User/Operator Manual

English

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Tempus Pro i2i

Response Center application

PHILIPS

Manufacturer's address

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About this manual

This is the user/operator manual for the i2i system that connects with Tempus Pro.

> **Important**
>
> Tempus Pro i2i is a legacy product that has been replaced by IntelliSpace Corsium. Because the i2i software is no longer updated, you may notice that some i2i screens do not fully align with the content displayed on the Tempus Pro screens. For more information, see *Training Bulletin (Tempus Pro Response Centre v4.16)* (part number 46-2056EN).

The i2i is intended to provide the ability to receive voice and data calls from the Tempus Pro Patient Monitors. These monitors allow the user to collect and transmit the following information:

- Medical data:

  Heart rate;

  3/5 Lead ECG (monitoring);

  Real time arrhythmia detection;

  Real time ST and QT measurement and alarming;

  SpO2;

  SpHb;

  SpMet;

  SpOC;

  SpCO;

  Non-invasive blood pressure (discrete readings);

  Respiration rate and end tidal CO2;

  Temperature;

  Invasive pressure; up to 4 channels;

  Full 12 lead ECG recording;

  12 lead ECG recording Interpretation.

- Other data:

  Real time simultaneous voice connection;

  Transmission of video images, patient notes (TCCC card or Summary Record of Care) and photos;

  Saved images from ultrasound scans;

  Saved images taken from the Video Laryngoscope.

The i2i receives this information and has additional features to make the manipulation and handling of data easier and more meaningful. These features include:

- Easy to use – has all the same ease of use features as the Tempus Pro Patient Monitors and incorporates standard Windows interface style in the patient record database.

- Patient database – automatic recording and linking of patient records with full retrieval and back-up facilities.
- Allows complete interaction with the Tempus Pro Patient Monitors, the patient database and all patient records (including ECG) data from one application.
- Allows annotation of uploaded still-video images and re-transmission of the annotated image back to the remote device.
- Analysis and presentation of transmitted data.

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 i2i. Failure to comply with the information contained in this manual e.g. warnings, cautions, instructions etc. will violate the safety standards of design, manufacture and intended use of the product. Remote Diagnostic Technologies Ltd. ('RDT') assumes no liability for customer failure to comply with the information contained in this manual.

Users of the Tempus Pro patient monitors and their accessories are advised to read this manual thoroughly and convey the following safety information to any other operating personnel as well as to incorporate applicable information into their own internal literature where necessary.

This manual is for the operator of the i2i. The i2i is the hospital or Response Center based system which acts in tandem with the Tempus Pro patient monitor (the remote device) to enable medical data to be transmitted from the remote location to a physician, thus enabling a diagnosis to be made. Essentially the i2i is the software which enables the physician to receive and view the data being transmitted by the Tempus Pro.

The manual is designed to give a basic technical understanding of the i2i as well as specific information on the functions that the device delivers. This manual has been written to be specific to the i2i and as such does not cover the operation of the Tempus Pro patient monitors.

The Tempus Pro patient monitors can be controlled from the i2i. Therefore, to completely understand the operation of the i2i in relation to that of the Tempus Pro, you must read the *Tempus Pro User/Operator Manual* .

It is assumed that the readers of this manual are:

- trained healthcare professionals or Response Center operatives who are supported by trained healthcare professionals;
- who are experienced in dealing with medical situations over the telephone;
- who have acceptable, basic computer skills;
- who have read this manual and familiarized themselves with the operation of the i2i;
- who have read the *Tempus Pro User/Operator Manual* and familiarized themselves with the operation of the Tempus Pro.

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:

Important

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.

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 i2i. 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.

Tempus Pro, Tempus ALS, Tempus LS, Tempus LS-Manual, Tempus IC2, Tempus IC, IntelliSpace Corsium, IntelliSpace Corsium Crew, Smart Mount, i2i and EDS are trademarks of RDT.

The Bluetooth® name and logo are owned by the Bluetooth® SIG Inc. and any use of this name or mark is under license.

Limited warranty

Remote Diagnostic Technologies Limited ('RDT') warrants each new i2i to be free from defects in workmanship and materials under normal conditions of use and service for a period of one (1) year from the date of shipment. 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 i2i is in any way modified or if it is 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.

Service

Repairs to the i2i under warranty must be made by the manufacturer. If the i2i requires repair, contact your local distributor or Remote Diagnostic Technologies.

CE statement

Marking by the CE 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/EURadio and Telecom Terminal Equipment Directive (RTTED) 1995/5/EC (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 i2i is a class IIb device under the MDD.

A Declaration of Conformity in accordance with the above regulations has been made and is on file with RDT at the "Manufacturer's address".

FDA prescription statement

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

1 Introduction to i2i

1.1 Basic principles

The i2i is software running on computers at a Response Center which is intending to receive voice and data calls from people using the Tempus Pro monitor in remote locations.

Once the software has been installed on the Response Center's systems, they will be alerted to incoming calls from Tempus Pro users via a normal incoming telephone call, i.e. a user will call in and advise that they need the Response Center's support and that they are using the Tempus Pro.

This manual describes how incoming calls can be identified, selected and managed. It also describes how the data from old calls may be subsequently examined.

This manual does not cover how to back up the data at the Response Center or how to maintain security to the computers on which the i2i software is installed. Both of these activities are the responsibility of the i2i user's organization.

RDT recommends (as a minimum) that Response Centers have at least two computers running with the i2i software on them at all times. It is preferable to have at least one additional computer as a back-up. This means that in the case of hardware failure or many incoming calls occurring simultaneously, there should always be sufficient resource at the Response Center to meet minimum potential demand. Ultimately, the size of the installation and the amount of redundant equipment installed is the user's responsibility.

1.2 Indications for use

The i2i is a telemedicine system intended to be used by clinicians and medically qualified personnel for the monitoring of single or multiple vital signs received from Tempus Pro patient monitors in clinical and pre-hospital care applications. The i2i 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 pressure and extended pulse oximetry capability including; carboxy hemoglobin (SpCO), methemoglobin (SpMet), total hemoglobin (SpHb) and total oxygen content (SpOC) measurements.

The i2i is indicated for adults, pediatrics and neonates.

The i2i does not replace a physician's care.

The i2i is not a patient record system.

Contraindications

The i2i is only intended to be used in the manner described in this manual. Failure to follow the instructions within this manual may lead to a mistake in the correlation of patient data to the patient's record.

No alterations of any kind (including updates or changes to any settings) may be made to the software installed onto the i2i without the authorization of RDT. No additional software of any kind may be run or installed on the i2i without the authorization of RDT. No changes may be made to the hardware used for the purpose of supporting the i2i without the authorization of RDT.

1.3 Warnings, cautions and notes

CAUTION

The i2i 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.

It is the user's responsibility to ensure that the i2i system is installed, used, managed and maintained in accordance with all requirements described within this manual and associated labelling.

The i2i alone does not represent a complete system. To provide a real-time telemedicine service, it is the user's responsibility to provide appropriate communications links, infrastructure, trained operators, security, IT and backup facilities etc.

- All references to dates are only ever in the European convention i.e. DD/MM/YY.
- While the i2i will display the same information as the Tempus, user should note that the actual display size and aspect ratio of waveforms will vary slightly depending on the native resolution of the display that the i2i user has i.e. the i2i user's display may have differently sized and shaped pixels to the display of the Tempus and so very minor differences may be present between the two displays.
- The i2i application could, in exceptional circumstances crash. In the unlikely occurrence of a crash during an incident, restart the application as normal. The incident data will automatically be saved and the client will automatically reconnect so the incident can continue. See "2.1.3 Automatic continuation of an existing incident"for more information on the automatic continuation of an incident. During a crash a dialogue box may invite the user to send an error report, which the user can choose to send or not as they see fit.
- This manual does not describe the use, control or features of the Tempus Pro patient monitors. This information is given in the monitor user manual which **must** be read in conjunction with this manual: *Tempus Pro User/Operator Manual*.
- If in exceptional circumstance the measurements or video stop running at the i2i application, ask the Tempus user to stop and then restart the connection.

1.4 Data transmission and transfer times

The Tempus is designed for use in pre-hospital care, remote clinics and remote field locations. The Tempus has been designed to allow the transmission of most of the medical parameters in "real-time" that is without significant delays existing between the display of the data on the Tempus and the display of the same data on the i2i. However, this is not possible for ECG recordings, photos, Ultrasound images, and video laryngoscope images, because of the large amount of data that they represent. Therefore this data is sent in a batch that will take 30 seconds or more to arrive. It should be remembered that while these files are being transmitted, the real-time data will continue to arrive and the system can still be used for other activities.

To summarize:

Type of data	Nature of transmission
Heart rate	Real-time (*1)

Type of data	Nature of transmission
ECG waveform (ECG monitoring)	Real-time (*1)
Blood pressure	Real-time (*1)
Pulse rate (from pulse oximeter if the ECG is not attached)	Real-time (*1)
SpO2	Real-time (*1)
Plethysmogram (SpO2 waveform)	Real-time (*1)
Respiration rate	Real-time (*1)
ETCO2	Real-time (*1)
Capnogram (ETCO2 waveform)	Real-time (*1)
Temperature	Real-time (*1)
Invasive pressure	Real-time (*1)
Photos	Store and forward (typically 30 seconds)
Photo annotation	Store and forward (typically 15 seconds)
12 Lead ECG recording	Real-time (*2) or store and forward of 10 second trace (up to 2 minutes) where bandwidth does not permit real-time transmission

(*1) Software installation should be performed by suitably qualified IT personnel. Installation is covered in the *Tempus Pro Reachbak and i2i Installation Manual* (part number 41-2010US). Software installation can be supported by RDT if required.

(*2) “Real-time” refers to real-time transmission, readings are normally delayed by 3-5 seconds depending on the nature of the communications link.

1.5 Accessing the i2i

Once you have received a voice call from a Tempus Pro user notifying you that they have made a connection, you should start the i2i application. The application icon on your desktop is shown below:

i2i application

Double click the icon to start the i2i application.

1.6 Awaiting connection screen

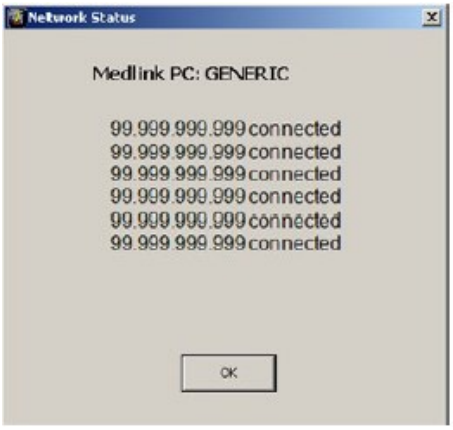
Once the i2i has started you may see a blank screen if the data connection from the Tempus Pro has not yet been established.

The center of the screen shows that no connections are present from Tempus devices.

