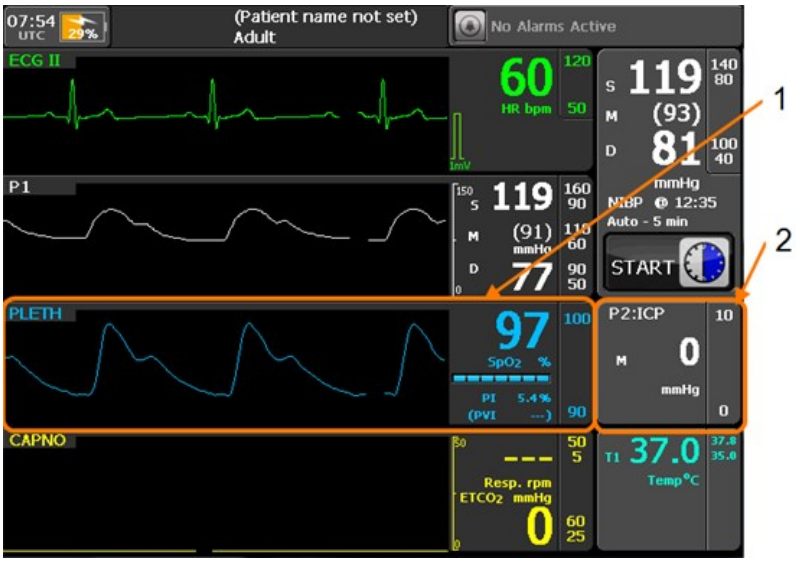
(4) AA gas vitals (optional)

(5) IBP sensors (availability depends on the number of IBP sensors connected)

There are two ways to update the waveform display:

- Either: press a waveform region and then press a waveform. For example, press **Waveform 3** followed by **PLETH**.
- Or: press a waveform and then press a waveform region. For example, press **PLETH** followed by **Waveform 3**.

If you assign **Waveform 3** to **PLETH** by following either of the above methods, the four-waveform home screen will look like this:



(1) Plethysmogram

(2) P2

- You can swap two waveforms around by pressing one waveform region and then pressing the other waveform region.
- The waveform selection feature is not available when iAssist Mode is activated.

3.10 Changing the date and time (optional)

You can change the date and time setting of Tempus Pro only if the maintenance user has allowed user control.

> **CAUTION**
> Do not change the date or time during a patient incident, as it will cause a new patient to be admitted.

To change the date and time:

1. Press **Main Menu** button  .
2. Press the **Power and Clock Settings** button to display the **Power and Clock Settings** menu:
   If the **Date** and **Time** button contains chevron characters, this indicates that the maintenance user has allowed user control and you can press the button to update the date and time:
   

   If the chevrons are not present and the message panel displays "**To change the date or time refer to the maintenance manual**", you cannot update the date or time.
3. Press the **Date** and **Time** button (if selectable). The Tempus Pro displays the **Date and Time Settings** screen.
4. Use the keyboard and arrow controls to set time zone, time, day, month and year.
   > To avoid confusion, do not adjust time zone and clock at the same time.
   > Always check the clock after making changes.
5. Press the **Save** button.
6. A confirmation dialog is displayed: press **Yes** if you wish to confirm the date/time change and admit a new patient, otherwise press **No**.
7. If you have confirmed the date/time change, the **Discharge/admit patient** screen is displayed.

4 Medical functions

This chapter explains how to use the Tempus Pro to monitor a patient's vital signs.

When a medical module is started, the word **initializing** may appear for a few seconds in the associated results area.

This chapter contains the following topics:

4.1 Medical Functions - General

4.1.1 Sterile Accessories

The Tempus Pro is supplied with no sterile accessories.

4.1.2 Cable connections

WARNING
Hoses and sockets are easily damaged.

Where a moulded connector is provided the user must always grip the moulded connector when connecting or disconnecting a hose or cable.

4.1.3 Accessory Interactions

Refer to the IFU for the specific accessory in use.

The accessory IFU gives user information for the accessory including information on where the accessory interacts with the Patient.

Accessory	Patient Interaction
Electrocardiography (ECG)	
• ECG Electrodes	Skin, for more information refer to "1.4.1 Electrocardiograph (ECG)"
Non-Invasive Blood Pressure	
• Blood Pressure Cuff	Skin, for more information refer to the accessory IFU
Pulse Oximetry	
• SpO_2 Sensor	Skin, for more information refer to the accessory IFU
Invasive Pressure	
• Invasive pressure transducers	Interact by measuring pressure, typically blood pressure, through invasive fluid ports
Capnography	
• Capnography sample line	Skin, for more information refer to the accessory IFU
Contact Temperature	
• Contact thermometer	Skin, for more information refer to the accessory IFU

4.2 Electrocardiography (ECG)

You can display up to two of a possible twelve ECG waveforms on the home screen. The waveforms available are dependent on the cable type used:

- 3-lead cable = three waveforms, but only one waveform is viewable at a time;
- 4-lead cable = six waveforms, the Tempus Pro can display any two you select;
- 5-lead cable = seven waveforms, the Tempus Pro can display any two you select;
- 12-lead cable = twelve waveforms, the Tempus Pro can display any two you select.

WARNING
The Tempus Pro is not intended for use in a sterile environment. Do not use for direct cardiac application.

WARNING
The ECG device is reusable, other than disposable single-use electrodes.

WARNING
Do not attempt to insert the ECG device (including patient cables) into an electrical outlet.

Make sure that the electrodes are connected only to the patient.

Conductive parts of electrodes and connectors, including neutral electrode, should not contact other conductive parts including earth.

The Tempus Pro is rated as being proof against the effects of a defibrillator discharge. Follow these warnings if using an AED or defibrillator with the Tempus Pro:

- Follow the instructions of the defibrillator or AED when using it with the Tempus Pro.
- Do not touch the patient during defibrillation.
- Do not touch the defibrillator's paddle-electrode surface when discharging the defibrillator.
- Do not touch the patient, bed, or any conductive material in contact with the patient during defibrillation.
- Keep defibrillation electrodes well clear of other electrodes or metal parts in contact with the patient.

The Tempus Pro is protected against defibrillator discharge. However, rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.

Do not use electrodes of dissimilar metals.

WARNING
The ECG is for resting recordings and should not be used in stress testing environments.

WARNING
The Tempus Pro may not operate effectively on patients who are experiencing convulsions or tremors, or who are moving or are in motion (transport) environments. In such cases remember to use best practise for electrode site selection (torso rather than limbs), site preparation (cleaning/scrubbing with an alcohol wipe) and cable securement at the sensor site and as much as possible along the cable's length. In motion environments the Tempus Pro should be secured using a clamp or strap and to obtain the best possible readings the device should be damped to reduce shocks or vibrations if possible.

WARNING
Always set the Tempus Pro to the correct patient age to ensure the QRS detector is set to detect appropriate R wave amplitudes. The Tempus Pro uses the definitions of patient age provided as follows:

- Neonate – Children 28 days old or less if born at term (based on 37 week gestation), otherwise up to 44 gestational weeks.
- Pediatric (Child) – Children of 29 days up to and including 12 years old.
- Adult – Individuals 13 years old or older.

Failure to set the correct age may result in the Tempus Pro mis-detecting R waves and providing incorrect heart rate values.

Setting the patient age to 8 years or less will mean that the ECG monitor will be set to detect pediatric R waves.

If you do not set the patient age, the Tempus Pro will use the default patient age group (see the *Tempus Pro Maintenance Manual*). Ensure that the patient age/type is always entered for non-adult patients (see "Starting and stopping the Tempus Pro and selecting a patient".

WARNING
Tempus is suitable for use in the presence of electrosurgery. Burn hazard protection is provided via a 1K current-limiting resistor contained in each ECG lead wire. Proper lead placement (see 6.1.2 to 6.1.4), avoiding the site of the electrosurgery, is important to reduce burn hazards in the event of a defect in the electrosurgical equipment. Do not entangle the ECG cables with the electrosurgical equipment wires; do not place the ECG cabling near the electrosurgical equipment's grounding plate.

WARNING
Defibrillator protection requires the use of RDT specified accessories such as:

- patient cables
- lead wires
- transducers.

WARNING
To prevent return currents through electrodes or other patient applied parts of the monitor, make sure that the electrosurgery return electrode is correctly connected. To reduce risk in the event of a defect in the return electrode, keep electrode cables away from earth, ground and other parts and cables of the electrosurgery equipment.

WARNING
When two or more items of equipment are connected to the patient, make sure that the sum of leakage currents is within a safe limit.

CAUTION
As the following sections will explain, the Tempus Pro will present results in a different layout depending on whether the device is set to ECG monitoring or Diagnostic ECG. The alarm functions will be the same in either case.

CAUTION
Certain line-isolation monitors may cause interference on the ECG display and may inhibit heart rate alarms. Users should ensure electrodes are placed correctly, with the skin prepared in advance as instructed.

CAUTION
The Tempus Pro may not operate effectively on patients who are in motion. If you are in a transport environment, or the patient experiences convulsions or tremors, make sure that you:

- Place electrodes on the torso rather than limbs.
- Clean the skin extra carefully.
- Secure the cables, especially near the sensors.
- Secure the Tempus Pro with a clamp or strap.
- Position the Tempus Pro to reduce shocks or vibrations.

CAUTION
ECG electrodes must be applied carefully. Follow the electrode manufacturer’s instructions in the storage, removal and application of the electrodes to the patient to ensure the electrode is placed optimally.

CAUTION
Care must be taken to ensure that ECG electrodes do not contact live (electrical) parts or earthed metal parts of local systems or structures.

CAUTION
If the patient is attached to a cardiac defibrillator, care must be taken not to touch any part of the ECG cables while the patient is being shocked.

CAUTION

- Check all leads and cables of the ECG for fraying, tears, knots or other signs of damage before and after use.
- Make sure that you follow all instructions for ECG electrodes.
- Check that all labels are correct and that use-by date has not passed.
- Make sure that no electrodes are dry.
- If you have no ECG cable connected, or the electrodes which the heart rate is measured from are disconnected, heart rate can be derived from the pulse oximeter.
- Ensure that all labelling including instructions for use, printed warnings and use-by dates associated with third-party ECG electrodes are adhered to.

CAUTION
If an ECG lead does not work, Tempus Pro can display a “Leads off” error for that lead. If it does not display "Leads off", it can display one of the errors given in section "5.5 Technical alarms".

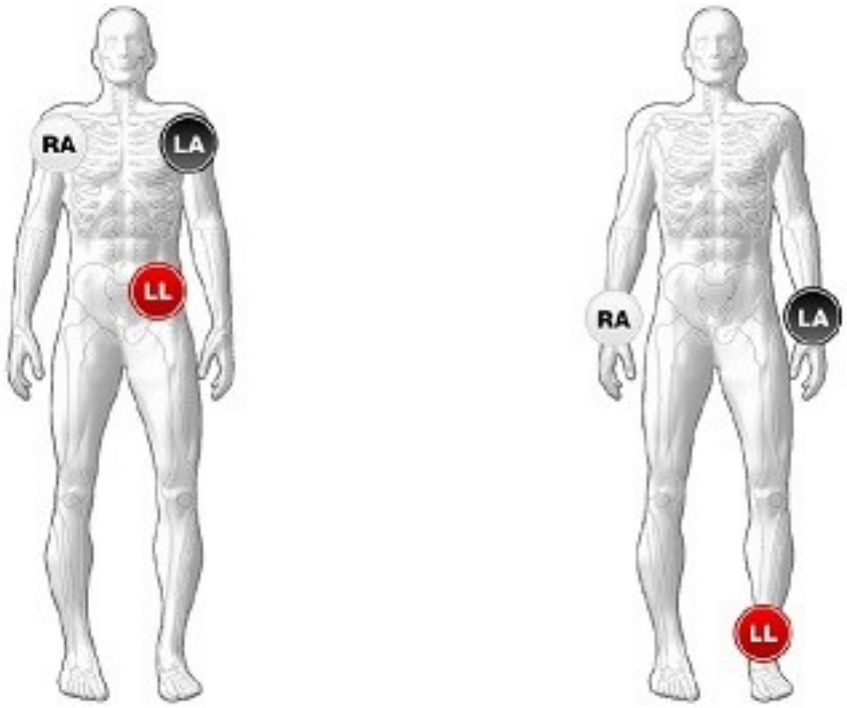
(1) ECG socket

4.2.1 Getting started

1. To measure correct R wave values, make sure that the right age group is selected in the patient details. For instructions, see "3.4.3 Selecting or entering patient information".
2. Make sure that you have read the monitoring standards in "Tempus Pro medical specifications".
3. Ensure that the ECG cable is properly inserted into the green connector on the Tempus Pro.
4. Prepare the patient's skin at the electrode sites:
    1. Shave or clip excess hair.
    2. Clean the skin thoroughly with an alcohol wipe.
    3. Rub the skin to dry.
5. If the patient has a pacemaker, turn on pacemaker indication:
    1. Press the **ECG** area of the touchscreen or navigate to the **Medical Parameter Settings** in the **Main Menu** and select **ECG Settings**.
    2. Switch **Pacemaker indication** on.
6. Make sure the ECG power filter is on to reduce the effect of mains frequency interference on ECG signals.
    1. Refer to the Maintenance manual for instruction on how the frequency can be set.

4.2.2 Monitoring ECG with a 3-lead cable

1. Attach the electrodes to the patient using AAMI or IEC cables.

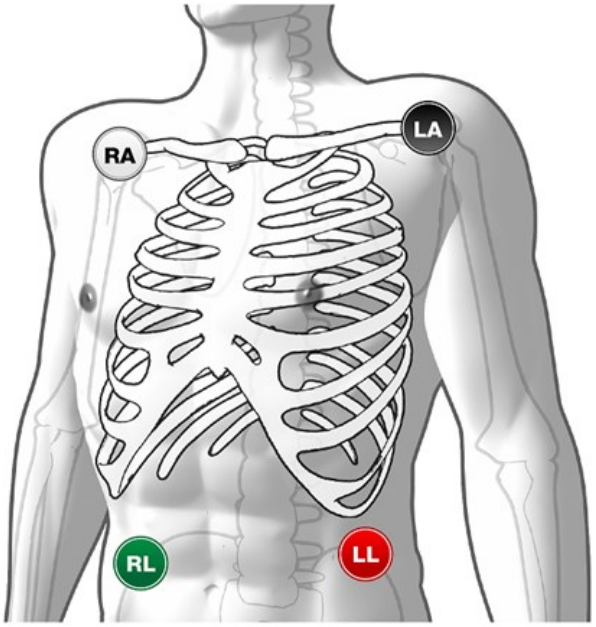


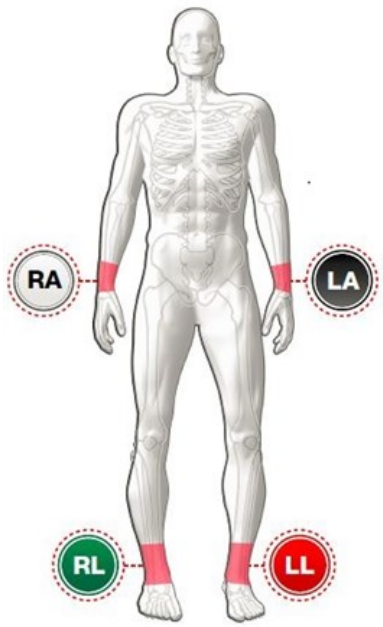
Position of electrode	AAMI	IEC
Right mid-clavicular line under clavicle or right wrist	RA White	R Red
Left mid-clavicular line under clavicle or left wrist	LA Black	L Yellow
Left hip or left ankle	LL Red	F Green

2. The Tempus Pro will automatically detect the cable type - AAMI or IEC.
3. The Tempus Pro will start displaying ECG signals immediately.

4.2.3 Monitoring ECG with a 4-lead cable

1. Attach the electrodes to the torso or limbs of the patient using AAMI or IEC compliant cables:





Position of electrode	AAMI	IEC
Right mid-clavicular line under clavicle or right wrist	RA White	R Red
Left mid-clavicular line under clavicle or left wrist	LA Black	L Yellow
Left hip or left ankle	LL Red	F Green
Right hip or right ankle	RL Green	N Black

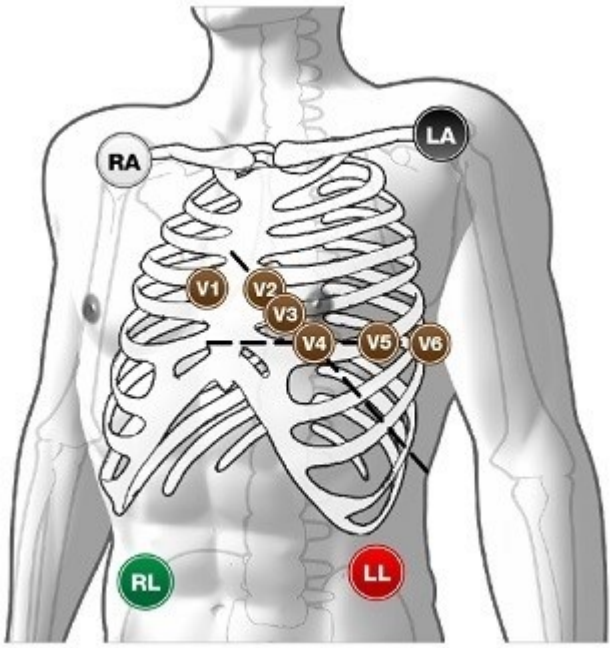
If the ECG is inoperable then the ECG will either:

- Show a "Leads off" error or
- Show a technical error as described in "5.5 Technical alarms"

2. The Tempus Pro will automatically detect if the cable is AAMI or IEC compliant.
3. The Tempus Pro will start displaying ECG signals immediately.

4.2.4 Monitoring ECG with a 5-lead cable

1. Attach the electrodes to the patient using AAMI or IEC compliant cables.



Position of electrode	AAMI	IEC
Right mid-clavicular line under clavicle or right wrist	RA White	R Red
Left mid-clavicular line under clavicle or left wrist	LA Black	L Yellow
Left hip or left ankle	LL Red	F Green
Right hip or right ankle	RL Green	N Black
In any of the following positions: ◦ V1 - 4th intercostal space at right sternal margin ◦ V2 - 4th intercostal space at left sternal margin ◦ V3 - midway between V2 and V4 leads ◦ V4 - 5th intercostal space at mid-clavicular line ◦ V5 - Same transverse level as V4 at left anterior-axillary line ◦ V6 - Same transverse level as V4 at left mid-axillary line	V Brown	C White

If the ECG is inoperable then the ECG will either:

- Show a "Leads off" error or
- Show a technical error as described in "5.5 Technical alarms"

2. The Tempus Pro will automatically detect if the cable is AAMI or IEC compliant.
3. The Tempus Pro will start displaying ECG signals immediately.

4.2.5 Previewing a 12-lead ECG

The **12 Lead Preview** screen is to preview the ECG in advance of acquiring, printing, transmitting and storing a 12-lead ECG. It displays real-time 12-lead ECG data to verify signal quality before acquiring a diagnostic 12-lead ECG.

WARNING
Possible misinterpretation of ECG Data: the preview display does not provide the facility for diagnostic and ST segment interpretation. For diagnostic or ST segment interpretation, or to enhance internal pacemaker pulse visibility, a diagnostic quality 12-lead must be recorded and viewed either as a static 12-lead (with background grid) or a 12-lead print out.

WARNING
Before previewing a 12-lead ECG, ensure you have selected the appropriate **12 lead filter** settings.

WARNING
Do not use the **Monitoring filter** for diagnostic purposes, as it may lead to incorrect diagnosis.

WARNING
When acquiring a 12-lead ECG, encourage the patient to remain as still as possible.

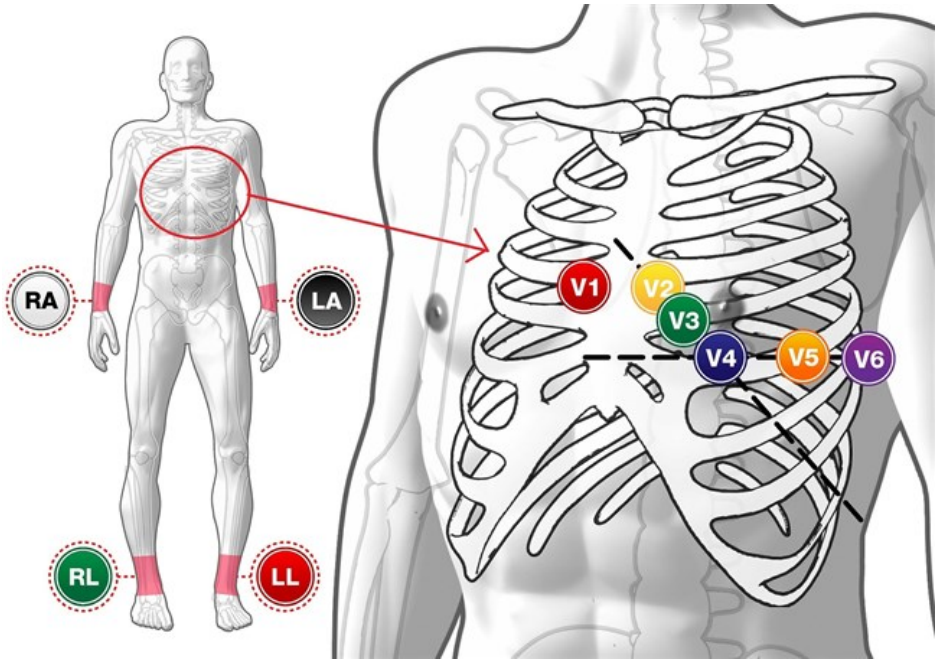
If the **12 LEAD** button is not available in the selected screen format, there are two alternative ways to view a 12-lead ECG:

- Press the ECG area of the home screen to display the **ECG Settings** menu, then press **View 12 lead ECG**.
- Press the **Display**  membrane button, then press the twelve lead diagnostic view icon.

If the Glasgow Interpretation option is used but you have not yet entered the patient's age or sex, the **Patient Age/Sex** screen is displayed: enter age and sex (if known) and press **OK**.

You can use a standard 12-lead ECG cable or a 12-lead modular cable (a 4-lead cable connected to an additional 6-lead cable). For part numbers see "B.8 Electrocardiogram accessories".

1. Connect the 12-lead ECG cable to the Tempus Pro.
2. Attach the electrodes to the patient as illustrated below.



Position of electrode	AAMI	IEC
Right mid-clavicular line under clavicle or right wrist	RA White	R Red
Left mid-clavicular line under clavicle or left wrist	LA Black	L Yellow
Left hip or left ankle	LL Red	F Green
Right hip or right ankle	RL Green	N Black
V1 - 4th intercostal space at right sternal margin	V1 Red	C1 Red
V2 - 4th intercostal space at left sternal margin	V2 Yellow	C2 Yellow
V3 - Midway between V2 and V4 leads	V3 Green	C3 Green
V4 - 5th intercostal space at mid-clavicular line	V4 Blue	C4 Brown
V5 - Same transverse level as V4 at left anterior-axillary line	V5 Orange	C5 Black
V6 - Same transverse level as V4 at left mid-axillary line	V6 Violet	C6 Violet

If the ECG is inoperable then the ECG will either:

- Show a "Leads off" error or
- Show a technical error as described in "5.5 Technical alarms"

3. The Tempus Pro will automatically detect if the cable is AAMI or IEC compliant.
4. The Tempus Pro will start displaying ECG signals in standard (one or two waveform) view.
5. Press **12 LEAD**.
6. The Tempus Pro will display the **12 Lead Preview** screen.

4.2.6 Monitoring heart/pulse rate with no leads

If no ECG cable is connected, the heart rate can be derived from the pulse oximeter.

This option can also be selected manually using the **HR/PR source** control in the **ECG Settings** menu.

If the ECG cable is not connected but the pulse oximeter is, the heart rate will be shown in the same place, in green but the signal will be derived from the pulse oximeter. In this event the reading will be labelled **Pulse bpm** as shown below. In this condition the systole (heart symbol) is not shown and the systole tone will be replaced by the pulse ox tone. High and low heart rate alarms will operate as before.

If the ECG is inoperable then the ECG will either:

- Show a "Leads off" error or
- Show a technical error as described in "5.5 Technical alarms"

4.2.7 ECG Filter guidance

ECG monitoring filter Bandwidth	Guidance for use	Remark
0.67 – 20 Hz	To remove excessive motion artefact from the ECG for basic monitoring of rhythm and rate.	This setting is optimised for removing motion artefact from the displayed ECG while monitoring rate and rhythm. Distortion may occur to the ECG shape.
0.5 – 40 Hz	To remove motion artefact from the ECG for basic monitoring of rhythm and rate.	This setting reduces distortion to ECG complex shape and has a fast response to baseline wander. Overshoot may occur to distort the ECG shape.

ECG monitoring filter Bandwidth	Guidance for use	Remark
0.05 - 40Hz	To reduce motion artefact from the ECG for monitoring of rhythm and rate with ST segment displayed.	This setting allows ST segments to be viewed. It complies to IEC60601-2-27 section 201.12.1.108.8. It has a slow response to baseline artefact.
0.05 – 150Hz	ECG display of rhythm and rate with ST segment displayed but with more motion artefact.	This setting allows ST segments to be viewed. It complies to IEC60601-2-27 section 201.12.1.108.8. It has a slow response to baseline artefact. It has the widest bandwidth.

4.2.8 Detecting arrhythmias during ECG monitoring

During ECG monitoring, the Tempus Pro analyzes the 2 ECG waveforms on the home screen to detect arrhythmias. All results are displayed as text on the results screen.

WARNING
ECG monitoring arrhythmia analysis is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times.

The Automated ECG Arrhythmia Analysis software is designed to be used by qualified medical personnel.

The clinician and/or medically qualified personnel are responsible for determining the clinical significance of each detected arrhythmia event or alarm.

The arrhythmia detection feature on the Tempus Pro is not a diagnosis tool and is an optional tool to support the clinician in their own diagnosis only. The classification performance of the arrhythmia feature has been tested using the FDA recognized consensus standard. The analysis algorithm has also been tested and approved in other products. The monitor cannot be relied upon to detect all arrhythmias. Do not rely solely on the displayed arrhythmia data and alarms to assess the patient's condition. Always observe the patient closely and monitor all of their vital signs carefully.

WARNING
The arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect atrial or supraventricular arrhythmias. The program may incorrectly identify the presence or absence of an arrhythmia. A physician must analyze the arrhythmia information with other clinical findings.

WARNING
The system can filter out some interference but corrupted or excessively noisy signals may cause artifacts. If the ECG waveform is too noisy, "Noise" is displayed on screen. If no arrhythmias are detected and there is no noise in the signal, "Arrhythmia Analysis On" is displayed to ensure the operator is aware arrhythmia analysis is running.

WARNING
Heart parameters can be affected by the use of drugs. Patient drug use history should be reviewed when reviewing detected arrhythmia.

WARNING
For patients with pacemakers, ensure pacemaker indication is turned on.

WARNING
Arrhythmia analysis is sourced from the ECG signal (including detection of extreme bradycardia, extreme tachycardia). This is independent of the heart rate display source selection (**ECG** or **Pulse**).

CAUTION
Only start arrhythmia learning during periods of predominantly normal rhythm, and when the ECG signal is relatively noise-free. If arrhythmia learning takes place during ventricular rhythm, the ectopics may be incorrectly learned as the normal QRS complex. This may result in missed detection of subsequent arrhythmias.

CAUTION
If arrhythmia analysis is not restarted when a template changes.

- Inaccurate arrhythmia alarms can be triggered
- Inaccurate heart rates can be recorded.

To optimize arrhythmia detection, select leads with the largest amplitude and the least amount of noise to be analyzed.

An arrhythmia detection relearning period can also be triggered when you:

- Change patients
- Change **Waveform / Lead selection**.

To optimize arrhythmia detection, select leads with the largest amplitude and the least amount of noise to be analyzed.

1. Turn on **Arrhythmia analysis** (**ECG Settings** menu). Arrhythmia detection starts up and performs a learning period.
2. To change the waveforms being analyzed, press **Waveform / Lead selection** on the **ECG Settings** menu.
3. If a patient's ECG template changes dramatically, turn **Arrhythmia analysis off** and **on**. Arrhythmia detection performs a relearning period based on the new template.

The following arrhythmia events are detected and recorded:

Arrhythmia	Screen text	Description	High priority patient alarm triggered	Event/waveform capture
Extreme bradycardia	**Extreme Brady**	The average heart rate is 5 bpm below the low heart rate set on the Tempus Pro (with a maximum of 60 bpm).	Yes	Yes
Extreme tachycardia	**Extreme Tachy**	The atrial and ventricular rates are equal. The heart rate is 5 bpm above the high heart rate limit set on the Tempus Pro (with a minimum of 100 bpm)	Yes	Yes
Ventricular tachycardia	**Vent Tachy**	Ventricular HR is greater or equal to the Tachycardia rate threshold and the number of PVCs is greater than 6.	Yes	Yes
Asystole	**Asystole**	No QRS complex for 5 consecutive seconds (in absence of ventricular fibrillation or chaotic signals)	Yes	Yes
Ventricular fibrillation	**Vent Fib**	Ventricular fibrillation occurs and persists for more than 6 seconds.	Yes	Yes

A medium priority alarm is triggered when:

- **Arrhythmia analysis** is turned **off**, and either the low heart rate or high heart rate alarm limits are breached.
- **Arrhythmia analysis** is turned **on**, and either the low heart rate or high heart rate alarm limits are breached.

A high priority **Extreme Brady** or **Extreme Tachy** alarm is triggered when the heart rate continues past already breached alarm limits.

A 20 second waveform snapshot is captured for all arrhythmia events that trigger an alarm. See "6.1 Event capture" for more details.

4.2.9 Measuring ST elevation and QT interval (optional)

During ECG monitoring, the Tempus Pro takes ST and QT measurements using the 2 ECG waveforms on the home screen. The following measurements are displayed on the results screen:

- ST measurement - elevation (+) or depression (-)
- QT duration

To take ST and QT measurements, you can use any of the lead types for the ECG cable.

To change the waveforms being measured, press **Waveform / Lead selection** on the **ECG Settings** menu. An ST measurement for each waveform is taken along with a single global QT measurement:

- A 3-lead ECG cable only produces 1 ECG waveform, and 1 ST measurement. Use a 4- or more lead cable to report both ST measurements.
- The QT interval is a measurement of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. The QT value is reported in milliseconds (ms).
- QT measurements are accurate only when T wave amplitude exceeds 0.1 mV.
- The ST measurement is taken between the ECG isoelectric line (PR segment) and a point in the ST segment. The point taken for measurement is 80 milliseconds after the J point if the heart rate does not exceed 115 bpm, and 60 milliseconds after the J point if the heart rate exceeds 115 bpm. The ST measurement value is updated every 10s. If the measurement is not available the display will show **- - -**.
- The ST value measured is a voltage, and is displayed as the equivalent measurement height for a standard ECG gain of 10 mm/mV. Using this convention 0.1 mV is displayed as 1.0 mm. The ST measurement height gain is fixed at 10 mm/mV and does not depend on the ECG gain setting.

WARNING
ST and QT measurements should always be verified by the clinician and/or medically qualified personnel.

WARNING
The ST and QT measurements are not available for patients aged below 18 years. They are not intended for use on neonate and pediatric patients.

WARNING
Some conditions make it difficult to achieve reliable ST monitoring. Restless patients can produce noisy physiological signals, resulting in inaccurate measurements. For best results, the patient should be able to cooperate and be relaxed.

WARNING
The QT algorithm has been tested for accuracy. The significance of the QT segment should be determined by a clinician. This feature is only intended to help the clinician in monitoring the change in QT.

WARNING
The ST algorithm has been tested for accuracy. The significance of the ST segment should be determined by a clinician. This feature is only intended to help the clinician in monitoring the change in ST, and not diagnosing STEMI or ischemic events.

WARNING
For very high heart rates (>250 bpm), no ST value is reported.

WARNING
Some arrhythmia conditions may make it difficult to reliably produce ST measurements.

WARNING
With ECG waveforms with T waves smaller than 0.1 mV, the accuracy of the QT measurement may be reduced, therefore select leads with large T waves.

A medium priority alarm is triggered and the measurement value flashes when:

- An ST alarm limit is exceeded for more than 1 minute.
- A QT alarm limit is exceeded for more than 1 minute.

4.2.10 ECG settings

To change settings:

1. Press any part of the **ECG** area of the touchscreen.
2. Select the setting to change:
    - **Heart rate limits (bpm)**
    - **Waveform / Lead selection**
    - **HR/PR source**: **ECG**/**Pulse** (see also **HR/PR beat volume** and **EMS Heart Rate Mode**).
    - **ECG gain (mm/mV)**
    - **View 12 lead ECG**
    - **Arrhythmia analysis**: **on**/**off**
    - **ST/QT analysis**: **on**/**off**
    - **ST lead selection**
    - **ST1 limits (mm)**
    - **ST2 limits (mm)**
    - **QT upper limit (ms)**
    - **Cardiac wave speed (mm/s)**
    - **HR/PR beat volume**
    - **Pacemaker indication**: **on**/**off**

- **Monitoring filter**:
  - **0.5 - 40 Hz**
  - **0.67 - 20 Hz**
  - **0.05 - 150 Hz**
  - **0.05 - 40 Hz**
- **12 lead filter**:
  - **0.05 - 150 Hz**
  - **0.05 - 40 Hz**
- **ECG power filter**: **on**/**off**

3. Change settings as required.

When using a 3-lead ECG, the heart rate is derived from the waveform displayed.

When the primary monitoring lead is a derived lead, the Heart Rate and Pacer Detection will be sourced from Lead II.

HR/PR beat volume

HR/PR beat volume is the volume of the audible “tone” that the Tempus Pro emits every time a heartbeat is detected. Pressing the up and down arrows will adjust the volume. The beat volume goes from zero (no tone) to 100%. The tone is based on the **HR/PR source** setting (see above). When set to “**ECG**”, QRS beats trigger a single tone at 1 kHz. When set to “**Pulse**”, pulse beats trigger pulse tones (see "4.6 Pulse oximetry").

EMS Heart Rate Mode

If the organizational **EMS Heart Rate Mode** is selected, in periods where the rate may be impacted by ECG signal artefact, the rate display may automatically switch between ECG derived rate and pulse oximeter derived rate. In the absence of an available pulse oximeter rate the heart rate may revert to displaying “- - -“. This feature may temporarily override **HR/PR source**.

CAUTION
RDT recommends that this mode is used with **Arrhythmia analysis** set **on**. There is no impact on ECG arrhythmia detection or arrhythmia alarming.

CAUTION
If there is excessive noise when in **EMS** mode, heart rate will not be displayed.

Heart Rate and Pacer Detection will be sourced from the primary monitoring lead, i.e. the ECG lead in the top waveform position on the Tempus Pro home screen. See section 2.9.

When the primary monitoring lead is a derived lead, the Heart Rate and Pacer Detection will be sourced from Lead II.

4.3 Performing a diagnostic ECG

If this feature is installed on your Tempus Pro, it can be used for 12-lead diagnostic ECG recording and 12-lead ECG recording interpretation.

WARNING
All numerical, graphical and interpretive data should be evaluated with respect to the patient's clinical and historical picture.

WARNING
ECG interpretation performed by software is not a substitute for review and evaluation of ECG recordings by a qualified clinician.

WARNING
The accuracy of the Interpretation will be affected by poor quality recordings, i.e. noise, small amplitude signals.

WARNING
Motion artifact or noise in the ECG recording could result in erroneous interpretations.

Interpretations are unconfirmed and need to be reviewed by a clinician.

4.3.1 Making a 12-lead ECG recording

1. Make sure that the correct age is entered in the patient details before you do the recording. See "3.4 Starting and stopping the Tempus Pro and selecting a patient" for details.
2. Confirm that the Tempus Pro is displaying the 12-lead ECG view. For instructions, see "4.2 Electrocardiography (ECG)"".
3. Press **Start Record** on the right-hand side of the screen.
4. A 10 second recording will be added to the patient record.

12 Lead Recorded screen

If an internal printer is fitted to the Tempus Pro, you can print the 10 second recording using the **Print** button.

If the Tempus Pro is fitted with an internal printer and automatic printing is enabled, it will print waveforms as soon as they are captured.

4.3.2 Viewing an ECG recording interpretation

Once an ECG recording is complete, view the interpretation, summary and review by pressing **Interpretation and Review** on the right side of the touchscreen.

Your Tempus Pro may be configured with 12-lead ECG interpretation option.

The Glasgow ECG algorithm may only be installed if it is approved for commercial distribution in your territory.

Users should contact RDT to acquire the licensed Glasgow 12-lead ECG analysis/interpretation and automated measurements feature.

Refer to the maintenance manual for installation instructions.

The key ECG interpretation characteristics are:

- Valid for any age.
- If patient age is not entered, Glasgow interpretation depends on selected age group: adult 55 year old male, pediatric 10 year old male, neonate 0 year old male.

Refer to the *Tempus Pro Maintenance Manual* for full configuration instructions.

Glasgow 12-lead ECG interpretation (optional)

If Glasgow interpretation is configured, it includes up to 10 interpretation statements with a summary statement:

ECG interpretation screen (Glasgow)

For more information, please see the *Glasgow 12-lead ECG Analysis Program Physician's Guide* (part number 42-2034EN).

4.3.3 Settings

See "4.2.10 ECG settings" for details of how to adjust ECG settings.

The ECG gain (mm/mV) setting in the 'ECG Settings' menu controls the gain at which ECGs are presented in the 12-lead recordings on the Tempus Pro display and in the printed and exported 12-lead ECG reports.

The Cardiac wave speed (mm/s) setting in the 'ECG Settings' menu controls the speed at which ECGs are presented in the 12-lead recordings on the Tempus Pro display.

The 12 Lead ECG Print Speed (mm/s) setting in the 'Internal Printer' settings menu controls the speed at which ECGs are presented on 12-lead ECG reports printed from the Tempus Pro internal printer.

Heart Rate and Pacer detection will be sourced from the primary monitoring lead, i.e. the ECG lead in the top waveform position on the Tempus Pro home screen. See "3.9 Waveform and lead selection".

4.4 Monitoring respiration rate with ECG cable

If the ECG cable is connected and no capnometer is fitted or no filter line is attached, the Tempus Pro can perform impedance pneumography. Impedance pneumography calculates the respiration rate from changes in the patient's impedance as the chest wall moves in and out.

WARNING
Do not use the Tempus Pro as an apnoea monitor.

WARNING
Do not operate the Tempus Pro with any other monitor with respiration measurements on the same patient. The two devices could affect the respiration accuracy of each other.

Impedance pneumography detects respiratory effort through changes in chest volume. No-breath episodes with continued respiratory effort may go undetected. Always monitor and set alarms for SpO_2 when using impedance pneumography to monitor respiratory function.

WARNING
If capnography is used, the Tempus Pro will always obtain its respiration rate measurement from this parameter. If capnography is not available then respiration will be derived from the ECG leads using an impedance-based method. In this case, users are reminded that the reading represents a cyclic change in measured impedance which is interpreted to be the change of impedance as the chest moves out and in. Users should note that this is therefore an indirect reading of respiration.

WARNING
Impedance pneumography is not recommended for use on patients with pacemakers. Pacemaker pulses may be falsely counted as breaths.

WARNING
Impedance pneumography is not recommended for use with high frequency ventilation.

WARNING
With any monitor that detects respiratory effort through impedance pneumography, artifact due to patient motion, apnoea mattress shaking, or electrocautery use may cause apnoea episodes to go undetected. Always monitor and set alarms for SpO_2 when using impedance pneumography to monitor respiratory function.

WARNING
Since impedance pneumography uses the same leads as the ECG channel, the Tempus Pro determines which signals are cardiovascular artifact and which signals are the result of respiratory effort. If the breath rate is within five percent of the heart rate, the monitor may ignore breaths and trigger a respiration alarm.

WARNING
Impedance pneumography is not recommended for use on patients during active transport due to the impact on reliable reading which is susceptible to motion and vibrations.

CAUTION
Users should note that in the case of supine patients, breathing may involve relatively greater movement of the abdomen (and consequently less expansion of the chest) during breathing. In this case chest impedance changes may not be significant to produce reliable readings.

CAUTION
If impedance respiration is being used, the ECG electrodes should be placed on the torso and not the limbs.

CAUTION
Impedance respiration measurements are highly subject to patient movement. The impedance changes across the chest during breathing can be easily masked by patient movement or muscle noise during movement.

CAUTION
In motion environments, care should be taken to observe best practise on electrode site preparation, electrode and cable securement, securement of the Tempus Pro and securement of the patient. RDT recommends using capnography to measure respiration in motion environments.

RDT recommends using capnography to measure respiration in motion environments.

4.4.1 Getting started

1. Attach the ECG cable to the Tempus Pro.
2. Attach electrodes to the patient's torso. Follow the instructions in one of the following sections, according to the type of cable you are using:
   - "4.2.2 Monitoring ECG with a 3-lead cable"
   - "4.2.3 Monitoring ECG with a 4-lead cable"
   - "4.2.4 Monitoring ECG with a 5-lead cable"
   - "4.2.5 Previewing a 12-lead ECG"

4.4.2 Taking readings

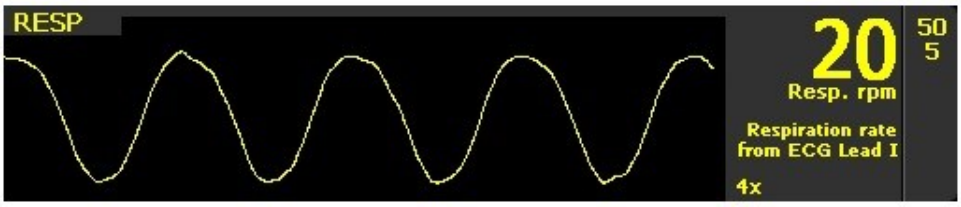
If no capnometer is connected, impedance pneumography is performed as default.

1. Press the **RESP** area of the touchscreen or navigate to the **Medical Parameter Settings** in the **Main Menu**.
2. Select **Lead I** (RA-LA) or **Lead II** (RA-LL). The lead with the largest R-wave will give the most reliable reading. Your choice depends on the ECG cable type connected and the lead chosen for ECG waveform monitoring:

ECG cable type connected	Lead selected for ECG waveform monitoring	Leads available for respiration monitoring
3-lead	Lead I	Lead I only
	Lead II	Lead II only
	Lead III	Lead I or Lead II

ECG cable type connected	Lead selected for ECG waveform monitoring	Leads available for respiration monitoring
4-, 5- or 12-lead	Any	Lead I or Lead II (independent of ECG waveform)

3. Tempus Pro calculates the respiration rate as an average of 3 readings. This may take 30 seconds or more.



If capnography is in use, the waveform will automatically change to **CAPNO** and will display the end tidal CO_2 reading as well as respiration rate.

4.4.3 ECG respiration settings

To change settings:

1. Press any part of the **Respiration** area of the touchscreen.
2. Select the setting to change:
   - **Respiration limits (rpm)**
   - **Respiration wave speed (mm/s)**
   - **Respiration lead**
   - **Respiration wave gain**
   - **Respiration monitoring** (**on**/**off**)
3. Change setting as required.

4.5 Non-invasive blood pressure (NIBP)

The Tempus Pro is designed to take non-invasive blood pressure (NIBP) readings from neonates, children, and adults (13 years or older).

NIBP is suitable for use in the presence of electrosurgery.

WARNING
You must use the right size of blood pressure cuff to suit the patient. The cuff's bladder length should be at least 80% of the limb's circumference while the cuff width should be equal to 40% of the limb's circumference. Selecting a cuff that is too small will result in measurements higher than the patient's actual blood pressure. Conversely using too large a cuff will result in too low a reading.

WARNING
This device should not be used when oscillometric pulses may be altered by other devices or techniques such as External Counter pulsation (ECP) or Intra-Aortic Balloon Pump Counter pulsation.

WARNING
Do not use the blood pressure monitor for any other purpose than specified in this manual.

Do not use the blood pressure monitor on patients who are:

- Pregnant, including pre-eclamptic.
- Undergoing cardiopulmonary bypass.
- Receiving treatment that affects the pulse, such as external counter pulsation (ECP) or intra-aortic balloon pump counter pulsation.
- Experiencing convulsions, tremors or are being transported.

When a cuff is going to be positioned on a patient for an extended length of time, be sure to occasionally check the limb for proper circulation.

WARNING
The Tempus Pro may not operate effectively on patients who are experiencing convulsions or tremors, or who are moving or are in motion (transport) environments.

WARNING
Prolonged or repetitive use of the blood pressure cuff may harm skin integrity and circulatory status. Observe the limb concerned to check that circulation is not impaired.

WARNING
If you suspect a non-invasive blood pressure measurement is invalid, repeat the measurement. If you remain unsure about the validity of the reading then take another measurement using another piece of equipment or a different method.

WARNING
Do not fit the cuff over a wound, as this can cause further injury.

Do not attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to the patient.

Do not apply and pressurize the cuff on any limb where intravascular access or therapy such as an IV line, saline lock or an arteriovenous (A-V) shunt, is present as it may cause temporary interference with blood flow and result in injury to the patient.

Do not apply the cuff on the arm on the side of a mastectomy or lymph node clearance.

WARNING
Application of continuous cuff pressure due to kinking of the blood pressure hose can interfere with blood flow and result in harmful injury to the patient.

WARNING
If the user measures NIBP too frequently, this can interfere with blood flow and cause injury to the patient.

CAUTION
Incorrectly sized cuffs may cause measurement inaccuracy or errors.

CAUTION
If the blood pressure cuff is on the same limb as a pulse oximeter probe, the oxygen saturation results will be altered when the cuff occludes the brachial artery.

Do not place the cuff on the same limb as the pulse oximeter sensor as the cuff may prevent the pulse oximeter sensor from reading reliably during NIBP measurement cycles.

CAUTION
Only use hoses and cuffs provided by RDT. Hoses of a certain material and/or durometer may cause the module to perform in an improper fashion.

CAUTION
Ensure the cuff is wrapped firmly around the arm; a loosely applied cuff can result in artificially high readings.

CAUTION
Allergic exanthema, symptomatic eruption, in the area of the cuff may result, including the formation of urticaria, allergic reaction including raised edematous patches of skin or mucous membranes and intense itching, caused by the fabric material of the cuff.

Petechia, a minute reddish or purplish spot containing blood that appears in the skin, formation or Rumple-Leede phenomenon, multiple Petechia, on the forearm, following the application of the cuff, may lead to Idiopathic thrombocytopenia, spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions, or phlebitis, inflammation of a vein, may be observed.

CAUTION

- The non-invasive blood pressure monitor is not supplied with any specific burn-protection parts.
- Compression or restriction of the blood pressure hose or cuff, induced movement or vibration, very low pulse volumes may prevent the monitor from taking a reading or may influence the accuracy of the reading obtained.
- The Tempus Pro non-invasive blood pressure monitor is designed to work with the cuffs and hoses supplied. Use of other cuffs and hoses may compromise performance and accuracy.
- The Tempus Pro non-invasive blood pressure monitor does not provide any specific burns protection parts for non-invasive blood pressure (in accordance with IEC 80601-2-30 cl 201.7.9.2.101).

CAUTION

Trained medical staff should interpret all blood pressure results. A patient's condition, position and location may affect results.

CAUTION

Rapid Cuff will only allow a short period between measurements for arterial recovery. Repeated use of the Rapid Cuff mode could have physiological effects including effects on the readings obtained.

Important

Blood pressure results for patients with very weak pulses may be inaccurate or unavailable.

The performance of the blood pressure monitor can be affected by extremes of temperature, humidity and altitude.

4.5.1 NIBP socket

The NIBP hose and socket are easily damaged. When you remove or connect the NIBP hose to the Tempus Pro you must always grip the moulded connector and not the NIBP hose.

(1) NIBP socket

4.5.2 Getting started

Always set the Tempus Pro to the correct patient age to ensure the initial inflation pressure is set correctly. The Tempus Pro uses the definitions of patient age provided in IEC 80601-2-30 as follows:

- Neonate – Children 28 days old or less if born at term (based on 37 week gestation), otherwise up to 44 gestational weeks.
- Pediatric (Child) – Children of 29 days up to and including 12 years old.
- Adult – Individuals 13 years old or older.

WARNING
Failure to set the correct age will result in the Tempus Pro using an inappropriate cuff inflation pressure which could cause serious harm to a neonate or infant (see section "10.3 Tempus Pro medical specifications".

Setting the patient age to 2 years or less will mean that inflation pressures, alarm defaults and alarm ranges will be set to those for a neonate (per IEC80601-2-30).

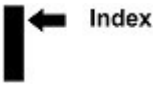
If you do not set the patient age, the Tempus Pro will use the default patient age group (see the *Tempus Pro Maintenance Manual*). Ensure that the patient age/type is always entered for non-adult patients (see "3.4 Starting and stopping the Tempus Pro and selecting a patient").

CAUTION
Accuracy of any blood pressure measurement may be affected by the position of the subject, his or her physical condition and use outside of the operating instructions detailed in this manual. Interpretation of blood pressure measurements should be made only by a physician or trained medical staff.

CAUTION
To obtain accurate blood pressure readings, the cuff must be the correct size, and also be correctly fitted to the patient. Incorrect size or incorrect fitting may result in incorrect readings.

Blood pressure readings can be affected by patient movement, speech, incorrect sizing and placement of the cuff or environmental factors (vibration, motion, noise etc.). Care should be taken to ensure that motion and other artifacts are removed or reduced when taking blood pressure readings.

1. The operator should be positioned close to the device and the patient.
2. Make sure the patient's age is selected. See "3.4.3 Selecting or entering patient information" for details.
3. Reduce or remove any motion, noise or vibration in the treatment location.
4. Make sure that the patient:
   - If seated, has legs uncrossed, feet flat on the floor and back and arms supported.
   - If lying down, has legs uncrossed.
   - Is comfortable, relaxed and not talking or moving.
   - Has no tight clothing constricting the limb being used for measurement.
5. Ensure that the NIBP hose is properly inserted into its connector on the Tempus Pro.

6. Fit the cuff correctly:
   - Choose the correct cuff size. Use the  **XX-YY cm** marker on the cuff for guidance.
   - Make sure the cuff is orientated correctly on the limb.
   - Wrap the cuff firmly round the arm or leg. Ensure the 

mark is between the  mark, with the 

mark aligned with the patient's artery.
   - Remove any objects that could prevent the cuff from inflating and deflating.
   - Move the cuff and hose away from any vibrating surfaces.
   - Check there are no kinks in the hose.
7. When the cuff is attached, wait 5 minutes for the patient’s blood pressure to stabilize.

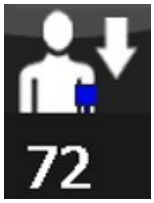
4.5.3 Taking readings

WARNING
Cuff pressure displayed during the inflation/deflation cycle is not an indication of blood pressure. Blood pressure readings are displayed after the reading cycle has completed.

1. On the touchscreen, in the blood pressure area, press the **START** button. If you need to terminate a measurement, press the button again to stop the reading.
2. The icon on the **START** button changes to show whether the cuff is inflating or deflating:

   Inflating OR Deflating

   The cuff pressure is an indicator of where the NIBP is in its cycle. Cuff pressure is not displayed when the start button is small, e.g. when three IBP channels are active.

3. When complete, the blood pressure result is displayed:

   If the monitor is in auto mode, the **START** button icon changes into a timer.

4. If you get any unexpected results, take the reading again. Make sure that the cuff is fitted correctly and that the hose has no leaks or kinks.

4.5.4 NIBP settings

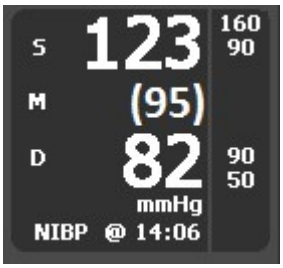
To change settings:

1. Press any part of the **NIBP** area of the touchscreen.
2. Select the settings to change:
   - **Mode** - **Auto**, **Manual** and **Rapid Cuff**. In **Rapid Cuff** mode, the Tempus Pro takes as many readings as it can in 10 minutes and will then reset to **Auto** mode. If an NIBP technical alarm occurs while in **Rapid Cuff** mode, the alarm will be reported and the mode will reset to **Auto**.
   - **Auto interval time (mins)** .
   - Alarm limits.
3. If necessary, adjust the **Initial inflation (mmHg)** . The default is set by the Tempus Pro depending on patient age group. NIBP adjusts its inflation pressure dynamically between readings so this setting only applies to the first reading and when it is manually adjusted. The default settings are:
   - **Adult** - initial inflation 160 mmHg, range 120 to 280 mmHg.
   - **Paediatric** (29 days to 12 years) - initial inflation 140 mmHg, range 80 to 280 mmHg.
   - **Neonate** (<29 days) - initial inflation 90 mmHg, range 60 to 140 mmHg.
4. If necessary, change the **Reading format** - see "NIBP reading format".
5. To save settings, press **Back**.

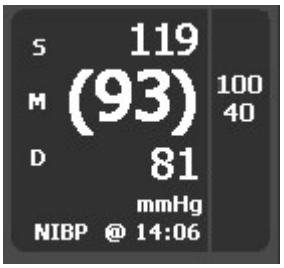
The *Tempus Pro Maintenance Manual* describes how to set the Tempus Pro to automatically clear the NIBP reading after 5 minutes if a new reading has not been taken.

NIBP reading format

The **Reading format** control allows you to choose between two formats for displaying NIBP readings:



NIBP reading format **S/D (M)**



NIBP reading format **(M) S/D**

- S = systolic
- D = diastolic
- M = mean

Regardless of the **Reading format** chosen, the Tempus Pro will continue to monitor the systolic, mean and diastolic pressures and will still output alarms when thresholds are exceeded.

4.6 Pulse oximetry

The Tempus Pro uses pulse oximetry to measure and monitor a patient's blood oxygen levels and pulse rate. Your Tempus Pro will have the Masimo SET measures supplied as standard:

- Oxygen saturation (SpO_2)
- Pulse Rate (PR)
- Perfusion Index (PI)

Masimo rainbow SET measurements are optional:

- Total Hemoglobin (SpHb)
- Oxygen Content (SpOC)
- Carboxyhemoglobin (SpCO)
- Methemoglobin (SpMet)

Other optional measurements, available with Masimo SET or rainbow SET measures:

- Pleth Variability Index (PVI)

WARNING
Do not use this device in the presence of high EMI/RFI radiation. High EMI/RFI radiation may cause induced current to the SpO_2 sensor resulting in patient injury.

WARNING
Verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result.

WARNING
This device may give inaccurate readings in the presence of strong electromagnetic sources, such as electrosurgery equipment.

WARNING
This device may give inaccurate readings in the presence of computed tomography (CT) equipment.

WARNING
This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

WARNING
Prolonged use for the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours. Prolonged use may cause blisters, skin deterioration, and discomfort.

WARNING
Incorrectly applied sensors may give inaccurate readings.

WARNING
SpO_2 measurements may be inaccurate in the presence of high ambient light. This may be more noticeable with disposable probes. If necessary, shield the sensor area (e.g. with a towel) or a Masimo® light shield.

WARNING
Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO_2 readings.

WARNING
Remove fingernail polish or false fingernails before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

WARNING
Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, will affect the accuracy of the SpO_2 measurement.

WARNING
Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium and meta-tetra(hydroxyphenyl)chlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes or inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

WARNING
Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with opaque material. Optical cross-talk may adversely affect the accuracy of the SpO_2 readings.

WARNING
Obstructions or dirt on the sensor's red light or detector may cause a sensor failure or inaccurate readings. Make sure there are no obstructions and the sensor is clean.

WARNING
Under certain clinical conditions, pulse oximeters may not display SpO_2 and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

WARNING
Do not use the pulse oximeter for any other purpose than specified in this manual. It should not be used as an apnoea monitor.

WARNING
Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.

WARNING
A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

WARNING
For measurements of high or low SpHb readings, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.

WARNING
A pulse oximeter cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.

For increased COHb: COHb levels above normal tend to increase the level of SpO_2. The level of increase is approximately equal to the amount of COHb that is present.

For increased MetHb: the SpO_2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO_2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.

WARNING
Hemoglobin synthesis disorders may cause erroneous SpHb readings.

WARNING
Elevated levels of Total Bilirubin may lead to inaccurate SpO_2, SpMet, SpCO, SpHb, and SpOC measurements.

WARNING
Motion artifact may lead to inaccurate SpMet, SpCO, SpHb, and SpOC measurements.

The plethysmogram may become unstable on patients who are experiencing convulsions or tremors, who are moving or are in motion (transport) environments.

WARNING
Severe anaemia may cause erroneous SpO_2 readings.

WARNING
Very low arterial Oxygen Saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements.

WARNING
With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.

WARNING
Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings.

Use of additional tape can cause skin damage or damage the sensor.

If the sensor is wrapped too tightly or supplemental tape is used, venous congestion/pulsations may occur causing erroneous readings.

WARNING
Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).

WARNING
Venous pulsations may cause erroneous low readings (e.g. tricuspid valve regurgitation).

WARNING
The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display.

WARNING
Verify patient's pulse rate against the ECG heart rate.

WARNING
Do not use the Pulse CO-Oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Pulse CO-Oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.

WARNING
Before use, carefully read the sensor's *Directions for Use*.

WARNING
Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide.

See the cleaning instructions in the directions for use for the Masimo® re-usable sensors.

WARNING
Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

WARNING
High intensity extreme lights (including pulsating strobe lights) directed on the sensor may not allow the Pulse Oximeter to obtain readings.

WARNING
Always read and follow the instructions on the packaging of SpO_2 sensors regarding their storage, use and disposal. In particular take into account any information regarding toxicity.

WARNING
To avoid cross contamination, only use a Masimo® single-use sensor on one patient.

WARNING
Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.

WARNING
The SpO_2 sensor should snugly fit the finger without straining it and if not alternative fingers should be tried. The probe is sized for patients who weigh 20 kg /44 lbs or more. The probe can be used either on patient's fingers, thumbs or largest toe.

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor's *Directions for Use* to ensure skin integrity and correct positioning and adhesion of the sensor.

Reposition the oximeter probe at least once every hour to allow the patient's skin to respire. This time should be reduced in ambient temperatures over 41°C. No other special actions are required for use in such ambient temperatures although users are advised to check the sensor site frequently in high temperatures to avoid skin damage.

WARNING
Loss of pulse reading can occur if the patient has:

- A cardiac arrest or is in shock.
- An arterial occlusion proximal to the sensor.
- Hypotension, severe vasoconstriction, severe anaemia, or hypothermia.
- The sensor is fitted too tightly.
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.
- A blood pressure cuff is inflated on the same extremity as the one with a SPO_2 sensor attached.

The patient's pulse rate will be higher if they are receiving the following treatments:

- External counter pulsation (ECP).
- Intra-aortic balloon pump counter pulsation.

WARNING
The section "B.4 Pulse oximetry accessories" displays the correct accessories. With each accessory, there is a Masimo manual that gives the permitted:

- age of the patient
- weight of the patient
- part of the patient
- type of tissue
- environment
- number of times to use
- location
- motion

WARNING
If the pulse oximeter probe can be hotter than 41 °C, the user must be careful to prevent skin damage. The user must be much more careful with neonate, geriatric and burns patients.

CAUTION
Unplug the sensor from the monitor before cleaning or disinfecting to prevent damaging sensor or monitor, and to prevent user safety hazards.

CAUTION
Do not attempt to alter the finger sensor in any way. Alterations may affect the sensor's performance and or accuracy.

CAUTION
A functional tester cannot be utilized to assess the accuracy of the Pulse CO-Oximeter or any sensors.

CAUTION
Users are reminded that because pulse oximeter measurements are statistically distributed, only about two-thirds of measurements can be expected to fall within ±Arms of the value measured by a co-oximeter. Information on the clinical desaturation trials performed to validate the oximeter is available on request.

CAUTION
Use only Masimo® oximetry sensors for SpO_2 measurements. Other oxygen transducers (sensors) may cause improper results.

The list of compatible sensors and accessories is given in "Annex B : Accessories list".

CAUTION
Exercise caution when applying a sensor to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.

Circulation distal to the sensor site should be checked routinely.

CAUTION
If the low perfusion indication is frequently displayed, find a better-perfused monitoring site. In the interim assess the patient and if indicated verify oxygenation status through other means.

CAUTION
Inaccurate or zero readings may be caused by:

- Changes in blood flow.
- Intravascular dyes, such as indocyanine green or methylene blue.
- Incorrect sensor application or use.
- Low perfusion in the tissue near the sensor.
- Exposing the finger sensor to irradiation during total body irradiation. Keep the finger sensor out of the irradiation field.
- Exposing the finger sensor to excessive light, including infrared, fluorescent, bilirubin and strobe lights, surgical lights and direct sunlight. Cover the finger sensor with a dark or opaque material.
- Significant levels of dysfunctional hemoglobins, such as SpCO and SpMet.
- Illnesses, such as anaemia and hemoglobin synthesis disorders.
- Excessive patient movement, including tremors, convulsions or transportation.
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

During defibrillation, readings may be inaccurate for up to 20 seconds.

Increased levels of COHb or MetHb will affect oxygen saturation readings. If this is suspected, send a blood sample for analysis (co-oximetry).

CAUTION
In Max sensitivity mode, a warning may not be shown if the sensor becomes dislodged from the patient.

CAUTION
Users are reminded that because pulse oximeter measurements are statistically distributed, only about two-thirds of measurements can be expected to fall within ±Arms of the value measured by a co-oximeter. Information on the clinical desaturation trials performed to validate the oximeter is available on request.

Important

- SpO_2 averaging is the number of pulse beats over which the SpO_2 value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.
- DESAT trials were performed in the normal sensitivity mode.
- The plethysmogram is not normalized.
- The pulse oximeter probe is for use with intact skin only. The probe used is not sterile and contains no latex. Patient contact materials have undergone extensive biocompatibility testing, further information is available on request.
- Any condition that restricts blood flow, such as use of a blood pressure cuff (other than the Tempus Pro cuff used in accordance with the instructions herein) may cause an inability to determine accurate pulse and SpO_2 readings.
- High levels of COHb may occur with a seemingly normal SpO_2. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Remove fingernail polish or false fingernails before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.
- The graphical displays of pulse rate, SpO_2 and pulse strength are not proportional to the pulse volume. The amplitude of the waveform is adjusted on an on-going basis to provide the largest size waveform possible. Do not attempt to normalize the waveform to any scale.
- If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the MS board pulse oximeter for proper functioning.

The user must obey local regulations to discard the sensor after use.

SpO_2 readings are not affected by **Alarm trigger delay (secs)** or by the alarm signal generation delay.

The following warnings, cautions and notes are reproduced verbatim from Masimo document R-CSD-1117 (revision P):

GENERAL

The pulse co-oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

WARNING

- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse co-oximeter or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse co-oximeter unless the setup was verified to be correct.
- Do not use the pulse co-oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the pulse co-oximeter if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the pulse co-oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.

WARNING

To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this operator's manual.
- Do not attempt to clean the device while monitoring a patient.

WARNING

- To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient’s vital signs by alternate means and then check the pulse co-oximeter for proper functioning.

WARNING
Inaccurate SpCO and SpMet readings can be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Abnormal hemoglobin levels
- Low arterial perfusion
- Low arterial oxygen saturation levels including altitude induced hypoxemia
- Elevated total bilirubin levels
- Motion artifact

WARNING
Inaccurate SpHb and SpOC readings may be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated PaO2 levels
- Elevated levels of bilirubin
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation levels
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Vasospastic disease such as Raynaud's
- Elevated altitude
- Peripheral vascular disease
- Liver disease
- EMI radiation interference

WARNING
Inaccurate SpO2 readings may be caused by:

- Improper sensor application and placement
- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of bilirubin
- Elevated levels of dyshemoglobin
- Vasospastic disease, such as Raynaud's, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Severe anemia
- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders

WARNING

- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- The pulse co-oximeter should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
- The pulse co-oximeter is not an apnoea monitor.
- The pulse co-oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse co-oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse co-oximeter should not be used for arrhythmia analysis.
- SpCO readings may not be provided if there are low arterial saturation levels or elevated methemoglobin levels.
- SpO2, SpCO, SpMet, and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Do not adjust, repair, open, disassemble, or modify the pulse co-oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse co-oximeter for servicing if necessary.

CAUTION

- Do not place the pulse co-oximeter where the controls can be changed by the patient.
- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the pulse co-oximeter on electrical equipment that may affect the device, preventing it from working properly.
- If SpO2 values indicate hypoxaemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- The device must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.
- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse co-oximeter is used.

CAUTION

- Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient’s clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory devices prior to clinical decision making to completely understand the patient’s condition.
- Do not submerge the pulse co-oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse co-oximeter.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse co-oximeter.
- Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

Important

- A functional tester cannot be used to assess the accuracy of the pulse co-oximeter.
- A calibrated function tester can be used to assess the accuracy of the Pulse oximeter.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse co-oximeter to obtain vital sign readings.
- When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

(1) Pulse oximeter socket

4.6.1 Getting started

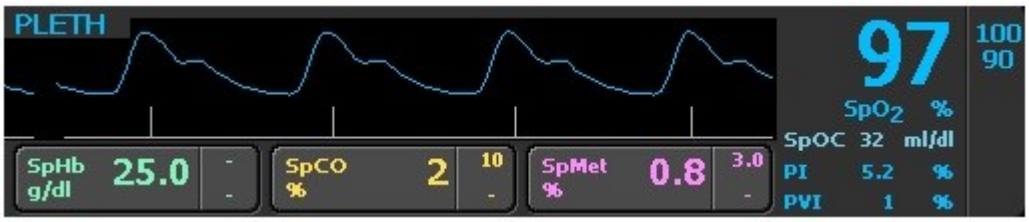
The Modified Bland and Altman plot can be located in the Instructions for use (IFU) for the sensors

The ARMS Value can be located in the Instructions for Use for the sensors

1. Choose which type of sensor you need to use:
   - SpO_2 sensor measures SpO_2, PI and PVI.
   - SpCO sensor measures SpCO, SpMet, SpO_2, PI and PVI.
   - SpHb sensor measures SpHb SpMet, SpO_2, PI and PVI.
2. Read the finger sensor's *Directions for Use*.
3. Make sure that the patient:
   - If seated, has their arm still and below the shoulder.
   - If lying down, has their arm horizontal to their shoulder.
4. Choose a finger that is undamaged, with good skin condition and circulation.
5. Remove any fingernail polish or false fingernails.
6. Choose the correct sensor size. The sensor should snugly fit the patient's finger without straining it. Do not use tape to secure it.
7. Ensure that the SpO_2 cable is properly inserted into its connector on the Tempus Pro.

4.6.2 Taking readings

1. Fit the sensor to the patient's finger.
2. Readings are displayed immediately:



Important
The pleth waveform is auto-scaled to fit the display. The vertical lines under the pleth waveform show the signal strength.

Low readings are indicated by the alternating reading label: "Low signal" or "Low PI"

Readings available but with low confidence are displayed in grey.

If a valid reading is not available, the display shows "---"

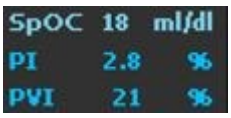
- SpO_2 sensor readings:

- SpCO sensor readings:

- SpHb sensor readings:

- SpMet sensor readings:

- SpOC sensor readings:



3. Fit the sensor to another finger with better perfusion, if:
   - The signal quality is low.
   - The PI is lower than 1.00%.

4. Check the pulse rate is similar to the heart rate shown on the ECG monitors.
5. If there are significant differences, check the following:
   - The patient's condition and vital signs.
   - The sensor is fitted correctly. Make sure the finger is inserted all the way into the clip.
   - The cable is attached and undamaged.
   - All instruments are working properly.
6. If readings show that the patient's oxygen levels are falling, send a blood sample for analysis (co-oximetry) for more detailed results.

You can use the PVI reading to help you decide which patients may respond to fluid administration. A PVI of >14% prior to volume expansion predicts that a mechanically ventilated patient will respond to fluid administration (81% sensitivity).

4.6.3 Pulse oximeter settings

Masimo - Specialty Sensors

Neonatal sensors/Trauma Sensors will override the Tempus Pro default settings and automatically configure Masimo SET® and rainbow SET devices upon connection for the fastest averaging time and maximum sensitivity settings.

These changes are made at SpO_2 module level and are not changed in the Tempus Pro $Sp0_2$ software settings and will not be shown on the SpO_2 settings page

SpO_2 readings are not affected by Alarm Trigger delay or by Alarm Signal Generation delay.
To change settings:

1. Press any part of the **Plethysmogram** area of the touchscreen.
2. Select the setting to change:
   - **SpO2 limits** – Set upper and lower alarm limits.
   - **SpCO limits** (if activated) - Set upper and lower alarm limits.
   - **SpMet limits** (if activated) - Set upper and lower alarm limits.
   - **SpHb limits and settings** (if activated) - Set upper and lower alarm limits, measurement mode, averaging time and sensor life.
   - **HR/PR source** - Set ECG or pulse oximeter as the heart or pulse rate source.
   - **Large pleth waveform** - Moves Masimo rainbow SET measurements to below the SpO_2 reading to give space for a larger wave form.
   - **Sensitivity mode**:
     - **Norm** (normal sensitivity) – Recommended for patients with poor blood flow or perfusion, in a care setting where they are checked frequently.
     - **APOD** (adaptive probe off detection) – Recommended for most patients who are not continuously monitored.
     - **Max** (maximum sensitivity) – Recommended for patients with poor perfusion who are not continuously monitored.

- **Average time(s)** - Decrease to make the readings more responsive.
- **FastSAT** - Switch on to use rapid oxygen saturation tracking. Oxygen saturation data is averaged to give a more accurate view of the patient's oxygen levels. The averaging time ranges from 2-4 to 4-6 seconds according to the input signal.
- **Cardiac wave speed** - Set to 12.5, 25 or 50.
- **HR/PR beat volume** - Set the volume of the audible tone emitted every time a pulse beat is detected.
- **SpOC limits** - Set upper and lower alarm limits.
- **PI limits** - Set upper and lower alarm limits.
- **PVI limits** - Set upper and lower alarm limits.

3. Change setting as required.
4. Press **Save & Back** button.

- After power off, the Tempus Pro will restart in either **APOD** or **Norm** modes. You will need to manually select **Max**, if required.
- PI and PVI alarms are only available in Tempus Pro devices with part numbers ending in "-R".

Pulse tones

Pulse tones can be turned on from either the Pulse Oximeter Settings menu or the ECG Settings menu using the settings:

- HR/PR source = Pulse
- HR/PR beat volume = 20% (or above)

When pulse tones are turned on, Tempus Pro emits a beep for each pulse beat detected. The beep tone (frequency) depends on the value of pulse ox saturation (SpO_2). Higher SpO_2 values mean that each beat is emitted with a higher tone beep and vice-versa. So the tone drops as SpO_2 (%) falls; with the lowest frequency tone at values of SpO_2 = 80% or below.

- Alarm tones have priority over pulse tones. When pulse tones are enabled, user interface touch screen sounds are suppressed.
- Pulse tones are automatically enabled if the laryngoscope is used.

4.7 Invasive pressure

The Tempus Pro is designed to take Invasive Blood Pressure (IBP) readings using 1-4 channels (with 3 waveforms):

- P1 and P2 - Internal to the Tempus Pro
- P3 and P4 - Optional, using an external USB IBP module - part number 01-2017. Please contact RDT for more information. An external Invasive Pressure Module can be used to add 2 channels (P1 and P2) to a unit without internal channels fitted.

See "B.2 Invasive Blood Pressure accessories" for details of supported cables and transducers.

WARNING
Do not use the invasive pressure monitor for any other purpose than specified in this manual.

Always read and follow manufacturer's instructions when you store, use or dispose of transducers. In particular take into account any information regarding toxicity.

Do not reuse any components that are labelled for single use only.

Follow local medical waste regulations when you dispose of all single-use items.

WARNING
Invasive Pressure is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times.

WARNING
If electrocautery is used, always avoid using any transducer with a conductive (metal) case connected to its ground shield. Using a conductive transducer that is connected to its cable shield risks high-frequency burns at the ECG electrodes if the transducer case becomes grounded to earth.

Do not touch any metal parts of the transducer when it is in contact with the patient.

If defibrillation is being used, follow all related transducer instructions carefully.

WARNING
Normal alarm functions will detect complete disconnections of invasive pressure transducers; however the alarm functions will not detect a partial disconnection or a partial short-circuit, nor will it detect the use of incompatible transducers. Use only approved transducers and ensure that they are connected properly.

WARNING
Although complete disconnections of invasive pressure transducers will be detected by the normal alarm functions, partial disconnection will not be detected, nor will the use of some incompatible transducers. The user must exercise reasonable measures to ensure that approved transducers are used and that pressure transducers are connected properly.

WARNING
Remember to differentiate the different transducers that are connected to the Tempus Pro. The adaptor cables are labelled P1 & P2. The Tempus Pro provides features to additionally label these channels with their site description on the display.

WARNING
Always zero the transducer before using it.

WARNING
Always zero the transducer when the battery pack is replaced.

CAUTION
When more than one transducer is in use, make sure that you understand which transducer is attached to which channel.

CAUTION
Replace any cables or connections showing signs of wear or damage.

CAUTION
If the USB module is unplugged and reconnected, the transducers will require zeroing.

CAUTION
Remember to zero the channel/transducer that you are using. Take care to differentiate between the two transducers and their settings.

CAUTION
Inaccurate readings can be caused by:

- A clogged catheter.
- The placement of the catheter in the vasculature.
- The position of the transducer stop cock, catheter and flush port.
- The position of the transducer relative to the patient's phlebostatic axis or the catheter tip.
- Saline line flushes. These can interrupt readings.
- Air bubbles in the catheter or transducer dome.

Flush the catheter regularly while taking invasive pressure measurements. Always view the waveform to ensure that pressure measurements are based on a physiological waveform.

CAUTION
Changes to the settings for one channel are never automatically applied to other channels.

Important

- The invasive pressure meter will require warming up if it is started from cold. The warm up time is specified in the "10.3 Tempus Pro medical specifications"section. Once the Tempus Pro is turned on and the invasive pressure parameter functional, the pressure waveform will appear on the display.
- Check all cables and connections before use. Request that an appropriate service technician check the function of the device, including operation of all audible and visual alarms, on a regular basis.