Network Status button shows if the i2i is connected properly.

i2i waiting for a connection

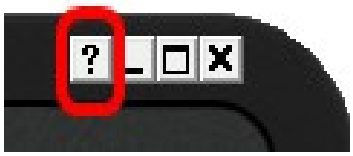
The **Network Status** button in the bottom right corner shows a green light in the example above. This light shows that the i2i application running at the Response Center has access to RDT's TempusNET system and is therefore able to receive Tempus Pro calls. If the light was red or yellow, this would indicate that the i2i terminal is unable to connect to all or some of the TempusNET system. In this instance users should click on the **Connection Status** button and the following window will be shown:



Connection status

This window lists the TempusNET machines that your i2i terminal is able to access. Any machines that cannot be accessed will be listed as "fail" instead of "connected". Users should inform their IT departments of any access problems. RDT can be contacted by pressing the help (**?**) button at the top of the i2i window.

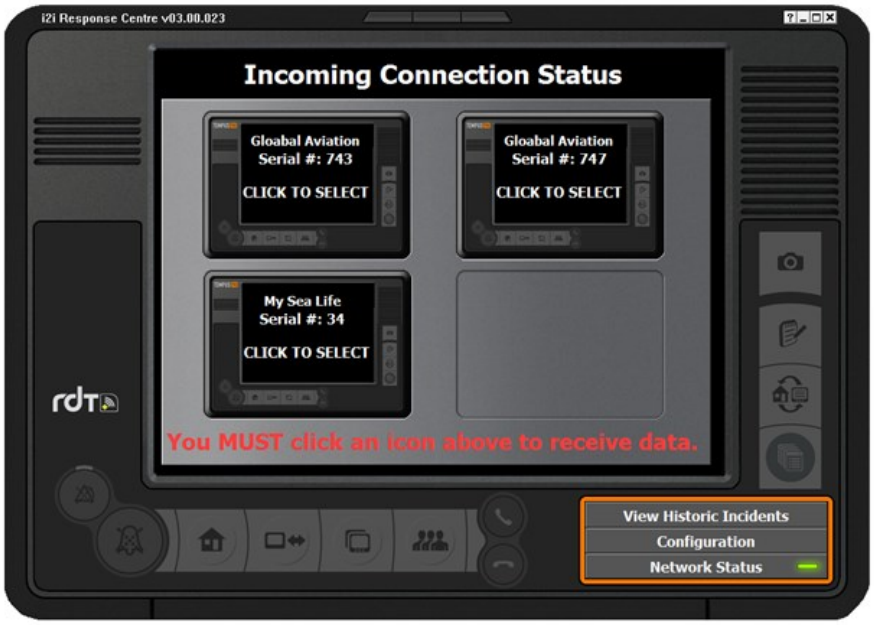
If the i2i shows an orange or red light in the network status box this could be caused by network changes at the Response Center e.g. changes in firewall settings. Users must ensure that no changes are made to their IT policies that would prevent the i2i installation from operating. Further information can be obtained in the i2i Installation Manual. This can be obtained by pressing the Help button on the i2i window.



Help button

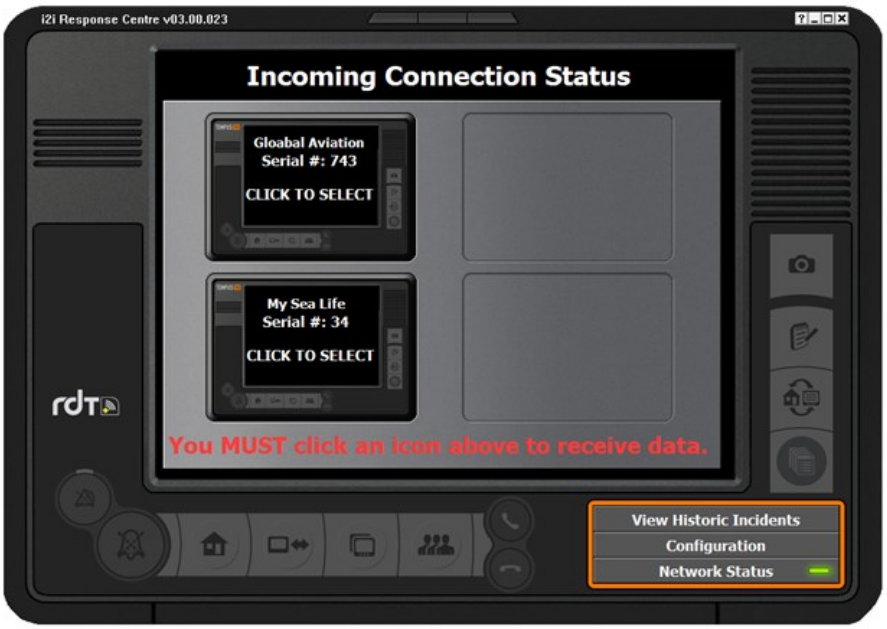
Pressing the help (**?**) button will bring up the “About i2i” window. This lists contact details for RDT and also provides a button that brings up this manual.

Once a data connection has been received, it will show in the window. An example of how a data connection will appear is shown below:



i2i with three incoming connections

In the example shown above there are three data connections shown. None have been responded to by an operator so any of the three could be accessed.



i2i with two incoming connections

In the example above, one call is now being responded to by another i2i operator at the same Response Center, consequently this call is no longer shown.

The two remaining connections shown as **CLICK TO SELECT** are free to be selected by double clicking on them.

Multiple calls from the same organization – different serial numbers

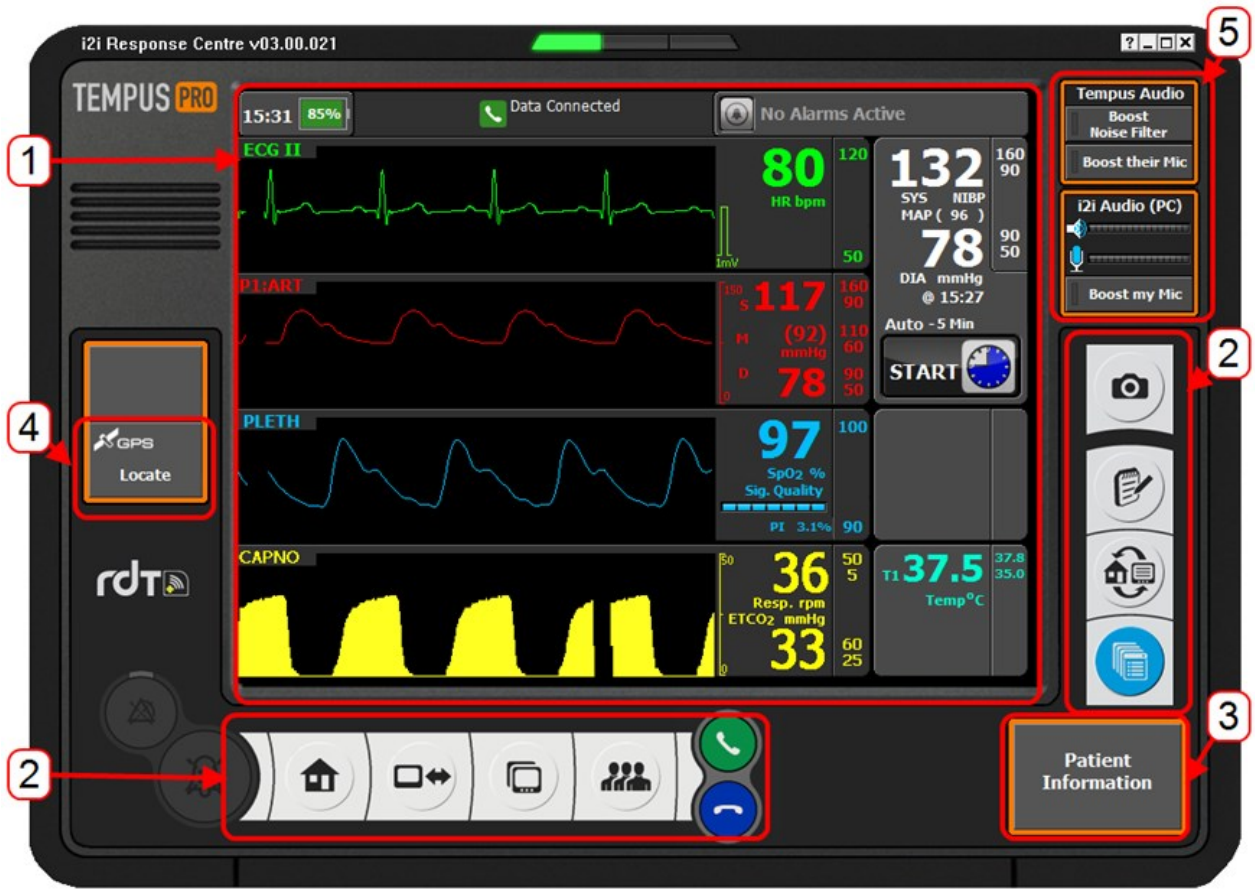
If multiple waiting connections were shown, you could identify which connection is from the Tempus Pro user that you are dealing with by asking them for what organization they work for (the organization's name will be shown on the connection icon). If two connections are from the same organization then you can ask for the Tempus Pro serial number (shown on the back of the Tempus Pro) to differentiate the connections.

1.7 The i2i window

The i2i window is designed to replicate the look and feel of the Tempus itself. Consequently it has representations of the slats on the front of the device. You should note that these are not features of the i2i.

The i2i window may be dragged, minimized, maximized etc. like a normal window.

The i2i window screen comprises the following main sets of controls:



i2i window with a data connection in progress

- (1) The central portion shows exactly what the Tempus shows. You will typically expect a delay of only 2-5 seconds before your screen is updated to show what the Tempus is showing. This delay can increase to up to 8 seconds if an ECG or Video is being received. These times are for the slowest links available.

  The delay is dependent on the type of communications link the Tempus is using to transmit the data over. 2-5 seconds is typical for an Ethernet or WiFi link over a broadband connection >64k baud.

- (2) The Tempus Pro control buttons. These graphically labelled buttons replicate the functions of the Tempus Pro. Clicking on them will bring up the instructions pertinent to that function.
- (3) The i2i database buttons. Clicking on these buttons will bring up a separate window which contains the patient database. The database is described later in this manual.
- (4) GPS button – this enables the i2i user to get a map-based location of the Tempus Pro .

Obtaining the position of the Tempus requires the GPS feature to be switched on and for the GPS to be able to obtain a fix e.g. to have a clear view of the sky – see the *Tempus Pro User/Operator Manual* for information on the use of GPS.

- (5) VoIP speaker and microphone level monitors – where the Tempus is transmitting voice to the Response Center using VoIP these give an indication of how loud the Tempus speaker should be coming through in the i2i user's headset and how loud the i2i user's voice is being picked up in their microphone.

Once a live incident is in progress the i2i will always show exactly what is being seen on the Tempus you are connected to. This concept means you will always be aware of what the Tempus operator is doing. This facilitates a team-based approach to dealing with the incident. Every time a key is pressed on the Tempus Pro you will see the result of it on the i2i window.

There are some exceptions to this rule:

1. During video capture and display on the Tempus
2. During ECG recording and viewing on the Tempus
3. When the data connection is being re-established by the Advanced Data Robustness (ADR) technology

These exceptions will be explained in more detail later in this manual.

You are also provided with a virtual keypad that allow you to control the Tempus remotely.

Important

The Tempus manages the data that it collects and transmits using device incident numbers. The device incident number is made up of a unique device serial number and an incremental incident number. This gives a device incident number that is unique in the world and cannot be duplicated. All data in a device incident is stored and transmitted using this number. A new device incident number is created every time the Tempus is turned on. This is the mechanism that is used at the Response Center to ensure that data for different patients is not mixed up.

1.8 Receiving voice calls using VoIP

The Tempus Pro can transmit voice signals to the Response Center in two ways, either:

- using the PSTN - where the voice call arrives in the conventional way on the i2i user's telephone handset on their desk i.e. as a normal telephone call or;
- using Voice over IP (VoIP) - where the voice communication is made through PC that the i2i is running on i.e. like a Skype call.

Receiving voice calls over the PSTN is the same as receiving a normal voice call at any home or business. The i2i user simply hears the phone ringing and answers it as normal. The Tempus user will inform the i2i user that they are transmitting data from a Tempus and the i2i user can receive the data as described in this manual.

Receiving VoIP calls is different in that the call is answered on the PC that the i2i user will also use to receive the Tempus data.

Important

It is important that the i2i user ensures their PC and network connection are suitable to receive VoIP traffic. Unlike a normal voice call, the user has controls on their PC which could disable their use of the PC for VoIP communications. Users should ensure their installation has been performed by a suitable IT operative who has confirmed VoIP operation.

While a VoIP connection is full duplex and real-time, the nature of all VoIP connections (such as those used in common or smart-phone based VoIP applications) is that a short delay occurs while the speaker's voice is coded, transmitted and then decoded at the recipient's end. RDT's VoIP implementation is no different. Users should expect a delay of approximately 1 second between their speech and the recipient hearing them. RDT advises that users avoid speaking over each other and adopt a means of handover when they finish speaking e.g. saying "over" when one has finished speaking.

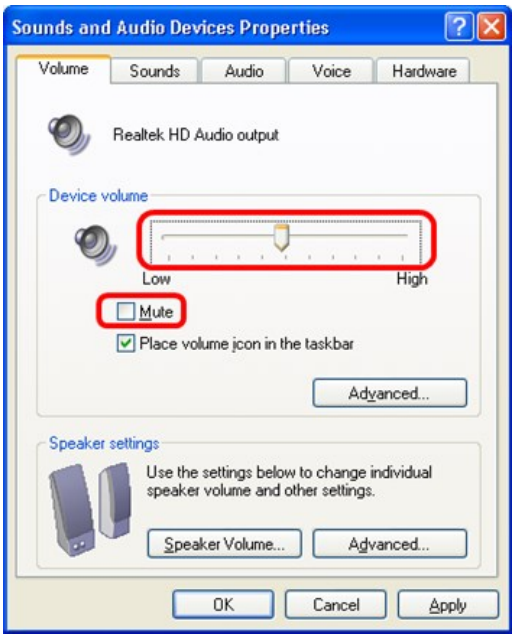
1.8.1 Configuring a PC to receive VoIP calls

To receive VoIP calls, users must ensure they have:

- A PC with a suitable headset or microphone/speaker attached.
- The PC properly configured to enable the use of both the speaker (to hear the Tempus user) and the microphone so the i2i user can be heard.
- Any additional equipment (headset) must be attached to the PC.

Setting the PC's speaker controls

For optimal headset speaker volume, check the PC control panel, sounds/audio devices. The volume must be turned up and not muted. PC control panel views will differ from those shown below depending on the hardware installed. An example of a PC control panel is shown below.



Adjusting the PC speaker volume

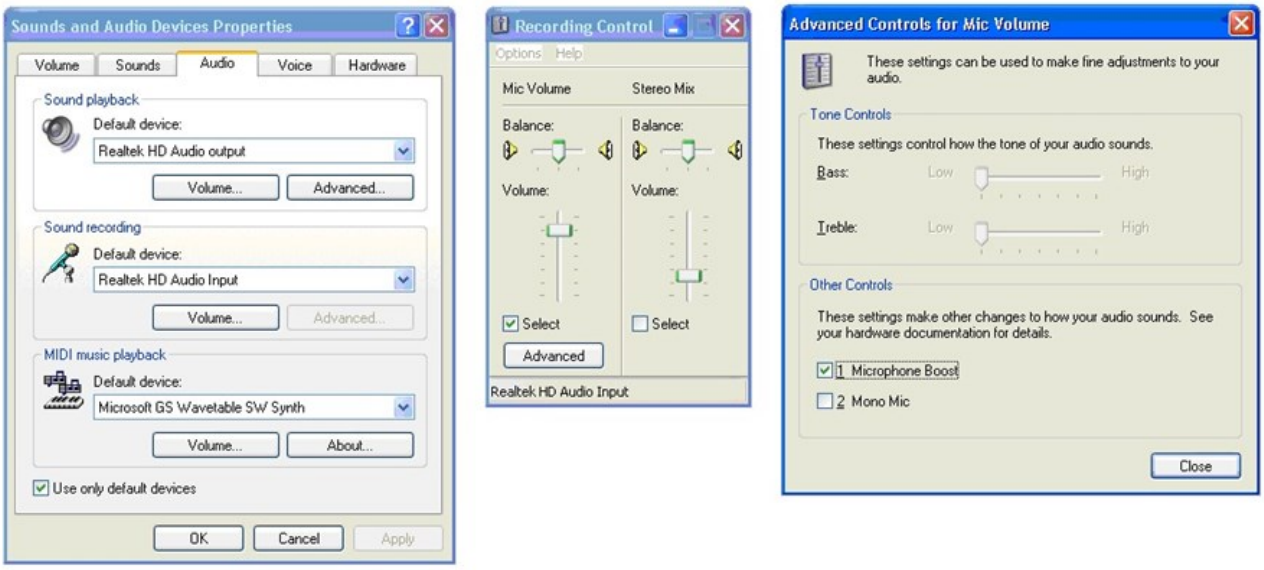
Ensure the PC speaker's volume is turned up.

Ensure the speaker mute function is NOT checked.

RDT recommends that wherever possible users use USB-based headset devices which provide in cable speaker volume control buttons which are easy to use. Users should take caution not to disconnect USB headsets from the PC while a VoIP connection is in progress.

Setting the PC's microphone controls

For optimal microphone performance, view the audio input control panel on the PC (also referred to as the "recording" device). Select "volume" to adjust the level that the remote user on the Tempus will hear. Some PC audio devices have a microphone "boost", where available this should be enabled as shown below. The "advanced" options are only available if selected in the "options" menu in the middle dialog shown below. An example of a PC control panel is shown below.



Example of PC microphone controls

1.8.2 Receiving VoIP calls

An incoming VoIP call can be recognized in two ways that are dependent on whether the data call has already been received within the i2i application.

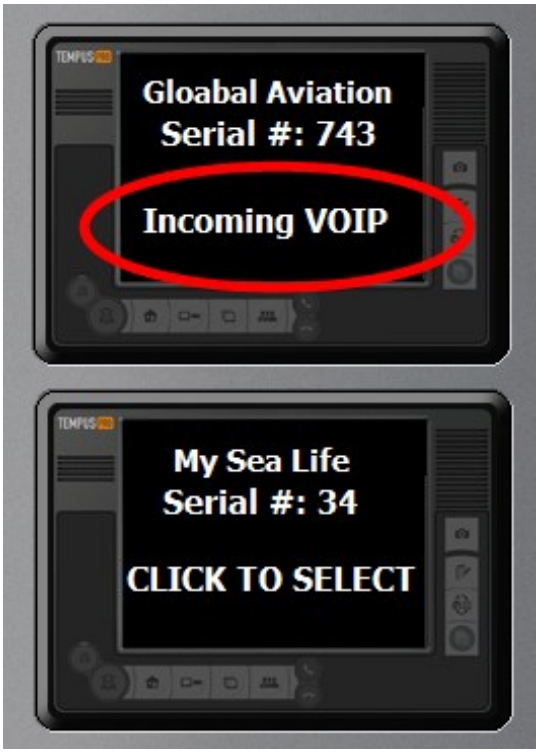
Important

Users MUST have the i2i application running on their PC to receive VoIP calls. If the application is not running users will not be alerted to the incoming VoIP call.

If the Tempus is already connected for data and a VoIP call is then connected, the i2i user will hear a telephone-style ringing sound from their PC and will see a window appear on their desktop alerting them that a VoIP call is being made (shown below). Clicking on the Accept button will connect the VoIP call.

Incoming VoIP call

If the data connection has not been made then the user will hear the ringing sound but when they look at the i2i window will see that the call has a VoIP connection associated with it (shown below).



VoIP call identification

Managing VoIP connections

Once connected, the i2i interface will show two VoIP Sound Monitors at the top right corner of the Tempus window (shown below).

VoIP sound monitors

The Sound Monitors show controls for the Tempus audio (at the top) and for the i2i audio (at the bottom). The Tempus is optimized for high quality VoIP audio call quality (even in high ambient noise environments such as aircraft) so users should find the voice quality acceptable in most situations. If the ambient noise where the Tempus is used is very high, or the Tempus user too quiet, the i2i user can adjust the Tempus headset settings remotely.

1. The “Boost their noise filter” control will increase active noise filtering to help remove additional background noise. Users should note that pressing this will result in a temporary (1-2 seconds) interruption of voice communication while the additional filters are engaged. i2i users should note that the additional noise filtering will result in a slightly lower quality voice reproduction (users may sound more nasal, less natural) although remaining perfectly understandable.
2. The “Boost their Mic” control increases the gain (or sensitivity) of the Tempus user’s microphone so that their speech will then be louder for the i2i user.
3. The i2i controls consist of two dynamic indicators of the loudness of the sound that the VoIP connection is transmitting between the i2i and Tempus users. The upper monitor indicates the loudness of the sound being played out of the PC speaker (i.e. how loud the i2i user should be able to hear the Tempus user). If this is low then the Tempus user needs to speak more loudly or the PC speaker volume needs to be turned up. The headset speaker level indicator will light as the remote Tempus user speaks to the i2i user. If this indicator lights but no sound is heard then check the Response Center PC speaker settings as described above – the speaker mute function may be checked.
4. The lower of the two monitors indicates the loudness of the sound being picked up by the PC microphone (i.e. how loud the i2i user is speaking). If this is low then the i2i user needs to speak more loudly or the PC microphone volume needs to be turned up. The Response Center microphone level indicator will light as the i2i user speaks to the Tempus user. If this indicator is not moving check the Response Center PC microphone settings as described above – the microphone level may be too low.
5. The “Boost my Mic” control increases the gain (or sensitivity) of the i2i user’s microphone so that their speech will then be louder for the Tempus user.

The Tempus Pro user does not see these monitors and they do not have controls for easily adjusting the volume of the link. If any volume adjustment is needed, the i2i user should ensure they optimize the controls on their PC (as described in "1.8.1 Configuring a PC to receive VoIP calls").