(1) Invasive pressure socket

4.7.1 Getting started

1. Unpack the transducer.
2. Choose the correct Tempus Pro adaptor cable for the transducer.
3. Attach the transducer to the patient. Follow the instructions on the transducer packaging.
4. Attach the adaptor cable to the Tempus Pro's white socket.
5. Connect the transducer to the adaptor cable.
6. Attach more transducers if required.

If you want to use P3 or P4 with the external USB module:

1. Plug the module in. A USB symbol  will appear at the top of the screen to show the module is connected.

1 USB socket

When a patient cable, with transducer, is attached the channel appears on the Tempus Pro display.

You may need to wait for up to 10 seconds for a waveform to appear.

4.7.2 Taking readings

- If alarms are suspended and an IBP technical alarm or arterial catheter disconnect condition occurs the alarm suspend period will be terminated.
- If the IBP alarms are switched off checks are not made for physiological alarm related pressure changes or for catheter disconnect conditions.

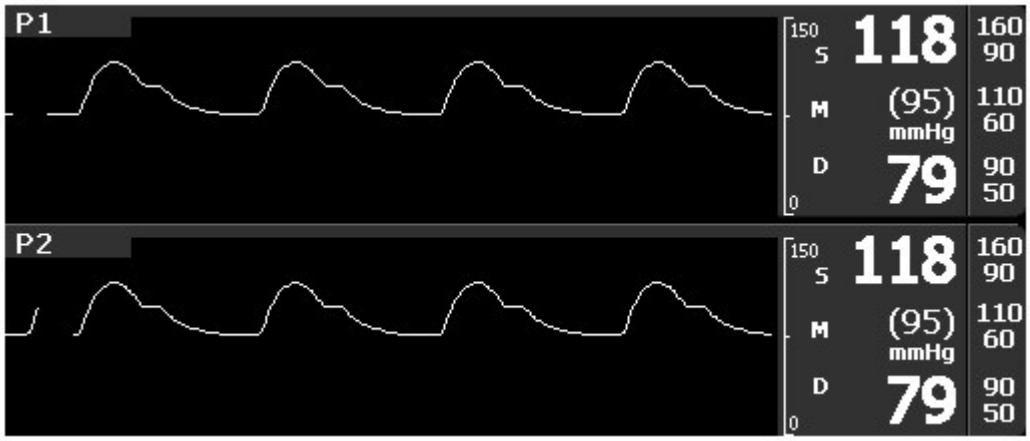
1. Always zero the transducer before taking a reading:

   There are 4 Pressure settings menus, available on the Medical Parameter Settings 2 of 3 page, that are used to zero a transducer, each one of the four menus relate to 1 of a possible 4 transducers, labelled P1 to P4.

   1. Read the zeroing instructions on the transducer packaging.
   2. Use the **Zero transducer** option in the applicable **Pressure Settings** menu, to zero the transducer.
   3. Wait a few seconds until a confirmation message appears.
   4. If the message fails to appear:
      a. Make sure that the transducer is correctly connected to the Tempus Pro.
      b. Make sure that the transducer stop cock is open.
      c. Attempt to zero the transducer again.
      d. If the process fails again, replace the transducer.

- You can zero the transducer as often as required.
- If a new transducer is connected or an existing transducer is reconnected, always wait at least 5 seconds before zeroing it.
- Always zero the transducer if it is moved.
- Do not use transducers or pads that are out of date. Do not use damaged transducers.

2. Readings are displayed on the Tempus Pro home screen:



View the waveform to confirm the measurement is working as expected.

- The USB external module settings are changed in the same way for all channels.
- Users should review the default alarm and parameter settings and decide if these are compatible with the clinical protocols in place locally for attended and unattended monitoring of patients and make any procedural changes required in light of this review.

4.7.3 Pressure settings

To change settings:

1. Press any part of the invasive pressure area of the touchscreen (e.g. **P1**) or navigate to the **Medical Parameter Settings** in the **Main Menu**.
2. Select the channel settings to change (e.g. **P1 Pressure Settings**):
   - **Channel configuration**
   - **Zero transducer**
   - **Systolic limits (mmHg)**, **Mean limits (mmHg)** and **Diastolic limits (mmHg)**
   - **Cardiac wave speed (mm/s)**
3. Change setting as required.

4.7.4 Configuring a channel/transducer

On the invasive pressure settings menu, press **Channel configuration** to adjust the labelling, results format and waveform height for each channel.

Channel Label controls are grouped by color:

- Red - **Arterial** labels.
- Blue - **Venous** labels.
- Pale yellow - pulmonary arterial pressure labels.
- White - labels for other applications.

These are the default settings for each type of label:

Label	Application	Color	Reading format	Waveform height
ART – Arterial Blood Pressure	Arterial	Red	**S/D (M)**	0-150 mmHg
BAP – Brachial Artery Pressure	Arterial	Red	**S/D (M)**	0-150 mmHg
RAP – Radial Artery Pressure	Arterial	Red	**S/D (M)**	0-150 mmHg
AO – Aortic pressure	Arterial	Red	**S/D (M)**	0-150 mmHg
FAP – Femoral Artery Pressure	Arterial	Red	**S/D (M)**	0-150 mmHg
UAP – Umbilical Artery Pressure	Arterial	Red	**S/D (M)**	0-150 mmHg
ABP – Abdominal Aorta Pressure	Arterial	Red	**S/D (M)**	0-150 mmHg
LAP – Left Atrial Pressure	Arterial	Red	**S/D (M)**	0-150 mmHg

Label	Application	Color	Reading format	Waveform height
CVP – Central Venous Pressure	Venous	Blue	**(M) S/D**	0-30 mmHg
UVP – Umbilical Venous Pressure	Venous	Blue	**(M) S/D**	0-30 mmHg
PAP – Pulmonary Artery Pressure	Pulmonary artery	Pale yellow	**S/D (M)**	0-50 mmHg
ICP – Intra-Cranial Pressure	Intra-cranial	White	**M**	0-50 mmHg
BDR – Bladder Pressure	Bladder	White	**M**	0-30 mmHg

4.7.5 IBP sensor/catheter alarms

If an IBP sensor is disconnected or the IBP cable is unplugged from Tempus an “**IP Sensor Disconnected**” alarm is displayed.

If the IBP channel is configured without a label or has an arterial channel label, if the mean pressure drops from above 10 mmHg to less than 10 mmHg without a waveform being detected a high priority alarm will be generated. For channel number ‘x’ “**Px Catheter Disconnected**” alarm is displayed.

4.8 Capnography

If a capnometer is fitted to your Tempus Pro, you can use Oridion®, Microstream®, Filterline® and Capnoline® systems to monitor CO_2.

WARNING
The Tempus Pro is not for apnoea detection. The Tempus Pro is not an apnoea monitor and does not provide apnoea alarming.

WARNING
If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly.

WARNING
Do not use the Microstream® CO_2 accessories in the presence of flammable anesthetics or other flammable gases or when directly exposed to laser or ESU devises.

WARNING
Loose or damaged connections may compromise ventilation or cause inaccurate readings. Securely connect all components and check connections for leaks according to standard clinical procedures.

CO_2 readings and respiratory rate can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.

WARNING
Do not use the capnometer for patients who cannot tolerate the removal of 50 ml/min from their total minute ventilation.

WARNING
During MRI scanning:

- Do not use the FilterLine® H Set Infant/Neonatal. It may harm the patient.
- Place the module outside the MRI suite.

WARNING
Carefully route the FilterLine® to avoid entanglement or strangulation.

Do not lift the monitor by the FilterLine®. It may disconnect from the monitor, causing the monitor to fall on the patient.

The FilterLine® may ignite in the presence of oxygen if it is exposed to high heat.

WARNING
The use of accessories, transducers, sensors and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system.

WARNING
When you use a sampling line for intubated patients with a closed suction system, do not place the airway adaptor between the suction catheter and the endotracheal tube. The airway adapter may interfere with the suction catheter if not placed correctly.

WARNING
Do not cut or remove any part of the sample line. Cutting the sample line may give incorrect readings.

WARNING
If too much moisture enters the sampling line (i.e., from ambient humidity or breathing of unusually humid air), the message **Clearing FilterLine** will appear in the message area. If the sampling line cannot be cleared, the message **FilterLine Blockage** will appear in the message area. Replace the sampling line once the **FilterLine Blockage** message appears.

WARNING
When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent flammability of the FilterLine or surrounding surgical drapes.

WARNING
Loose or damaged connections may compromise ventilation or cause an inaccurate measurement of respiratory gases. Securely connect all components and check connections for leaks according to standard clinical procedures.

WARNING
Always ensure the integrity of the patient breathing circuit after insertion of the airway adapter by verifying a proper CO_2 waveform (capnogram) on the monitor display.

CAUTION
Before use, carefully read the Microstream® $ETCO_2$ sampling line's *Directions for Use*.

CAUTION
Do not reuse Microstream® $EtCO_2$ sampling lines. Any attempt to clean, disinfect, sterilize or flush any part of the sampling line may damage the monitor.

Dispose of sampling lines according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

CAUTION
In high-altitude environments, $EtCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high-altitude environments, it is advisable to consider adjusting $EtCO_2$ alarm settings accordingly.

CAUTION
Use of monitoring during continuous nebulized medication delivery may result in damage to the Tempus Pro which is not covered by the warranty. Disconnect the Capnometer sample line from the Tempus Pro or switch off the Tempus Pro during medication delivery.

CAUTION
During MRI scanning, the module must be placed outside the MRI suite. When the module is used outside the MRI suite, $EtCO_2$ monitoring can be implemented using the FilterLine XL.

CAUTION
Use of a CO2 sampling line with H in its name (indicating that it is for use in humidified environments) during MRI scanning may cause interference. The use of non H sampling lines is advised.

CAUTION
Dispose of Microstream® $EtCO_2$ consumables according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

CAUTION
The FilterLine set is intended for the CO2 monitoring of intubated patients.

Do NOT place the airway adapter between the ET tube and the elbow as this may allow patient secretions to accumulate in the adapter.

If pooling does occur, the airway adapter and sampling line must be replaced.

CAUTION
The oral/nasal cannulas are intended for monitoring CO2 in non-intubated patients.

Oral/nasal sampling cannulas are especially valuable for patients who are prone to mouth breathing, since most (if not all) of the CO2 is exhaled through the mouth. If a standard nasal CO2 sampling cannula is used on such patients, the $EtCO_2$ values and capnogram displayed will be substantially lower than the actual CO2 levels present in the patient's expired breath.

Remove the cannula from the package. Verify that the cannula is clean, dry, and undamaged. Replace if necessary.

CAUTION
Always ensure the cannula is fully inserted and fully tightened. Failing to tighten the cannula may result in the sample being diluted and an artificially low reading being produced.

CAUTION
If the door snaps shut this will only provide functional protection against dust/fluids etc. to the capnometer. For IP66 sealing the door **must** be pushed closed to engage the door's latch. When the capnometer door is open the capnometer has an IPX1 rating.

Do not use the capnometer for connection to a gas scavenging system.

Important

- The capnometer will require warming up if it is started from cold. The warm up time is specified in the "10.3 Tempus Pro medical specifications"section. Once the capnometer is warmed up, the capnogram will appear on the display.
- In order to avoid moisture build up and sampling line occlusion during nebulization or suction for intubated patients, remove the sampling line luer connector from the Tempus Pro.

Important
The capnometer door must be shut at all times when a cannula is not fitted. This is important to prevent dust, fluids or foreign objects from entering the capnometer. Ensure the door is only kept open for the minimum time necessary to plug and unplug a cannula into the Tempus Pro.

If the door is broken it must be replaced as soon as possible. The door and spring assembly can be removed and replaced with spare items by an appropriate technician without the unit being returned to RDT.

Allowing dust, fluids or foreign objects to enter the capnometer can cause permanent damage to the device.

Below the hole for the cannula inlet is a small hole for the capnometer exhaust. Take care not to block this hole (an error will be caused if it becomes blocked) and ensure that dust, fluids or foreign objects do not enter it.

Do not use transducers or pads that are out of date. Do not use damaged transducers.

(1) Capnometry socket

4.8.1 Getting started

CAUTION
The exhausted gas from the capnometer will contain elevated concentrations of CO_2 from respiration or calibration gases. If necessary ensure the environment is ventilated

1. Select the appropriate airway adapter based on:
   - The patient's age
   - Use of ventilation and whether ventilation is humidified
   - The probability that the patient will switch between oral and nasal breathing
   - Duration of use
   - Use of intubation
2. Verify that the airway adapter is clean, dry and undamaged. Replace if necessary.
3. Place the airway adaptor at the proximal end of the airway circuit between the elbow and the ventilator circuit wye. Follow the instructions for the airway adaptor.

4. Open the capnometer door on the left side of the Tempus Pro marked with  .
5. Attach the airway adaptor to the Tempus Pro.
6. To make sure that the airway adaptor is fully inserted, twist it clockwise until it is finger-tight.

4.8.2 Taking readings

1. When the capnometer is connected, wait up to 30 seconds for the capnogram to be displayed.
2. Check that the capnogram waveform appears correctly.

When a valid $EtCO_2$ or respiration reading is not available no reading will be displayed.

When a reading is out of range or breath detection is starting the reading will display "- - -".

If impedance respiration was in use, the waveform will automatically change to **CAPNO** and will display the end tidal CO_2 as soon as the cannula is connected. As soon as the cannula is disconnected (and the consequent error is cleared) the device will resume monitoring using impedance respiration.

4.8.3 Capnometer settings

To change settings:

1. Press any part of the **CAPNO** area of the touchscreen or navigate to the medical parameter setting in the Main Menu.
2. Select the settings to change:
   - **Respiration limits (rpm)**
   - **No breaths (sec)** time
   - **ETCO2 limits**
   - **ETCO2 units** - **mmHg** or **kPa**
   - **Wave range**
   - **Respiration wave speed (mm/s)**
   - **Operating mode** – **Normal**, **Pause 5 mins**, **Pause 10 mins**.
3. Change setting as required.

4.8.4 Capnometer filter line blocked

The message **Capnometer filter purging in progress** is displayed while the an attempt is made to clear any blockage.

If the blockage has not been cleared after approximately 30 seconds the Technical Alarm (Low Priority) **Capnometer filter line block (Replace filter line)** is displayed.

4.9 Contact temperature

The Tempus Pro lets you monitor contact temperature. One channel is standard, an additional channel is optional. If you have two channels, the Tempus Pro will display both channels as well as the difference. The Tempus Pro uses YSI series 400 sensors only. Temperature measurements are displayed when a sensor is connected.

WARNING
Application and use of metal-jacketed temperature sensors that come into contact with conductive objects or clinical personnel during electrocautery may cause burns at the patient-probe/electrode contact points.

WARNING
Always read and follow the instructions on the packaging of temperature sensors regarding their storage, use and disposal. In particular take into account any information regarding toxicity.

WARNING
The thermometer is only intended for use with YSI series 400 sensors. Disposable and reusable 400 series sensors may be used. Do not use series 700 sensors with the Tempus Pro.

Important
The contact temperature probes must be attached to the parts of the body which their labelling shows they are indicated for.

The contact temperature displays direct readings that are not adjusted.

A single temperature channel (T1) is provided on the Tempus Pro as standard. The second channel may be activated as an option using a software update.

(1) Temperature sockets

4.9.1 Getting started

The operator is responsible to check compatibility of the probe with the device. Make sure that your sensor is a YSI series 400 Sensor

The Contact temperature probe must be attached to the parts of the body which their labelling shows they are indicated for.

Refer to the Sensatronic IFU for further clarity of use.

You must wait for the temperature reading to settle, as per your medical standard practice.

Make sure that you have read the specifications in "10.3 Tempus Pro medical specifications".

1. Plug a YSI series 400 temperature sensor into the Tempus Pro ' ¼ " socket marked T1 or T2. If the unit supports only one temperature channel, you can use either T1 or T2. If the unit supports two temperature channels, you can use either T1 or T2 or both.

4.9.2 Taking readings

1. Attach the sensor to the patient. Make sure that you follow the instructions for the sensor.
2. The Tempus Pro displays the contact temperatures immediately.

   - Ensure the probe is suitably secured to the patient.
   - Monitor the temperature to observe when the reading settles. Settling time depends on patient and environmental factors.

3. If necessary, change measurement units and set alarm limits.

4.9.3 Temperature settings

To change settings:

1. Press any part of the **Temperature** area of the touchscreen or navigate to the **Medical Parameter Settings** in the **Main Menu**.
2. Select the settings to change:
   - **Temperature units** - **°C** or **°F**
   - **Temp limits** (if the Tempus Pro supports only one temperature channel), or **T1 limits** and **T2 limits** (if the Tempus Pro supports two temperature channels).
   - **Delta limits** (if the Tempus Pro supports two temperature channels) - set the limits for the difference between T1 and T2.
3. Change setting as required.

The thermometer performs a self-check to 38.8°C ±0.1°C constantly to ensure that its readings are accurate and within specification.

If only one temperature channel is supported:

- The values in the **Temperature Settings** screen apply regardless of whether the temperature sensor is connected to socket T1 or T2.
- The maintenance user can still configure default alarm limits for two channels (T1 and T2), but the T2 default alarm limits are ignored and the initial temperature limits in the **Temperature Settings** screen are equal to the T1 default alarm limits.

5 Alarms

This chapter describes how to deal with alarms and how to ensure that the alarms are working correctly.
This chapter contains the following topics:

5.1 Managing alarms

The Tempus Pro produces both physiological (patient) alarms and technical alarms. You can configure the patient alarms for each patient, and these are reset to the defaults when a new patient is admitted or if you switch back to monitor a previous patient.

All alarms are “non-latching”, i.e. the audible and visual alarm indicators will cease when the alarm condition ceases to exist. For example, if the heart rate goes from 80 to 105 and the alarm threshold has been set to 100, both visual and audible alarms will be generated. They will cease automatically when the heart rate drops below 100.

Alarms are audible in a 360° direction from the Tempus Pro. The alarm volume will be loudest when the user is facing the Tempus Pro and quieter to the side or rear of the unit. Alarm volumes are specified at 1 m from the front of the device.

The visual alarms are visible in a 360° direction around the Tempus Pro. Alarms will be more visible from the front of the device. While the alarms are visible from the sides (via light dispersed in the handle) and the rear, the visibility of the alarms is reduced in these positions.

When using the Tempus Pro, move to a position where you can see and hear all alarm signals, taking into account local light and noise levels.

The alarm bar and the audible alarm will operate shortly after start up. Ensure both functions are operating before using the device.

When a patient alarm is triggered:

- For medium priority alarms:
  - The alarm bar LEDs will flash amber
  - The Alarm Status area will display a description of the alarm
  - A sound will be heard dependent on the type of alarm.
- For high priority alarms
  - The alarm bar LEDs will flash red.

When a technical alarm is triggered:

- For low priority alarms:
  - The alarm bar LEDs will illuminate in amber
  - The Alarm Status area will display a description of the alarm.
- For medium priority alarms:
  - The alarm bar will flash amber
  - The Alarm Status area will display a description of the alarm.

In the optional tactical mode, when an alarm triggers the only indication is the alarm message displayed on the software screen with the relevant patient parameter being highlighted.

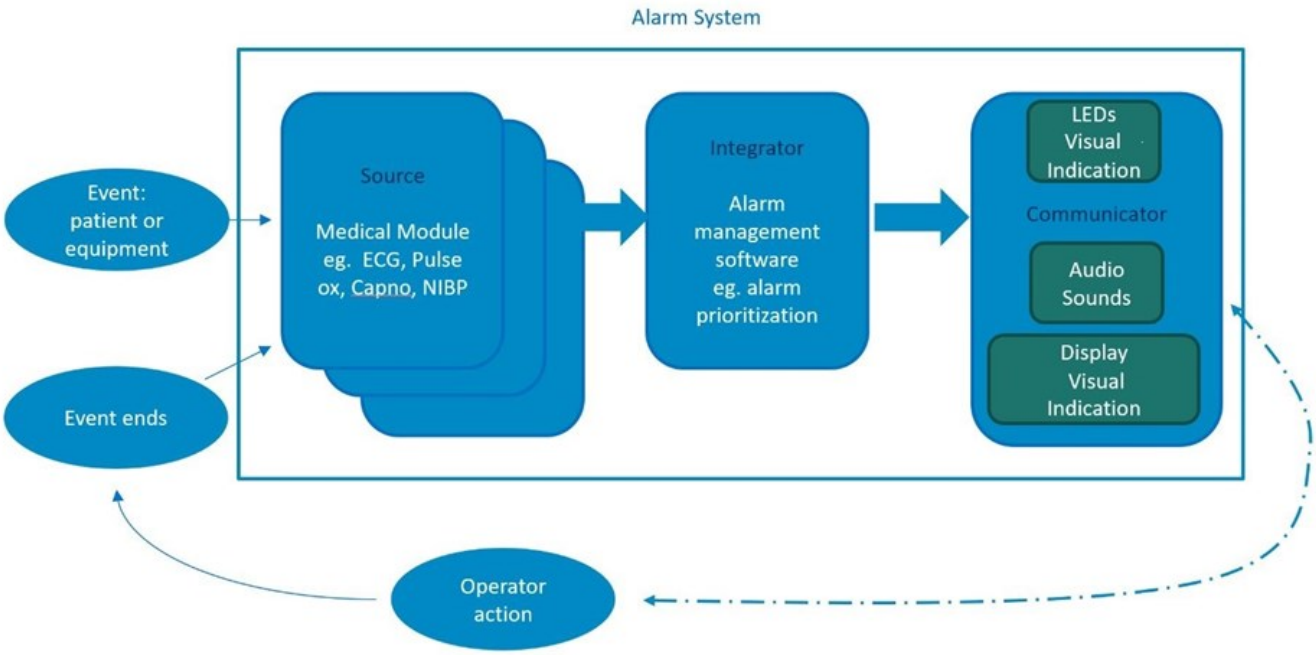
When you start up the Tempus Pro, ensure the alarm functions are operating before using the device.

Alarm settings are retained in the following scenarios:

- When you switch off the Tempus Pro for less than 30 seconds.
- When you tell the Tempus Pro to continue monitoring after it has been switched off and on.

5.1.1 Alarm system functions

The function of the alarm system is shown in the illustration that follows:



5.1.2 Warnings and cautions

WARNING
Do not silence the audible alarm if patient safety may be compromised.

WARNING
Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.

WARNING
Before each use, verify that the alarm limits are appropriate for the patient being monitored.

WARNING
Check the alarm suspend duration before temporarily suspending all the alarms. Alarm suspend feature pauses all audio and visual alarms.

WARNING
When operating the Tempus Pro make sure:

- You can clearly see the display and alarm bar.
- The handle and rear alarm light are clean and unobstructed.
- The alarm speaker is unobstructed and alarm volume is set to an appropriate level.

WARNING
The alarm functions of the Tempus Pro are intended to be used by the attendant user only. If the Tempus Pro is connected to an alternate location, this is to share vital signs data in real time, between two users for the purpose of obtaining additional clinical support. The system is not a distributed alarm system (e.g. nurse monitoring station system) in the terms of IEC 60601-1-8.

WARNING
Too many of the same or similar pieces of equipment in an area, with different alarm presets, may make it difficult for the operator to know how the alarm system will operate.

WARNING
Ensure all alarm settings are appropriate prior to use.

WARNING
Do not leave a unit in tactical mode without careful observation for alarm conditions on the screen.

CAUTION
Ensure alarm values are not changed to extreme levels simply to disable the alarms system.

Ensure alarm levels are brought into a more sensitive state for severe or critical patients or for patients who will be left unattended.

CAUTION
The Tempus Pro's alarms are intended to alert attendant users. They are not intended to alert users who remove themselves from the patient’s vicinity. Users should consider the levels of background ambient noise and light if they will not be in close proximity to the patient. The alarms provided by the system do not replace user care.

Important

- Every time you use the Tempus Pro, make sure the alarm speaker is working. To test the speaker, press anywhere on the touchscreen. A noise should be produced every time you touch the screen.
- All patient alarms have a user configurable delay of 0 - 8 seconds (2 seconds default, 0 seconds minimum) to help prevent spurious alarms being generated.
- There are three default alarm presets based upon patient type, these cannot be altered by the operator. There is a function to change the alarm settings for an individual patient if required but it only lasts for one patient. Once complete the default setting will return.
- The Tempus Pro will not report any alarm for the first 10 seconds after a sensor is attached. This is to prevent false positive alarms being generated.

Important
The technical alarm conditions that follow take priority over patient alarms:

- **Battery Empty** (lasts for 10 seconds or so before automatic shutdown occurs)
- **Temperature Too High**
- **Temperature Too Low**.

Important
The alarm system on Tempus Pro is controlled through the keypad Alarm Silence and Alarm Pause buttons as well as managing acknowledgement of technical conditions through the alarm screen (activated by touching the alarm status area). Tempus Pro does not implement reset control as defined by IEC 60601-2-27 section 208.6.9 and IEC 60601-1-8 section 6.9.

5.2 Alarm displays

The Tempus Pro signals alarm conditions using the indications that follow:

- Alarm bar LEDs
- The Display screen
- Alarms screen.

(1) Alarm bar LEDs

(2) Alarm Status area - Press the Alarm Status Area to access the Alarms screen.

(3) Alarm Limits bar

CAUTION
In strong daylight, users should ensure that the alarm status area is visible.

If multiple alarms occur, they will be displayed in rotation in the alarm status area.

5.2.1 Alarm Bar LEDs

The LEDs on the alarm bar on the top front face of the Tempus Pro light up when an alarm is triggered:

- Solid amber LED - for low priority technical alarms
- Flashing amber LED - for patient alarms and specific medium priority technical alarms
- Flashing red LED - for specific high priority alarms

You can configure the green LED to light up when there are no active alarms. This is done using the Maintenance menu. See the *Tempus Pro Maintenance Manual* for more details.

5.2.2 The Display screen

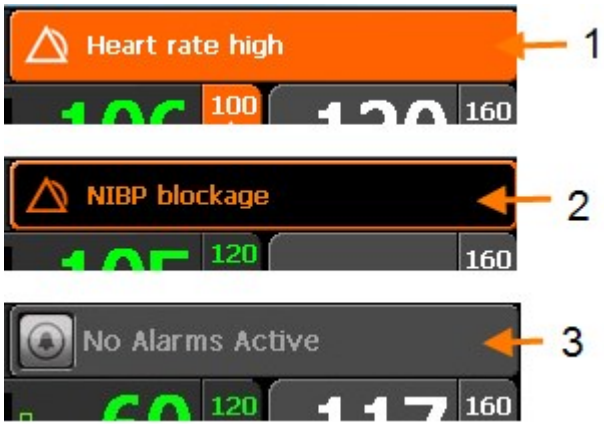
The Display screen shows the alarms in the areas that follow:

- Alarm Status area
- Alarm Limits bar
- Bottom Status bar

5.2.3 Alarm Status area

For both patient and technical alarms, the Tempus Pro shows the alarm symbol and a description of the alarm in the alarm status area at the top right of the display.

Press the alarm status area to view a list of all active alarms and to clear low priority technical alarms.



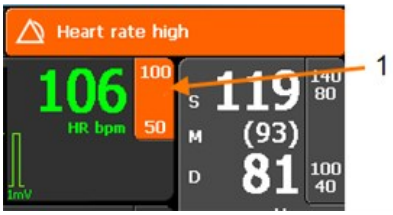
(1) Active patient alarm

(2) Active technical alarm

(3) No active alarms

5.2.4 Alarm limits bar

The Tempus Pro highlights the alarm limits bar for the patient parameter that triggered the alarm. It is shown as white text on an orange background.



(1) Alarm limits bar

5.2.5 Bottom status bar

For patient alarms only, on screens that have a bottom status bar, the Tempus Pro displays the parameter that triggered the alarm in flashing white text on an orange background.

(1) Patient alarm in bottom status bar

5.2.6 Alarms screen

The alarms screen is accessed by pressing the Alarm Status area.

A list of active patient and technical alarms can be viewed on the Alarms screen.

Low priority Technical alarms can be selected to display more information and to acknowledge and/or clear the alarm.

Medium Priority technical alarms can be selected to display more information and to acknowledge.

Patient alarms can be acknowledged.

(1) Patient alarms

(2) Technical alarms

To the left of the Alarm name that is displayed on both the Alarms screen and in the Alarm Status area is a symbol that identifies the status of the alarm. The symbols have the meaning that follows:

Symbol	Meaning
	Active alarm with audible tone
	Active alarm with audio paused
	Acknowledged alarm with audio off

5.2.7 Optional Tactical mode

CAUTION
Do not use the optional Tactical switch to silence alarms. When in tactical mode, the device will not emit audible alarms from the speaker and will present a display that may be too dim to see in daylight conditions.

When the optional tactical mode is activated, the alarm status area will display the message that follows, in rotation with other active alarms.

Tactical mode will override the audio alarm source and LED indicators without changing the display of active alarms. Tactical mode must only be used when alarm audio and the LEDs are not required.

In the tactical mode, alarms are not compliant with IEC60601-1-8.

5.3 Silencing or suspending alarms

The Tempus Pro is designed to only display active alarms. If the reason for the alarm has been corrected then the alarm state automatically clears.

5.3.1 Alarm Silence

Alarm suspend and silence buttons

To silence the alarm while you work on the cause of the alarm trigger:

1. Press the **Alarm Silence** button  .

- When a patient alarm is silenced the visual indication will remain on screen, in the Alarm Status bar, alarm limits bar and bottom status bar, until the condition that triggered the alarm has been resolved.
- The patient alarm in the Alarm Status area will be preceded by the Alarm Silence symbol  .

2. Press the **Alarm Silence** button again  .

- The patient alarm will no longer be silenced, if it has not been resolved
- The patient alarm in the Alarm Status area will be preceded by the Active Alarm symbol  .

During the alarm silence period, if a new alarm occurs (patient or technical) the alarm will sound as normal.

5.3.2 Alarm Suspend

If you know you are about to do something to the patient which will trigger an alarm, you can suspend the alarm for a configurable time period.

- For most patient alarms, pressing the alarm suspend button will suspend the audible alarm for the configured time period.
- At the conclusion of the suspension period, the alarm will sound again if the alarm state is still present.
- 2 minutes is the default Alarm Suspend time but this can be configured.

1. Press the **Alarm Suspend** button  .
   All audio and visual displays are suspended for 2 minutes. The yellow LED above the suspend button lights and a countdown appears to the right of the alarm text in the Alarm Status area..
2. Press the **Alarm Suspend** button again to resume monitoring during the countdown.

5.4 Patient alarms

All patient alarms are medium priority alarm states as defined by IEC60601-1-8, with the exception of “catheter disconnected” for invasive pressure (arterial pressure only) and ECG arrhythmia alarms.

If the arterial catheter pressure drops from a value of greater than 10 mmHg to less than 10 mmHg, then the red alarm bar LED will flash and a high priority alarm tone will be emitted.

If any alarms are turned off, the relevant parameter is highlighted in blue on the touchscreen:

See the table below for the patient alarms settings.

For details of how to adjust alarm settings, see "5.6 Setting alarms".

Parameter	Measurement range	Patient type	Default alarm low	Alarm low range	Default alarm high	Alarm high range
ECG heart rate	30-300 bpm	Adult	50 bpm	30-238 bpm	120 bpm	32-250 bpm
	30-300 bpm	Pediatric	50 bpm	30-238 bpm	150 bpm	32-250 bpm
	30-300 bpm	Neonate	100 bpm	30-238 bpm	200 bpm	32-250 bpm
ST	-50 – +50 mm	Adult	-2.0 mm	-10 – +2 mm	+2.0 mm	-2 – +10.0 mm
	N/A	Pediatric	N/A	N/A	N/A	N/A
	N/A	Neonate	N/A	N/A	N/A	N/A
QT	1 - 2000 ms	Adult	N/A	N/A	500 ms	10 - 1990 ms
	N/A	Pediatric	N/A	N/A	N/A	N/A
	N/A	Neonate	N/A	N/A	N/A	N/A
PI	0-20%	Adult	OFF	Off, 0.1 to 18	OFF	0.2 to 19, Off
	0-20%	Pediatric	OFF	Off, 0.1 to 18	OFF	0.2 to 19, Off
	0-20%	Neonate	OFF	Off, 0.1 to 18	OFF	0.2 to 19, Off
PVI	0-100%	Adult	5%	Off, 1 to 98	40%	2 to 99, Off
	0-100%	Pediatric	5%	Off, 1 to 98	40%	2 to 99, Off
	0-100%	Neonate	5%	Off, 1 to 98	40%	2 to 99, Off
SpOC	0 to 35 ml/dl	Adult	10 ml/dl	Off, 1 to 33	25 ml/dl	2 to 34, Off
	0 to 35 ml/dl	Pediatric	10 ml/dl	Off, 1 to 33	25 ml/dl	2 to 34, Off
	0 to 35 ml/dl	Neonate	10 ml/dl	Off, 1 to 33	25 ml/dl	2 to 34, Off

Parameter	Measurement range	Patient type	Default alarm low	Alarm low range	Default alarm high	Alarm high range
SpO_2 pulse rate	25-239 bpm	Adult	50 bpm	30-238 bpm	120 bpm	32-239 bpm
	25-239 bpm	Pediatric	50 bpm	30-238 bpm	150 bpm	32-239 bpm
	25-239 bpm	Neonate	100 bpm	30-238 bpm	200 bpm	32-239 bpm
Impedance respiration	3-150 rpm	Adult	5 rpm	3-145 rpm	30 rpm	5-149 rpm
	3-150 rpm	Pediatric	5 rpm	3-145 rpm	30 rpm	5-149 rpm
	3-150 rpm	Neonate	12 rpm	3-145 rpm	80 rpm	5-149 rpm
SpO_2	1-100%	Adult	90%	50-98%	100%	52-100%
	1-100%	Pediatric	90%	50-98%	100%	52-100%
	1-100%	Neonate	85%	50-98%	95%	52-100%
SpCO	0-99%	Adult	OFF	1-97%	10%	2-98%
	0-99%	Pediatric	OFF	1-97%	10%	2-98%
	0-99%	Neonate	OFF	1-97%	10%	2-98%
SpHb	0-25 g/dl	Adult	7.0 g/dl	1.0-23.5 g/dl	17.0 g/dl	2.0-24.5 g/dl
	0-25 g/dl	Pediatric	7.0 g/dl	1.0-23.5 g/dl	17.0 g/dl	2.0-24.5 g/dl
	0-25 g/dl	Neonate	7.0 g/dl	1.0-23.5 g/dl	17.0 g/dl	2.0-24.5 g/dl
SpMet	0.0-99.9%	Adult	OFF	0.1-99.0 %	3.0%	1.0-99.5 %
	0.0-99.9%	Pediatric	OFF	0.1-99.0 %	3.0%	1.0-99.5 %
	0.0-99.9%	Neonate	OFF	0.1-99.0 %	3.0%	1.0-99.5 %
Capnometer respiration	1-149 rpm	Adult	5 rpm	2-145 rpm	30 rpm	5-149 rpm
	1-149 rpm	Pediatric	5 rpm	2-145 rpm	30 rpm	5-149 rpm
	1-149 rpm	Neonate	12 rpm	2-145 rpm	80 rpm	5-149 rpm
Capnometer respiration – no breaths detected	-	Adult	30 seconds	10-60 seconds	-	-
	-	Pediatric	30 seconds	10-60 seconds	-	-
	-	Neonate	30 seconds	10-60 seconds	-	-
Capnometer $EtCO_2$	0-150 mmHg 0-20 kPa	Adult	25 mmHg 3.3 kPa	0-145 mmHg 0-19.3 kPa	60 mmHg 8 kPa	5-150 mmHg 0.7-20 kPa
	0-150 mmHg 0-20 kPa	Pediatric	25 mmHg 3.3 kPa	0-145 mmHg 0-19.3 kPa	60 mmHg 8 kPa	5-150 mmHg 0.7-20 kPa
	0-150 mmHg 0-20 kPa	Neonate	25 mmHg 3.3 kPa	0-145 mmHg 0-19.3 kPa	60 mmHg 8 kPa	5-150 mmHg 0.7-20 kPa
Non-Invasive Blood Pressure - Systolic	40-260 mmHg	Adult	90 mmHg	40-255 mmHg	160 mmHg	45-260 mmHg
	40-230 mmHg	Pediatric	70 mmHg	40-155 mmHg	120 mmHg	45-160 mmHg
	40-130 mmHg	Neonate	40 mmHg	40-125 mmHg	90 mmHg	45-130 mmHg

Parameter	Measurement range	Patient type	Default alarm low	Alarm low range	Default alarm high	Alarm high range
Non-invasive blood pressure - diastolic	20-200 mmHg	Adult	50 mmHg	20-195 mmHg	90 mmHg	25-200 mmHg
	20-160 mmHg	Pediatric	40 mmHg	20-155 mmHg	70 mmHg	25-160 mmHg
	20-100 mmHg	Neonate	20 mmHg	20-95 mmHg	60 mmHg	25-100 mmHg
Non-invasive blood pressure - mean	26-220 mmHg	Adult	60 mmHg	26-215 mmHg	110 mmHg	30-220 mmHg
	26-183 mmHg	Pediatric	50 mmHg	26-155 mmHg	90 mmHg	30-160 mmHg
	26-110 mmHg	Neonate	24 mmHg	26-155 mmHg	70 mmHg	25-160 mmHg
Contact temperature	20-45 °C / 68-113 °F	Adult	35 °C / 95 °F	20-44 °C / 68-111 °F	37.8 °C / 100 °F	21-45 °C / 69.8-113 °F
	20-45 °C / 68-113 °F	Pediatric	35 °C / 95 °F	20-44 °C / 68-111 °F	37.8 °C / 100 °F	21-45 °C / 69.8-113 °F
	20-45 °C / 68-113 °F	Neonate	35 °C / 95 °F	20-44 °C / 68-111 °F	37.8 °C / 100 °F	21-45 °C / 69.8-113 °F
Invasive Pressure – Systolic Arterial	-99 – 310 mmHg	Adult	90 mmHg	-99 – 310 mmHg	160 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	70 mmHg	-99 – 310 mmHg	120 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	40 mmHg	-99 – 310 mmHg	90 mmHg	-99 – 310 mmHg
Invasive Pressure – Diastolic Arterial	-99 – 310 mmHg	Adult	50 mmHg	-99 – 310 mmHg	90 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	40 mmHg	-99 – 310 mmHg	70 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	20 mmHg	-99 – 310 mmHg	60 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean Arterial	-99 – 310 mmHg	Adult	60 mmHg	-99 – 310 mmHg	110 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	50 mmHg	-99 – 310 mmHg	90 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	24 mmHg	-99 – 310 mmHg	70 mmHg	-99 – 310 mmHg
Invasive Pressure – Systolic Venous	-99 – 310 mmHg	Adult	6 mmHg	-99 – 310 mmHg	14 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	2 mmHg	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	2 mmHg	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg

Parameter	Measurement range	Patient type	Default alarm low	Alarm low range	Default alarm high	Alarm high range
Invasive Pressure – Diastolic Venous	-99 – 310 mmHg	Adult	-4 mmHg	-99 – 310 mmHg	6 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	-4 mmHg	-99 – 310 mmHg	2 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	-4 mmHg	-99 – 310 mmHg	2 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean Venous	-99 – 310 mmHg	Adult	0 mmHg	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	0 mmHg	-99 – 310 mmHg	4 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	0 mmHg	-99 – 310 mmHg	4 mmHg	-99 – 310 mmHg
Invasive Pressure – Systolic PAP	-99 – 310 mmHg	Adult	10 mmHg	-99 – 310 mmHg	34 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	24 mmHg	-99 – 310 mmHg	60 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	24 mmHg	-99 – 310 mmHg	60 mmHg	-99 – 310 mmHg
Invasive Pressure – Diastolic PAP	-99 – 310 mmHg	Adult	0 mmHg	-99 – 310 mmHg	16 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	-4 mmHg	-99 – 310 mmHg	-4 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	-4 mmHg	-99 – 310 mmHg	-4 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean PAP	-99 – 310 mmHg	Adult	0 mmHg	-99 – 310 mmHg	20 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	12 mmHg	-99 – 310 mmHg	26 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	12 mmHg	-99 – 310 mmHg	26 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean ICP	-99 – 310 mmHg	Adult	0 mmHg	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	0 mmHg	-99 – 310 mmHg	4 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	0 mmHg	-99 – 310 mmHg	4 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean BDR	-99 – 310 mmHg	Adult	-	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Pediatric	-	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	-	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg

5.5 Technical alarms

Technical alarms can relate to the state of the Tempus Pro itself or its connection to the patient. Technical alarms are low priority alarm states or medium priority alarm states as defined by IEC60601-1-8.