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2 Handling an incoming incident

2.1 New incidents and continuations of previous incidents

When a new connection has been made, the following dialogue will be presented in the top right hand corner of the screen:

Incident context dialog

This dialog is asking you to define the data connection as either **New**, **Continuation** or **Not Sure**.

2.1.1 New incident

Select **New** if this is a completely new incident for the current patient. This will be the most common selection you make as most incidents will be new ones.

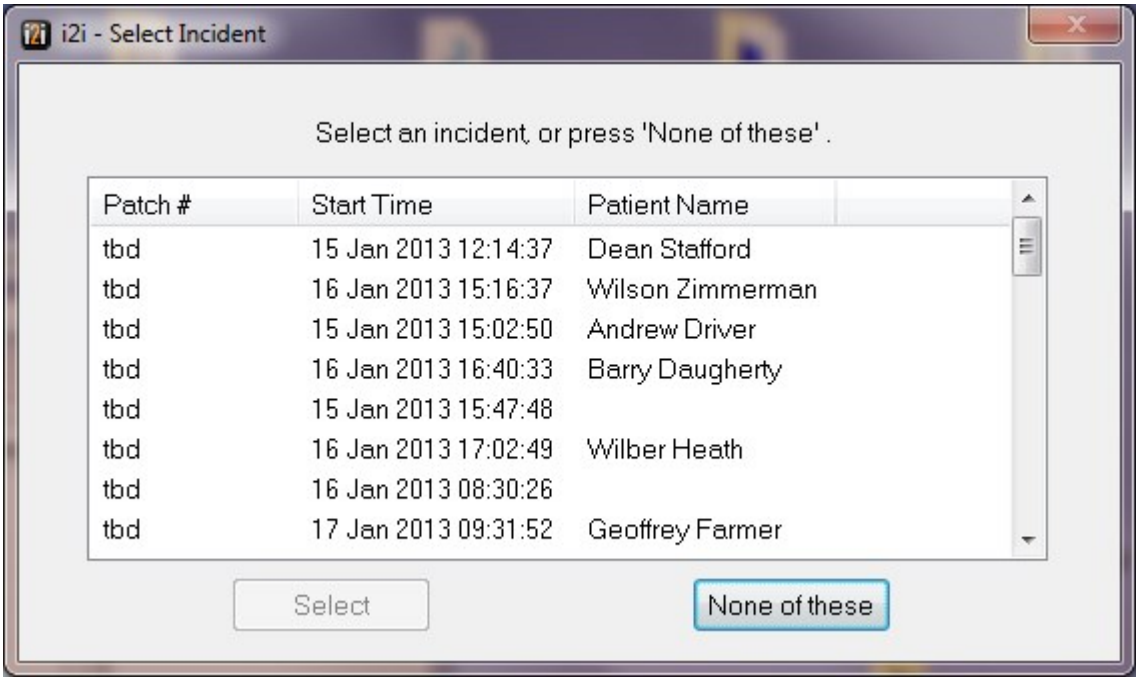
Selecting **New** when the incident is a continuation of a previous incident will mean the doctor will not have easy access to all the previous data for this patient. However it does not cause any serious problems such as mixing patient data up.

You will see that there are two radio buttons next to the **New** button:

- **Enter details now**: If this option is selected then when you press **New** you can enter the patient details now.
- **Enter details later**: If this option is selected (this is the default) then you can enter the patient details later.

2.1.2 Continuation or not sure

Select **Not Sure** or **Continuation** if you know that this incident is a continuation of a previous incident from this Tempus Pro for the current patient or think it might be. You will need to ask the Tempus operator some questions to confirm this. If you select **Not Sure** or **Continuation** you will be presented with the following dialogue:



Selecting a previous incident

This dialogue shows all the incidents on the connected Tempus Pro for the last 7 days.It is important that you check the details with the Tempus Pro operator. You can confirm the original incident start time and date, the patient name and the incident location with the Tempus operator. In some cases not all this information will be displayed. However the original incident start time and date will always be available and you should always check this with the Tempus Pro operator.

You can select one of two buttons:

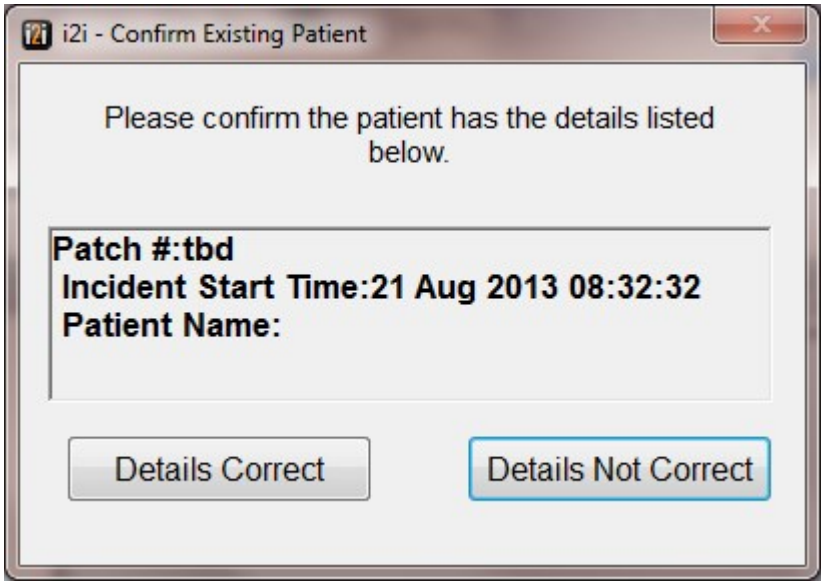
- **Select**: This button will be greyed out until you have highlighted an incident from the list by clicking once on the item you want in the list with the mouse. The item will then be highlighted in the normal windows fashion. Before pressing **Select**, confirm the details with the Tempus operator. Once you have pressed select data from the current incident will be merged with the previous incident and the patient name will be set to that of the current incident if it is set and differs from that of the previous incident. This is an important decision. If you are not sure press **Cancel** and you will be returned to the “Select Incident” dialogue.
- **None of These**: Press this button if none of the incidents or patients in the list matches the information being given to you by the Tempus operator. When you press **None of These** you will return to the new or existing incident dialog box as seen in "2.2 Establishing patient context".

2.1.3 Automatic continuation of an existing incident

If the Tempus is connected to the i2i and then for some reason it is disconnected and reconnected without being switched off and on, then the i2i will assume that the same patient is still connected to the Tempus.

If the Tempus has been put on a different patient and not switched off and on between patients then the assumption that the Tempus is being used on the same patient would not be valid.

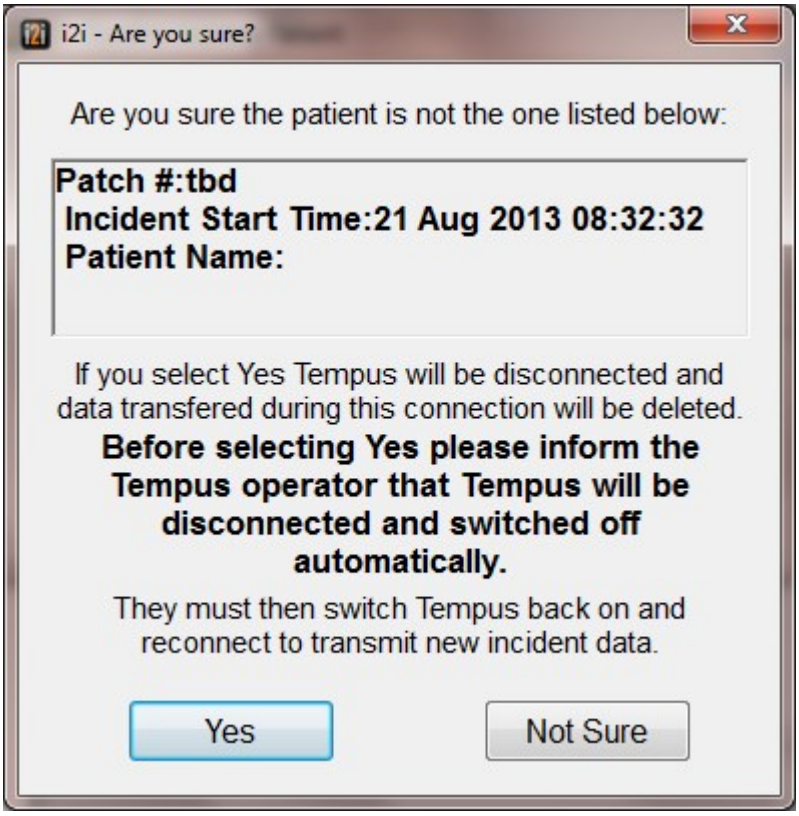
In order to enforce this protocol you will be presented with the following screen when the Tempus is reconnected to the i2i without being switched on and off. This is a perfectly valid thing to do as long as the Tempus is still being used on the same patient.



Confirming the patient is the same

You can select one of two buttons:

- **Details Correct**: Pressing **Details Correct** will confirm that the patient connected is the one shown. Before pressing **Details Correct** you should check with the Tempus operator that the patient shown is the one currently connected to Tempus. In some cases not all this information will be displayed. However the original incident start time will always be available and you should always check this with the Tempus operator. Once you have pressed **Details Correct** you have completed the Incident and Patient Context process for this connection. You may need to go on and enter patient and incident details if these are not yet complete.
- **Details Not Correct**: Press this button if the patient connected to the Tempus is not the one listed in the dialogue box. When you press this button you will be presented with the following dialogue box:



Details not correct dialog

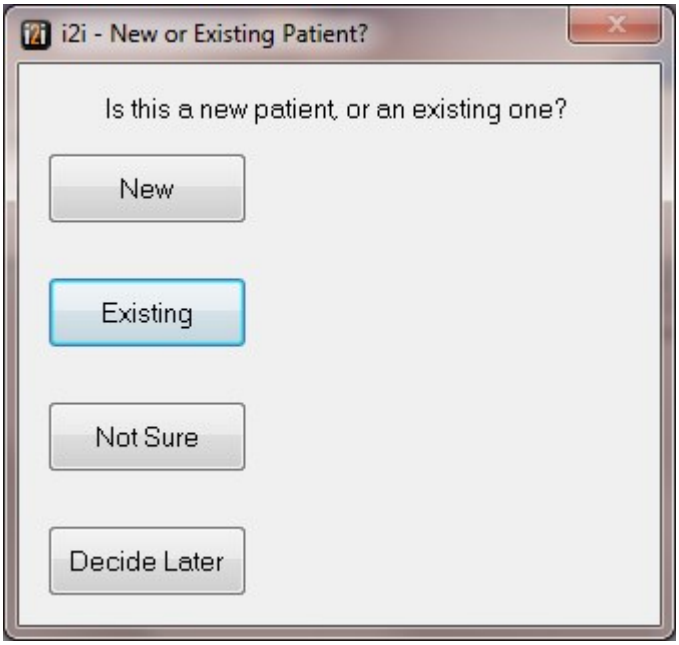
This dialog box asks you to confirm that the connected patient is not the one listed: You can select one of two buttons:

- **Yes**: Select **Yes** if the patient connected to the Tempus **is not** the one listed or if the incident start time **does not** match with what the Tempus operator is telling you. **Selecting Yes will cause the automatic disconnection and switch-off of the Tempus**. You should inform the operator of this before pressing **Yes**. You should also tell the operator they will need to switch the Tempus back on and re-connect, in order to start a new incident for the new patient.
- **Not Sure**: Selecting **Not Sure** will bring you back to the previous dialogue.