The majority of technical alarms are self-explanatory and should be addressed by following the on-screen instructions. Additional information is provided below for certain technical alarm conditions.

Technical alarms can be cleared by the operator (see section "5.2 Alarm displays").

On screen alarm text	Condition	Additional instructions
Attention - Bluetooth **Unable to initialise bluetooth.** **If the problem persists use a wired headset.**	Bluetooth linking error	Repeat the process.
Attention - Data Cable **The data cable is not plugged in correctly.**	Communications error - cable not plugged in	Repeat the process.
Attention - Data Connecting **Initialising data encryption engine.**	Communications notification	No action - initialization process lasts less than 15 seconds
Attention - Data Connection **The data link was unable to connect at this time.**	Communications error – connection failed	Repeat the process.
Attention - Data Export **There is patient record data from other devices/times. Do you want to over-write it?**	Data export option	Press the appropriate touchscreen button.
Attention - GPS **A GPS location has not yet been obtained; leave the GPS on and check this screen again in a few minutes.**	GPS error	Repeat the process.
Attention - Headset **The headset has not linked to the Tempus. Repeat step 3 of the instructions.**	Bluetooth headset linking error	Repeat the process.
Attention - Low Battery	Low Battery	The on screen text will indicate how low the battery is. Recharge or replace the battery.
Attention - Switch To A Previous Patient **To switch patient you must first stop monitoring the current patient.**	Patient switching error	Disconnect leads from the current patient before discharging. Then admit a new patient.

On screen alarm text	Condition	Additional instructions
Attention - Voice Connection **Headset voice connection will be started after connecting data.**	Voice connection not possible, a data connection must be made first	Repeat the process.
Attention - Voice Connection **The voice link was unable to connect at this time.**	Voice connection error	Repeat the process.
Attention - WiFi **WiFi was unable to connect at this time. If the problem persists restart the Tempus and attempt the connection again.**	WiFi connection error	Repeat the process.
Warning - Wifi **Wifi is not activated on this device.**	WiFi not activated	Refer to the maintenance manual.
Warning – GSM (Cell-phone) **GSM is not activated on this device**	GSM not activated	Refer to the maintenance manual.
Bluetooth Pairing Error **The required bluetooth device not found.**	Bluetooth pairing error	Repeat the process. See the Sennheiser manual supplied with your headset.
Bluetooth Pairing Error **Entered PIN is incorrect.**	Bluetooth pairing error	Repeat the process. See the Sennheiser manual supplied with your headset.
Warning - Bluetooth **Bluetooth is not activated on this device.**	Bluetooth pairing error	Repeat the process. See the Sennheiser manual supplied with your headset.
Attention - Restart Required **Fault detected**	System error	Further details of the fault are given in the text. Log the exact details of the fault and restart the Tempus Pro. At an appropriate time contact your supplier and give the details of the error.
Invalid IP Address **Please check the IP Address is in the format x.x.x.x and multiple addresses are separated by 'XX'.**	IP address error	Correct the format of the IP address
Network Settings Error **There are no network settings in this mode**.	Network Settings Error	Enter network settings
Option Key Check Failed **One or more option key checks have failed. Some features may be disabled. If the problem persists contact the service representative.**	Software update error	A software upgrade may have occurred incorrectly. Log the exact details of the fault and restart the Tempus Pro. At an appropriate time contact your supplier and give the details of the error.

On screen alarm text	Condition	Additional instructions
Temperature Warning **The device temperature is low, Tempus may shutdown.**	Low ambient temperature warning	Attempt to warm the device and then restart
USB - Connection **The USB memory stick is not plugged into the Tempus USB socket, please plug in. If plugged in, check it's the USB and NOT the RJ45 socket.**	USB connection error	Remove and re-insert the stick into the USB socket
USB - Connection **Failed to connect with USB, please retry.**	USB error	Remove and re-insert the stick into the USB socket
USB - Import **The USB memory stick does not have any settings data on it.**	USB error	Use the correct stick or ensure the files are on the stick you have
USB - Import **The USB memory stick is empty; there is no handover data on it.**	USB error	Use the correct stick or ensure the files are on the stick you have
USB - Import **The imported data was previously exported for the current patient. You cannot re-import this data.**	USB error	You are attempting to re-write the current patient record with itself, this cannot be done
Warning - Settings **Settings were not saved at power down and have been reset to defaults.**	Maintenance notification	Reset settings as required

Technical alarms are low priority alarm states or medium priority alarm states as defined by IEC60601-1-8.

5.6 Setting alarms

Most patient alarms have a user configurable delay of 0 - 8 seconds (2 seconds factory default, 0 seconds minimum) to help prevent spurious alarms being generated. In addition to this user-configurable time, the Tempus Pro will produce alarms after the durations specified below.

CAUTION
The **Reset to defaults** button resets the following to their new patient default values: all alarm limits, **Alarm trigger delay**, **Alarm silence time**.

5.6.1 Default alarm settings

Alarm	Nominal delay to alarm (excluding user configurable delay)
Heart rate (from ECG) high	2 seconds
Heart rate (from ECG) low	2 seconds
ECG heart rate out of range (low)	4 seconds
Pulse rate (from Oximeter) high	3 seconds
Pulse rate (from Oximeter) low	3 seconds
Pulse rate out of range (from Oximeter) (low)	4 seconds
Pulse rate out of range (from Oximeter) (high)	4 seconds
SpO2 high	3 seconds
SpO2 low	3 seconds
SpHb low	2 seconds
SpHb high	2 seconds
SpMet low	2 seconds
SpMet high	2 seconds
SpCO low	3 seconds
SpCO high	4 seconds
PI low	2 seconds
PI high	2 seconds
PVI low	2 seconds
PVI high	2 seconds
SpOC low	2 seconds
SpOC high	2 seconds
ETCO2 high	4 seconds
ETCO2 low	4 seconds
Respiration rate (from Capnometer) high	4 seconds
Respiration rate (from Capnometer) low	4 seconds

Alarm	Nominal delay to alarm (excluding user configurable delay)
ECG Respiration high	4 seconds
ECG Respiration low	4 seconds
No breaths detected (from Capnometer)	10 - 60 seconds (depending on delay setting)
NIBP systolic high	0 seconds at end of measurement - Not user configurable
NIBP systolic low	0 seconds at end of measurement - Not user configurable
NIBP mean high	0 seconds at end of measurement - Not user configurable
NIBP mean low	0 seconds at end of measurement - Not user configurable
NIBP diastolic high	0 seconds at end of measurement - Not user configurable
NIBP diastolic low	0 seconds at end of measurement - Not user configurable
Temp T1 and **Temp T2** low	4 seconds
Temp T1 and **Temp T2** high	4 seconds
P1 systolic high	4 seconds
P1 systolic low	4 seconds
P1 diastolic high	4 seconds
P1 diastolic low	4 seconds
P1 mean low	4 seconds
P1 mean high	4 seconds
Extreme Brady (ECG monitoring arrhythmia)	6 seconds
Extreme Tachy (ECG monitoring arrhythmia)	7 seconds
Vent Tachy (ECG monitoring arrhythmia)	5 seconds
Vent Fib (ECG monitoring arrhythmia)	9 seconds
Asystole (ECG monitoring arrhythmia)	6 seconds
ECG QT	60 seconds
ECG ST1 and **ECG ST2**	60 seconds

5.6.2 Changing alarm settings

Alarm limits are set in either the individual parameter settings menu or through the Alarms menu. To set the limits:

1. Press either:
   the parameter area of the alarm
   or
   select **Main Menu** > **All Alarms**

2. Press the alarm you want to set. An editor appears, this shows the range of settings available for that alarm
3. Edit the upper and lower limits of the alarm.

- The alarm limit shown is the number that the Tempus Pro will display before the alarm is activated. For example, if the alarm limit for heart rate is set to less than 50 (49 or less) or greater than 120 (121 or more), the Tempus Pro will not alarm at 50-120 inclusive.
- It is possible to have the lower and upper alarm limits set to the same value.

4. Press the **Save & Back** button.

In the alarm settings screen you can also switch individual alarms on and off, or all alarms on.

Other system configuration changes e.g. ECG lead selection, QRS beat volume, gain or waveform speed changes, communications mode and communications settings, iAssist mode etc. are stored on the Tempus Pro. Any changes to the Tempus Pro configuration, other than alarm settings, will remain unchanged if the Tempus Pro is switched off and on again and patient monitoring continued within 72 hours.

5.7 Audio alarm characteristics

WARNING
When operating the Tempus Pro make sure:

- You can clearly see the display and alarm bar.
- The handle and rear alarm light are clean and unobstructed.
- The alarm speaker is unobstructed and alarm volume is set to an appropriate level.

If alarm volume is less than the ambient sound level, the operator may not recognize alarm conditions.

CAUTION
Do not attempt to clean beneath the grille with a sharp or rough implement. This can damage the waterproof sealing and cause reduction or impairment of the ingress protection barrier.

Audible alarms are separated into either patient (physiological) alarms, “inop” (technical) alarms or alarm off/suspend reminder tones. These alarm signals are specified as follows:

Nominal characteristics	Patient alarm (red)	Patient alarm and medium priority technical alarms (amber)	Technical alarm (Amber)	Reminder tone
Pulse sequence	10 x 175 ms pulses	3 x 125 ms pulses at 440 Hz (with 4 harmonics under 4 kHz)	2 x 250 ms pulses	1 x 500 ms pulse at 1 kHz
Repetition rate	Every 10 seconds	Every 5 seconds	Every 30 seconds	Every 3 minutes
Duration of gap between pulse sequences	50 ms silence between pulses 1 and 2, 2 and 3, 4 and 5, 6 and 7, 7 and 8, 9 and 10. 270 ms silence between pulses 3 and 4, 8 and 9. 625 ms silence between pulses 5 and 6	250 ms silence between pulse sequences		

The alarm off/suspend reminder tone plays a beep every three minutes to remind the operator that alarms are off or suspended. “Off” only applies to parameters that are being monitored.

Default alarm values will differ across different patient ages. The default alarms are configurable by the operating institution.

The Volume of the Audio Alarms are as follows:

Audio	Minimum	Maximum (High)
Alarm audio	47 dB(A)	82 dB(A)

Audio (Information signals)	Minimum	Maximum (High)
ECG QRS Beep	51 dB(A)	70 dB(A)
Pulse Beep (Variable Tone)	56 dB(A)	78 dB(A)
Alarm Reminder Tone	58 dB(A)	82 dB(A)

The volume may be reduced using the **All Alarms** menu **Alarm Volume** settings: **Min**, **Low**, **Mid** and **High**. The maintenance user may have disabled one or more of these settings.

5.8 Testing alarms

RDT recommends that visual and audible alarms are tested before use. When the Tempus Pro is switched on (see "3.4.1 Switching on") the alarm should sound and the alarm bar light up.


No sound or light will occur if the Tempus Pro is started in tactical mode.

If you need to test the alarm after the Tempus Pro has been switched on you can:

1. Connect the pulse oximeter probe to the Tempus Pro
2. Insert finger into probe
3. Wait for reading to appear
4. Remove finger
5. Check Tempus Pro alarm works correctly

5.9 Logging of Alarms

More information on the logging of alarms, refer to section 2.13 of the Tempus Pro Maintenance manual.

6 Summary record of care

This chapter explains how to use the Tempus Pro Summary Record of Care (SRoC) feature.

Event general, assessment, intervention, fluid and drug names and details are organizationally configurable. The default names and details can all be changed to match the organization's needs.

> **WARNING**
> Event naming and detailed configuration must be reviewed and checked before the Tempus Pro is deployed in service. Read the details of event configuration in the *Tempus Pro Configuration Utility User Guide*.

This chapter contains the following topics:

6.1 Event capture

To capture events in the Summary Record of Care (SRoC) screen, press the **Event** membrane button  . The Tempus Pro displays the SRoC **Events** tab, **General** category.

6.1.1 General event entry

The SRoC **General** screen allows you to quickly record a category marker or multiple events up to a maximum of 200 events. General events are a subset of the assessments, interventions, fluids and drugs, typically the most commonly needed events. All general events are also accessible from one of the **Assessment**, **Intervention**, **Fluid** or **Drug** screens.

(1) Navigation buttons

(2) Category markers

(3) Event buttons

(4) Notes editor

(5) Page up and down

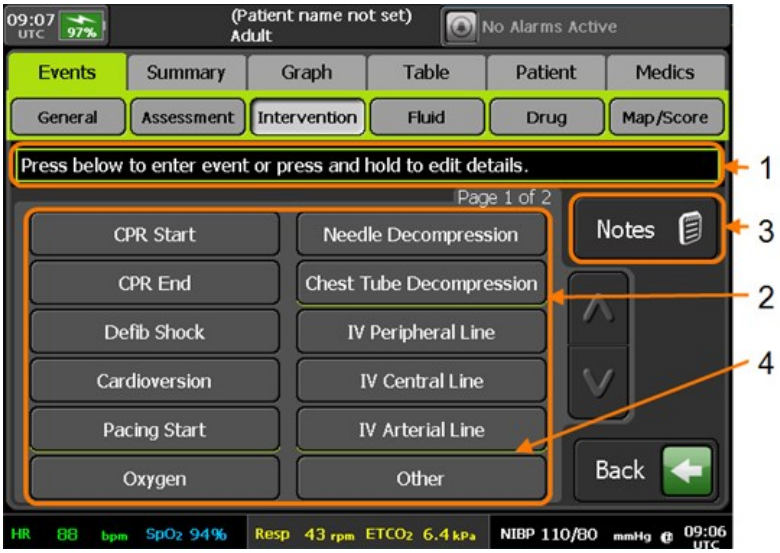
Use the **General** screen to record events:

- To record an event category for later editing, press one of the category markers on the left of the screen (2). The Tempus Pro will record the category marker and automatically return to the monitoring screen.
- To record an event with the current time but no other details, press and release one of the event buttons (3).
- To edit the time and details before recording the event, press and hold one of the event buttons (3). The Details Editor screen is displayed.

If you subsequently change the time of a recorded event, the Tempus Pro will clear the recorded vitals.

6.1.2 Assessment, intervention, fluid and drug entry

The **Assessment**, **Intervention**, **Fluid** and **Drug** screens behave in a similar way to the **General** screen, allowing you to record multiple events of the corresponding type. Category markers are not available in these screens. The group end markers (green lines) can be configured using the Tempus Pro Configuration Utility.



(1) Last event recorded

(2) Event buttons

(3) **Notes** editor

(4) Group end markers (green lines)

Assessment events

Use the **General** or **Assessment** screens to record assessment events:

- To record an assessment event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the assessment event, press and hold the event button. The Assessment Details Editor screen is displayed, allowing you to edit the date and time, add an event note, or delete the event.

Intervention events

Use the **General** or **Intervention** screens to record intervention events:

- To record an intervention event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the intervention event, press and hold the event button. The Intervention Details Editor screen is displayed, allowing you to edit the date and time, add an event note, or delete the event.

Fluid events

Use the **General** or **Fluid** screens to record fluid events:

- To record a fluid event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the fluid event, press and hold the event button. The Fluid Details Editor screen is displayed, allowing you to edit the date and time, edit the volume, add an event note, or delete the event.

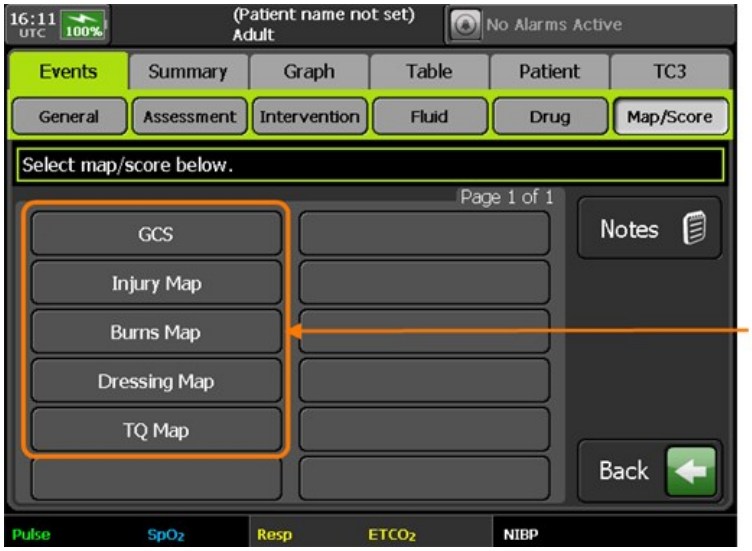
Drug events

Use the **General** or **Drug** screens to record drug events:

- To record a drug event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the drug event, press and hold the event button. The Drug Details Editor screen is displayed, allowing you to edit the date and time, edit the route, edit the dose, add an event note, or delete the event.

6.1.3 Map/Score screen

The **Map/Score** screen allows you to record the patient's Glasgow Coma Scale (**GCS**) score and to record injuries, burns, dressings and tourniquets on graphical body maps.



(1) Map/score event buttons

GCS screen

When you press **GCS** on the **Map/Score** screen, the **GCS** screen is displayed. This allows you to record the patient's GCS score:

1. To display help text, press **Help**. When you select a score with help enabled, the Tempus Pro will automatically move to the next entry screen.
2. Record the **Best Eye** score by pressing one of the numbered buttons.
3. Record the **Best Verbal** score by pressing 'T' (if patient is intubated) or one of the numbered buttons.
4. Record the **Best Motor** score by pressing one of the numbered buttons.

The Tempus Pro sums these three scores and displays the resulting GCS score.

> **CAUTION**
> If you exit the **GCS** screen without entering all three scores, then no GCS data is recorded.

Injury map

When you press **Injury Map** on the **Map/Score** screen, the **Injury Map** screen is displayed. This allows you to record patient injuries on a graphical representation of the front and rear of the body (a body map):

1. Identify the injury by pressing one of the injury type buttons. If you need to define new injury types, use the **Other 1** and **Other 2** buttons.

2. Locate the injury by pressing an area of the body map. The numbers indicate approximate percentage of total body area.
3. Repeat steps 1 and 2 for each observed injury.
4. To add injury assessment notes, press the note button. When notes have been entered, the note icon changes color to green.

Dressing map

When you press **Dressing Map** on the **Map/Score** screen, the **Dressing Map** screen is displayed. This allows you to record patient dressings on a body map. To use this screen, follow the injury map procedure (above).

Burns map

When you press **Burns Map** on the **Map/Score** screen, the **Burns Map** screen is displayed. This allows you to record patient burns on a body map. To use this screen, follow the injury map procedure (as above, but the **Burns Map** screen does not contain **Other** buttons). When you have entered all observed burns, press the **Total Burn Area** button to record the total percentage of body area affected.

TQ map

When you press **TQ Map** on the **Map/Score** screen, the **TQ Map** screen is displayed. This allows you to record limb tourniquet positions and start times on a body map:

1. Locate the tourniquet by pressing an area of the body map.
2. Enter the time of application by pressing the corresponding clock symbol (right arm, left arm, right leg or left leg).

6.1.4 Automatic event capture

The Tempus Pro responds to certain events by automatically logging them with patient encounter data in the SRoC. The following events are captured in this way:

- Arrhythmia alarms. When an arrhythmia alarm is triggered, the Tempus Pro logs the event and records a waveform snapshot from 10 seconds before until 10 seconds after the event.
- Patient alarms. When a patient alarm is triggered, the Tempus Pro logs the event. You can configure the Tempus Pro to store a snapshot of the waveform when alarms are triggered: use the **All Alarms Menu**, **Waveform Snapshot on alarm** option.
- Waveform snapshots. When the operator records a snapshot of a waveform by pressing and releasing the **Camera & Waveform Snapshot** button, the Tempus Pro logs the event.
- 12-lead ECG recordings. When the operator records a 12-lead ECG, the Tempus Pro logs the event.
- Camera or laryngoscope images. When the operator records a camera or laryngoscope image, the Tempus Pro logs the event. For laryngoscope details, refer to *Tempus Pro Laryngoscope Supplement Guide*.
- Ultrasound images. When the operator records an ultrasound image during a general or FAST exam, the Tempus Pro logs the event. For ultrasound details, refer to *Tempus Pro Ultrasound Supplement Guide*.

If the Tempus Pro is fitted with an internal printer and automatic printing is enabled, it will print waveforms as soon as they are captured.

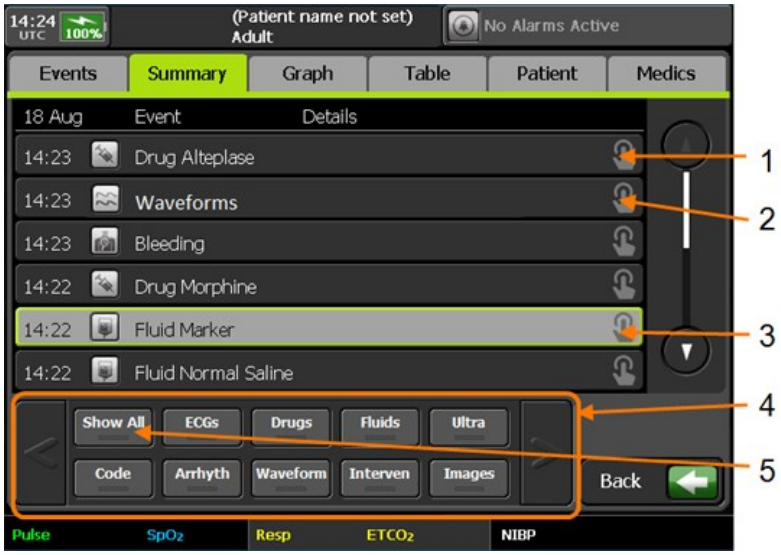
6.2 Events summary list

To view a list of captured events and select events for updating:

- If the Summary Record of Care (SRoC) screen is not displayed, press the **Event** membrane button  .
- In the SRoC screen, select the **Summary** tab.

6.2.1 Summary screen

The SRoC **Summary** tab displays a list of all the events entered by the user together with any events automatically captured.



(1) Drug event

(2) Waveform event

(3) Category marker

(4) Filter buttons

(5) Button to clear all filters

Each event is shown with the associated event icon as detailed in the table below.

Event type	Icon	Filter button
All	All	**Show All**
Arrhythmia		**Arrhyth** or **Waveform**
12-lead ECG		**ECGs**
Camera image		**Images**
Drug		**Drugs**

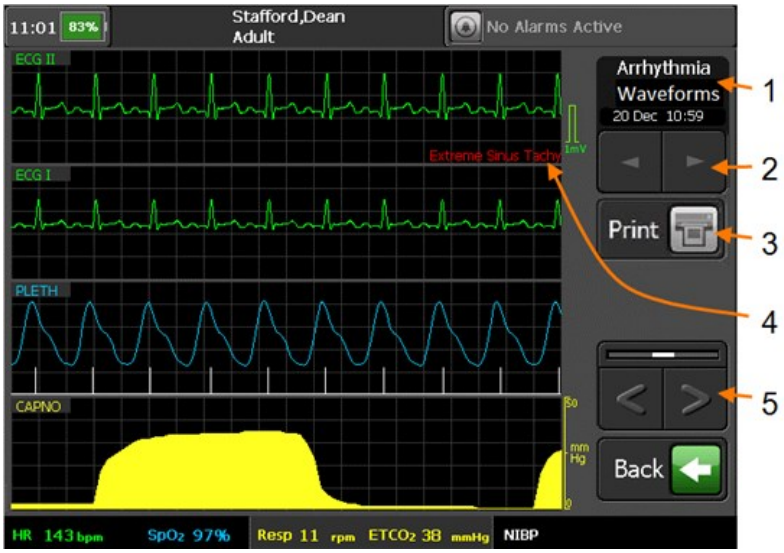
Event type	Icon	Filter button
Fluid		**Fluids**
Note		**Notes**
Intervention		**Interven**
Laryngoscope image		**Images**
Assessment		**Assess**
Waveform (manual)		**Waveform**
Alarm waveform		
Medics		**Medics**
Injury, burn, dressing or TQ		**Maps**
GCS		**Scores**
Ultrasound image		**Ultra**
Category marker: assessment, intervention, fluid or drug	Icon matches marker type	**Markers**
Tempus LS		**Code**

Use this screen to view and update recorded events:

- Press an event to access the associated editor or viewer (only automatically recorded events can be viewed).
- Press and hold an event to display the trend graph centered at the event time (if the event is less than 72 hours old). The graph will show events with a 45 minutes zoom.
- Press a waveform event to access the waveform snapshot viewer.
- Press a category marker to add the associated event details.
- Press one or more of the filter buttons to filter the display by event type.
- Press the **Show All** button to clear all filters and display all events.

6.2.2 Waveform viewer

To view a waveform, press the waveform event in the SRoC Summary screen.



(1) Waveform type and date

(2) Previous and next waveforms

(3) Print waveform (optional)

(4) Arrhythmia details

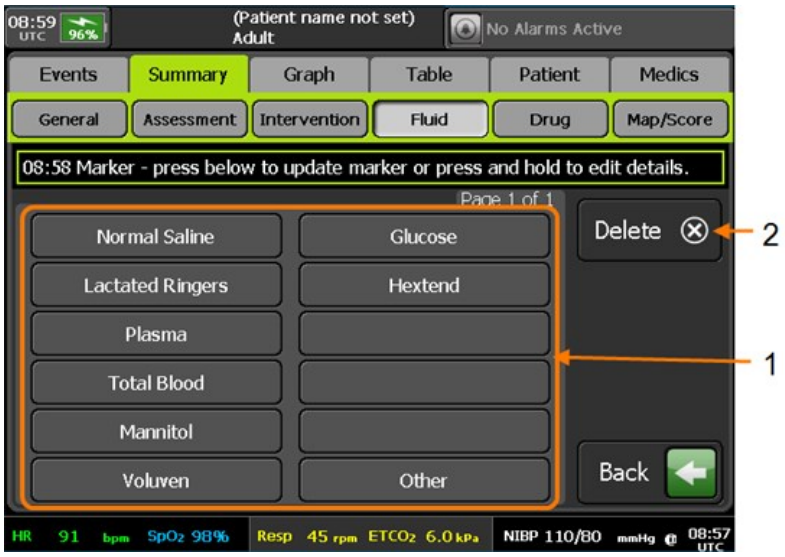
(5) Previous and next pages

If an internal printer is fitted to the Tempus Pro, you can print the waveform using the **Print** button. For printer instructions see "8.5.5 Send patient report to the internal printer (optional)".

If the Tempus Pro is fitted with an internal printer and automatic printing is enabled, it will print waveforms as soon as they are captured.

6.2.3 Updating a category marker

To convert a category marker to a fully recorded event, press the category marker entry in the SRoC Summary screen. The Tempus Pro displays the entry screen for the relevant event category.



(1) Buttons for converting marker to an event

(2) Button for deleting marker

Use this screen to convert or delete markers:

- Press one of the event buttons to convert the marker to a fully recorded event.
- Press and hold an event button to edit event details. Any further events buttons pressed are recorded as new events.
- Press the **Delete** button to delete the event marker.

6.3 Trends

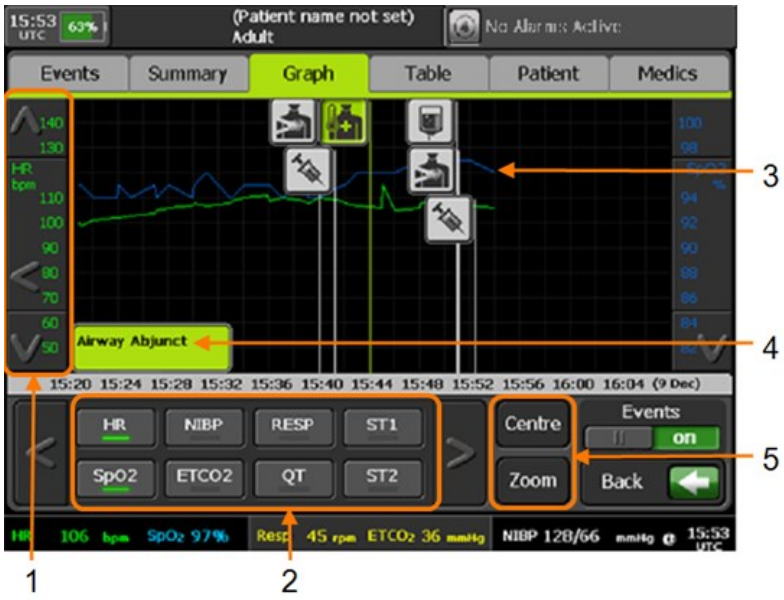
Tempus Pro automatically samples all continuous medical readings once per minute and stores these in the patient record. For readings taken less often, such as non-invasive blood pressure, all readings are stored in the patient record. The last 72 hours of trend data are available in the **Trends** and **Table** tabs of the SRoC screen.

To access trend data, use one of the following methods:

- Press the **Event** membrane button to display the SRoC screen, then select the **Trends** or **Table** tab.
- From the Main Menu and other medical menus - press the **Trends** button. The Tempus Pro displays the SRoC **Trends** tab.
- From the Home Screen - press and hold any waveform. The Tempus Pro displays the SRoC **Trends** tab with the results of the waveform you pressed.
- From the SRoC **Summary** tab - press and hold any event. The Tempus Pro displays the **Trends** tab, centered at the time of the event you pressed.

6.3.1 Trend graph

The SRoC **Trends** tab allows you to select two vitals to be shown together, each vital having its own scale. A maximum of four events can be displayed on the graph in a four minute interval. There can be a delay of up to one minute before events are displayed.



(1) Left/right and up/down buttons

(2) Vitals to be displayed

(3) Event icons

(4) Details of selected event

(5) **Centre** and **Zoom** buttons

When enabled, icons for the following events are shown on the graph at the event time:

- Arrhythmia
- 12-lead ECG
- Drugs
- Fluids

- Assessments
- Interventions
- GCS events, but not body maps
- Laryngoscope image

To use this screen:

- Press the left / right scroll buttons to move backwards / forwards in time.
- Press the up/down arrows to adjust position of the vitals.
- Select the vitals to be displayed.
- Select an event icon to cause the events details to displayed.
- Press the **Centre** or **Zoom** buttons to reposition the graph. The zoom button can be used to select a different time scale for the X axis.

6.3.2 Trend table

The SRoC **Table** tab allows you to scroll through all the one minute sample readings. Data is shown from the last entry (last minute) and then the preceding entries.

(1) Time filter buttons

(2) Left/right and up/down buttons

(3) Events display on/off

When enabled, the following events are also displayed:

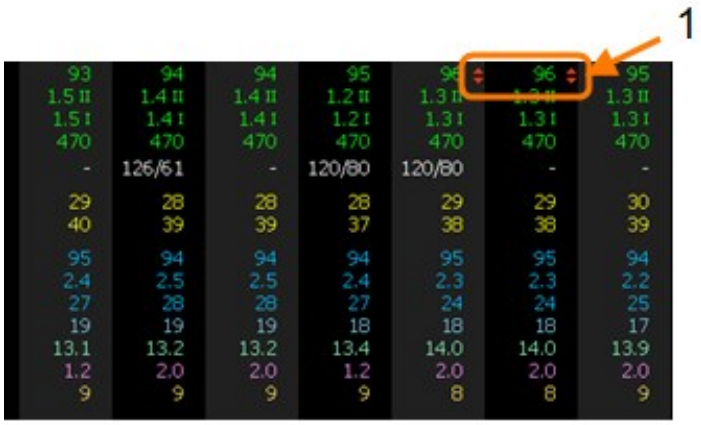
- Waveform
- Arrhythmia
- Patient Alarm
- Camera Images
- Laryngoscope Images
- 12-lead ECG
- Drugs

- Fluids
- Assessments
- Interventions
- Body Maps and GCS
- Ultrasound Images

To use this screen:

- Press one of the **1 min**, **5 mins**, **1 hr** or **2 hrs** buttons to filter the data by time.
- Use the arrow buttons to scroll through the readings.
- Use the **Events** switch to turn the display of events on and off.

An outside limits symbol placed to the right of reading indicates that the value was outside the limits set when the measurement was taken. In the case of a reading containing multiple values, such as non-invasive blood pressure, the alarm symbol will not show which value was outside the limits.



(1) Outside limits symbol

The outside limits symbol will only be shown for patient alarms. It will not be shown to reflect any technical alarms such as low battery, finger out of SpO_2 sensor etc. It will not be shown for invasive pressure “transducer removed” but will be shown for Capnometer “No breaths detected”. The symbol shows only that the value at the time was outside the alarm limit that was set at the time – it will not change based on subsequent editing of the alarm threshold. It will not be shown for “out of range measurements”. It will not reflect if an audible alarm was present i.e. will not differentiate if an alarm is muted, alarms suspended etc. it will merely reflect that the measured parameter was outside of the alarm threshold set at the time.

The trend table shows a single reading where multiple readings may have occurred e.g. 60 individual readings for heart rate that are taken in a minute are represented as a single reading; this is the first reading recorded in that period. If a single alarm on a given parameter occurs within the time period set then this will be shown in preference to the first reading taken within the period. If multiple alarms occur in the same period on the same parameter then the trend table will show the first to occur.

6.4 Starting a TCCC card

WARNING
Ensure the information recorded in the TCCC is accurate and complete. Omissions or inaccuracies could lead to mis-diagnosis resulting in death or serious injury.

CAUTION
When handling patient data, do so in accordance with the privacy policies that apply in your healthcare environment and privacy laws that apply in your region.

To complete an electronic version of the military TCCC card (if the TCCC feature is installed):

1. Press the **TC3 Card** tab in the SRoC screen.
2. Enter the patient's details.

The electronic TCCC card behaves in a similar way to the paper version. It has the same layout. Patient details can be added, updated or deleted until the card is passed on, i.e. the data is exported to a USB stick.

Selecting a previous patient's details allows you to access and update their TCCC card.