2.2 Establishing patient context

Once you have completed the Incident Context process you will be presented with the following dialogue, unless one of the following conditions is true:

- If you had **Enter Details Later** selected on the main incident context dialogue. In this case you will not be asked to establish Patient Context until you are ready to. You can establish the patient context at any point during the rest of the incident by pressing the **Select Patient** button in the main Patient Record Display. Doing this will bring up the dialogue shown below. Remember this is accessed by pressing any of the four active Patient Record buttons in the bottom left hand corner of the main screen. This will be covered in more detail in "3 The i2i patient record".
- If the connection is a “Forced Continuation” or you have selected **Continuation** on the main incident context dialogue then Patient Context and patient details will normally have been completed. However you may need to enter some patient and incident details, this is explained in section "3.3 Incident data".



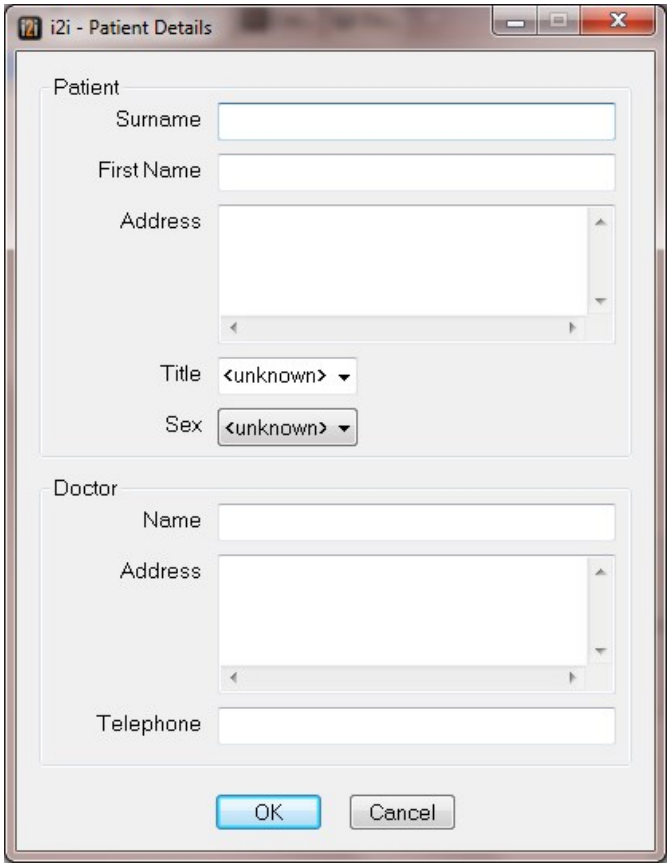
New or existing patient

You can select one of four buttons: **New**, **Existing**, **Not Sure** or **Decide Later**.

2.2.1 New patient

Select **New** if the connected patient is a new patient who has not been connected to the i2i before. This will be the most common situation.

When you press **New** you will be presented with the following dialogue box:



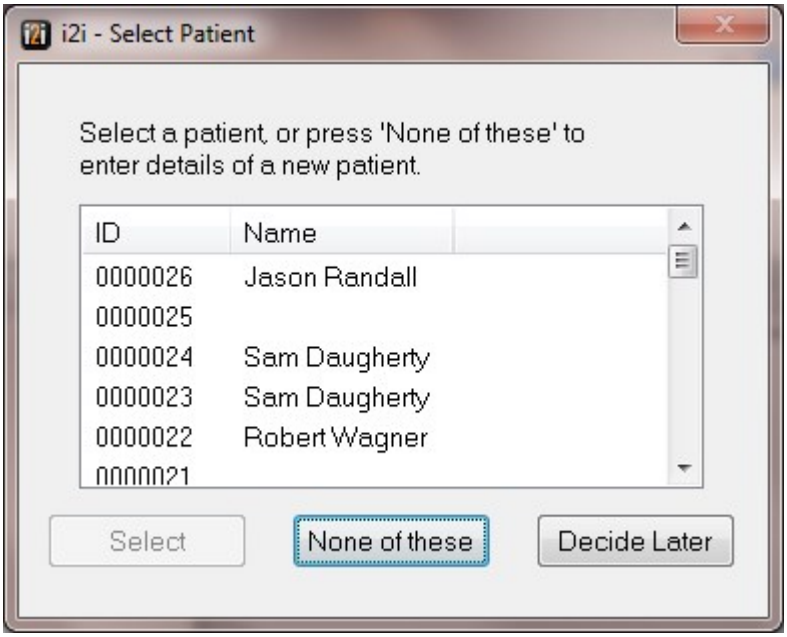
Patient details

This dialogue box is used to enter all the patient details. This dialogue should be completed by filling in each field. You can tab from field to field. None of the fields are compulsory but the more information you fill in the more useful the record will be in future. As a minimum you should aim to complete Name. You can defer the process of filling in this dialogue by pressing **Cancel**.

2.2.2 Existing patient

Select **Existing** if you think the connected patient may already have a record in the i2i database. If you are wrong in thinking this you will still be able to say the patient is new.

When you press **Existing** you will be presented with the following dialogue box:



Existing patient dialog

This dialogue shows all the patients already in the database. You can sort them by ID or Name by clicking on the relevant column header with the mouse. If the patient currently connected appears in this, you can select one of three buttons:

- **Select**:

  This button will be greyed out until you have highlighted a patient from the list by clicking once on the item you want in the list with the mouse. The item will then be highlighted in the normal windows fashion. When You press **Select** you will be presented with the following confirmation dialogue:

Confirming the patient

Before pressing **OK** you should check with the Tempus operator that the patient shown is the one currently connected to Tempus. In some cases not all this information will be displayed. Once you have selected **OK** you have completed the Patient Context process for this connection. You may need to complete additional patient details.

This is an important decision. If you are not sure press **Cancel** and you will be returned to the “Select Patient” dialogue.

- **None of These**:

  Select **None of These** if the connected patient does not appear in the list. When you press **None of These** you will be presented with the following dialogue:

Confirming a new patient

  If you select **Yes** you will be presented with the “Patient Details” dialogue. This dialogue box is used to enter all the patient details. Completing this dialogue is explained in detail in section "3.6 Using the tabs for the patient notes, video images, chart data and ECG views". You can defer the process of filling in this dialogue by pressing **Cancel**.

  If you select **No** you will be taken back to the “Select Patient” dialogue.

- **Decide Later**:

  Select **Decide Later** if you want to defer this decision until later in the incident. If you select **Decide Later** you can establish the patient context at any point during the rest of the incident by pressing the **Select Patient** button in the main Patient Record Display. Remember this is accessed by pressing any of the four active Patient Record buttons in the bottom left hand corner of the main screen. This will be covered later in the manual.

You should now have entered what type of incident it is and either completed or deferred entering the patient details. You can complete the process later by pressing the **Select Patient** button in the main Patient Record Display. Remember this is accessed by pressing any of the four active Patient Record buttons in the bottom left hand corner of the main screen. This will be covered later in the manual.

2.3 More detail on the initial screen

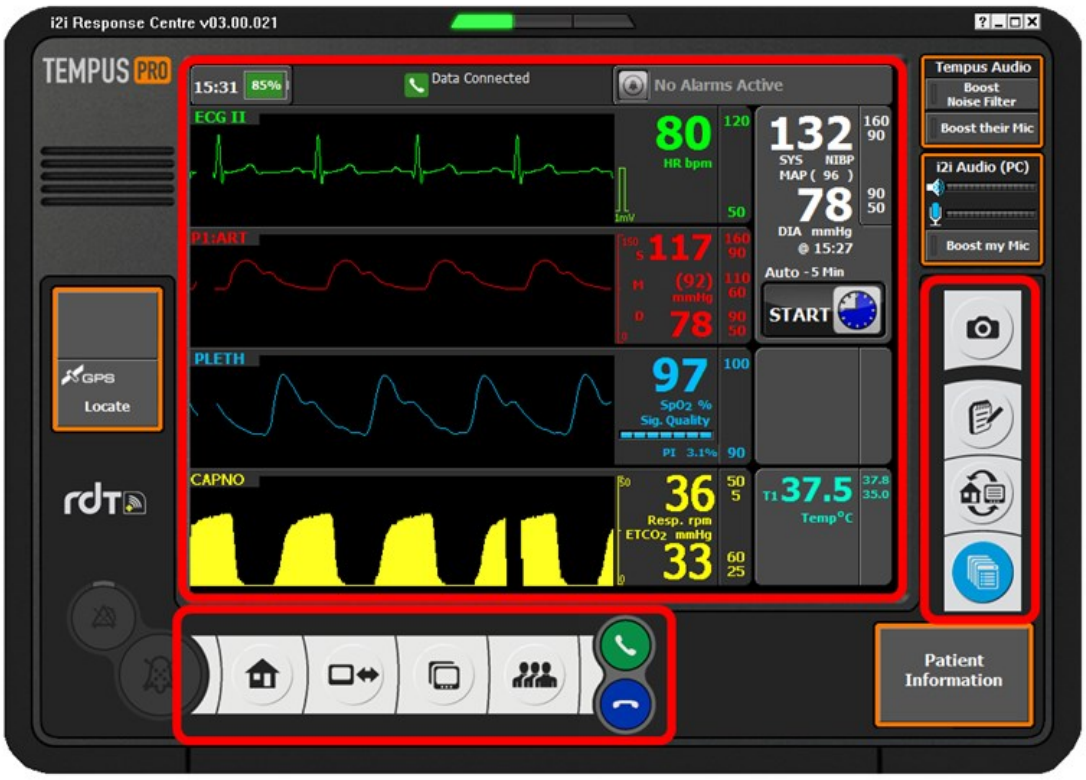
The image below shows what the screen would look like if all the medical parameters were being measured.

2.3.1 Controlling the Tempus Remotely

> **WARNING**
>
> When connected to a Tempus, the i2i application displays the waveforms that are displayed on the Tempus Pro. Users of i2i are advised that this data is transmitted using the UDP protocol and therefore any data that is dropped, lost or delayed during the streaming process will not be replaced. In the event that packets of waveform data are lost, they will appear as gaps in the waveform that is displayed on the i2i interface.

The i2i allows the user to control all aspects of the Tempus remotely (except any controls that turn off, suspend or silence alarms).

The i2i window gives all the same controls as the Tempus, this includes pressing the touchscreen. For full details of how to control the Tempus, refer to the *Tempus Pro User/Operator Manual*. The various controls are shown below.



The remote controls of the Tempus

Pressing these buttons or controls at any time will cause the same effect as if they were pressed on the Tempus . Consequently, if pressing the button on the Tempus would bring up a menu or cause a device to take a reading, then the same effect will be caused if the button is pressed at the i2i.

> The Camera button in the i2i application only evokes the photo taking process in the same way as if the button is press and held on the Tempus Pro itself. The waveform snapshot feature is not possible from i2i.

2.3.2 The remote display area (RDA)

This area always displays what is being displayed on the Tempus. This means you can always see and react to what the Tempus operator is seeing. This concept, in conjunction with the virtual keypad, encourages a team-based approach to handling the incident.

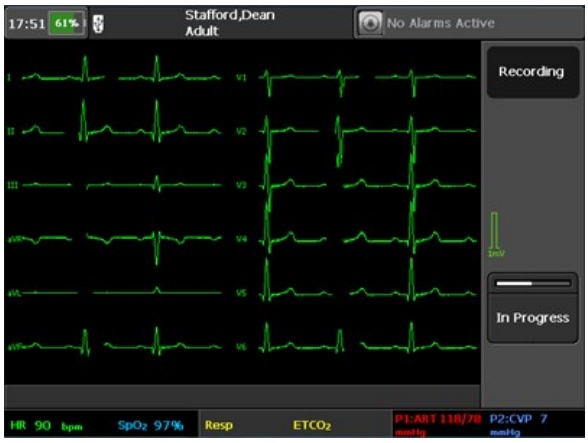
The layout and function of the Tempus screen is explained in detail in the *Tempus Pro User/Operator Manual*.

Differences between the Tempus display and the RDA on the i2i

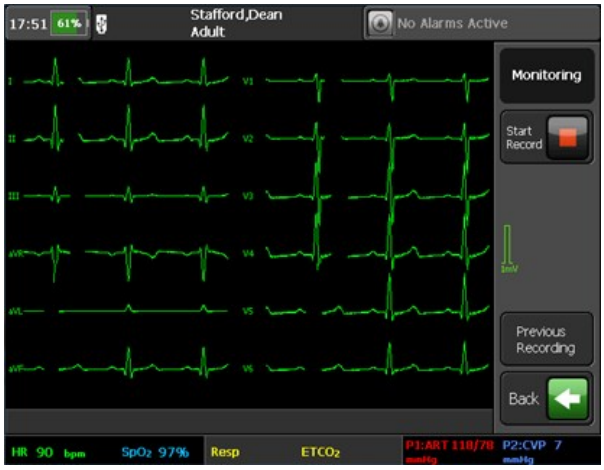
In the following cases the RDA will not show exactly what is being displayed on the Tempus. This is because in these cases the Tempus is collecting large volume information for later transmission, such as still videos and ECG traces.

> The Tempus Pro displays filter settings in the bottom left hand corner of the 12-lead ECG display. However, these filter settings are not reproduced in the i2i remote display area.

- Recording an ECG:

Tempus screen (Tempus Pro patient monitor)	Remote data area (i2i)
	

- Viewing an ECG:

Tempus screen (Tempus Pro patient monitor)	Remote data area (i2i)
	

- Taking a video picture:

Tempus screen (Tempus Pro patient monitor)	Remote data area (i2i)
	

2.4 Tempus alarms

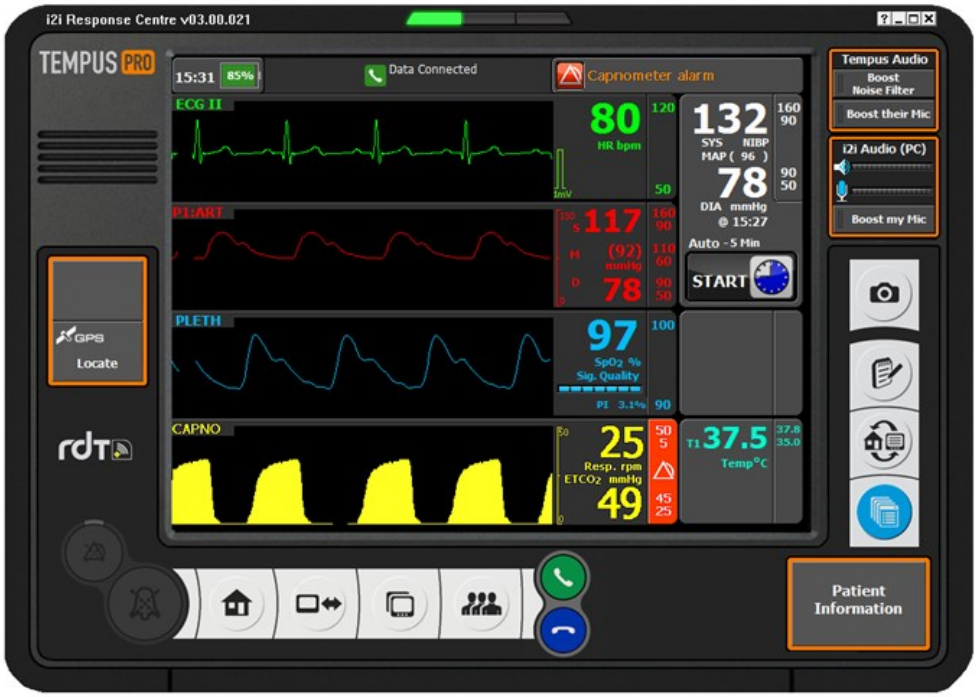
Since the i2i displays in real time the same information as the Tempus, it will also display visible alarm manifestations. These are detailed in the Tempus Pro User Manual.

WARNING

The alarm functions of the Tempus are intended to be used by the attendant user only. If the device is connected to a Response Center 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. The i2i system at the Response Center is not equipped with alarm silencing or suspending controls.

CAUTION

The i2i only displays the visible alarm manifestations from the Tempus, it does not generate any audible alarms.



i2i showing an alarm

The i2i is intended to allow users to see and share data in real time, it does not allow users to silence or cancel any alarms or to enable users to turn alarms off. Therefore the alarm silence and alarm suspend buttons are not functional (this includes both the buttons on the main window and the alarm controls that can be accessed through the All Alarms Menu and individual parameter settings menus).

Alarm Suspend and Silence buttons are inactive on i2i

2.5 Receiving photos and 12-lead ECG recordings

When photos or ECGs are being transmitted to the i2i the “File Transmission Status Bar” will show the progress of transmission as a percentage.

2.5.1 Receiving and annotating video pictures

When a video image arrives on the i2i the following window will be displayed:

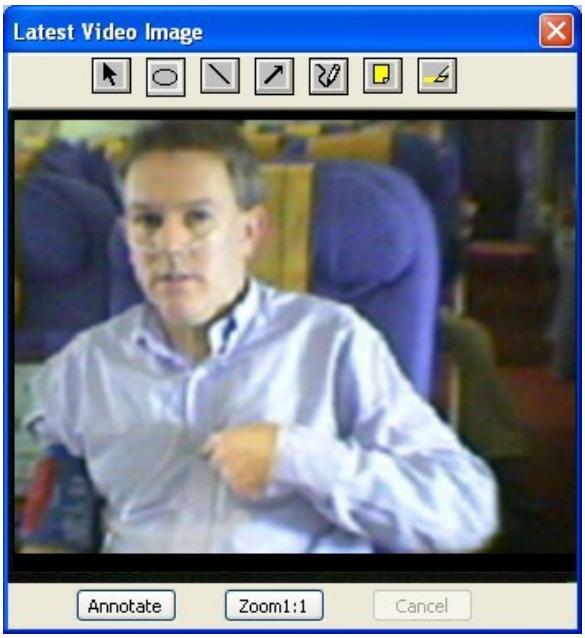


Image window

This window has two buttons on it: **Annotate** and **Zoom 1:1**.

Annotating videos

Selecting **Annotate** will allow bring up a tool bar that will allow you to mark the video image up for transmission back to the Tempus. Once you have pressed the **Annotate** button the window will be as shown below:

Annotated image – ready to send

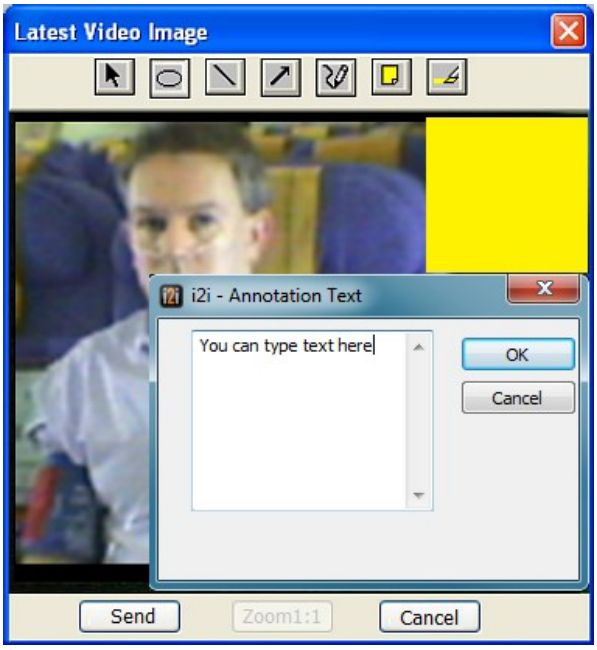
The tools provide the ability to draw:

- ellipses;
- straight lines;
- arrows;
- free lines;
- colored boxes (which can include text);
- highlighted areas.

To select a tool, click on it with the left mouse button, then click on the image with the left mouse button and keep the button pressed to draw or select on the image with the tool you are using.

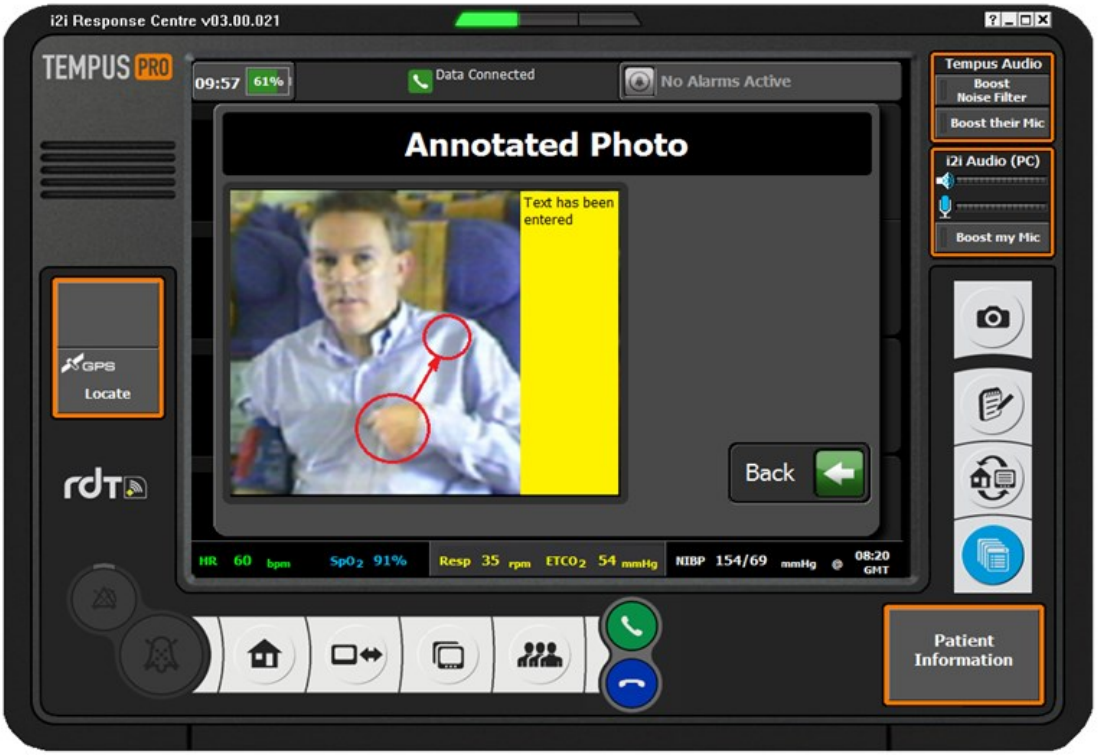
To delete annotations from the image, click on the **Cancel** button.