If the Tempus Pro is connected to an alternate location, updates to the TCCC card will be transmitted every 2 minutes. Users in the alternate location can only view, not edit, the TCCC card.

If GPS is turned on, see section "8.4 Identifying your location (GPS)", and a fix is available, drug records will be geo-tagged with the location where the record is entered.

7 Connecting to IntelliSpace Corsium

This chapter describes how to connect the Tempus Pro to an alternate location to share data, typically a telemedicine support center or response center.

This chapter contains the following topics:

7.1 IntelliSpace Corsium (optional)

CAUTION
Tempus LS users:

If the Tempus LS software version is v1.3.4 or greater, automatic transfer of Tempus LS resuscitation data is active for devices set to connect to IntelliSpace Corsium. To ensure code review data is fully synchronized for update in IntelliSpace Corsium, keep your Tempus Pro powered up after using the Tempus LS with the TDL link on. Wait for the Tempus LS to synchronize with Tempus Pro at power off (as indicated on the Tempus LS shutdown screen) and leave Tempus Pro connected to IntelliSpace Corsium for a period to upload the data. This can also be done at any time within a few days of the resuscitation. When synchronization is complete, the sync icon disappears from the Corsium ReachBak menu:

Tempus LS users:

Throughout these instructions, 'Tempus LS' refers to whichever defibrillator model is in use, either Tempus LS or Tempus LS-Manual.

If the Tempus LS software version is v1.3.4 or greater, Tempus LS resuscitation data is automatically transferred to Tempus Pro over the TDL Link. You can also import data from the Tempus LS to Tempus Pro via a USB memory stick; use the **Import Tempus LS data** option in the Tempus Pro **Data Input / Output Menu**.

7.1.1 Corsium ReachBak (optional)

The Corsium ReachBak feature allows Tempus Pro to send live monitoring data, SRoC events and 12-lead ECG review requests to the IntelliSpace Corsium support center. It also allows the support center to send ECG review results to the Tempus Pro, and for the operator to send review acknowledgements back to the support center.

Tempus Pro and IntelliSpace Corsium may be in different time zones, for example local and UTC. If so, their displayed incident times will be different.

Corsium ReachBak connection status

The status bar displays information about the carrier network and the connection. For example when the Tempus Pro is connected via a Wi-Fi network and is streaming live data, the status bar looks like this:

The patient age group, patient name (if entered), device serial number and device name are displayed next to the IntelliSpace Corsium status icon.

If there is no carrier network connection:

- Check your Wi-Fi network - see "8.1 Managing Wi-Fi networks"
- Consider using a different connection mode, e.g. cell phone or Ethernet - press and then press **Connect in other ways**.

The connection status may be one of the following:

- Tempus Pro is not yet connected to IntelliSpace Corsium, or connection has been interrupted for more than two minutes.
- Tempus Pro is connected and streaming monitoring data to IntelliSpace Corsium.
- Connection has been interrupted for more than 30 seconds and less than 2 minutes.

Corsium ReachBak connection policies (optional)

The IntelliSpace Corsium administrator may set up the Tempus Pro connection policies. Depending upon which policies have been set, Tempus Pro connects to IntelliSpace Corsium when one of the following events occurs:

- A 12-lead ECG is recorded.
- The first trended vitals set is captured.
- Tempus Pro is connected to Tempus LS .

If you want to connect manually and begin streaming data before any of these events occur, press and then set **Connection to Corsium** to **on**.

Corsium ReachBak menu

Press to display this menu:

Connection to Corsium - connect manually and begin streaming data to IntelliSpace Corsium (**on**/**off**). The sync icon indicates that there is pending historic data to be sent to IntelliSpace Corsium.

Support centre - select a support center to send data from this Tempus Pro.

ECG Summary - view a list of 12-lead ECG recordings made during this patient incident.

Connect in other ways - choose a different network carrier, e.g. cell phone or Ethernet.

(a) This panel shows the Tempus Pro device identity and device group.

(b) This panel shows the Corsium connection status. This is only displayed if **Show status in Corsium screen** is **on**.

Sending intervention data to IntelliSpace Corsium

Corsium ReachBak allows you to send completed intervention data from Tempus LS via Tempus Pro to IntelliSpace Corsium.

CAUTION
When handling patient data, do so in accordance with the privacy policies that apply in your healthcare environment and privacy laws that apply in your region.

CAUTION
This procedure is only possible if **Transmit Review Data** in the Corsium Settings menu is enabled. If this feature is required, Contact your IntelliSpace Corsium system administrator or Tempus Pro maintenance personnel.

Proceed as follows:

1. Export from Tempus LS:
   - Plug a USB memory device into Tempus LS, select menu option **Menu > System > Intervention Management** and select one of the available options.
   - Export the intervention data to USB.
   - Remove the USB memory device from Tempus LS and plug it into Tempus Pro.
2. Import to Tempus Pro:
   - Press **Data Input / Output** and press **Import Tempus LS data**.
   - Follow the instructions on the **Import Tempus LS Data** screens. On completion, Tempus Pro displays a message indicating the number of interventions imported.
   - Remove the USB memory device from Tempus Pro.
3. Send from Tempus Pro to IntelliSpace Corsium:
   - Press **Connect** to display the **Corsium ReachBak** menu.
   - If there are Tempus LS interventions or stored Tempus Pro waveforms waiting to be sent to IntelliSpace Corsium, the **Connection to Corsium** menu option will contain this icon:  .

     This icon will disappear when all outstanding Tempus LS interventions and stored Tempus Pro waveforms have been successfully transfered to Corsium.
   - Set **Connection to Corsium** to **on**. On successful connection, the intervention data will be automatically sent to IntelliSpace Corsium.

7.1.2 Corsium ECG (optional)

The Corsium ECG feature allows Tempus Pro to send 12-lead ECG review recordings to the IntelliSpace Corsium support center.

- The support center cannot send ECG review results back to the Tempus Pro; this is only possible if Corsium ReachBak is enabled in the Tempus Pro.
- Tempus Pro and IntelliSpace Corsium may be in different time zones, for example local and UTC. If so, their ECG recording times will be different.

Corsium ECG connection status

The status bar displays information about the carrier network and the IntelliSpace Corsium connection:

If there is no carrier network connection:

- Check your Wi-Fi network - see "8.1 Managing Wi-Fi networks"
- Consider using a different connection mode, e.g. cell phone or Ethernet - press and then press **Connect in other ways**.

Corsium ECG connection policy

When you send an ECG review request to IntelliSpace Corsium, the status indicator briefly changes to , then to and then it disappears when transmission is complete.

Corsium ECG menu

Press to display this menu:

Support centre - select a support center to send ECG data from this Tempus Pro.

ECG Summary - view a list of 12-lead ECG recordings made during this patient incident.

Connect in other ways - choose a different network carrier, e.g. cell phone or Ethernet.

(a) This panel shows the Tempus Pro device identity and device group.

(b) This panel shows the Corsium connection status. This is only displayed if **Show status in Corsium screen** is **on**.

7.1.3 ECG review with IntelliSpace Corsium (optional)

WARNING
Do not delay patient care while waiting to correct a communications issue or while waiting for ECG review results.

If the Tempus Pro has Corsium ReachBak capability, the ECG review and acknowledgement process is:

- Tempus Pro operator sends ECG recording to IntelliSpace Corsium support center.
- Support center user reviews ECG and sends results to Tempus Pro operator.
- Tempus Pro operator sends acknowledgement and optional estimated time of arrival back to support center.

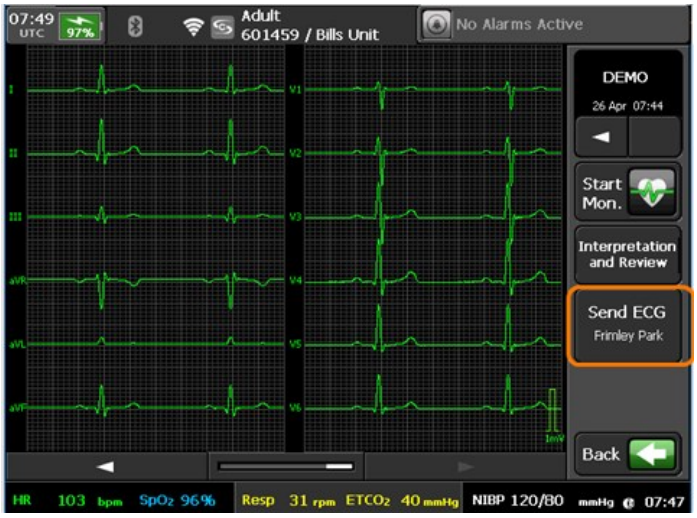
If the Tempus Pro is limited to Corsium ECG capability, the ECG review process is:

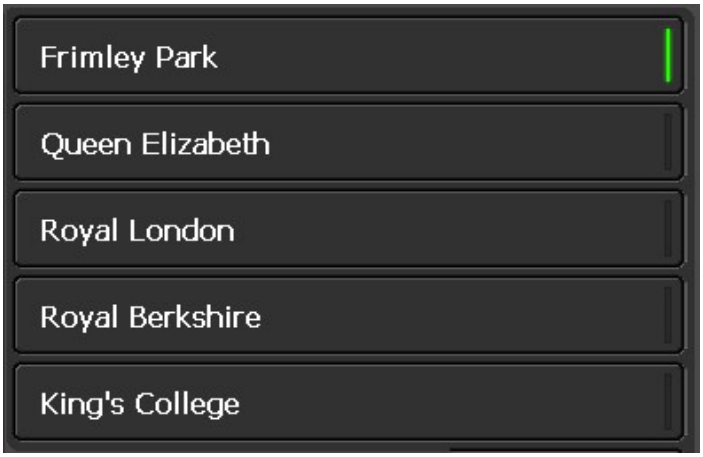
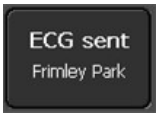
- Tempus Pro operator sends ECG recording to IntelliSpace Corsium support center.
- Support center user reviews ECG and records results.
- Results cannot be transmitted to Tempus Pro.

For connection instructions, see "7.1.3 ECG review with IntelliSpace Corsium (optional)" or "7.1.2 Corsium ECG (optional)".

Sending an ECG report to IntelliSpace Corsium

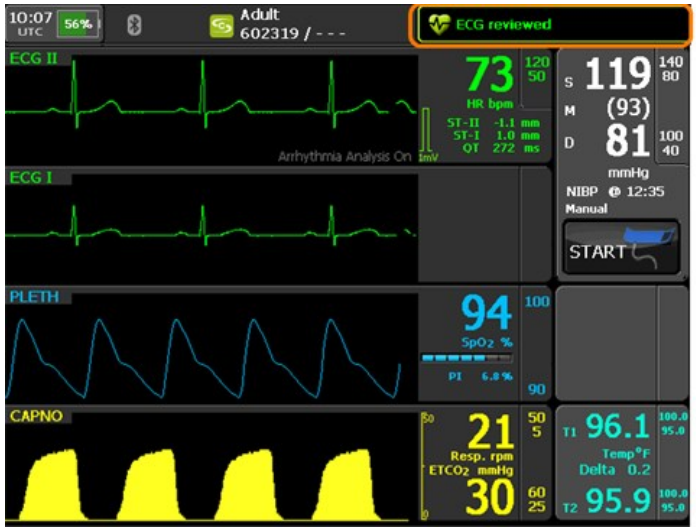
This feature is available with Corsium ReachBak and Corsium ECG.

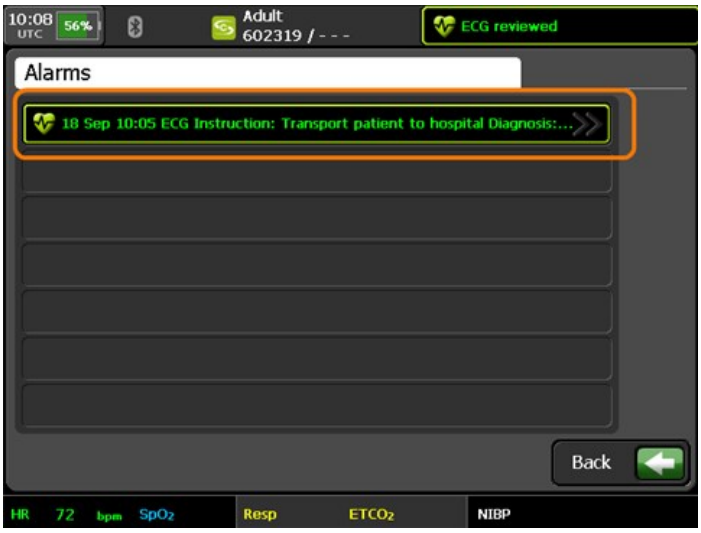
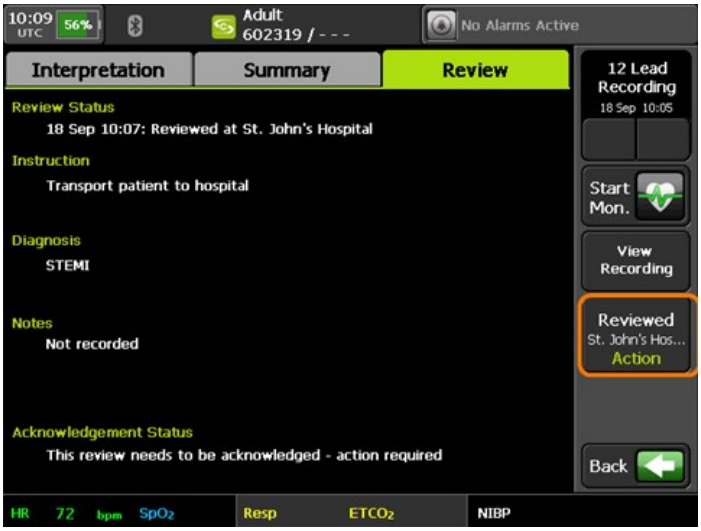
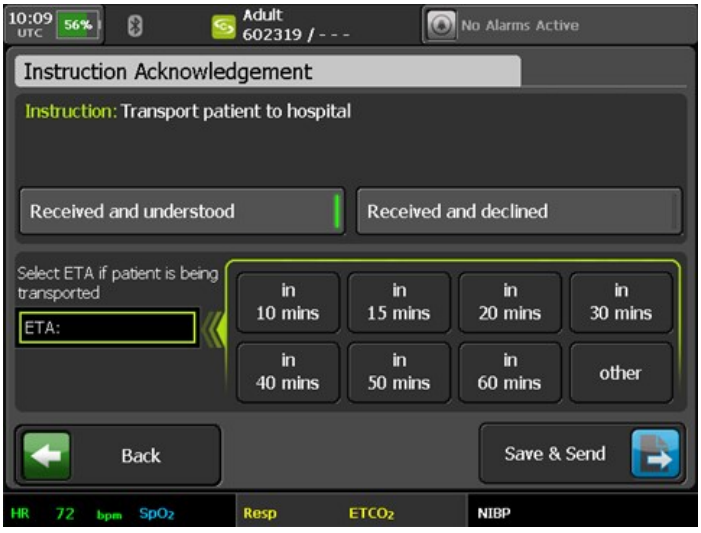
Step	Description	Screen
1.	When you have taken a 10 second ECG recording, press **Send ECG**.	

Step	Description	Screen
2.	A list of available support centers is displayed with a green bar next to the default selection. If you want to send your ECG to a different support center, press one of the other buttons in the list. Press **Send**.	
3.	When transmission is complete, the send button text changes to **ECG sent**.	

Receiving and acknowledging the review result

This feature is available with Corsium ReachBak only.

Step	Description	Screen
1.	When your Tempus Pro receives ECG review results from the support center, the message **ECG reviewed** appears in the status bar. Press this message.	

Step	Description	Screen
2.	The active alarms are displayed. Press the ECG acknowledgement alarm.	
3.	The review results are displayed. If instructions are present, press **Action**.	
4.	If you have pressed **Action**, read the ECG reviewer's instructions and press either **Received and understood** or **Received and declined**. If you are transporting the patient to hospital, press an estimated time of arrival (**ETA**) button, for example **in 20 mins**. Press **Save & Send**.	

7.2 Recording data offline and transmitting data online

If a connection to IntelliSpace Corsium has not been established, all data for that patient can be transmitted later only if the connection to IntelliSpace Corsium has been triggered.

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8 Non-medical functions

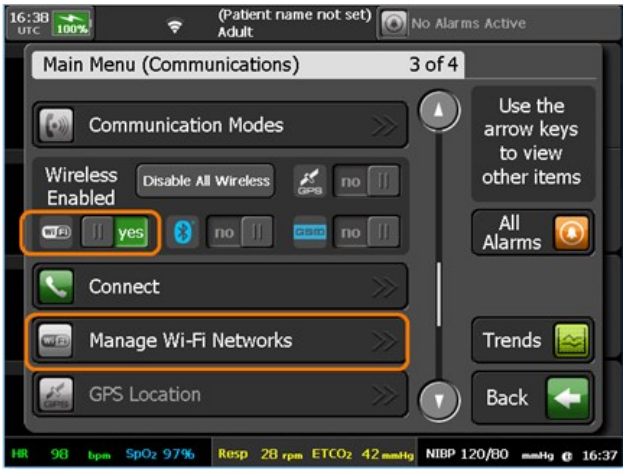
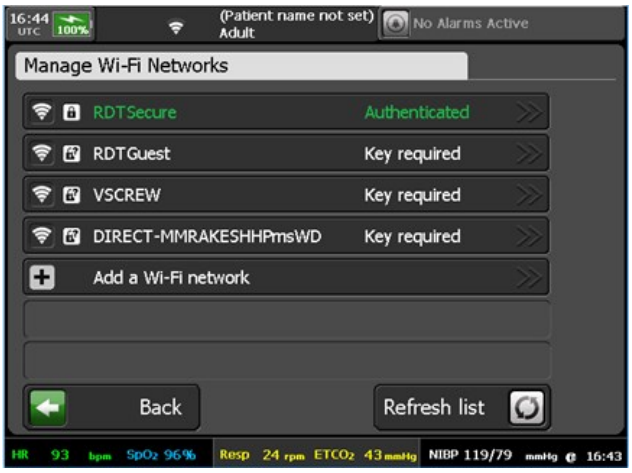
This chapter covers the non-medical functionality of the Tempus Pro.

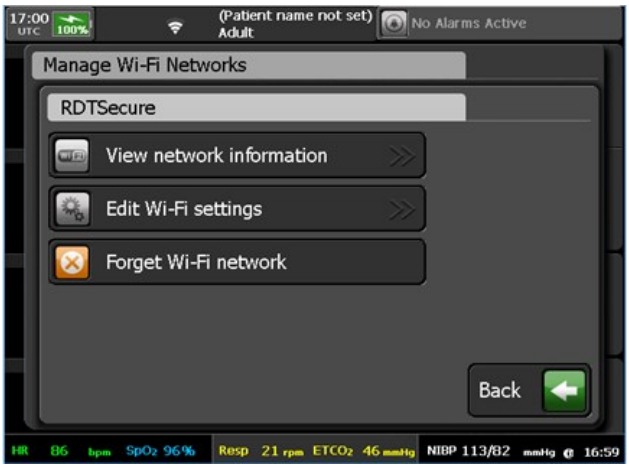
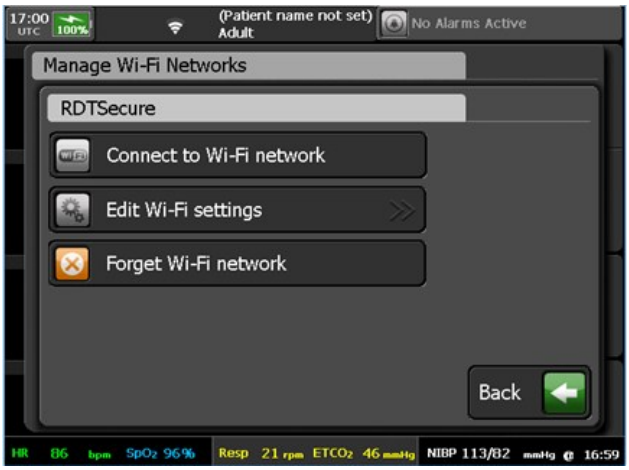
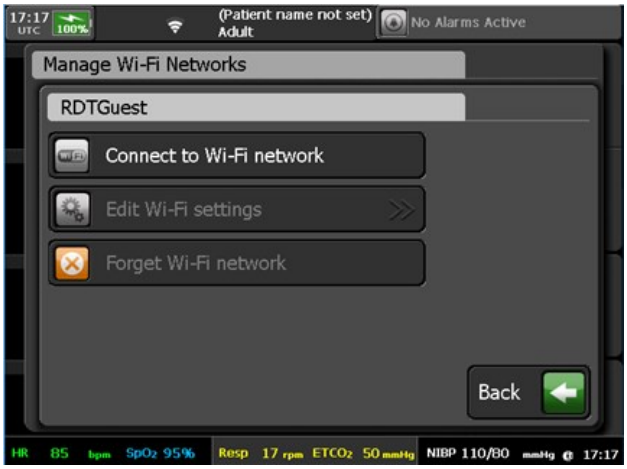
This chapter contains the following topics:

8.1 Managing Wi-Fi networks

If Wi-Fi is the communication mode for your Tempus Pro, you can scan and connect to available Wi-Fi networks. Smart management of Wi-Fi enables Tempus Pro to automatically connect to any Wi-Fi network that it finds in range where the configuration details are already stored.

To manage your Wi-Fi networks, proceed as follows:

Step	Description	Screen
1.	Press **Main Menu**  . In the **Wireless Enabled** control area, ensure that **Wi-Fi** is set to '**yes**'. Press **Manage Wi-Fi Networks**.	
2.	Tempus Pro displays the **Manage Wi-Fi Networks** menu. It may take up to 30 seconds to scan for and display the available networks. Each network is displayed with its connection status: **Connecting...** (blue) - Tempus Pro is attempting to connect to this network. **Authenticated** (green) - Tempus Pro is now connected to this network. Press this button to view settings, update settings or forget the network (step 3a). **Saved** - Tempus Pro knows the key for this network. Press this button to connect to the network, update settings or forget the network (step 3b). **Key required** - Tempus Pro does not know the key for this network. Press this button to connect to the network (step 3c). You can also connect to a hidden network (if you know its key and other settings) - press **Add a Wi-Fi network** (step 3d).	

Step	Description	Screen
3a.	If you have selected the **Authenticated** network, choose an option: **View network information** - view **IP Address**, **IP Subnet** and **IP Gateway/DNS**. **Edit Wi-Fi Settings** - edit **Wi-Fi SSID**, **Wi-Fi Network Key** and **Hidden Network** status. **Forget Wi-Fi Network** - if you forget this network the Tempus will no longer be able to connect to it automatically. Press **Back**.	
3b.	If you have selected a **Saved** network, choose an option: **Connect to Wi-Fi network** - press this button to connect. Tempus Pro redisplays the Manage Wi-Fi Networks menu showing the status of this network as **Connecting...**. If connection is successful, status changes to **Authenticated**. **Edit Wi-Fi Settings** - edit **Wi-Fi SSID**, **Wi-Fi Network Key** and **Hidden Network** status. **Forget Wi-Fi Network** - if you forget this network the Tempus will no longer be able to connect to it automatically.	
3c.	If you have selected a **Key required** network, choose this option: **Connect to Wi-Fi network**: • Press this button. • Enter the network key. • Press **Connect**. Tempus Pro redisplays the **Manage Wi-Fi Networks** menu showing the status of this network as **Connecting...**. If connection is successful, status changes to **Authenticated**.	 If the "**Wi-Fi error**" message appears, check the connection assumptions in **Edit Wi-Fi settings** and try to connect again. If this does not help, press **Forget Wi-Fi network**, power cycle Tempus Pro and restart the connection to the required network.

Step	Description	Screen
3d.	If you have selected **Add a Wi-Fi Network**: Enter the **Wi-Fi SSID**, **Wi-Fi Network Key**, **Hidden Network** status and other details as requested. Press **Save**. Press **Back**.	

8.2 Using the wireless headset (optional)

The Tempus Pro uses the Presence or VMX200 headset provided by Sennheiser®.

CAUTION
Volume must be adjusted to reduce constant exposure to high volume as it may affect hearing.

Important
The headset is a Sennheiser® wireless device. It is supplied “paired” with the Tempus Pro it was delivered with. You must use this paired device with your Tempus Pro.

RDT recommends that you do not attempt to use the Sennheiser wireless device with any other wireless device. This includes other Tempus Pro monitors you have and any communications devices such as mobile phones.

The headset will be supplied in a charged state and its charge level is automatically maintained so long as it is regularly connected using a USB Cable to the device.

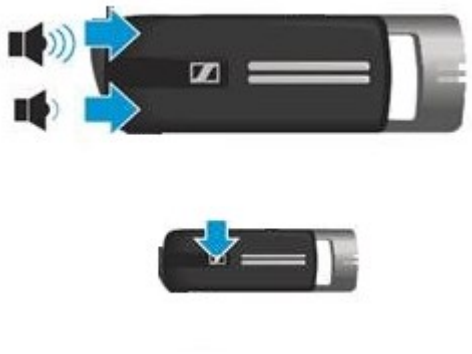
If the Sennheiser is lost or is damaged, contact RDT for a replacement.

RDT recommends that the Sennheiser instructions are read in addition to the instructions below.

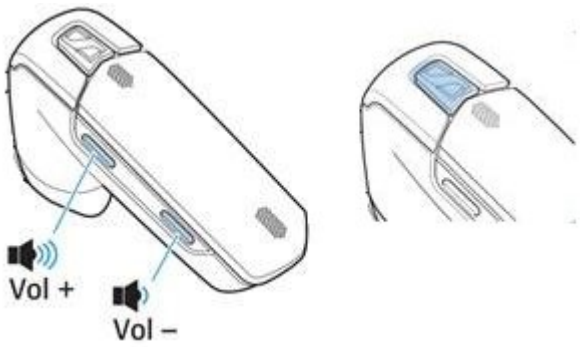
8.2.1 Headset controls

The headset has 3 buttons:

- Volume up
- Volume down
- Multi-function button



Sennheiser Presence



Sennheiser VMX200

Users should avoid using the headset speaker volume controls. The speaker volume can be controlled through the Tempus Pro and is preset to maximum.

8.2.2 Wearing the headset

To put the headset on, follow the instructions given on screen.

Important

- If you keep the multi-function button held down after the headset is on, you can put the headset into pairing mode. Do not do this because it could stop the headset being paired with the Tempus Pro, preventing it from operating with the device.
- If the indicator light is slowly flashing red and then blue the headset is in pairing mode. Disconnect the call, turn the headset off by closing the silver bar (push it towards the body of the headset), You can then restart your voice call following the on screen instructions.

8.2.3 Switching the headset on and off

To check if your headset is on press the multi-function button once. If the indicator light flashes blue then the headset is on.

To switch your headset off either:

- Use a USB cable to connect the headset to the Tempus Pro
- Press and hold the Multi-function button for 3 seconds until the LED flashes blue three times.

Important

- If you turn the headset off during a call, you will not be able to receive the call again with the headset i.e. if you turn the headset back on you will not hear the call again. If the headset is turned off during a call, disconnect the call using the Tempus Pro and then call again.
- RDT recommends that users only use the Multi-function button to turn the headset on.
- If you use the Multi-function button then other functions and features of the headset can be engaged – these may cause confusion.
- If you press and hold the “vol-” button for 1 second you will mute the headset. To release muting, quickly press the “vol-” button on the headset. RDT does not recommend that you use the muting function as this could cause confusion during a call.

8.2.4 Changing headset settings

To pair the headset or change headset settings, select **Main Menu**  > **Printer and Headset**:

- **Pairing Bluetooth** – gives step-by-step instructions on pairing the Tempus Pro with the headset.
- **Headset Settings** – allows access to the headset’s noise filter setting (applicable only to the Bluetooth® headset) and also allows you to change the default headset between wired and wireless.

  Headset settings are pre-set for the best performance in environments with a range of ambient noise levels. Change the settings if you are struggling to hear or be heard.

8.3 Using the digital camera

With the built-in digital camera, the Tempus Pro can take, save and send images to an alternate location.

Important
Do not use Tempus Pro as a teledermatology system or similar. The camera is intended to be used for taking photos for the patient's care record or to let the alternate location operator see the patient.

Voice and Video is only available to those customers with i2i installed. i2i customers should refer to their current IFU for all i2i information.

8.3.1 Taking still photographs

WARNING
Do not look directly at the backlight. Avoid shining into eyes as far as possible.

1. To view The **Camera & Video** screen, press and hold the **Camera & Waveform Snapshot** button  .
2. Aim the Tempus Pro camera at the patient
3. Make sure that the **Camera & Video** screen displays a suitable image.
4. If you need more light, press the **Backlight** button:  .
5. When you are satisfied with the image displayed on the screen, press the **Take a photo** button.
6. The photo will be displayed for 3 seconds to give you a chance to cancel. If you do not cancel the photo:
   - It is automatically saved to the patient record.
   - If you are connected to the alternate location, the photo is sent immediately.

The transmission time for photographs is < 30 seconds in good conditions, depending on signal strength of the network.

8.3.2 Taking video images

The Transmit Video button will be greyed out if the function is not enabled.

To transmit video in near real-time press the **Transmit Video** button.

8.4 Identifying your location (GPS)

Tempus Pro has a built-in GPS receiver so that you can provide the alternate location with your location.

WARNING
GPS signals are vulnerable to jamming, spoofing and interference from electronic warfare systems. When operating Tempus Pro in a conflict zone, always use alternative mapping and geolocation techniques to validate your GPS position.

The GPS is intended to provide you and the alternate location with your location. Do not use it as a guidance or navigation device.

Tempus Pro does not rely on GPS for intended clinical use. The GPS feature may be switched off without any impact to live vital signs monitoring.

8.4.1 Getting started

If possible, make sure that you are outside with a clear view of the sky. Any objects or buildings may block the satellite signals.

8.4.2 Using the GPS

1. Press the **Main Menu** button.
2. Scroll down to page 3.
3. Press **GPS Location**.
4. The GPS calculates your position. The message "**Locating**..." is displayed until your location is found. This may take up to 4 minutes.
5. See the result:
   - **Fix:** Your position is displayed.
   - **Approximate Fix:** Signals were received from a limited number of satellites. Your position is within a 2.5 km radius from the displayed approximate fix.
   - **Error:** Satellite signals could not be received. Please try again.

The last known fix or approximate fix will always be displayed when you are looking at the GPS location screen.

8.5 Sending patient data/report

The Send patient report option allows you to output the SRoC patient data or report to one of four types of recipient:

- USB memory device – patient report (PDF);
- External printer – patient report;
- Email address (if the feature is installed) – patient report (PDF);
- ePCR (electronic Patient Care Reporting system) (if the feature is installed) – patient data;
- Internal printer (if fitted) - summary report or 30 second waveform.

WARNING
The reports created are medical records, the use and control of which may be subject to local regulations, e.g. HIPAA in the USA. It is the responsibility of the user to maintain compliance with these regulations. It is the responsibility of the individual or organization who created the record to maintain this information in a secure and confidential state where the integrity and security of the information is not in question.

CAUTION
Patient reports (PDFs) must be encrypted and password protected. The password must be preconfigured (Maintenance and Settings, Change Passwords, Patient Report Password) by following the procedure in the *Tempus Pro Maintenance Manual*. Configuration must be checked before deployment in service. The encryption type is AES128.

CAUTION
When handling patient data, do so in accordance with the privacy policies that apply in your healthcare environment and privacy laws that apply in your region.

- RDT recommends only Adobe® Acrobat® PDF readers that are capable of reading Acrobat V5 or later files are used.
- RDT recommends users check that their selected PDF reader can open the created report before deploying the Tempus Pro.

When sending the patient report to email, USB or external printer, you can select one of the following report formats:

- 12-lead report
- Summary report
- Detailed report

The contents of the report depend on the method used to share the report as detailed in the following table:

Contents	USB, external printer and email (detailed report)	ePCR (patient data)	Internal printer (summary report)
Recorded events	All	All	Last 100 events

Contents	USB, external printer and email (detailed report)	ePCR (patient data)	Internal printer (summary report)
Trend data	Up to 72 hours	All	Last 200 minutes limited to HR, NIBP, Resp, $EtCO_2$, SpO2, T1 and T2
Latest 12-lead ECGs	Up to 10	Up to 10	None
Latest camera / intubation images	Up to 10	Up to 20	None
Latest image annotations	Up to 10	None	None
Latest waveforms	Up to 20	Up to 20	None
Latest ultrasound images	Up to 5 and FAST exam	Up to 5	None

Detailed reports are automatically formatted such that graphs and tables are not too long. Consequently, if the recorded incident is up to 40 minutes long, all vital signs graph and table data are shown sampled at one minute intervals. Longer incidents are reformatted as follows:

- Duration 40-200 minutes 2-24 hours: samples at 5 10 minute intervals.
- Duration over 200 minutes 24 hours: sampled at 5 30 minute intervals (latest 200 minutes 72 hours only).

8.5.1 Send patient report to a USB memory device

To send the patient report via USB:

1. Press **Send patient data/report** in the **Data Input / Output Menu**.
2. Insert a USB memory device into the Tempus Pro USB port.
3. Press **USB** (if it is not highlighted).
4. Press a report format button: **12 Lead Report**, **Summary Report** or **Detailed Report**.
5. Select the contents of the report (if this feature is enabled). Use the arrow buttons to scroll to next and previous pages.
6. If handover data is required in the report, press **Include Tempus to Tempus Data**.
7. Press **Send**. This will cause a PDF report of the selected format to be created and output to the USB memory device. The Tempus Pro will return to the main monitoring screen. Progress information will be displayed at the top of the screen.

To check progress or cancel USB output, return to the **Send Patient Data/Report** screen. If the Tempus Pro has been configured to encrypt the SRoC patient report using a random password, then the password details will be displayed on the **Send Patient Data/Report** screen under the list of report formats.

8.5.2 Send patient report to an external printer

The Send Patient Report Screen also has an option to send the SRoC patient report directly to a PCL3 compliant USB printer which operates in a similar way to sending to USB memory device. Ensure the printer is attached, switched on and provided with ink and paper before beginning. For printer instructions see "9.6.1 External printer configuration"

WARNING
Printer connections should only be made when no connections are made to a patient. Do not connect to a patient and a printer at the same time as this could cause a leakage current hazard or could affect the clinical performance of the Tempus Pro.

To send the SRoC patient report to an external printer:

1. Press **Send patient data/report** in the **Data Input / Output Menu**.
2. Press **Ext. Printer** on the **Send patient Data/Report** screen.

8.5.3 Send patient report via email

CAUTION
Email services are generally very reliable but do not guarantee successful delivery. Email send times vary depending upon network conditions. You should always check that an emailed patient report has been received, e.g. by phoning the recipient.

CAUTION
The email service requires a valid email account on a server accessible from the internet. It is your responsibility to understand the local regulations regarding emailing patient data.

CAUTION
Tempus Pro emails must be sent using secure communications.

- For email transmission, the maximum allowed patient report size is 8 megabytes. Email service provider limits may differ.

To send the patient report via email:

1. Press **Send patient data/report** in the **Data Input / Output Menu**.
2. Press **Email** (if it is not highlighted).
3. Press a report format button: **12 Lead Report**, **Summary Report** or **Detailed Report**.
4. Select the contents of the report (if this feature is enabled). Use the arrow buttons to scroll to next and previous pages.
5. Press the **To:** button to display the **Email Recipients** screen. Update email recipients and communications mode as required, then press **Back** to return to the **Send Patient Data/Report** screen.
6. Press **Send**. This will cause a PDF report of the selected format to be created and emailed. The Tempus Pro will return to the main monitoring screen and display email status at the top of the screen.

To check progress or cancel emailing, return to the **Send Patient Data/Report** screen. When the email has been sent to the email server, the '**report sent**' text will be displayed on the top status area for a further 30 seconds.

If the Tempus Pro has been configured to use a random password then a second email containing the random password will be sent to the recipients.

In the event of communication problems, the Tempus Pro will attempt to resend for 20 minutes before aborting the send and displaying a warning message.

8.5.4 Send patient data to an electronic patient care reporting system (ePCR)

CAUTION
Communications with ePCR systems are generally reliable but do not guarantee successful delivery and storage of the patient data.

CAUTION
It is your responsibility to understand the local regulations regarding sending and storing patient data.

- Tempus Pro patient data is sent using secure communications to one of the configured ePCR systems. The configuration must be checked before deployment in service.
- For ePCR data transmission, the maximum allowed patient data size is 8 megabytes on the Tempus Pro.
- All patient data is sent.

To send the SRoC patient data files to an ePCR:

1. Press **Send patient data/report** in the **Data Input / Output Menu**.
2. Press **ePCR**.
3. Press the **To:** button to display the **ePCR Selection** screen. Select the ePCR system and communications mode as required, then press **Back** to return to the **Send Patient Data/Report** screen.
4. Press **Send**. This will cause patient data to be sent to the selected ePCR system.

To cancel before sending is complete, press **Cancel**.

In the event of communication problems, the Tempus Pro will attempt to resend for 20 minutes before aborting the send and displaying a warning message.