To add text to the image draw a text box using the “Note Tool”. Once you have drawn your text box (shown in yellow in the image below) then a dialog appears asking for the text to be typed in as shown below:



Inserted text - ready to send

When you have finished annotating the image you can click **Send** to send the annotation to the Tempus or **Cancel** to cancel the annotation. Once you have sent the annotation it will be displayed on the Tempus Pro and also on the i2i. The i2i will look as shown below:



Annotated image and text – received on Tempus Pro

Annotations cannot be sent if the annotation or the original image originates from previous incidents. Annotations can also not be sent whilst video images or ECGs are being recorded or captured on Tempus or whilst images and ECGs are being transmitted from Tempus.

The video window can be resized in the normal Windows fashion by dragging it with the cursor.

Zooming videos

The **Zoom 1:1** button is used to remove any zoom from the image. The image can be zoomed by “Left Clicking” on the image with the mouse and drawing a rectangle round the area you wish to zoom whilst keeping the left mouse button depressed. Pressing **Zoom 1:1** will remove any zoom factor from the image.

2.5.2 Viewing moving video images

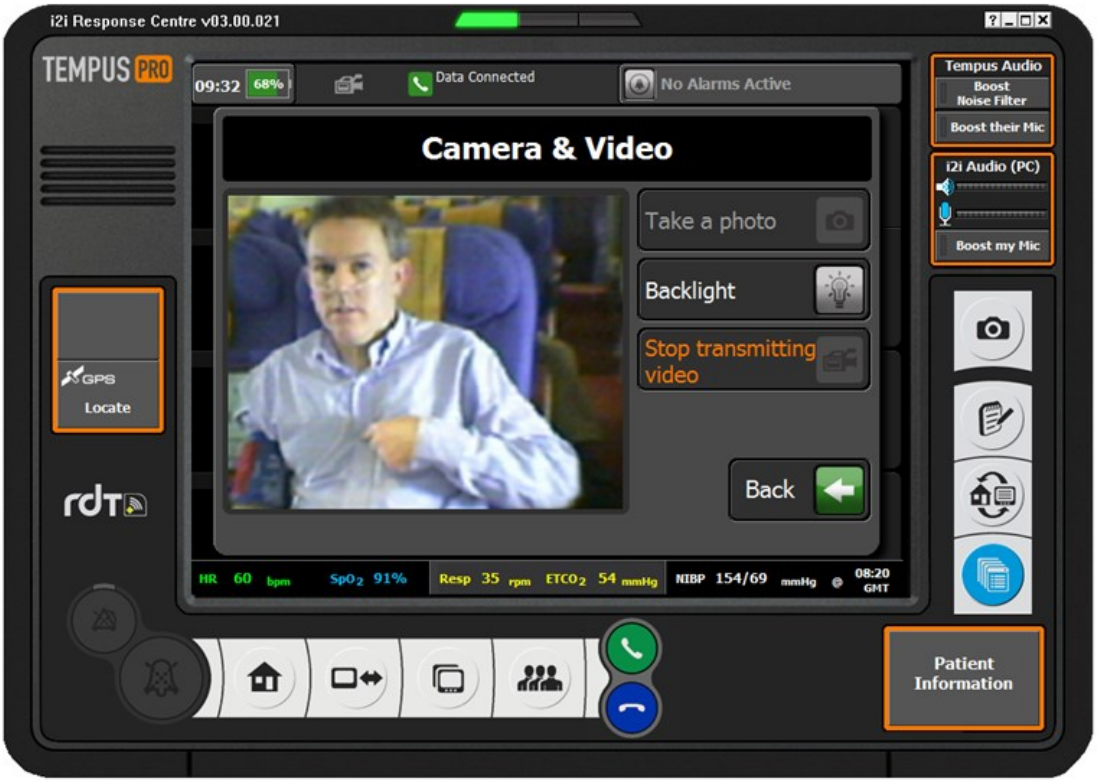
In addition to sending still digital pictures, the Tempus Pro is also capable of sending moving video images if it is connected over an Ethernet or WiFi network with suitable bandwidth (typically 64 kbps or more).

To receive moving video, once the camera is on, the **Transmit Video** button must be pressed.

Transmit moving video button

You will then receive the moving image stream on your screen.

The image will be better quality if the user moves the camera slowly. Fast panning of the camera may produce poor quality images.



Receiving moving video images

2.5.3 Receiving and viewing 12-lead ECG recordings

When an ECG arrives at the i2i the ECG Tab of the Patient Record Display will automatically be displayed showing the latest 12-lead ECG recording. The i2i screen will look as shown below:

12-lead ECG recording ECG window

The details of this view are explained in "3.6 Using the tabs for the patient notes, video images, chart data and ECG views". The details of analysing and viewing an ECG are explained in "3.7 Functions of the ECG".

2.6 Ending a connection

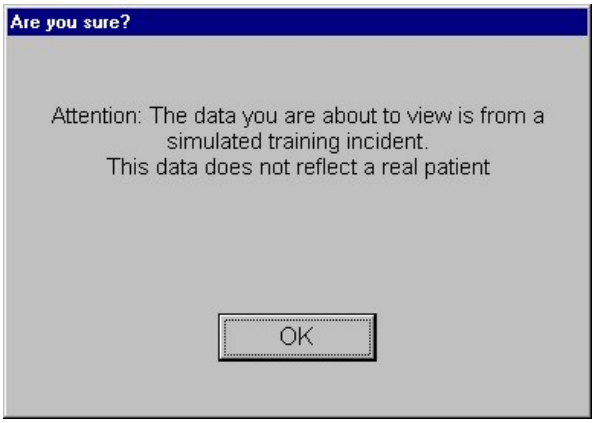
The process of ending a connection is explained in detail in the *Tempus Pro User/Operator Manual*.

Ending a connection is a two-stage process:

- Press  once to disconnect the voice and data links (a 10 second countdown will appear before the links are disconnected).
- You will be given options for disconnecting either the voice or data links during the countdown.

2.7 Demonstration data warnings

The Tempus can be set to transmit computer generated data for use in demonstrations. If the Tempus has been set into “Demo Mode” at any point while it is switched on then it should not be used with a real patient (only to demonstrate the product e.g. for training purposes). If the Demo function has been switched on then the i2i will display a dialog to note this.

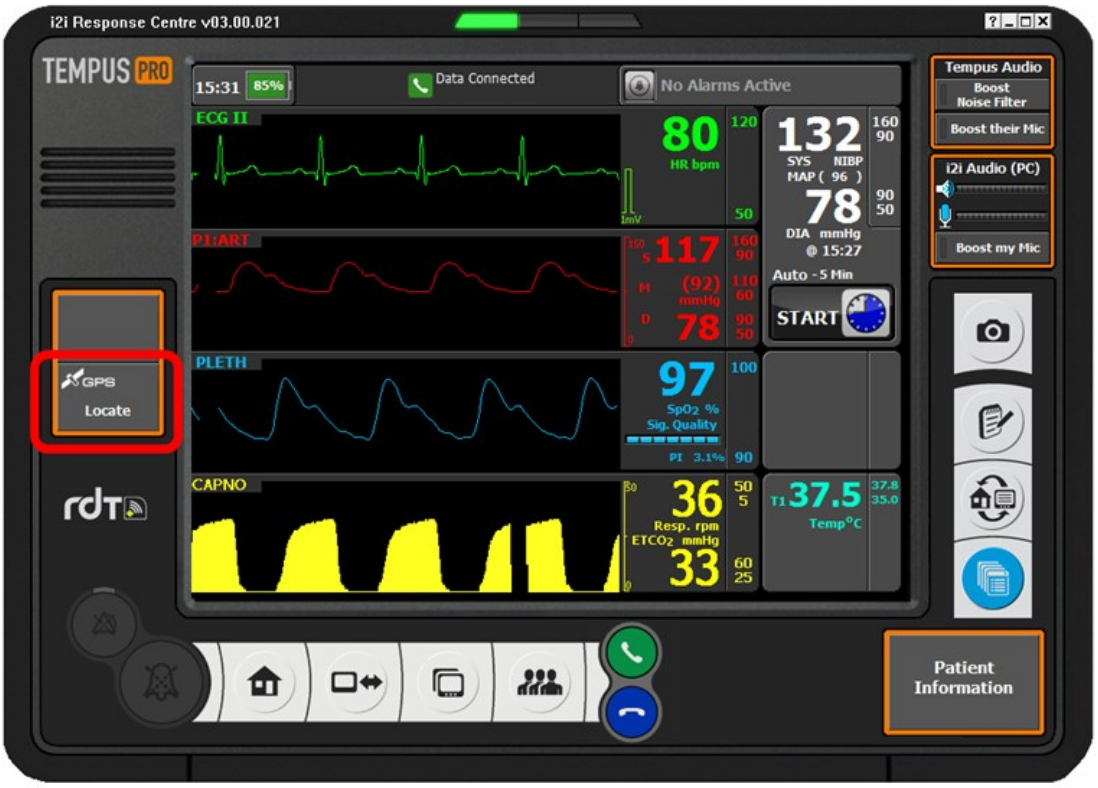


Simulated data notice

This warning will be displayed every time the record for this incident is accessed.