8.5.5 Send patient report to the internal printer (optional)

To send the summary report or 30 second waveform to the internal printer (if fitted):

1. Press **Send patient data/report** in the **Data Input / Output Menu**.
2. Press **Print** (if it is not highlighted).
3. Press a report type button: **Summary Report** or **30s Waveform**.
   If you choose **30s Waveform** and the Tempus Pro is connected to a Tempus LS via the TDL link, select **Tempus LS** or **Tempus Pro** as the waveform source.
4. Press **Print**.

Waveform scales and sweep speeds are indicated on the printed output.

8.6 Tempus to Tempus data handover

The Tempus Pro allows you to send or receive patient data using a USB memory device or Tempus to Tempus USB data cable (part number 01-2243). The output is a complete patient data package for handover from one Tempus Pro to another. This allows Tempus Pro data to move with the patient and for the next level care giver to see the history of injuries and treatment in the field.

WARNING
When importing, ensure that you select the correct patient record. Records can be identified by patient name (last and first), ID number, or incident start time. If you are not sure if the record you wish to select is the correct one, select **Admit as new patient**. Mixing different patient records could lead to confusion and misdiagnosis.

CAUTION
Do not import patient records back onto the originating Tempus Pro (directly or once-removed). Exporting and importing are for handing over data from one Tempus Pro to another only.

CAUTION
When handling patient data, do so in accordance with the privacy policies that apply in your healthcare environment and privacy laws that apply in your region.

Prerequisites – ensure that you have the following:

- Tempus Pro to send patient data;
- Tempus Pro to receive patient data;
- a USB memory device or a Tempus to Tempus USB data cable (part number 01-2243).

8.6.1 Handover via USB memory device

To export patient data:

1. Insert a USB memory device into the sending Tempus Pro. The Tempus Pro automatically opens the **Data Input / Output Menu** screen.
2. Press **Tempus to Tempus data handover**. The Tempus Pro opens the **Tempus to Tempus data handover** screen.
3. If the PDF patient report is required by the recipient, set **Include pdf in export** to **yes**.
4. Press **Export for handover**. If the USB device contains any existing Tempus Pro patient data records, you will be asked if you want to keep or overwrite them.
5. The **Tempus to Tempus data handover** screen displays a blue progress bar with status messages. When the export progress bar displays **Finished**, remove the USB memory device and hand it to the next level care giver.

To import patient data:

1. Insert the USB memory device into the receiving Tempus Pro. The Tempus Pro automatically opens the **Data Input / Output Menu** screen.
2. Press **Tempus to Tempus data handover**. The Tempus Pro opens the **Tempus to Tempus data handover** screen. Press **Import for Handover**.
3. The Tempus Pro displays a list of all patient incidents found on the USB memory device. Select the patient incident record to be imported.

4. The Tempus Pro displays the **Import Patient Record** screen. Press one of the following options:
   - **Merge** – this merges the imported incident data into the current patient's data record.
   - **Admit as new patient** – this discharges the current patient and imports the incident data as a new patient.
5. Press **Confirm**.
6. The screen displays a blue progress bar with status messages. When the import progress bar displays **Finished**, remove the USB memory device.

8.6.2 Handover via USB data cable


When the Tempus Pro detects the USB data cable, it disables the **Include pdf in export** option.

To transfer the patient incident data from one Tempus Pro to another:

1. Insert the Tempus to Tempus USB data cable (part number 01-2243) into the sending and receiving Tempus Pros.
2. Both Tempus Pro devices automatically open the **Tempus to Tempus data handover** screen. Either press **Export for Handover** on the sending Tempus Pro, or press **Import for Handover** on the receiving Tempus Pro.
3. The **Tempus to Tempus data handover** screen displays a blue progress bar as it zips and sends the data.
4. The receiving Tempus Pro displays the **Import Patient Recorf** screen. Press one of the following options:
   - **Merge** – this merges the imported incident data into the current patient's data record.
   - **Admit as new patient** – this discharges the current patient and imports the incident data as a new patient.
5. Press **Confirm**.
6. The **Tempus to Tempus data handover** screen displays a blue progress bar with status messages. When the import progress bar displays **Finished**, remove the USB data cable.

8.7 Demonstration and training

The Tempus Pro can be set so that it can be used in a training environment using data which it randomly generates. Once set for this purpose, the Tempus Pro can simulate:

- All medical readings including ECG monitoring and recording - no patient is needed.
- All other features such as the transmission of photos, videos, GPS positioning etc.
- Data and voice connections – the device simulates the appearance of a connection even when none has been made.

WARNING
Training and demonstration features are only for use in non-clinical settings i.e. training environments. Activation of these features in clinical settings could lead to confusion of the patient's real vital signs.

WARNING
If a Tempus Pro is set into either Demonstration or Training mode, it will remain set in this way after the power has been cycled and after a new patient has been admitted.

If the Tempus Pro is put into a Training Communications mode, **Training** is displayed to the left of the iAssist connection process instruction.

To start:

1. Press **Main Menu** membrane button  .
2. Press the **Demonstration and Training** button.
3. Clear the Caution message which is displayed: press **Clear this message**.
4. Set **Demo Medical Reading** to **on**s and/or enable **Training Communication Modes**. The home screen and the 12-lead ECG recording screen will both say **Demo Medical Readings**.

To put the Tempus Pro back into normal operational mode:

1. Return to the **Demonstration and Training** menu
2. Reset **Demo Medical Reading** to **Off**.

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9 Maintenance

This chapter covers day-to-day maintenance and cleaning of the Tempus Pro. There is little maintenance which the user is expected to perform, as most must be carried out by an RDT trained engineer and is covered in the *Tempus Pro Maintenance Manual*.

The *Tempus Pro Maintenance Manual* contains the necessary technical information, schematics, parts designation and process description for specified maintenance and testing to be performed.

This chapter contains the following topics:

9.1 Inspecting the Tempus Pro

WARNING
Do not open the battery case or in any way disassemble, modify or repair the battery.

CAUTION
All leads, cables and accessories should be checked before and after use to ensure that they are not subject to wear, fraying, tears, knots or other signs of damage. Damaged or worn parts should be replaced.

CAUTION
The ECG cables contain components to protect against the effect of a defibrillator. The ECG cables should be measured on an annual basis (or more frequently at the user's discretion if they are subject to a high number of defibrillation discharges) to ensure that they retain a resistance of 1 kΩ ±10% as per AAMI EC53. Cables should be replaced if this resistance is not maintained.

CAUTION
You must position the Tempus Pro in order that the Tempus Pro and its power adapter can be quickly and easily disconnected from the power source.

If the Tempus Pro is no longer serviceable and is beyond repair, it may be scrapped. Scrapping the device and its accessories must be performed in compliance with local regulations. Special conditions may apply when scrapping the rechargeable battery. It should be discharged, and should not be crushed or incinerated.

Specific calibration curves should be used with the SpO_2 simulators of the Tempus Pro's Masimo® pulse oximeter. Please contact RDT for details. These functional tests should not be used to determine the accuracy of the device, only its correspondence to the particular calibration curve provided by the tester.

After using the Tempus Pro, always inspect the device, its accessories (including power supplies, mains cable, batteries and charger) for signs of damage or wear. Make the following checks:

- Check the strain reliefs of cables and connectors to ensure they remain fit for use.
- Check that all connectors engage properly and that cable securements work acceptably.
- Check connector covers, particularly the capnometer door cover, to ensure they close and latch acceptably.

Inform your service department about any signs of wear, damage or malfunction.

At least once a year inspect the whole unit, in particular the battery charger, for signs of extreme damage. This inspection should be performed by appropriately trained and equipped personnel who are able to perform locally prescribed safety tests.

In addition, RDT recommends the Tempus Pro, the Mains Power Supply and the Battery Charger are tested by an appropriately trained and equipped biomedical engineer to confirm the medical and other functions are within specification, and locally prescribed safety limits.

9.1.1 Daily checks

RDT recommends that Tempus Pro users perform the following daily checks and replace any damaged parts or missing equipment:

- Cleanliness:
  - Tempus Pro, cables and accessories are clean with no fluid spills.
- Damage and wear:
  - Tempus Pro, cables and accessories have no damage or excessive wear, e.g. cuts in insulation, fraying or broken wires, bent or damaged connector pins.
  - Internal printer (if fitted) is not damaged.
- Consumables:
  - Appropriate quantities of all disposable supplies available.
  - Any accessories or consumables are within the shelf life printed on their packages.
  - Internal printer (if fitted) contains sufficient paper for at least one day's use.
- Battery:
  - Properly inserted into the Tempus Pro and fully charged.
  - Fully charged spare is available.
- Power and controls:
  - Tempus Pro powers on.
  - Make sure that the speaker and all Alarm LEDs function correctly.
  - All buttons and touchscreen areas operate as described.

9.1.2 Weekly checks

RDT recommends that Tempus Pro users perform the following weekly checks:

Battery

CAUTION
To prevent battery failure, perform this check every week when the Tempus Pro is in use.

Remove the battery from the Tempus Pro and inspect its contacts:

- If contacts are damaged, replace the battery.
- If contacts are dirty, clean them - see "Cleaning the battery contacts".

9.1.3 List of User serviceable parts

The Tempus Pro has are no user serviceable parts

9.1.4 List of user replaceable parts

The Tempus Pro has the replaceable parts that follow:

- Battery
- Headset
- Power supply
- Printer paper.

9.2 Cleaning the Tempus Pro

This procedure describes how to clean the Tempus Pro case, touchscreen, connectors, cuffs, hose and cables.

You must clean the Tempus Pro after each use.

CAUTION
If you suspect that dirt or fluids have entered the battery compartment, remove the battery and clean the battery contacts with isopropyl alcohol electronic cleaning solvent. See "9.4.5 Changing the battery".

CAUTION
Use only the approved cleaning agents that are listed in this section. Do not use any of the more aggressive agents such as acetone and other solvents.

CAUTION
If the Tempus Pro is contaminated by human fluids or other waste matter, withdraw it from use. Before redeploying it, thoroughly decontaminate and disinfect it. In this event, the handle should be removed and discarded and replaced with a new part sourced from RDT.

CAUTION
Under no circumstances should any abrasive substance be applied to the screen.

CAUTION
If unsuitable materials are used to clean the touchscreen, the anti-reflective (AR) coating may be impaired.

CAUTION
Do not use processes such as steam, EO, or radiation to sterilize cables or parts of the Tempus Pro.

CAUTION
Do not immerse ECG cables. The defibrillation protection may be reduced.

CAUTION
Cables or connectors with corroded contacts should be replaced.

CAUTION
Do not use stiff or sharp objects to remove detritus from underneath the louvered vents in the front and rear panels of the device, as this could compromise the IP66 sealing of the product.

The front panel vent is located where shown in the image below (1). The rear panel vents are located behind the accessory pockets.

9.2.1 Cleaning the case of the Tempus Pro

Approved cleaning agents

- 70% IPA
- warm water;
- liquid soap;
- Wex-cide®

Cleaning

1. Make sure that connector pins are covered during cleaning and that they remain dry.
2. Moisten a clean and dry cloth with an approved cleaning agent and wipe the surfaces of the Tempus Pro.
3. Wipe off any excess cleaning agent from the Tempus Pro with a clean and dry cloth.

9.2.2 Cleaning the touchscreen

Approved cleaning agents for the touchscreen

- NaOH 3% aq. solution;
- Na4OH 3% aq. solution;
- HCl 3 % aq. solution;

- kitchen cleaner 5% aq. solution;
- glass cleaner.

Cleaning

1. Moisten a clean and dry cloth with an approved cleaning agent and wipe the touchscreen.
2. Wipe off any excess cleaning agent from the Tempus Pro with a clean and dry cloth.

9.2.3 Cleaning connectors

Approved cleaning agents

- water;
- compressed air.

Cleaning

1. If the connectors are wet, rinse them with tap water and then dry them.
2. If the connectors are dry, use compressed air to remove all loose material.

9.2.4 Cleaning the NIBP cuffs and hose

Approved cleaning agents

- Cidezyme®;
- Enzol®;
- 10% bleach solution;
- Sani-Cloth®.

Cleaning

1. The cuff may be sprayed with mild disinfectant solution (e.g. Cidezyme®, Enzol® or 10% bleach solution), rinsed with distilled water and line dried. Ensure that no liquid enters tubing.

   OR

   The cuff may be wiped down with a mild disinfectant wipe (e.g. Sani-Cloth®) and line dried.
2. Make sure that the cuff is completely dry before use.

9.2.5 Cleaning the SpO_2, ECG and Invasive Blood Pressure cables

Approved cleaning agents

- Clorox® 1:10 solution.

Cleaning

1. Moisten a clean and dry cloth with an approved cleaning agent and wipe the cables.
2. Make sure that the cables are completely dry before use.

9.2.6 Cleaning the battery contacts

Remove the battery. Inspect the electrical contacts of the Tempus Pro battery compartment and of the battery itself. If any battery contacts are dirty, clean them as described:

Approved cleaning agents

- Isopropyl alcohol electronic cleaning solvent.

Cleaning

1. Moisten a clean, dry cloth with the approved cleaning agent and wipe the battery contacts.
2. Wipe off any excess cleaning agent with a clean, dry cloth.
3. Refit the battery.

9.3 Tempus Pro Power Supplies

WARNING
Use only the AC/DC adapter (Part Number 989803219271) or the Tempus Pro vehicle power supply (Part number 989803219281) with the Tempus Pro.

Patient Safety can be compromised if any other power supply is used.

WARNING
The Tempus Pro vehicle power supply and the Tempus AC/DC adapter must be fixed in position. You must make sure that the Tempus Pro vehicle power supply and the Tempus AC/DC adapter cannot be removed from its fixed position with out the use of the correct tool.

The Tempus AC/DC adapter and the Tempus Pro vehicle power supply are used for charging the Tempus Pro battery, when mounted in a smart mount or claw mount.

Patient treatment is allowed while the battery in the device is charging. Essential performance or patient safety is not diminished while the battery is charging.

Both power supplies must be installed by service personal (technicians) and be non-removable from the EMS vehicle when Tempus Pro is removed to treat a patient.

Both power supplies must be installed in such a way where isolation of the circuit can be achieved.

If using a power invertor as the AC mains power supply, the AC/DC power supply must be connected to a “pure sine” inverter which is dedicated for medical devices only, with Live, Neutral and Ground connections. Deviating from that requirement might introduce noise to the ECG which would impact essential performance of Tempus Pro and patient diagnoses being delayed.

9.4 Tempus Pro battery

For battery specifications refer to "10.1.3 Rechargeable battery"

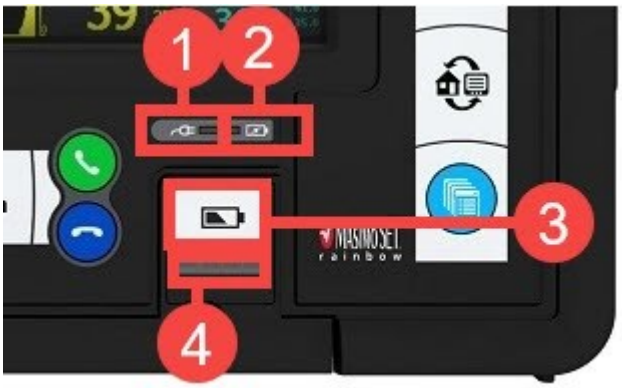
Important

- The Battery charger is not for ambulance use.
- Check the battery status at least twice per year. If the Tempus Pro is being used regularly then the battery should be checked monthly, weekly or daily depending on the frequency of use.
- Completely discharge and recharge the battery at least once a year.
- Older batteries will have a shorter battery life than those of new batteries. Replace as required.
- If the battery charge shows as less than 25%, we recommend you recharge it. However batteries can be used until they are fully discharged without damaging the Tempus Pro.
- Do not use batteries from previous RDT products because they will not fit.
- If you start the Tempus Pro using an empty battery or leave a battery in a low or empty state for a prolonged period it may enter a deep-discharged state. In this state it will take longer to recharge the battery. Monitor the remaining battery life to avoid the battery being too weak to power the Tempus Pro for the duration of an incident.
- The battery life should be monitored periodically when the device is in storage and also before and after use.
- New batteries should be charged for at least 4 hours on receipt.
- Using the battery down to the point where it is completely empty will not cause any hazards or damage to the system.

9.4.1 Battery interfaces

Front and rear views of a typical Tempus Pro battery:

Battery indicators on the front of the Tempus Pro unit:



(1) Mains power supply indicator
(2) Battery charging indicator
(3) Battery check button
(4) Battery charge indicators

9.4.2 Power save feature

Battery life can be extended by enabling the power-saving feature on the Tempus Pro. This feature switches off the display after 5 minutes with no operator intervention. The Tempus Pro remains on and performing any monitoring function it has been set to do. If any patient or technical alarms occur, the Tempus Pro display will come back on and the alarm functions sound as normal. If any controls are used, the display will come back on immediately.

To enable this feature, go to the **Display Menu** menu and then turn **Power save mode** to **on**.

9.4.3 Checking the charge

The battery charge can always be checked by pressing the battery gas gauge button, even when the Tempus Pro is switched off.

To check the charge:

1. Press the battery button  on the front of the battery or look at the status bar in the top left of the Tempus Pro display.
2. The battery LEDs show:
   - Four green LEDs – 76-100%
   - Three green LEDs – 51-75%
   - Two green LEDs – 26-50%

- One green LED – 1-25%
- One green flashing LED - less than 10%
- No LEDs - no power due to deep discharge

3. If below 25%, charge the battery.

If batteries do not retain their charge, try charging them fully on an external charger. As batteries become old, experiencing many charge/discharge cycles, expect to see a reduction in their capacity. Replace them as required.

9.4.4 Charging the battery when attached to the Tempus Pro

WARNING
Do not attempt to charge the battery using any charger other than those supplied by RDT.

CAUTION

- Do not recharge batteries if the temperature is above 40°C.
- Use the external battery charger if the battery is in a deep discharged state.
- Ensure you can access the mains power supply so you can disconnect if necessary. The means of isolation of mains power is to disconnect the mains lead from the power supply.
- Ensure the mains power cable is undamaged before use.
- Where the integrity of the external protective conductor (earth) in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source.

WARNING
Interruption of the mains supply for short periods e.g. 30 seconds, does not cause problems because the Tempus Pro automatically switches to battery power. If no battery is fitted (or the battery is completely flat) the Tempus Pro shuts down immediately. No patient data will be lost. If the device is restarted within 30 seconds, all patient settings remain unchanged. When mains power is resupplied, the Tempus Pro resumes as normal with default settings in place. You can switch back to monitoring the previous patient (and continue completing their record).

To charge the battery when attached to the Tempus Pro, proceed as follows:

Step	Description	Photos and notes
1.	Connect the power supply (Tempus AC/DC adapter Pt. No 989803219271 or the Tempus Pro Vehicle power supply, Pt No 989803219281) Ensure the DC plug is fully inserted into the socket; failure to do so may cause the device to stop working. The battery will automatically start charging. The Battery Charge indicator LEDs light up to indicate how charged the battery is. Charge times depend on whether the Tempus Pro is being used or not. If not in use then the charging will be faster. However it should take approximately 4 hours to fully recharge a battery when the Tempus Pro is switched off.	 The green charge light flashes for up to 20 seconds then lights up to indicate the battery is charging.

9.4.5 Changing the battery

Change the battery if it does not appear to retain its charge or if no battery charge indicator LEDs light up.

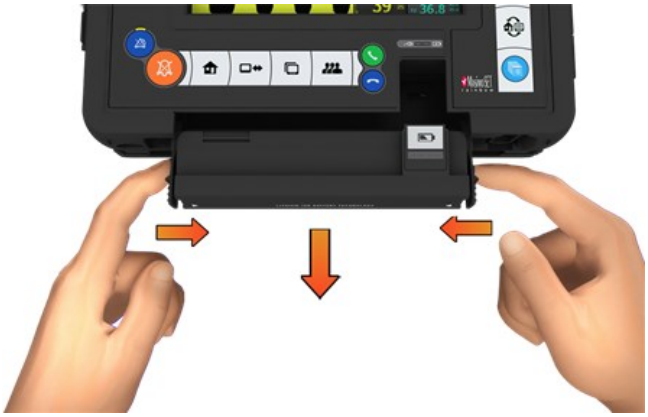
WARNING
Ensure battery is fully engaged. Incorrect fitting could result in the Tempus Pro losing power during use.

CAUTION
If the battery is low, recharge it immediately after use. If a battery is left in a low or empty state for a prolonged period, it can take up to 24 hours to recharge.

Important
Do not let the battery terminals touch any electrically conductive materials. You could short circuit the battery and irreversibly damage it.

To change the battery, proceed as follows:

Step	Description	Photos and notes
1.	Check the charge on the replacement battery, see "9.4.3 Checking the charge".	

Step	Description	Photos and notes
2.	If the Tempus Pro is on, turn it off. Ensure all lights on the front of the Tempus Pro are off before removing the battery.	If necessary, you can force a hard shutdown by pressing and holding the power button for 10 seconds. Remember that the battery cannot be removed until the lamp on the front panel has gone out. The Tempus Pro should not be used without the battery fitted.
3.	Squeeze the two latches holding the battery in. Slide battery out.	
4.	Slide replacement battery in. Insert the left hand side (annotated 1) before you insert the right hand side (annotated 2).	
5.	If necessary, force a hard shutdown by pressing and holding the power button for 10 seconds.	

9.4.6 Charging the battery with the battery charger

WARNING
Do not attempt to charge the battery using any charger other than those supplied by RDT.

Battery charger is rated at 100-240 V 50-60 Hz 0.9 A. Charge times depend on how discharged the battery is. It should take approximately:

- 5 hours to fully recharge a battery;
- 24 hours to recharge from a deep-discharged state.

Step	Description	Photos and notes
1.	Remove battery from the Tempus Pro.	

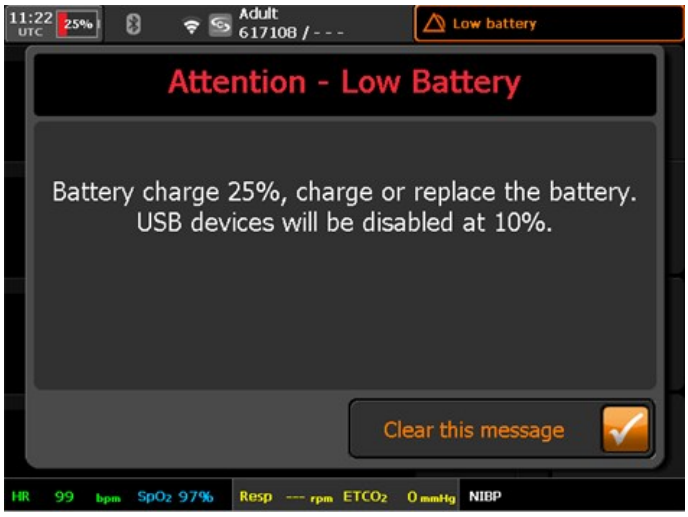
Step	Description	Photos and notes
2.	To attach the charger (part number 01-1012) to the battery, clip the battery charger clip firmly onto the battery connections. The clip only connects to the battery in one way. Attach the charger to the main supply.	
3.	Check the charger's LEDs: Orange = 0-85% charged. Yellow = 86-99% charged. Green = 100% charged.	

9.4.7 Battery Alarms

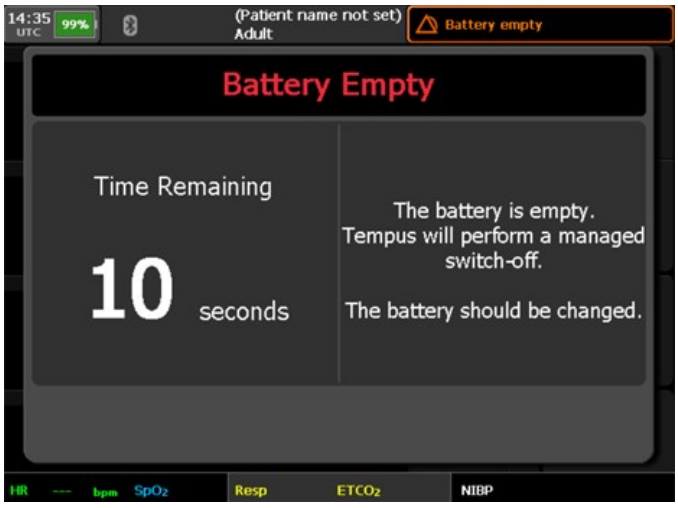
The Tempus Pro alerts the user to the level of battery charge using the Warning displays that follow:

9.4.7.1 Attention - Low Battery

Description	Screen
At 10% external USB as well as the ability to print or use 4G are disabled.	

Description	Screen
There is advanced alarm warning at 25% (approx. % based on battery capacity), gives advanced notice that USB won't be available below 10%.	

9.4.7.2 Battery Empty

Description	Screen
Battery empty occurs at 6.35volts on the battery where it reaches the limit for continued reliable monitoring.	

9.5 Wireless headset battery

The Bluetooth® headset contains a built-in, rechargeable battery. The battery automatically starts charging when you use a USB connector to connect the headset to the Tempus Pro.

While the headset is charging it displays a red light, once charged the LED will flash blue every 5 seconds.

The Tempus Pro recharges the headset for approximately 9 hours every time the headset is replaced. Charging continues whether the Tempus Pro is switched on or off. The Tempus Pro tops up the charge of the headset approximately every 97 days if the unit has not been used.

WARNING
Danger of explosion if battery is incorrectly replaced. Do not attempt to repair or replace the battery. If the battery is worn out a new headset is required from RDT. Dispose of the headset in accordance with local regulations. Do not dispose as household waste.

CAUTION
Always maintain a level of at least 10% in the Termpus Pro's battery. If the Tempus Pro's battery is low, the built-in headset charger may drain the battery.

Do not charge the headset using any other charging device. This will automatically suspend the warranty.

Read the manual for the Sennheiser headset before using.

9.5.1 General guidelines for safe use

- Do not drop or try to alter the shape of your headset.
- Do not expose the headset to liquid or moisture. Unlike the Tempus Pro, the headset has no protection against ingress of solids or liquids.
- Do not expose your headset to extreme temperatures. The temperature range of the headset is 10 - 40 °C.
- Do not try to disassemble your headset. Service and Maintenance can only be performed by RDT.
- Do not let children play with the headset since it contains small parts that could become detached and create a choking hazard.

Dispose of the battery in accordance with the applicable local regulations. These regulations can vary from country to country.

9.6 Printer maintenance

9.6.1 External printer configuration

You can use an external USB printer to print patient reports.
To configure an external printer:

1. Select **Main Menu**  > **Printer and Headset** > **External Printer Settings**.
2. Select the setting to change:
   - **Printer Type** - **HP PCL3** or **HP PCL3 GUI**.
   - **Paper** - **A4** or **Letter** (8.5 x 11“).
3. Press **Test Page** and check the resulting test print.
4. Press **Back**.

9.6.2 Internal printer test page (optional)

To print a test page on the internal printer (if fitted):

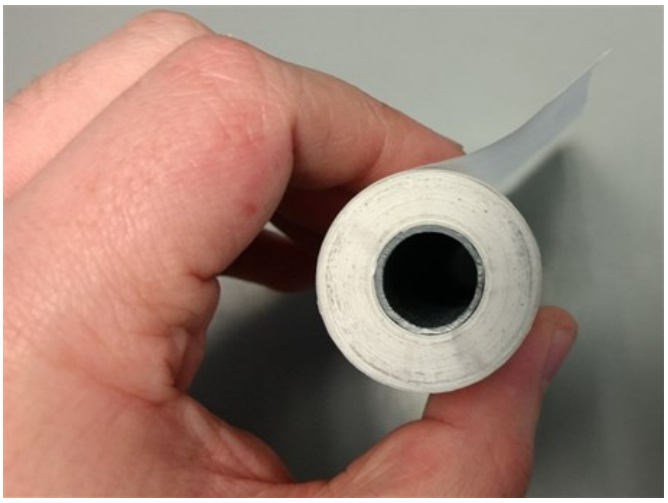
1. Select **Main Menu**  > **Printer and Headset** > **Internal Printer**
2. Press **Test Page** and check the resulting test print.
3. Press **Back**.

9.6.3 Changing the paper roll (internal printer only)

Important
To ensure ease of access to the printer roll, place the Tempus Pro on a flat surface, lying on its front.

Do not force the lid to open at an angle greater than 90° from the back of the unit. Excessive force will detach the lid from the printer body: if this happens see "9.6.4 Fitting the printer lid (internal printer only)".

To change the paper roll in the internal printer, proceed as follows:

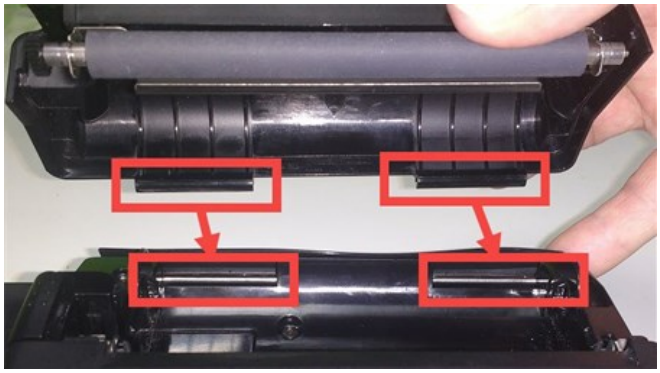
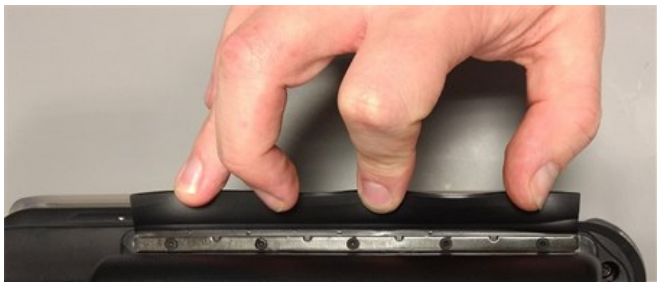
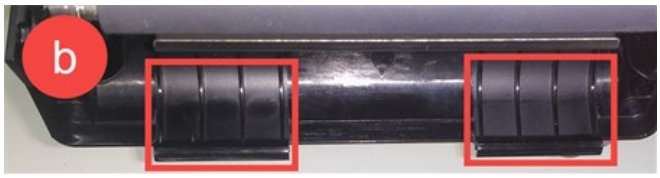
Step	Description	Photos and notes
1.	Open printer lid by pressing the button in the printer housing. Open the lid to an angle not greater than 90° from the back of the unit. Do not force it to open any more than this.	
2.	Remove the old paper roll spindle and discard.	
3.	Free the end of the new roll.	

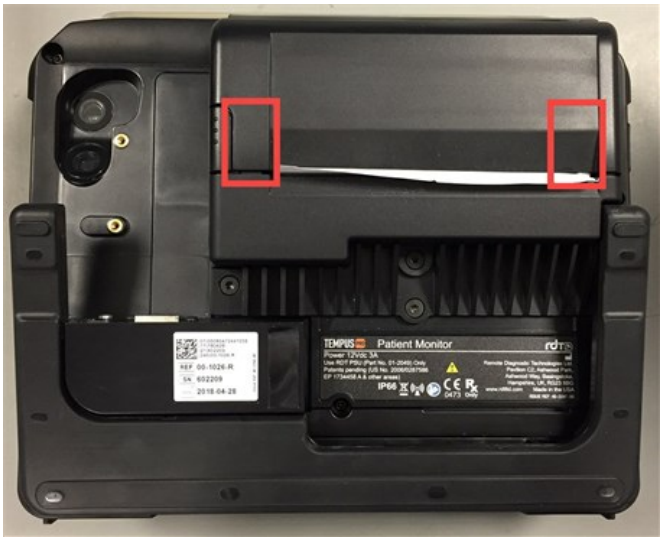
Step	Description	Photos and notes
4.	Place the roll into the housing, with the outside face of the paper against the printer mechanism.	
5.	Feed in one side of the roll, then the other.	
6.	Ensure the roll spindle is centerd on the fixing springs, pull the roll to ensure it rotates freely.	

Step	Description	Photos and notes
7.	Close the lid and press it down on both corners, listening for a click. Tear off any extra paper.	
8.	Set the paper type (**Plain** or **Grid**).	If required, print a test page.

9.6.4 Fitting the printer lid (internal printer only)

If the lid (part number 26-2035) becomes detached from the printer housing or needs replacing, refit it as follows:

Step	Description	Photos and notes
1.	Align the slotted ends of the lid hinges with the steel hinge pins in the printer housing.	
2.	Lower the lid onto the printer housing, ensuring that the top rubber seal is not trapped. Do not press the lid into position yet.	
3.	(a) Hold the lid open at an angle of not more than 45° to the back of the unit. (b) Place your thumbs on both lid hinges.	 

Step	Description	Photos and notes
4.	Push the slotted ends of the lid hinges down onto the steel hinge pins in the printer housing, ensuring they both click into place. **Important** Ensure that the lid rotates freely on its hinges to open and close.	
5.	Close the lid and press it down on both corners, listening for a click.	

9.7 Troubleshooting

Occasionally, problems may occur with the Tempus Pro. Operator error, sensor problems or a failure within the Tempus Pro could cause these problems. In most instances, the Tempus Pro will display an error message on the screen.

> **CAUTION**
> In the event that the Tempus Pro displays an error that is not described within this manual e.g. operating system applications errors, turn the Tempus Pro off and then on again. This should clear the error and allow normal operation to resume. Do not continue to use the device if such an error is displayed. If symptoms persist, please contact RDT

Error messages contain the following text:

- A title which identifies the sensor or system which is having trouble;
- A description of the problem;
- The effect that the error will have on the performance of the Tempus Pro;
- Which button to press to clear the error message off the screen.

For more information on Patient Alarms, refer to "5.4 Patient alarms"
For more information on Technical Alarms, refer to "5.5 Technical alarms" .

10 Specifications and standards

10.1 Tempus Pro physical and environmental specifications

CAUTION
Since the Tempus Pro is rated for use in high ambient temperatures, Users are reminded to give consideration to the potential for outer surfaces of the Tempus Pro to become hot in such ambients. Further to Table 23 of IEC60601-1, plastic parts (such as the sides, touchscreen, handle etc.) which may be acceptable for long term physical contact at ambient temperatures up to 48°C need to be touched for shorter durations (e.g. less than 1 minute) when used in higher ambient temperatures. Similarly users should note that while the rear heatsink may be touched permanently in ambient temperatures up to 36°C, in higher ambient temperatures contact with it should be reduced. Users should pay attention to this if instead of using the handle, they grip the device around its sides.

CAUTION
Do not use the Tempus Pro (when using its external power supply) to recharge batteries when the ambient temperature exceeds 40°C.

Important

- In ambients above 40°C users should ensure that the device is used in an upright position and that there is air flow around the back of the unit.
- Users are reminded that the specification of the power supply limits its use to 40°C maximum.

Important
The power supply's altitude rating must be adhered to. Do not use the power supply outside of its specifications.

10.1.1 Tempus Pro device

Item	Value
Size and weight - non-printer model	Standalone size and weight of Tempus Pro part number 00-1007-R with its battery and RapidPak clip but without external cables, sensors or accessories: 263 mm (10.3 in) x 216 mm (8.5 in) x 100 mm (3.9 in) (width x height x depth) 2.9 kg (6.4 lb) nominal.
Size and weight - printer model	Standalone size and weight of Tempus Pro part number 00-1026-R with its battery and printer but without external cables, sensors or accessories: 263 mm (10.3 ") x 216 mm (8.5 ") x 102 mm (4 ") (width x height x depth) 3.2 kg (7 lb) nominal Printer models without IP are slightly lighter (part number 00-1024-R).
Altitude	-200 m to 5000 m; 104 kPa to 54 kPa

Item	Value
Relative humidity	Tempus Pro with all accessories (unless stated) 15%-95% (non-condensing)
Operating temperature range	0 °C to 50 °C all medical modules, battery operation only and excluding ECG printing. -20°C to 55°C, transient temperature , Tempus Pro will operate outside of its normal operating temperature for 60 minutes.
Transport/storage temperature range	No conditions , unless otherwise stated -37 °C to +70 °C
Transport/storage pressure range	-200 to +5000 m; 104 kPa to 54 kPa
Transit drop	1.22 m (4 ft) MIL 810G, 26 drops all corners, faces and edges with and without accessories connected
Start-up time in normal use	Time for switching on or starting until the equipment is ready for normal use: 42 seconds
Start-up time from storage	Time required for the equipment to warm from the minimum storage temperature between uses until the equipment is ready for intended use at 20°C: 180 minutes Time required for the equipment to cool from the maximum storage temperature between uses until the equipment is ready for its intended use at 20°C: 180 minutes
Mode of operation	Continuous

IP66 (dust and water ingress under pressure) – whole device. According to IEC60529, “IP” means ingress protection. The following two numerals refer to grades of ingress protection for solid objects (the first numeral) and water (the second numeral). The first numeral “6” means the device is dust tight against the ingress of dust to a size <75 µm. The second numeral means the device is protected against the ingress of 100 l/m of water “jetting” at the device from 2.5 to 3 m.

Environmental performance and certification

Item	Value
Altitude and Pressure	Tempus Pro and all accessories, unless otherwise stated - 0 to 5000m, (1013 - 54 kPa)
Drop	1 m drop per IEC60601-1
Operational drop	0.75 m (2.5 ft) IEC60068-2-32 Procedure 1, 6 drops to all faces with the device fully operational and all accessories connected
Impact	500 g steel ball from 1.3 m as per IEC60601 including the display

Item	Value
Temperature : category: test standard,	Category A4 Temperature, RTCA/DO-160G Section 4, Para 4.5.1 to 4.5.4 Operating: -15 °C to +50 °C Storage: -37 °C to +70 °C Short Term high: +50 °C Short Term low: -20 °C Ground survival high +70 °C Ground survival low -37 °C
Test standard, altitude:	RTCA/DO-160G Section 4, Para 4.6.1 Device is completely operational up to an elevation of 18,000 ft.
Rapid decompression:	• MIL-STD-810 H Section 500.6, Procedure III. • RTCA DO 160G (Section 4.6.2)/Table 4-1 2,438m to 12,192m (8,000ft to 40,000ft) in 15 Seconds, excluding NIBP and Capnometry.
Temperature variation: Test standard:	RTCA/DO-160G Section 5 Cat C
Rate of variation:	2 °C per minute.
Humidity: Test standard:	RTCA/DO-160E Section 6 Cat A
Transport/storage:	15 to 95% RH Non-condensing (tested for 48 hours at 38-50 °C)
Operating:	15 to 95% RH Non-condensing (tested at the end of the storage cycle)
Operational shocks & crash safety: Test standard:	RTCA/DO-160E Section 7 Cat B
Operational shock:	40 g per MIL-STD 810G 6 g per RTCA DO-160E (6g for 11ms saw-tooth wave, repeated 3 times in all axis).
Crash safety:	20g in all directions (sustained).
Bump:	15 g per EN1789
Vibration: test standard:	MIL-STD-810G rotary, fixed wing (jet and turboprop profile) Ground Vehicle per EN1789
Explosion proofness:	Not tested. Not to be used in the presence or explosive gasses or vapours.
Water proofness:	Not tested to RTCA/DO-160G Section 10.
Fluids susceptibility:	Not applicable.

Item	Value
Protection class	You must wipe the Tempus Pro dry before you connect medical cables, ACDC adapter, DCDC adapter or you place the Tempus Pro into the dock. Tempus Pro - IP66 with the Capno dust cap closed Tempus Pro Printer - IP66 with the Capno dust cap closed
Fungus resistance:	Not applicable.
Salt spray:	Not applicable.
Magnetic effect:	Not applicable.
Power input:	Not tested to RTCA/DO-160E Section 16.
Commercial qualification:	EN61000-3-2:2006 inc A1/A2:2009 Mains harmonics EN61000-3-3:2008 Mains flicker EN61000-4-11:2004 voltage dips and interruptions
Voltage spike:	Not tested to RTCA/DO-160G Section 17.
Commercial qualification:	IEC61000-4-4:2012 Fast transient bursts
Audio frequency conducted susceptibility – power inputs:	Not tested to RTCA/DO-160G Section 18.
Commercial qualification:	IEC61000-4-5:2006 Surges
Induced signal susceptibility:	Not tested to RTCA/DO-160G Section 19.
Commercial qualification:	IEC61000-4-6:2013 Conducted RF field
Radio frequency susceptibility (radiated & conducted):	RTCA/DO-160G Section 20 Cat T.
Commercial qualification:	IEC61000-4-3:2006 inc A2:2010 Radiated RF Interference
Emission of radio frequency energy: test standard:	RTCA/DO-160G Section 21 Cat M.
Lightning induced transient susceptibility:	Not applicable.
Lightning direct effects:	Not applicable.
Icing:	Not applicable.
ESD:	Not tested to RTCA/DO-160G Section 25.
Commercial qualification:	IEC61000-4-2:2008 ESD
Main case material: Flame:	PC-ABS UL94V-0
Overmould material:	TPU (*)

(*) Contains 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol.

10.1.2 Invasive pressure USB module 01-2017

Item	Value
Channels	2

Item	Value
Sensitivity	5 µV/V/mmHg
Bridge	180 Ω minimum
Response	0-20 Hz (-3 dB)
Filters	50-60 Hz notch
Range	-99 – 310 mmHg
Accuracy	± 2% or ±2 mmHg with RDT's adaptor cable but without the transducer
Resolution	1 mmHg
Warm up time	10 seconds
Ingress protection	IP56
Size	108 mm x 63 mm x 36 mm
Weight	116g
EMC	IEC 60601-1-2 Class B
Operating altitude range	-200 – 5000 m (can be used at higher physical altitudes provided the local atmosphere is no higher than 5000 m, e.g. in a pressurized aircraft cabin)
Operating relative humidity range	15%-95% (non-condensing)
Operating temperature range	0 °C to +40 °C due to transducer specifications
Transport/storage temperature range	-37 °C to +70 °C
Transport/storage pressure range	-200 to 5000 m; 104 kPa to 54 kPa
Drop	1 m drop per IEC60601-1
Transit drop	1.22 m (4 ft) MIL 810G, 26 drops all corners, faces and edges with and without accessories connected (when not connected to the Tempus Pro)
Impact	500 g steel ball from 1.3 m as per IEC60601
Emission of radio frequency energy:	RTCA/DO-160G Section 21 Cat M.
Temperature	Category A4 RTCA/DO-160G Section 4, Para 4.5.1 to 4.5.4
Altitude	Category A RTCA/DO-160G Section 4, Para 4.6.1
Rapid decompression	2438 m to 15545 m (8,000 ft to 51,000 ft) in 1 second
Temperature variation: Test standard Rate of variation	 RTCA/DO-160E Section 5 Cat C 2 °C per minute.
Humidity	RTCA/DO-160E Section 6 Cat A
Transport/storage humidity range	15 to 95% RH Non-condensing (tested for 48 hours at 38-50 °C)

Item	Value
Operational shocks & crash safety: Test standard Operational shock	 RTCA/DO-160E Section 7 Cat B Para 7.2 (6g for 11ms saw-tooth wave, repeated 3 times in all axis)
Crash safety	20g in all directions (sustained)
Vibration test standard	MIL-STD-810F rotary, fixed wing (jet and turboprop profile)
Main case material Flame	PC-ABS UL94V-0
Test standards	IEC 60601-2-34 - Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment. IEC 60601-1 3.1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

10.1.3 Rechargeable battery

Item	Value
Battery pack specification	Rechargeable (Secondary)
Part Number	For the Tempus Pro - 01-2051
	For the Tempus IC2 - 01-2029

Item	Value
Battery life	A maximum battery life of 9 hours 45 minutes with: • Wireless settings set to OFF • Display brighness 60% (Default) • ECG • SpO2 • EtCO2 • IBP x2 • Temperature x2 • NIBP every 15 minutes. • Cannula attached but not connect to Gas A maximum battery life of 11 hours 30 minutes with: • Wireless settings set to OFF • Display brighness 30% • ECG • SpO2 • EtCO2 • IBP x2 • Temperature x2 • NIBP every 15 minutes. • Cannula attached but not connect to Gas A maximum battery life of 14 hours with: • Wireless settings set to OFF • Battery saving mode activated (display at default 60% brightness) - • Cannula attached but not connected to Gas.
Battery Service life	The recommended service life of the battery is 3 to 5 years, depending upon usage. The battery will have 80% charge after 300 complete charge and discharge cycles.
Number of Cells	6
Nominal voltage	7.2 V
Battery pack Ah	9.6Ah
Charging voltage	8.4 V ±1%

Item	Value
Cut-off Voltage	5V
Chemistry	Lithium - Ion
Nominal capacity	9.6 Ah, 69.1 Wh
Weight	0.42 kg nominal
Dimensions	152 x 42 x 62 mm max
Shelf life	Shelf life of a battery initially stored with 100% charge will see the charge reduce to approximately 75% remaining after 1 year.
Operating temperature	-20 °C to +50 °C
Cell charge Voltage	8.4V± 1%
Maximum Charge Current	2.4 Amps
Charge time	3 hours to 90% and approximately 4 hours to 100% Assumptions: • Battery fitted to Tempus Pro attached to mains power. • Subject to conditions of storage and use, times are approximate. • Tempus Pro is switched off while charging, charging takes longer when the device is active.
Tempus Pro battery operating temperature	Operating temperature during discharge (Tempus Pro operating) -20°C to 60°C Temperature during charging using an external charger 0°C to 50°C Tempus Pro Charging 0°C to 40°C
Transport/storage temperature range	RDT recommends a Battery transport/storage temperature range of between -20 °C to +50 °C RDT have demonstrated Battery function after storage between -37 °C and +70 °C
Humidity	15% to 95% (non-condensing)

10.1.4 Tempus AC/DC adapter

CAUTION
Do not use the Tempus AC/DC adapter in rotary or fixed wing aircraft.

The power supply's altitude rating of 5000m must be adhered to. Do not use the power supply outside of its specification.

The AC/DC adapter when connected to the Tempus Pro, is considered part of the Medical Electrical (ME) Device.

Item	Value
Mains input Supply	100 – 240 Vac, 50~60 Hz, Maximum 1.5 A

Item	Value
Output voltage	12 V dc
Output current	5 A
Relative Humidity	15%-95% (Non-Condensing)
Weight	0.3 kg nominal
Dimensions	105 x 50 x 29 mm (4.1" x 2" x 1.1")
Operating temperature range	0°C to 40°C
Transport/storage temperature range	-40°C to +85°C
Altitude	0 - 5000m (0 - 16,404 ft)
Ingress protection	IP22

10.1.5 Battery charger

Only the RDT battery charger (01-1012) can be used with the Tempus Pro.

Item	Value
Mains input voltage	100 – 240 V
Frequency	50/60 Hz
Input current	0.9 A max (at 100 V approx.)
Output voltage	8.4 V dc
Output current	<2.73 A
Charge time (from empty)	5 hours
Weight	0.25 kg nominal
Dimensions	107 x 67 x 36.5 mm

10.1.6 Tempus Pro Vehicle Power Supply

Item	Value
Battery input voltage	9 V dc – 36 V dc
Input connector type	Cigar plug
Output voltage	12 V dc ±5%
Output current max	6 A
Rated power	60 W
Efficiency	>85%
Operating temperature range	0°C to 50°C
Transport/storage temperature range	-40°C to +85°C
Weight	0.45 kg nominal

Item	Value
Dimensions	116 x 55 x 29 mm
Operational shock	30g
Altitude	0-5000m (0 - 16,404 ft)
Ingress protection	IP44

10.1.7 GPS

Item	Value
Antenna	Integral
Accuracy	±10 m (±2.5 km with <6 satellites – labelled as “Approximate Fix”)

10.1.8 Inseego 4G dongle (optional)

Item	Value
Manufacturer	Inseego
Name	USB8
Model	MC800
Approvals	FCC (North America); ISED (Canada); PTCRB
Weight	68 g (2.4 oz)
Dimensions	91.1 x 37 x 11.4 mm (3.58” x 1.45” x 0.45”)
Chip set	QUALCOMM® SDX20
Interface type	Fold-away, rotating USB
SIM	4FF
Operating temperature	-10°C to +55°C (+14°F to +113°F)
Storage temperature	-20°C to +65°C (-4°F to +149°F)
Relative humidity	5% to 90% over operating temperature
Drop	1 meter drop, no damage – fully operational
Vibration stability	5 Hz to 500 Hz, 0.1 octave/second

10.1.9 Other features

Item	Value
Display	Color 165 mm (6.5”) 640x480 pixels 130 klux daylight readable display
Printer (*)	High resolution 110 mm (4.3”) integrated thermal printer
Integral digital camera	Color 3.2M pixel camera Takes still pictures or video using the H264 algorithm (bandwidth dependent)

Item	Value
Pulse oximeter	See Masimo labels for storage temperature and pressure.

(*) Optional, additional feature

10.2 Tempus Pro standards compliance

The Tempus Pro complies with the applicable parts of the following standards:

Standard	Title
IEC 60601-1 3rd edition	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2 4th edition	Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6	Medical electrical equipment -- Part 1-6: General requirements for safety - Collateral standard: Usability
EN 60601-1-8	Medical electrical equipment -- Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-49	Medical electrical equipment -- Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
ISO 80601-2-56	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN 60601-2-34	Medical electrical equipment -- Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
EN 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN 80601-2-61	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN 80601-2-55	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN 62304	Medical device software -- Software life cycle processes
EN 62366	Medical devices -- Part 1: Application of usability engineering to medical devices

Tempus Pro device classification

The system is classified according to the requirements of EN60601-1, the standard for Medical Electrical Equipment, Part 1, General Requirements for Safety, as:

- The Tempus Pro is battery powered.
- The battery charger is class II .
- CE according to directive 93/42/EEC class IIb.

Applied parts type CF defibrillator proof.

All Tempus Pro medical accessories are classified CF except the Laryngoscope which is classified BF.

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Suitable for continuous use, for use with defibrillators and for use with electrosurgical systems.

The expected service life of the device (excluding batteries) is 5 years. This can be extended through maintenance of the device.

10.3 Tempus Pro medical specifications

All figures quoted are based on room temperature, pressure and humidity unless otherwise stated.

10.3.1 ECG monitoring

Item	Value
Regulatory standard	Meets IEC60601-2-27 (harmonized with ANSI/AAMI EC13:2007)
Cable	For use with RDT's proprietary 3-, 4-, 5- and 12-lead ECG cables with 4 mm snap disposable electrodes
Gain/sensitivity	1, 2, 4, 5, 10 (default), 15, 20, 30 & 50 mm/mV
Input range	±5 mV ac
Input impedance	>100 MΩ
DC offset	±300 mV dc
Time bases	12.5, 25, 50 mm/s
Aspect ratio	Standard aspect 0.4 at 10mm/mV and 25mm/s
Heart rate detection range	30 - 300 bpm
Accuracy	±3%
Acquisition sample rate	500 Hz
Monitoring bandwidth	0.67 Hz – 20 Hz 0.5 Hz – 40 Hz 0.05 Hz – 150 Hz 0.05 Hz – 40 Hz
Frequency response	0.05 Hz to 175 Hz (-3 dB)
Defibrillator protection	Patient leads are isolated from system and operator, with 5kV protection
Electrosurgery protection	Protected
Common mode rejection	95 dB
Leads off indicators	Connection status for each lead is shown on acquisition screen
Permanent filters	High Pass: 0.05 Hz 1st order Low Pass: 175 Hz 1st order Baseline Wander: Baseline reset by adaptive zeroing algorithm
Notch filter (mains noise rejection)	50 Hz (49.1Hz - 50.9 Hz) 4th order Butterworth, 60 Hz (59.1Hz - 60.9 Hz) 4th order Butterworth,
ST measurement range	-10 mm to 10 mm (-1 to 1 mV)

Item	Value
ST accuracy	±0.53 mm (±53 uV)
ST resolution	0.1 mm
ST measurement definition	J+80 ms (for heart rates < 115 bpm)
	J+60 ms (for heart rates > 115 bpm)
	ISO electric line taken from PQ segment
QT measurement range	10 ms - 1990 ms
QT accuracy	±25 ms mean
	30 ms standard deviation
QT resolution	1 ms
ST/QT, Arrhythmia Compliance	AAMI EC57

10.3.2 12-lead diagnostic ECG viewing and recording

These specifications relate to the performance of the product when it is configured to display and record the 12-lead diagnostic ECG view.

The filters in this section apply only when viewing a 12-lead ECG recording.

ECG tested at 150 Hz per EC11 and with a 175 Hz 3 dB bandwidth measurement.

A conservative baseline stabilization filter is applied to the 12-lead ECG signals; the 12-lead recorded ECG and measurements have diagnostic quality suitable for ST segment analysis.

Item	Value
Regulatory standard	Meets IEC 60601-2-25 (harmonized with ANSI/AAMI EC11:1991 inc R:2001
Cable	For use with RDT's proprietary 12-lead ECG cables with 4 mm snap disposable electrodes
Gain/ sensitivity	1, 2, 4, 5, 10 (default), 15, 20, 30 & 50 mm/mV
Input range	±5 mV ac
Input impedance	>100 MΩ
DC offset	±300 mV dc
Acquisition sample rate	500 Hz
12-lead bandwidth (preview and recording)	0.05 Hz – 40 Hz 0.05 Hz – 150 Hz
Frequency response	0.05 Hz to 175 Hz (-3 dB)
Defibrillator protection	Patient leads are isolated from system and operator, with 5 kV protection
Electrosurgery protection	Protected
Common mode rejection	95 dB
Leads off indicators	Connection status for each lead is shown on acquisition screen

Item	Value
Notch filter (mains noise rejection)	50 Hz - (49.1Hz - 50.9 Hz), 60 Hz - (59.1 Hz - 60.9 Hz),
Low pass (Muscle Artifact Filter)	40 Hz 4th order

10.3.3 Impedance pneumography (respiration)

Item	Value
Range:	30-150 rpm
Accuracy	±2 rpm or ±2% whichever is greater
Excitation current	<20 µA
Excitation frequency	56 kHz
Measurement leads available	Lead I & Lead II

10.3.4 $EtCO_2$ sensor

The capnometer is automatically compensated for local atmospheric pressure.

Item	Value
CO_2 units	mmHg or kPa
$EtCO_2$ range	0 - 150 mmHg
CO_2 waveform resolution	0.1 mmHg
$EtCO_2$ resolution	1 mmHg
CO_2 accuracy	0 - 38 mmHg: ± 2 mmHg 39 -150 mmHg: ± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) For operation above 35°C, add an additional ± 1 mmHg or ± 2% (whichever is greater).
Respiration rate range	1 - 149 bpm
Respiration rate accuracy	0 - 70 bpm: ±1 bpm 71 - 120 bpm: ±2 bpm 121 - 149 bpm: ±3 bpm
Flow rate	50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume
Waveform sampling	20 samples/s
Response time (warmed up)	7 s (typical) for$EtCO_2$, <13 seconds for respiration (assuming a breath rate of 15 rpm)
Calibration interval	Annual performance verification may be performed if required and calibration then performed if the system requires. Calibration required after 4000 hours usage of the capnometer.

Item	Value
Auto-zero	Adjusts the$EtCO_2$ level both by temperature and by altitude. Calibrates the $EtCO_2$ every 8 degrees change (Celsius) or every 8 mmHg change in barometric pressure.

10.3.5 Non-invasive blood pressure

Item	Value
Range:	Adult Systolic 40 - 260 mmHg
	Pediatric Systolic 40 - 230 mmHg
	Neonate Systolic 40 - 130 mmHg
	Adult Diastolic 20 - 200 mmHg
	Pediatric Diastolic 20 - 160 mmHg
	Neonate Diastolic 20 - 100 mmHg
	Adult MAP 26 - 220 mmHg
	Pediatric MAP 26 - 183 mmHg
	Neonate MAP 26 - 110 mmHg
Accuracy:	± 3 mmHg
Resolution:	1 mmHg
Pulse rate range over which measurement will function:	30 - 220 bpm ± 2% or ±3 bpm (whichever is greater)
Maximum inflation:	300 mmHg (150 mmHg neonate)
Initial inflation pressure:	160 mmHg adult, 140 mmHg pediatric, 90 mmHg neonate
Method:	Oscillometric, diastolic values correspond to Phase 5 Korotkoff sounds

10.3.6 Invasive pressure

Item	Value
Channels	Up to 4 (2 as standard)
Sensitivity	5 µV/V/mmHg
Bridge	180 Ω minimum
Response	0-20 Hz (-3 dB)
Filters	50-60 Hz notch
Range:	-99 – 310 mmHg
Accuracy:	± 2% or ±2 digits including RDT’s adaptor cable but excluding the transducer
Resolution:	1 mmHg
Warm up time	10 seconds

10.3.7 SpO_2 Masimo SET

Technology: Masimo SET for use in motion and low-perfusion applications

Compliance of the Tempus Pro with IEC80601-2-61 was evaluated with the following : Masimo 4067 sensor (LNCS-II^{tm} rainbow® DCI®) paired with the 4798 EMS Patient Cable.

Item	Value
Pulse range:	25 - 239 bpm
Pulse accuracy:	Accuracy (all ages): no motion ≤3 digits, motion ≤5 digits
Pulse resolution:	1 bpm
Pulse averaging:	8 seconds (configurable)
SpO_2 range:	1-100%
SpO_2 accuracy:	Accuracy (adults/child): no motion or low perfusion ±2 digits 70 - 100%, motion ±3 digits 70 - 100% Accuracy (neonate): motion, no motion and low perfusion ±3 digits 70 - 100%
SpO_2 resolution:	1%
Data update rate	3 seconds
Type:	Functional saturation (test methods available upon request)
Wavelength range:	Red 660 nm, infra-red 905 nm Information about wavelength range can be useful to users, especially those performing photodynamic therapy.
Perfusion Index range:	0.02 - 20%
Response	<1 second delay
Signal strength range:	0 - 7 bars
Plethysmogram:	1 – 100, auto-gain
Patient population:	Reusable soft walled probe – for use in clinical and pre-hospital applications, on fingers and toes for children/adults over 8 years old (other probe types are available from Masimo®)
LNCS Sensor Optical output	<= 15mW

SpO_2 was determined by testing on healthy adult volunteers in the range 60%-100% SpO_2 against a laboratory CO-Oximeter. SpO_2 accuracy was determined on 16 neonatal NICU patients ranging in age from 7 to 135 days old and weighting between 0.5 and 4.25 kg. Seventy-nine (79) data samples were collected over a range of 70 - 100% SaO_2 with a resultant accuracy of 2.9% SpO_2 .

The arterial oxygen saturation accuracy during no motion only applies to LNOP® Blue SpO_2 adhesive sensors.

Masimo® SET® technology with LNOP Adt sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 4Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The saturation accuracy of the neonatal sensors were validated on adult male and female volunteers with light to dark skin pigmentation and 1% was added to account for the properties of foetal hemoglobin.

The Masimo® sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at

2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Masimo® SET® technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

Masimo® sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

10.3.8 Masimo rainbow SET Co-Oximetry

Item	Value
Carboxyhemoglobin (SpCO)	
Accuracy (Adults/Pediatrics/Infants):	1 – 40% ± 3%
Resolution:	1%
Alarm:	1 - 98%
Measurement range:	0 – 99%
Methemoglobin saturation (SpMet)	
Accuracy (Adults/Pediatrics/Infants/Neonates):	1 – 15% ± 1%
Resolution:	0.1%
Alarm:	1 - 99.5%
Measurement range:	0 - 99.9%
Total hemoglobin concentration (SpHb)	
Accuracy (Adults/Pediatrics):	8 – 17 g/dL ±1 g/dL (arterial or venous)
Resolution:	0.1 g/dL
Alarm:	1 - 24.5 g/dL
Measurement range:	0 – 25 g/dL
Total oxygen content (SpOC)	
Measurement range:	0 – 35ml of O2/dL of blood
Rainbow Sensor Optical output	<= 25mW

SpO_2 , SpCO, and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60% - 100% SpO_2 , O% - 40% SpCO, and 0% - 15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5 - 4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet.

The Masimo® sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70 - 100% SpO_2 against a laboratory Co-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

The Masimo® SET® Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.2% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

The Masimo® sensors have been validated for pulse rate accuracy for the range of 25 - 240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 - 17 g/dl SpHb against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

The following substances may interfere with pulse CO-Oximetry measurements:

- Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO_2 and SpCO measurements
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements
- Very low arterial Oxygen Saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements
- Severe anemia may cause erroneous SpO_2 readings
- Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Elevated levels of total bilirubin may lead to inaccurate SpO_2 , SpMet, SpCO and SpHb readings.

10.3.9 Contact temperature

Item	Value
Channels	2 (first standard, second is optional)
Compatibility:	YSI series 400
Measurement range:	20 - 45 °C / 68 - 113 °F
Accuracy:	±0.1 °C / ±0.2 °F
Resolution:	±0.1 °C / ±0.2 °F
Measurement time	<10 seconds

10.3.10 ECG specifications

ECG monitoring disclosures

The following disclosures are made in accordance with the requirements of IEC 60601-2-27 (with cross references to the harmonized standard AAMI EC13 where applicable):

- The ECG's displayed include the isoelectric segments of the QRS.
- For leads off detection, the ECG device applies current < 10nA between electrodes; for impedance respiration a 56kHz <20uA current is applied; and for active noise suppression a driven reference electrode is used (eg. RL electrode).
- The Heart Rate Detection of the ECG monitor is accurate to +/-10% or +/-5 bpm for a T Wave of amplitude up to 1.0 mV in accordance with IEC 60601-2-27 section 201.12.1.101.17.
- The heart rate is calculated from the average of the 8 most recent RR intervals. Intervals are logged as "invalid" if the detections are unreliable, or if detections are absent over the maximum RR interval of 2.4 s. Invalid intervals are counted but not included in the average. If there are no valid intervals in the most recent 8, then no heart rate is reported. Heart rate is updated with every new valid or invalid interval.
- Further to IEC 60601-2-27 section 201.7.9.2.9.101 b4) (corresponding to clause 4.1.2.1e) of AAMI EC13, the system's response to:
    - Fig 3a is 40 bpm ±10% (inverted QRS are counted); an invalid rate will be displayed if **EMS Heart Rate Mode** and **Arrhythmia analysis** are active.
    - Fig 3b is 30 - 100 bpm (small QRS are intermittently counted).

- Fig 3c is 120 bpm ± 10% (all QRS are counted).
- Fig 3d is 60-100 bpm (bipolar QRS are intermittently counted).

- Electrical noise such as power line transients can cause false heart beat detection which may inhibit alarms. The problem may be minimized by ensuring good electrode contact. Power system noise may be reduced by running the monitor from its battery.
- The maximum response time of the heart rate meter to a change in heart rate from 80 to 120 bpm is 10 seconds, and for a change from 80 to 40 bpm is 14 seconds (according to the method in IEC 60601-2-27, section 201.7.9.2.9.101 b5).
- The system heart rate alarm will respond to the specified tachycardia signals of Figures 4a and 4b of AAMI EC13 within 5-7 s. In some cases, an out of range alarm may be given, with an indication of no valid heart rate. Invalid ECG rates do not trigger an alarm if the organizational **EMS Heart Rate Mode** is selected and **Arrhythmia monitoring** is active.
- Compliance with IEC 60601-2-27 section 208.6.6.2.103: the heart rate limit alarm will respond to a high or low rate condition 0-10 seconds after being activated with an alarm trigger delay set to 2 seconds or less.
- Pacemaker Pulse Rejection Capability: amplitude from +/-2mV to +/-700mV, width from 0.1ms to 2.0ms as per IEC 60601-2-27: 201.12.1.101.13,

  
  Without overshoot: pacers of single, double (150ms gap), double (250ms gap) are effectively rejected under conditions of synchronous pacing, no QRS and ineffective paced ECG when tested according to IEC 60601-2-27 201.12.1.101.13.

  except the full overshoot range of IEC 60601-2-27.

  
  With overshoot: pacers of single, double (150ms gap), double (250ms gap) are not effectively rejected and may impact the heart rate detected under conditions of synchronous pacing, no QRS and ineffective paced ECG when tested according to IEC 60601-2-27 201.12.1.101.13.

- Per EC13 4.2.9.12, the muscle filter will make pacemaker pulses appear smaller than 2mm. Switch muscle filters off (**0.05 - 150 Hz** filter setting) to see pacemaker pulses more clearly.
- Measurements of the ECG waveform should be normalized against the scale provided. The scale presents 1 mV as 10 mm with a gain setting of 10mm/mV.

  
  In the 4 waveform view, the channel height of the ECG is 21 mm and thus permits a maximum input signal of ±2.1 mV when using a gain of 5 mm/mV. In the large ECG view a maximum input signal of more than ±5 mV is achieved using a gain of 4 mm/mV.

- Compliance with IEC 60601-2-27 section 201.12.1.101.8 (corresponding to EC13 clause 4.2.9.8 b) requirements for frequency response are achieved with the **'0.05 - 40 Hz**' and **'0.05 - 150 Hz**' filter settings. Filters bandwidths are listed in section 15.1.1.
- The slew rate of the ECG as per AAMI EC13 4.1.4.3 is 3.7 V/s (all filters off).

ECG recording disclosures

The following disclosures are made in accordance with the requirements of AAMI EC11 and IEC60601-2-25:

- Frequency and impulse response has been evaluated in accordance with IEC 60601-2-25 section 201.12.4.107.1.1. As per section 201.12.4.107.1.1.1, Methods A and E were used to demonstrate high frequency response compliance. All 60601-2-25 tests have been performed using SCP files recorded on the Tempus Pro and compliance checked using the Corsium ECG viewer. Compliance requires that **12 Lead filter** is set to **0.05 - 150 Hz** and **ECG power filter** is **off**.

- ECG data in this system is contained in computer files, using a proprietary format based on the SCP-ECG standard. The ECG data is digitized using a sample rate of 500sps and a resolution of 2554nV/bit with 12 bit (4096 level) dynamic range. Per clause 201.12.4.107.3 the skew rate is 0.

10.4 Electromagnetic compatibility (EMC)

WARNING
Operating high frequency electrosurgical equipment in the vicinity of the monitor can produce interference in the monitor and cause incorrect measurements.

WARNING
Do not use the monitor with nuclear spin tomography (MRT, NMR, NMT) as the function of the monitor may be disturbed.

WARNING
This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Tempus Pro or shielding the location.

WARNING
The user may experience loss of communications, error message, out of range medical readings or device shut down due to excessive emitted electromagnetic (EM) radiation.

CAUTION
The Tempus Pro has been tested in “heavy” wireless environments consisting of different wireless technologies (Bluetooth, WiFi 802.11 b and cellular communications) with multiple transmitters used simultaneously. Users deploying the Tempus Pro in environments where other wireless technologies are being used should evaluate the potential risk of interference and aggregate spectrum usage.

CAUTION
The Tempus Pro is a Prehospital device. Do not use the Tempus Pro in or around the equipment that follows:

- an MRI machine
- electrocautery equipment
- diathermy equipment.

Device tested for use near electrosurgery equipment to IEC 60601-1-2 and 60601-2-25, IEC 60601-2-27, IEC 60601-2-49, IEC 60601-2-30 & IEC 60601-2-34.

The Tempus Pro remote patient monitor has been tested and approved to IEC/EN 60601-1-2. This means that the Tempus Pro meets or exceeds the requirements for electrical medical equipment in terms of its levels of emitted electromagnetic (EM) radiation and its susceptibility to electromagnetic radiation from other devices.

The Tempus Pro has been tested according to the requirements of RTCA DO-160G section 20 category T (immunity) and section 21 Category M (emissions).

It should be noted that the Tempus Pro may be affected by high levels of stray EM radiation from other electronic devices (even those which comply with relevant CISPR emission standards) that are being used in close proximity to it.

As required by international medical device standards, the Tempus Pro is intended for use in electromagnetic environments of ±8kV static contact (±15kV air discharge) and magnetic fields of 30 A/m (50/60 Hz). The Tempus Pro is proof against radiated RF emissions from 80 MHz to 2.7 GHz to a level of 10 V/m.

10.4.1 Manufacturer's declarations

Electromagnetic emissions (IEC EN 60601-1-2)

The Tempus Pro is intended for use in an electromagnetic environment as described below. The customer or user of the device should ensure that the device is used in such an environment.

The Tempus Pro can be configured to not emit RF energy, in which case it will be group 1 and will not be likely to cause any interference in nearby electronic equipment.

Emission measurements	Compliance	Electromagnetic environment
HF emissions acc. to CISPR11	Group 2	The Tempus Pro must emit RF energy in order to perform its function. Nearby electronic devices may be affected.
HF emissions acc. to CISPR11	Class B	The Tempus Pro is intended for use in all facilities including living quarters and such ones which are connected directly to a public power supply that supplies also buildings used for living purposes.
Emission of overtones acc. to IEC61000-3-2	Class B	
Emission of voltage fluctuation/ flicker acc. to IEC61000-3-3	Complies	

Electromagnetic emissions (IEC EN 60601-1-2)

The Tempus Pro is intended for use in an electromagnetic environment as described below. The customer or user of the device should ensure that the device is used in such an environment.

U^T is the AC mains voltage before the use of testing levels.

Interference resistance test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative air humidity must be at least 30 %.
Fast transient electric disturbances / bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines 100kHz repetition frequency	± 2 kV for power lines ± 1 kV for input and output lines 100kHz repetition frequency	The quality of the supply voltage should conform to a typical business or clinic environment.

Interference resistance test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Surge voltage acc. to IEC 6100-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV normal mode voltage ± 2 kV common mode voltage	Mains power should be that of a typical hospital or commercial environment.
Voltage drops, short interruptions and variations in supply voltage acc. to IEC 61000-4-11	0 % U^T; 0,5 cycle 0 % U^T; 1 cycle 70 % U^T; 25/30 cycles 0 % U^T; 250/300 cycles	0 % U^T; 0,5 cycle 0 % U^T; 1 cycle 70 % U^T; 25/30 cycles 0 % U^T; 250/300 cycles	Mains power should be that of a typical hospital or commercial environment. If the user of the Tempus Pro requires continued operation during power interruptions then the battery may be used for periods up to 6 hours or a UPS may be used.
Magnetic field at the supply frequency (50/60 Hz) acc. to IEC 61000-4-8	30 A/m	100 A/m	Magnetic fields at the supply frequency should conform to the typical values as they occur in the business or clinic environment.

Electromagnetic interference resistance (IEC EN 60601-1-2)

The Tempus Pro is intended for use in an electromagnetic environment as described below. The customer or user of the device should ensure that the device is used in such an environment.

Interference resistance test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF disturbances acc. to IEC61000-4-6	3 Vrms 150 kHz to 80 Mhz	3 Vrms	
	6 Vrms in ISM bands (*1)	6 Vrms	
Radiated RF disturbances acc. to IEC61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m for all parameters & 20 V/m for all parameters except IBP per EN 1789 and 60601-2-35.	Refer to "10.4.2 Recommended safety distances" for recommended safety distances
	Frequency spots as listed below (*4)	Frequency spots as listed below (*4)	

Interference resistance test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
			The field strength of stationary transmitters should be lower than the Compliance level for all frequencies according to a testing on location (*2) (*3). Interference may occur in the vicinity of devices with the following symbol: 

- For 80 Hz and 800 MHz the higher frequency range applies.
- These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.

(*1) The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

(*2) The field strength of stationary transmitters such as fixed parts of cellular phones and mobile radio sets, amateur radio stations, AM and FM radio and television cannot be determined exactly in theory. To detect the electromagnetic environment in regard to stationary transmitters a study of the location should be considered. If the measured field strength at the location where the device is being used exceeds the Compliance level above the device should be watched to verify the proper functions. If unusual features are watched additional actions might be necessary such as a modified orientation or another location of the device.

(*3) For the frequency range of 150 kHz to 80 MHz, the field strength should be lower than 10 V/m.

(*4) Immunity to proximity fields from RF wireless communications equipment:

Test frequency (MHz)	Service	Modulation	Immunity test level (V/m)
385	TETRA 400	Pulse modulation 18 Hz	27
450	GMRS 460, FR 460	FM ± 5 kHz deviation 1 kHz sine	28
710 745 780	LTE Band 13, 17	Pulse modulation 217 Hz	9
810 870 930	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
1720 1845 1970	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
2450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28

Test frequency (MHz)	Service	Modulation	Immunity test level (V/m)
5240 5500 5785	WLAN 802.11 a/n	Pulse modulation 217 Hz	9

10.4.2 Recommended safety distances

WARNING
The performance of the Tempus Pro may be degraded if portable RF devices are used within 30 cm of the device or its cables.

Recommended safety distances between portable and mobile RF telecommunication devices and the Tempus Pro (Table 9 according to IEC EN 60601-1-2): Section: recommended safety distances

The Tempus Pro is intended for use in an electromagnetic environment with controlled RF disturbances. The user of the device can help to avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile telecommunication devices (transmitters) and the device - depending on the output power of the telecommunication devices as described below.

	Safety distance depending on the frequency in metres		
Nominal power of the transmitter W	**150 kHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2.7 GHz**
	$d = 1.2\sqrt{P}$	**$d = 1.2\sqrt{P}$**	**$d = 2.3\sqrt{P}$**
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

- For 80 Hz and 800 MHz the higher frequency range applies.
- These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.

10.4.3 Cable length of the sensors and the accessories

WARNING
The use of longer cable lengths may cause an increased emission or a reduced interference resistance. The use of other sensors or cables except the ones mentioned above is not allowed.

CAUTION
For the purposes of compliance with IEC60601-1-2, all vital signs and communications functions were regarded as essential performance.

Tempus Pro cable	RDT part number	Cable length (typical)	Tested length
Ethernet cable	01-2025	2.1 m	2.1 m

Tempus Pro cable	RDT part number	Cable length (typical)	Tested length
Ethernet cable 10 ft	01-2109	3 m	3 m
$Sp0_2$ sensor	01-2014	2.4 m	2.4 m
3-lead ECG cable	Various	2.4 m	2.4 m
4-lead ECG cable	Various	2.4 m	2.4 m
5-lead ECG cable	Various	2.4 m	2.4 m
12-lead ECG cable	Various	2.4 m	2.4 m
IBP adaptor cable	Various	2.4 m	2.4 m
Wired headset	01-1019	1.2 m	1.2 m
Tempus Pro AC/DC adapter	989803219271	0.45 m	0.45 m
Mains lead	01-2055	2 m	2 m

10.5 Tempus Pro communications

WARNING
Per IEC60601-1-2 cl 5.2.2.5 b), the Tempus Pro may be interfered with by other systems even if they comply with CISPR emissions.

10.5.1 Ethernet specification

The ethernet connection has the following specifications:

- IEEE 802.3 compliant
- RJ-45 connection
- DHCP or fixed IP, Mask, Gateway
- Network cable: CAT5 at least 50 m

10.5.2 WiFi specification

The WiFi technology used by the Tempus Pro operates using IEEE 802.11b and 802.11g standard. It operates in the Industrial, Scientific and Medical (ISM) band between 2.412 GHz and 2.484 GHz.

WiFi specification	
The WiFi module has the following specifications:	
Range:	~ 91 m (300 feet)
Data rate:	CCK: 1, 2, 5.5, 11 Mb/s OFDM 6, 9, 12, 18, 24, 36, 48, 54 MB/s
Security:	WPA2-PSK(AES)
Baseband modulation:	802.11g: OFDM 802.11b: DSSS/CCK
Quality of service:	802.11 e EDCF

10.5.3 USB 4G dongle operating mode specification (Optional)

The 4G USB dongle has the following operating mode specifications:

Operating mode	Operating frequency range		Maximum transmit power (conducted) dBm
	Tx (MHz)	Rx (MHz)	
3G band I	1920 - 1980	2110 - 2170	24
3G band VIII	880 - 915	925 - 960	24
LTE band 1	1920 - 1980	2110 - 2170	24

Operating mode	Operating frequency range		Maximum transmit power (conducted) dBm
	Tx (MHz)	Rx (MHz)	
LTE band 3	1710 - 1785	1805 - 1880	24
LTE band 7	2500 - 2570	2620 - 2690	24
LTE band 20	832 - 862	791 - 821	24
LTE band 28	703 - 748	758 - 803	24

10.5.4 Bluetooth® module specification

Bluetooth® specification	
The Bluetooth® module has the following specifications:	
Indoor range	~ 9 m (30 feet) (typical office environment)
Data rate:	V2.0 up to 1 Mb/s EDR: 2.3 Mb/s
Baseband modulation:	V2.0: GFSK EDR: Pi/4 DQPSK, 8DPSK

10.5.5 Bluetooth® headset specification

The Tempus Pro uses the Sennheiser® Presence or VMX200 wireless headset. This is unmodified by RDT and is provided under FCC part 15C and an Industry Canada License 2099D. Users are reminded to refer to the Sennheiser user guide (available on the CD-ROM provided with the Tempus Pro) that provides instructions for use of the headset. These include environmental performance specifications which may differ from those of the Tempus Pro.


Battery shelf life and run times are based on a new, fully charged battery.

Description	General specifications
Bluetooth® type:	V4.0 class 1 (Presence) V3.0 class 2 (VMX200)
Range:	10 m max in an open field
Transmission frequency:	2402 – 2480 MHz
Bluetooth® profiles:	HSP, HFP, A2DP (Presence) HSP, HFP (VMX200)
Weight:	13 g (Presence) 10 g (VMX200)
Size:	51 mm x 19 mm x 23 mm (Presence) 55 mm x 26 mm x 58 mm (VMX200) (width x height x depth)
Talk time:	Up to 4 hours (Presence) Up to 6 hours (VMX200)
Stand by time:	Up to 240 hours
Operating temperature range:	+10°C (+50°F) to +40°C (+104°F)

Description	General specifications
Operating humidity range:	20 to 85% non-condensing
Storage temperature range:	-20°C (-4°F) to +60°C (140°F)
Storage humidity range:	10 to 95% non-condensing

10.5.6 Communications security specification

Data transmission from Tempus Pro to Corsium and 3rd party ePCR systems is protected in transit using TLS 1.2.

10.5.7 Communications compliance

FCC & Industry Canada compliance

> **CAUTION**
> Do not disassemble the device. There are no user-serviceable parts inside. Refer servicing to the manufacturer. Changes or modifications not expressly approved by RDT could void the user's authority to operate the equipment.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The user may find the following booklet helpful: *How to Identify and Resolve Radio-TV Interference Problems.* This booklet is available from U.S. Government Printing Office, Washington, D.C. 20402.

This equipment is also ETS 300 328, ETS 300 826, ETS 300 328-2, ETS EN301 489-1 and ETS EN301 489-17 compliant. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

FCC compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause interference and
- This device must accept any interference, including interference that may cause undesired operation of the device.

IC compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Industry Canada Standard ICES-003. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

4G USB dongle

For FCC & Industry Canada compliance information, refer to the user guide supplied with the Inseego USB8 4G Dongle.

Singapore compliance

Tempus Pro Singapore IMDA License Information:

Complies with IMDA standards
DB100486
DA102408

DA102408 for wifi/WLAN/Bluetooth/NFC capability

DB100486 for 4G/GSM capability.

10.6 Tempus Pro factory default settings

Settings	Range	Factory default
Communications mode	Various – customer specific	Uppermost listed mode within the customer specific communications mode menu
Patient	Neonate, Child, Adult	Adult
NIBP mode	Manual, Auto, Rapid Cuff	Auto
NIBP automatic measurement interval	2, 3, 5, 10, 15, 30 and 60 minutes	Automatic - 3 minutes
QRS volume	0-100% in steps of 20	0%
ECG waveform 1	Lead I-III – 3-lead ECG cable Lead I-III, aVL, aVR & aVF – 4-lead ECG cable Lead I-III, aVL, aVR, aVF & V – 5-lead ECG cable Lead I-III, aVL, aVR, aVF, V1-6 – 12-lead ECG cable	Lead II
ECG waveform 2	Lead I-III, aVL, aVR & aVF – 4-lead ECG cable Lead I-III, aVL, aVR, aVF & V – 5-lead ECG cable Lead I-III, aVL, aVR, aVF, V1-6 – 12-lead ECG cable	Lead I
ECG wave speed	12.5, 25, 50 mm/s	25mm/s
ECG gain	1, 2, 4, 5, 10, 15, 20, 30 and 50 mm/mV	10mm/mV
ECG monitoring filter	0.5 Hz – 40 Hz 0.05 Hz – 40 Hz 0.05 Hz – 150 Hz 0.67 Hz - 20 Hz	0.5 Hz – 40 Hz
ECG mains filter	ON-OFF	ON
Mains frequency	50-60 Hz	50 Hz
Pulse oximeter plethysmogram wave speed	12.5, 25, 50 mm/s	25 mm/s
Capnograph wave speed	3.1, 6.25, 12.5 mm/s	6.25 mm/s
Temperature readings	°C - °F	°C
Invasive pressure	See "Invasive pressure"	P1 – White with arterial settings P2 – White with arterial settings P3 - White with arterial settings P4 - White with arterial settings

10.7 Tempus Pro user agreements

Tempus Pro EULA

This license covers RDT's Tempus Pro software.

Warning: The software contained herein is protected by copyright law and international treaties. Unauthorized reproduction, distribution or reverse engineering of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.

You acknowledge that you will read and adhere to the user manual and ensure that users receive proper training from RDT or an appropriately trained individual. You also acknowledge that you will maintain the software by installing new software updates supplied by RDT within 5 working days of receiving or being notified of them.

License:

You may transfer the program and license to another party if the party agrees to accept the terms and conditions of this agreement. You will not share the program with other parties and will keep the program and details of its functions confidential. You will ensure that access to the software and use of it will be restricted to properly trained and authorized personnel only. You will not try to copy or reverse engineer the software.

The Tempus Pro operates over third-party communications links, such as telephone lines, cell phone or satellite links and the Internet. RDT does not accept liability for the failure of these links to reliably transmit information from RDT's products. Users are reminded that it is their responsibility to ensure that cell phone network and other communications contracts are maintained and suitably set up and configured for the areas in which they need to be used.

In order to function correctly Tempus Pro needs to operate over a communications link such as satellite communications, cell phone or a telephone line and other types of links. It is your responsibility to maintain these communications links. Such links may have security or other measures implemented on them such as firewalls. It is your responsibility to ensure that any such firewalls or other elements of the communication link are configured correctly to allow data from Tempus Pro to communicate over said link. RDT does not accept any responsibility for failure to transmit data or to transmit data reliably over such links if they have not been configured correctly. Support on configuring such links can be obtained from RDT upon request.

Neither the Tempus Pro or RDT are a "covered entity" under the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder ("HIPAA"). As a result, HIPAA does not apply to the transmission of health information by RDT or Tempus Pro to any third party. However, users of the Tempus Pro may be "covered entities" under the HIPAA act and so are reminded that they are responsible for acting accordingly. All users are reminded that it is their responsibility to maintain all patient records in a manner that is compliant with applicable local regulations.

The software gives users the ability to share and transmit medical data with third parties. Such activities are entirely the responsibility of the user.

RDT owns all proprietary rights to the Tempus Pro. RDT gives you a personal, revocable, non-assignable, and non-exclusive license to use the Tempus Pro.

Limited warranty and remedies:

In no event shall RDT or its distributors or agents, be liable for any damages resulting from loss of data, loss of revenue or for any incidental or consequential damages incurred arising out of or relating to the use of this software product. Some jurisdictions do not allow the exclusion of implied warranties, so the above exclusion may not apply to you. This warranty gives you specific legal rights and you may have other rights that vary from region to region.

RDT's Terms and Conditions apply.

RDT and its distributors make no representations with respect to the merchantability or fitness of the Tempus Pro software and the product is supplied "as is", without any warranty of any kind. Further, RDT reserves the right to revise its publications and program(s) without obligation to notify customer of such a revision.

You acknowledge that you have read this agreement, understood it, and agree to be bound by its terms and conditions. Failure to enforce any provision will not constitute a waiver of that provision. If any provision is found unenforceable, it and any related provisions will be interpreted to best accomplish the unenforceable provision's essential purpose.

This agreement is governed by UK law. The exclusive venue for any dispute relating to this agreement is London UK. You and RDT consent to the personal jurisdiction of these courts. Nothing in this agreement limits either party's ability to seek equitable relief.

MPEG4 EULA

NOTICE REGARDING VIDEO STANDARDS

This product is licensed under one or more video patent portfolio licenses such as and without limitation VC-1 and MPEG4 Part 2 Visual for the personal and non-commercial use of a customer to:

1. Encode video in compliance with the standards licensed under such patent portfolio licenses and/or
2. Decode video that was encoded by a consumer engaged in a personal and non-commercial activity and/or was obtained from a video provider licensed to provide video under such patent portfolio licenses.

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OpenSSL license

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11 Linking Tempus LS to Tempus Pro

This chapter describes how to set up a link to allow data to be transferred from the Tempus LS defibrillator to the Tempus Pro patient monitor. This is known as a TDL link.

Throughout these instructions, 'Tempus LS' refers to whichever defibrillator model is in use, either Tempus LS or Tempus LS-Manual.

The Tempus LS or Tempus LS-Manual defibrillator may only be used if it is approved for commercial distribution in your territory.

This chapter contains the following topics:

11.1 TDL link

When the TDL link is on, Tempus LS automatically transmits event data to Tempus Pro, which records these events in its summary record of care. Tempus Pro can print these events manually (when requested by the user) or automatically (on units with an internal printer).

The TDL link may be wireless (via Bluetooth) or direct (via any standard USB-A to USB-B data cable).

Tempus LS must be authenticated by the maintenance user before it can be linked to Tempus Pro. For instructions, see the *Tempus Pro Maintenance Manual*.

WARNING
Alarm limits must be selected carefully on Tempus Pro and Tempus LS when using them together on the same patient.

CAUTION
When handling patient data, do so in accordance with the privacy policies that apply in your healthcare environment and privacy laws that apply in your region.

Important

- If the software versions of the Tempus LS and Tempus Pro are found to be incompatible on connection, the following dialog will be displayed by the Tempus Pro:

  "Attention - Tempus LS Connection
  Unable to connect to the Tempus LS
  This could be because the software versions on the Tempus Pro and Tempus LS are incompatible.
  Ensure the Tempus Pro and Tempus LS are both updated with the latest software."

- If this message appears, contact RDT to obtain the latest software versions.
- If the software versions of the Tempus Pro and Tempus LS are incompatible, the Pro and LS will pair via the TDL Link as normal, however, no event data will be automatically transmitted from the LS to the Pro via the TDL link. The event data will continue to be stored on the LS as normal and can be exported using the Export feature in the LS device.

11.2 Pairing Tempus Pro with Tempus LS

To allow the TDL link to operate wirelessly, the Tempus Pro and Tempus LS must be paired via Bluetooth. This pairing is normally performed once only, the first time the two devices are used together. Pairing is normally retained after this.

- If Tempus Pro and Tempus LS are both currently unpaired, you can pair them via either Bluetooth or a USB data cable.
- When connected via USB data cable, the devices silently pair via Bluetooth, meaning that when they are no longer connected via USB data cable they remain paired via Bluetooth.

- The *Tempus Pro Maintenance Manual* describes how to configure Tempus Pro to not persist Bluetooth pairing with Tempus LS after powering off. If **Persist Tempus LS pairing** is switched off, you will need to repeat Bluetooth pairing every time Tempus Pro is powered on.

1. Put Tempus Pro and Tempus LS within 5 metres of each other (preferably in line of sight).
2. On the Tempus Pro, press and hold **Main Menu** for at least 2 seconds until the Bluetooth icon starts to blink (alternatively, select **Main Menu** > **TDL Settings** > **Connect to a Tempus LS**).
3. On the Tempus LS, press and hold the **Menu** button for at least 2 seconds until the Bluetooth icon starts to blink.
4. After 15 seconds (typical), the units pair and sound the link audio tones and flash their LEDs. The **TDL** icon appears in the Tempus Pro status bar:

Event data created on the Tempus LS will now be pushed to the Tempus Pro and incorporated into the Summary Record of Care.

11.3 Using the TDL link

Connecting via Bluetooth

If Bluetooth pairing has been completed and if Tempus Pro is configured to persist pairing, the TDL link is active as soon as Tempus Pro and Tempus LS are powered on.

Connecting via USB cable

Tempus Pro and Tempus LS can also be connected via USB data cable (with or without Bluetooth).
To set up the TDL link via USB data cable, use either a direct or an indirect connection:

- Direct connection - plug a USB data cable into the USB ports of Tempus Pro and Tempus LS.
- Indirect connection - plug a USB data cable into the USB ports of the Smart Mounts of Tempus Pro and Tempus LS, then dock the two units in their Smart Mounts.

If Bluetooth is enabled on the Tempus Pro, it silently pairs with the Tempus LS when the devices are connected via USB data cable. After 15 seconds (typical), the units pair and sound the link audio tones and flash their LEDs. The **TDL** icon appears in the Tempus Pro status bar:

Identifying the connected Tempus LS

On the Tempus Pro, select **Main Menu** > **TDL Settings** > **Identify connected Tempus LS**.
This triggers TDL link audio tones and LEDs on the connected Tempus LS.

11.4 Using the connected units on different patients

WARNING
To avoid mixing up patients, always discharge and admit when moving between patients.

If you need to use the connected Tempus Pro and Tempus LS on different patients:

1. On the Tempus Pro, select **Main Menu** > **TDL Settings**.
2. Set **TDL link** to **off**.
3. When the confirmation dialog is displayed, press **Confirm**. Data from the current Tempus LS patient will not be written to the Tempus Pro summary record of care.
4. Press **Back**.

When **TDL link** is **off**, Tempus Pro and Tempus LS remain connected.

To revert to using the connected Tempus Pro and Tempus LS on the same patient:

1. On the Tempus Pro, select **Main Menu** > **TDL Settings** .
2. Set **TDL link** to **on**.
3. When a dialog is displayed with the question "**Are the Tempus Pro and Tempus LS being used on the same patient?**", press **Yes - same patient**. Data from the current Tempus LS patient will be written to the Tempus Pro summary record of care.
4. Press **Back**.

Certain events will cause Tempus Pro to display the question "**Are the Tempus Pro and Tempus LS being used on the same patient?**". In response, select one of two options:

- **Yes - same patient** - data from the Tempus LS will be written to the Tempus Pro summary record of care.
- **No - different patient** - data from the Tempus LS will not be written to the Tempus Pro summary record of care.

11.5 Switching off

WARNING
Do not remove battery until the LED has gone off.

To power off quickly with no countdown or confirmation:

1. Ensure the Tempus Pro is not in use.
2. Press and hold the  button for 2 seconds.

To power off with countdown and confirmation:

1. Ensure the Tempus Pro is not in use.
2. Press and release the  button. The LED on the on/off button will start flashing.
3. The Tempus Pro displays a 10 second countdown timer.
   Press the **Confirm Power Off** button.

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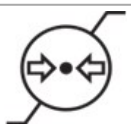
Annex A : Symbols used

	Consult the instructions for use.These are provided in paper format with the device.
	Name and address of the European Union Authorized Representative.
	A caution symbol indicating that federal law restricts the device for sale by or on the order of a physician (US market).
	Consult the instructions for use for important warning information.
	Consult the instructions for use for important cautionary information.
 0413	Signifies European technical conformity for a device/accessory, CE marked by notified body number 0413
	Signifies European technical conformity for a device/accessory. For class I devices.
	Regulatory Compliance Mark Indicates the device is in compliance with AS/NZS 4417.1 & 2 and the EESS.
	Indicates the medical device manufacturer.
 YYYY-MM-DD	Date of manufacture. The year that the item was manufactured is represented below the symbol in YYYY-MM-DD format.
	Country of Manufacture The country of manufacture is identified by the two-letter ISO 3166-1 country code. The date of manufacture of the device may be placed adjacent to this symbol in YYYY-MM-DD format.
 YYYY-MM-DD	The manufacturer’s batch code. The year that the item was manufactured as a part of a larger batch is represented below the symbol in YYYY-MM-DD format.
	Unique Device Identifier Indicates a carrier that contains unique device information

REF	Catalogue Number Indicates the manufacturer's catalogue number
SN	Serial Number Indicates the manufacturer's serial number
MD	Medical Device Indicates that the product is a medical device
PN	Technical Part Number Indicates the manufacturer's technical part number
	Indicates the number of pieces in the package.
	Keep away from sunlight.
	Pause audible alarms temporarily.
	Pause all alarm manifestations (visual and audible) temporarily.
	Alarm off (either individual parameter or all parameters).
	General alarm symbol.
	Type CF defibrillation-proof applied part complying with IEC 60601-1.
CO_2	Capnometer socket.
TEMP	Contact temperature sockets.
ECG	ECG socket.
P1/P2	Invasive pressure socket.
NIBP by SunTech.	NIBP socket.
SpO_2	Pulse oximeter socket.

	Tactical Mode associated with low emitted light and low emitted sound.
	Not for use with YSI 700 series sensors.
	Battery charge indicator – flashes green when the battery is on charge.
	Battery power level.
	System power on/off (push/push).
	Single use device only, discard item after use.
	Capnometer Cannula inlet connection.
	The user must check that the blood pressure cuff is the correct size. Once the blood pressure cuff is wrapped round the arm, the INDEX mark should be between the RANGE marks.
	Center point of blood pressure cuff bladder - to be aligned with the patient's artery.
 **XX-YY cm**	Diameter size for the blood pressure cuff.
	Item does not contain any latex (blood pressure cuffs).
	Item does not contain any PVC (blood pressure cuffs).

IP66	The device is dust-tight and protected against powerful water jetting according to IEC 60529. IP66 (dust and water ingress under pressure) – whole device. According to IEC60529, “IP” means ingress protection. The following two numerals refer to grades of ingress protection for solid objects (the first numeral) and water (the second numeral). The first numeral “6” means the device is dust tight against the ingress of dust to a size <75 µm. The second numeral means the device is protected against the ingress of 100 l/m of water “jetting” at the device from 2.5 to 3 m.
IP22	The device bearing this symbol has the Ingress protection that is indicated by the IP rating figures that follow: The first numeral indicates that the equipment is protected from ingress of foreign objects that have a diameter of greater then 12,5 mm. The second numeral indicates that the equipment is protected against water dripping vertically onto the equipment, when the equipment is tilted 15°
IP44	The device bearing this suymbol has the Ingress protection that is indicated by the IP rating figures that follow: The first numeral indicates that the equipment is protected from ingress of foreign objects that have a diameter of greater then 1 mm. The second numeral indicates that the equipment is protected against water splashing on to the equipment from any angle.
YYYY- MM-DD	Shelf life, where the time that the unit must be used by is represented below the symbol in YYYY-MM-DD format.
	EU Directive on Waste Electrical and Electronic Equipment (WEEE). This product must not be disposed of or dumped with household waste.
	Communications connections.
	WiFi connection mode.
	Bluetooth® connection to Bluetooth peripherals.
	Battery connection – to indicate positive terminal polarity.
	Global Positioning System (GPS).
	Global System for Mobile (GSM) communications.
	Headset connector.
	Ethernet socket (RJ-45).

	USB 2.0 & 1.0 sockets.
	Power Status (green indicates mains power is connected).
	Camera backlight.
	Device contains wireless transmitters.
	DC connector/Direct current
	AC Connector/Alternating current
	The NRTL (Nationally Recognized Testing Laboratory) program of OSHA (Occupational Safety & Health Administration) acknowledges private organizations and confirms their qualification to test technical products for their safety in the workplace according to the requirements of the US Occupational Safety & Health Administration. "US" stands for compliance with the requirements of US authorities, "C" for compliance with Canadian requirements.
	Signifies UK technical conformity for a device/ accessory.
	Store this way up.
	Fragile, handle with care.
	Indicates keep dry.
	Storage humidity range.
	Storage temperature range.
	Storage pressure/altitude range.

	Indoor Use Only
	Level 6 Energy Efficiency
	Meets the safety requirements specified in IEC 61140 for Class II equipment
	DC Power supply connections
	Certified by US Underwriters Laboratory
	Certified by RCM Electrical Safety
	Do not remove the cover

Annex B : Accessories list

Refer to the IFU for the specific accessory in use.

The accessory IFU gives user information for the accessory including information on where the accessory comes into contact with the Patient.

Do not use an accessory if the sterile barrier or its packaging is defective.

No sterile accessories are supplied with the Tempus Pro.

Follow the sterilization instructions given in the Accessory's IFU.

The following accessories and consumables are available from RDT:

B.1 Temperature accessories

Product name and description	Part number (RDT)	Part number (12NC)
Reusable Contact Temperature Probe		989803220781
Disposable Contact Temperature Probe		989803220771
Redy-Med TA008-A Contact Temperature Adaptor Cable	01-2316	989803217171

B.2 Invasive Blood Pressure accessories

Product name and description	Part number (RDT)
Part number 01-2113 connects to the Tempus Pro only via the universal cable (part number 01-2108). Part number 01-2108 accepts up to two adaptor cables for two IBP channels:	
Tempus Pro 2-Channel Invasive Pressure Universal Cable	01-2108
Transpac & Art-Line Transducer Adaptor Cable	01-2113
2 Channel Invasive Pressure Module	01-2017

The following Invasive Blood Pressure transducers are approved for use with the Tempus Pro:

Transducer manufacturer	Transducer model	Adaptor cable
ICU Medical (Abbott)	Transpac IV or IT	RDT part number 01-2113 C&S part number 10369 (*)
Biometrix	Art-Line	RDT part number 01-2113 C&S part number 10369 (*)
Smiths-Medical (Medex)	TranStar	RDT part number 01-2113 C&S part number 10369 (*)
Smiths-Medical (Medex)	LogiCal	C&S part number 10366 (*)
Merit Medical (Argon Medical / BD)	Meritrans / DTXPlus	C&S part number 10367 (*)
Codan PVB (ITL Healthcare)	Xtrans (DPT 9000)	Not yet available
Codan PVB (ITL Healthcare)	DPT-6000	C&S part number 10371 (*)
Utah Medical	Deltran	C&S part number 10370 (*)
Biosensors International	Biotrans	C&S part number 10370 (*)
Biosensors International	Accutrans	C&S part number 10370 (*)
Edwards Lifesciences (Baxter)	TruWave	C&S part number 10368 (*)

(*) www.CablesandSensors.com

B.3 Non-invasive blood pressure accessories

Product name and description	Part number (RDT)	Part number (12NC)
Tempus Blood Pressure Cuff – adult cuff (23 – 33 cm)	01-1002	989706000231
Tempus Blood Pressure Cuff – large adult cuff (31 – 40 cm)	01-1003	989706000241
Tempus Blood Pressure Cuff – child cuff (12 – 19 cm)	01-1004	989706000251
Tempus Blood Pressure Cuff – small adult cuff (17-25cm)	01-2119	989706000701
Tempus Blood Pressure Cuff – infant (8 - 13 cm)	01-2021	989706000331
Tempus Blood Pressure Cuff – adult thigh cuff (38 – 50 cm)	01-1032	989706000291
Tempus Blood Pressure Hose 4ft	01-1006	989706000261
Tempus Pro NIBP Cuff Kit (adult, large adult, thigh and child cuffs)	01-2155	989706010760
Tempus Pro Blood Pressure Hose 8ft	01-2074	989706000571
NIBP Infant Disposable Cuff (Box of 20)	01-2230	989706001001
NIBP Child Disposable Cuff (Box of 20)	01-2231	989706001011
NIBP Small Adult Disposable Cuff (Box of 20)	01-2232	989706001021
NIBP Adult Disposable Cuff (Box of 20)	01-2233	989706001031
NIBP Large Adult Disposable Cuff (Box of 20)	01-2234	989706001041

Product name and description	Part number (RDT)	Part number (12NC)
NIBP Thigh Disposable Cuff (Box of 20)	01-2235	989706001051
Tempus NIBP One-Piece Cuff - Small Adult Plus (18-29cm)	01-2270	989706002051
Tempus NIBP One-Piece Cuff - Adult Plus (28-40cm)	01-2271	989706002061
Tempus NIBP One-Piece Cuff - Large Adult Plus (40-55cm)	01-2272	989706002071

B.4 Pulse oximetry accessories

Masimo accessories

Product name and description	Part number (RDT)	Part number (12NC)
Masimo rainbow SET cables:		
MasimoSET Rainbow Patient Cable 12 ft 25-Pin R/A RC12 RA	01-2138	989706000851
MasimoSET Rainbow Patient Cable 4ft 25-Pin R/A RC4 RA	01-2088 or 989803182411	989803182411
Masimo rainbow SET DCI:		
Masimo Rainbow DCI Adt 3ft (SpO2, SpCO, SpMet) [1] - Clip	01-2086	989706000611
Masimo Rainbow DCI SC-400 Adt 3ft (SpO2, SpHb, SpMET) [1] - Clip	01-2092	989706000661
Masimo rainbow SET DCIP:		
Masimo Rainbow DCIP SC-400 Ped 3ft (SpO2, SPCO, SpMet)[1] - Clip	01-2136	989706000831
Masimo Rainbow DCIP Ped 3ft (SpO2, SpCO, SpMet) [1] - Clip	01-2137	989706000841
Masimo rainbow SET R1:		
Masimo Rainbow R1 25 Adt 1ft (SpO2, SpHb, SpMET) [10] - Adh	01-2128	989706000751
Masimo Rainbow R1 20 Ped 1ft (SpO2, SpHb, SpMET) [10] - Adh	01-2129	989706000761
Masimo Rainbow R1 20L Inf 1ft (SpO2, SpHb, SpMET) [10] - Adh	01-2130	989706000771
Masimo Rainbow R1 25L Neo/Adt 1ft (SpO2, SpHb, SpMET) [10] - Adh	01-2131	989706000781
Masimo rainbow SET R20:		
Masimo Rainbow R20 Ped 1ft (SpO2, SpCO, SpMET) [10] - Adh	01-2133	989706000801
Masimo Rainbow R20-L Inf 1ft (SpO2, SpCO, SpMET) [10] - Adh	01-2134	989706000811
Masimo rainbow SET R25:		
Masimo Rainbow R25 Adt 1ft (SpO2, SpCO, SpMET) [10] - Adh	01-2132	989706000791
Masimo Rainbow R25-L Neo/Adt 1ft (SpO2, SpCO, SpMET) [10] - Adh	01-2135	989706000821
Masimo SET M-LNCS:		

Product name and description	Part number (RDT)	Part number (12NC)
MasimoSET M-LNCS DBI Adt SpO2 Reusable Sensor [1] - Boot	01-2089	989706000631
MasimoSET® M-LNCS Adtx-3 Adult Sensor (20 box)	01-2090	989706000641
MasimoSET® M-LNCS Neo-3 Neonatal/Adult Sensor (20 box)	01-2091	989706000651
MasimoSET M-LNCS Pdtx-3 Ped 3ft [20] - Adh	01-2095	989706000671
MasimoSET M-LNCS DCI Adt 3ft [1] - Clip	01-2123	989706000711
MasimoSET M-LNCS DCIP Ped 3ft [1] - Clip	01-2124	989706000721
MasimoSET M-LNCS INF-3 Inf 3ft [20] - Adh	01-2126	989706000731
MasimoSET M-LNCS NEOPT-3 Neo 3ft [20] - Adh	01-2127	989706000741
Masimo RD:		
Masimo Rainbow Patient Cable 4ft 25-Pin R/A EMS	01-2267	989706010120
Masimo RD rainbow SET Patient Cable 5ft 25-Pin R/A	01-2268	989706001621
Masimo RD SET DBI Adult Soft Reusable Sensor 3ft	01-2269	989706001631
Masimo RD SET DCI Adult Reusable Sensor 3ft	01-2273	989706001911
Masimo RD SET DCIP Pediatric Reusable Sensor 3ft	01-2274	989706001921
Masimo RD SET Adt CS-3 Adult [20] - Adh 3ft	01-2276	989706001941
Masimo RD SET Pdt CS-3 Pediatric [20] - Adh 3ft	01-2278	989706001961
Masimo RD SET In CS-3 Infant [20] - Adh 3ft	01-2279	989706001971
Masimo RD SET Neo CS-3 Neonatal/Adult [20] - Adh 3ft	01-2280	989706001981
Masimo RD SET NeoPt CS-3 Neonatal [20] - Adh 3ft	01-2281	989706001991
Masimo RD rainbow SET-2 Adt SpO2 SpMet SpHb [20] - Adh 2ft	01-2282	989706002001
Masimo RD rainbow SET-2 Pdt SpO2 SpMet SpHb [20] - Adh 2ft	01-2283	989706002011
Masimo RD rainbow SET Patient Cable 12ft 25-Pin R/A	01-2284	989706002021
Masimo RD rainbow SET Patient Cable 8ft 25-Pin R/A	01-2285	989706002031
Masimo RD to M-LNC Adaptor Cable 1.5ft	01-2286	989706002041
Masimo LNCS-II rainbow		
Masimo LNCS-II rainbow DCI 8λ SpCO Adt 3ft [1]), PR, SpMet)	01-2705	989803218161
Masimo LNCS-II rainbow DCIP 8λ SpCO Pdt 3ft [1]), PR, SpMet)	01-2706	989803218171
Masimo LNCS-II rainbow DCI 8λ SpHb SC-400 Adt 3ft [1]), PR, SpMet)	01-2713	989803218241

B.5 Ultrasound accessories

Product name and description	Part number (RDT)
Tempus Pro USB 3.5 MHz General Abdominal Ultrasound Probe (GP)	01-2008
Tempus Pro USB 7.5 MHz Vascular Ultrasound Probe (LP)	01-2042

B.6 Video laryngoscope accessories

Product name and description	Part number (RDT)
Tempus Pro USB C-MAC S Imager Video Laryngoscope	01-2044
Video Laryngoscope Single Use D blade (pack of 10)	01-2063
Video Laryngoscope Single Use Size 3 Macintosh blade (pack of 10)	01-2010
Video Laryngoscope Single Use Size 4 Macintosh blade (pack of 10)	01-2011

B.7 Capnometer accessories

Product name and description	Part number (RDT)
Smart CapnoLine Plus Adult/Intermediate 02 25UN (P/N 015018)	01-2143
Smart CapnoLine Pediatric 02 25units (P/N 015027)	01-2144
VitaLine H Set Adult/Pediatric 25units (P/N 015026)	01-2145
FilterLine H Set Adult/Pediatric 25units (P/N 015016)	01-2146
FilterLine Set Adult/Pediatric 25units (P/N 015021)	01-2147
FilterLine H Set Infant/Neonates 25units (P/N 015028)	01-2148
Smart CapnoLine Plus Adult/Intermediate 02 25UN (P/N009822)	01-2151
Smart CapnoLine Pediatric 02 25units (P/N007269)	01-2247

B.8 Electrocardiogram accessories

Product name and description	Part number (RDT)
Tempus Pro 3-Lead ECG Cable (AAMI) 8 ft	01-2068
Tempus Pro 5-Lead ECG Cable (AAMI) 8 ft	01-2069
Tempus Pro 12-Lead ECG Cable (AAMI) 8 ft	01-2070
Tempus Pro 3-Lead Neonatal ECG Cable (AAMI) 6ft	01-2203
Tempus Pro 4-Lead ECG Modular Trunk Cable (AAMI) 8 ft	01-2177
AAMI Additional 6-Lead cable	01-2179
Tempus Pro 3-Lead ECG Cable (IEC) 8 ft	01-2071
Tempus Pro 5-Lead ECG Cable (IEC) 8 ft	01-2072

Product name and description	Part number (RDT)
Tempus Pro 12-Lead ECG Cable (IEC) 8 ft	01-2073
Tempus Pro 3-Lead Neonatal ECG Cable (IEC) 6ft	01-2202
Tempus Pro 4-Lead ECG Modular Cable (IEC) 8 ft	01-2181
Additional 6 Lead Cable(IEC)	01-2183
Ambu BlueSensor 'T' Adult Foam ECG Electrode - 10 Pack	01-2080
Ambu BlueSensor R 25 units (P/N 1559024)	01-2152

B.9 Power and charging accessories

WARNING
It is recommended that the Tempus Pro operates on batteries when in an emergency medical service environment.

CAUTION
The Tempus Pro AC/DC adapter is recommended for use in a non-emergency medical service environment.

CAUTION
The Tempus Pro DC/DC adapter is recommended for use in road ambulances.

CAUTION
If the Tempus Pro AC/DC adapter is used in a road ambulance, the installer must install this Class I Power Supply Unit in accordance with IEC 60601-1-12 and IEC 60601-1 to make sure that there is a stable and verified earth.

CAUTION
It is recommended that the Tempus Pro is powered by its rechargeable battery when used in a fixed or rotary wing air ambulance.

Product name and description	Part number (RDT)
AC/DC Adapter	989803219271
When ordering an AC/DC Adapter, select a mains cable for the country of operation:	
Mains Cable - Switzerland	01-2058
Mains Cable - UK	01-2056
Mains Cable - Schuko / Euro	01-2057
Mains Cable - Australian	01-2060
Mains Cable - Nigeria (as per UK)	01-2056
Mains Cable - Israel	01-2062
Mains Cable - South Africa	01-2054
Mains Cable - Thailand	01-2287

Product name and description	Part number (RDT)
DC-DC Adapter	989803219281
Tempus Lithium-ion Battery – two supplied with unit	01-2051
Tempus Battery Charger (including 2-core figure 8 mains cable)	01-1012
When ordering a Battery charger, select a mains cable for the country of operation:	
Battery Charger cable - South African 2	01-2162
2-core Battery Charger cable - UK	01-2159
2-core Battery Charger cable - Euro	01-2160
Battery Charger cable - Australian 2	01-2061
Battery Charger cable - Swiss (2 core)	01-2059

B.10 Telemedicine accessories

Product name and description	Part number (RDT)
Tempus Wired Headset	01-1019
Sennheiser Presence headset	01-2098
Tempus Pro Tactical Headset Adaptor Cable	01-2041
Inseego USB8 4G Dongle	01-2302
Inseego USB8 4G Dongle Mounting Kit	26-4000

B.11 Miscellaneous accessories

Product name and description	Part number (RDT)
Tempus Pro Litter Mount	01-2035
Tempus Pro Hard Transit Case	01-2400
Tempus to Tempus USB Data Cable	01-2243
Tempus Pro SMART mount (order PSU and power cable separately)	01-2244
Tempus Pro Printer paper with grid 100mm (1x roll)	01-2186
Tempus Pro shoulder strap only (with locking mech)	01-2200
Left Saddlebag for Tempus Pro	01-2241
Left Tactical Saddlebag for Tempus Pro	01-2259
Right Saddlebag for Tempus Pro	01-2238
Right Tactical Saddlebag for Tempus Pro	01-2260

B.12 Anesthetic gas monitoring accessories

Product name and description	Part number (RDT)
ISA OR+ sidestream analyzer	01-2167
Tempus to ISA OR+ adaptor cable	01-2168
Nomoline Airway Adapter Set 2.0m (Box of 20) Sampling line with straight airway adapter, single-patient use, Adult/Pediatric	01-2171
AA gas exhaust port kit (Masimo #4409)	01-2255
ISA OR+ Ferno Mount Bracket	01-2258

B.13 Corsium Crew accessories

Product name and description	Part number (RDT)
Corsium Crew Cable (USB-A to USB-C)	01-2252

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Remote Diagnostic Technologies Limited
Ascent 1
Farnborough Aerospace Centre
Aerospace Boulevard
Farnborough
Hampshire
GU14 6XW
United Kingdom

Tel: +44 (0) 1256 362 400
www.philips.com

Part number: 41-2036EN-12

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