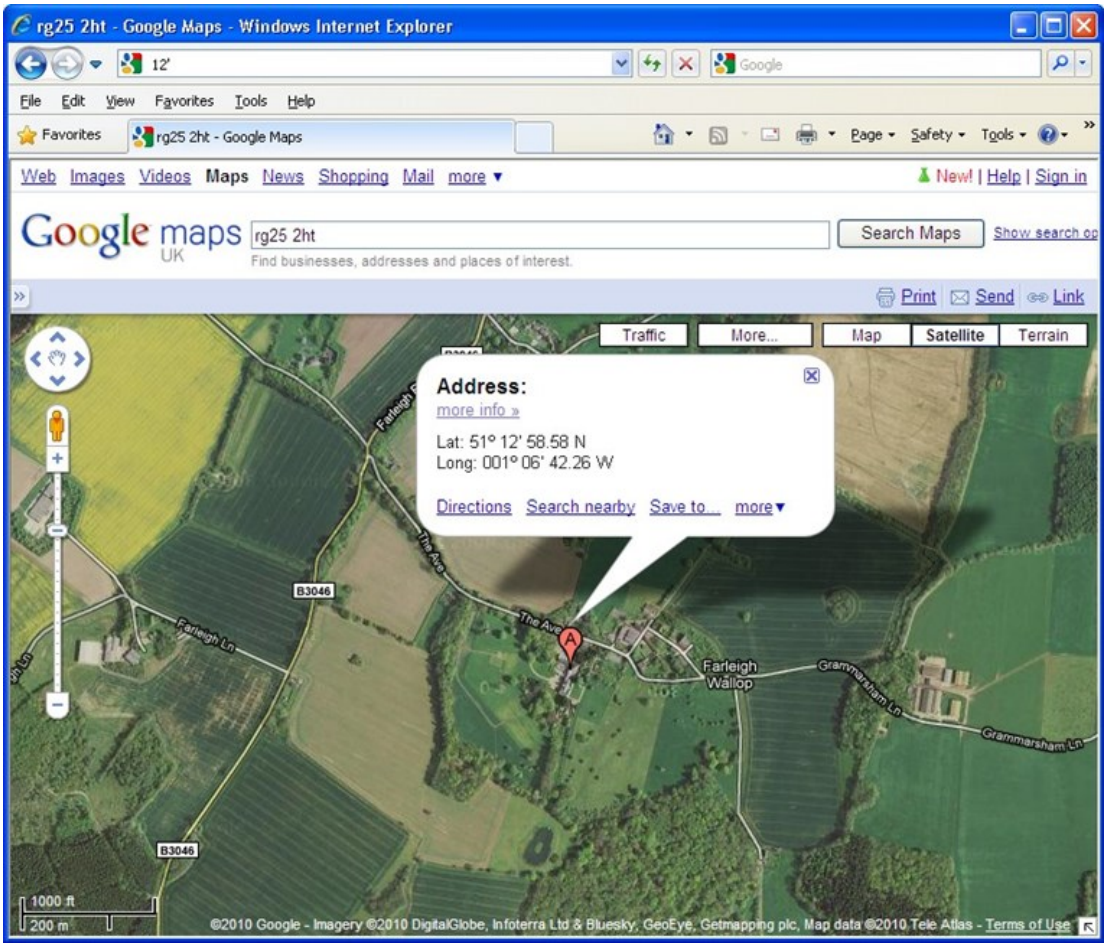
2.8 GPS location

If the GPS receiver on the Tempus is turned on and is able to obtain a fix of the unit's location, then you can use the **GPS** button on the i2i to identify the unit's location.



The GPS button

Simply click on the **GPS** button and then the i2i will bring up a new window (using whichever web browser is enabled on your PC). This will show the unit's location superimposed onto a 'Google maps' webpage, an example is shown below.



GPS position

This shows the unit's location and its longitude and latitude.

Blank page

3 The i2i patient record

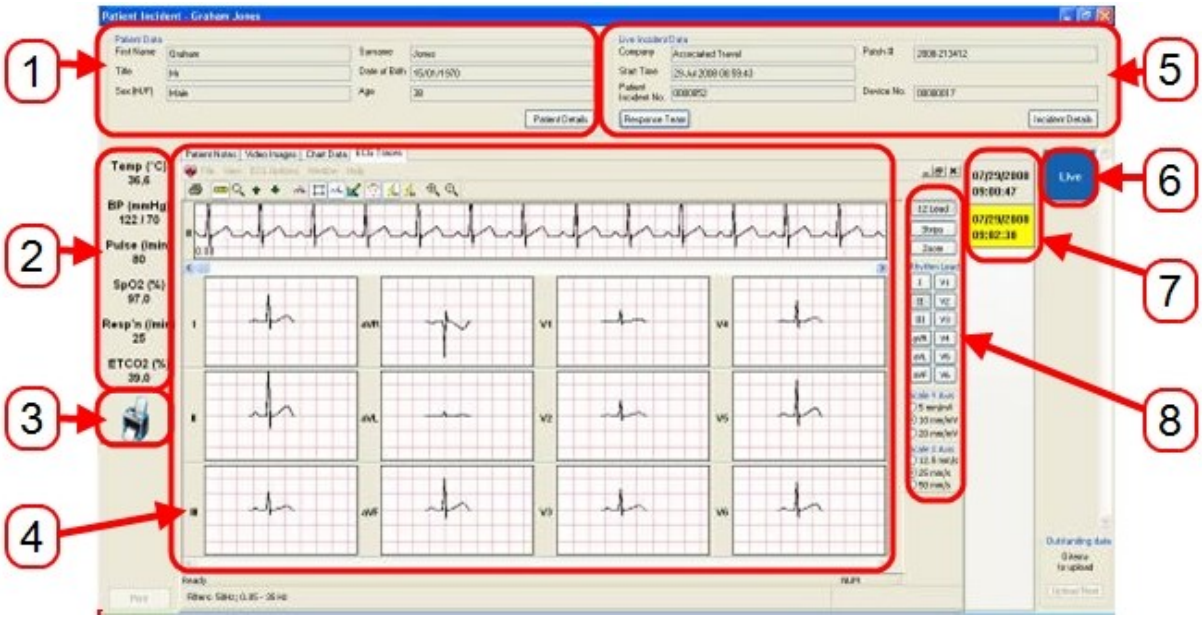
3.1 Patient record display

All information transmitted to the i2i is displayed as it arrives. In addition this data is stored in a database for later retrieval, analysis and comparison.

All information in the database, whether being accessed during a live incident or off line after an incident, is accessed via one of the four buttons in the patient records group.

Database button

To access the patient records during a live incident click either **Patient Notes**, **Chart**, **Video Images** or **ECG**. Clicking **ECG** will display the window shown below:



Patient record display

(1) Patient details

(2) Real time vital signs readings

(3) Print button

(4) ECG

(5) Incident details

(6) Incident selector

(7) ECG time and date stamp

(8) ECG tools

There are six main areas of information on the patient database. These are described in detail in the following sections.

3.2 Patient data

This section contains all information entered about the patient. In the view above, the patient data has already been entered. If no patient data has been entered then this section will be as shown below:

Patient data area

Pressing **Select Patient** will display the “Patient Details” dialogue.

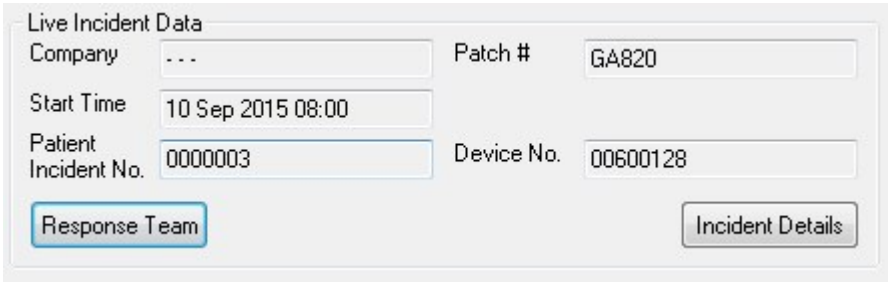
If patient data has been entered this section will be as shown below:

Patient data entered

To edit the patient details select **Patient Details** this will display the “Patient Details” dialogue.

3.3 Incident data

This area is used to display and enter information about the incident. If no incident details have been entered then this section will be as shown below:



Incident data entered

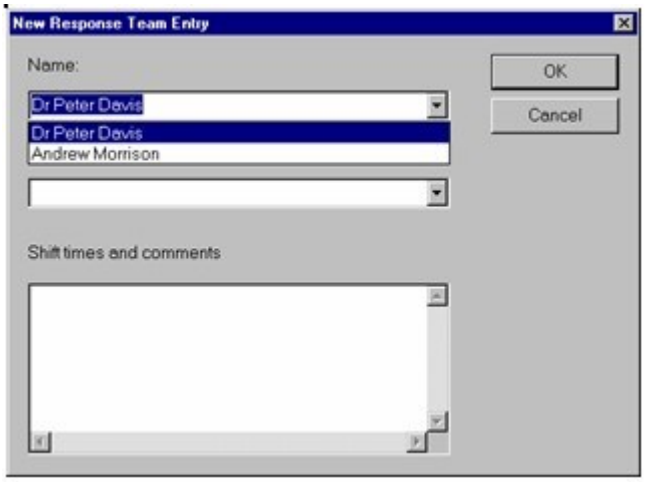
It should be noted that the Incident Start Time, Patient Incident Number and Device Number are completed automatically.

3.3.1 Entering and editing response team details

You can add information about the individuals handling the incident at the Response Center by clicking **Response Team** this will display the following dialogue:

Response Team window

You can select **Add** to add a new team member or you can select **Close** to exit the dialogue. You can also view and edit entries by selecting an entry from the list with the mouse and then pressing **View** or **Edit**. If you select **Add** the following dialogue will be shown:

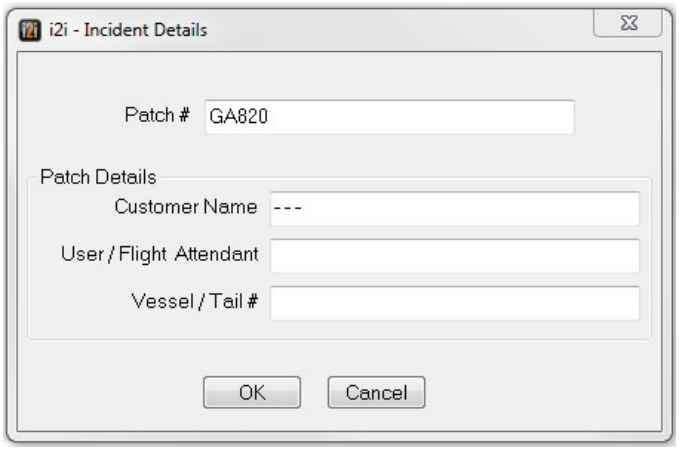


Editing the response team

You can either select existing names and roles from the drop down list boxes or type new Names or roles into the edit box. You can type free format notes such as shift times and other comments in the “Shift times and comments” box. Selecting **OK** will save any changes and take you back to the previous dialogue. To exit without saving changes select **Cancel**.

3.3.2 Entering and Editing Incident Details

Clicking **Incident Details** will display the dialogue below.



Incident Details window

Important

The patch number field must be completed for every incident.

None of the fields under “Company Details” are compulsory. However the database will be more useful if as much information as possible is entered. To save changes and exit click **OK**. You will then be asked to confirm changes. To exit without saving changes select **Cancel**.

3.4 Real time data display area

When you are in the patient database you will not be able to see any real time readings being transmitted from the Tempus and displayed on the i2i window. To allow you to continue monitoring real time data whilst in the patient database any real time readings are displayed on the left hand side of the window. These readings are updated in real time at the same rate as those shown in the i2i window.

3.5 Outstanding data area

This area shows if there are any outstanding video images or ECGs to upload. This information is only shown if the ECG or the Video tab is selected.

3.5.1 Uploading pictures, ultrasound images or ECGs recorded off-line during the current device incident

If Tempus is connected to the i2i then any video images or ECGs that are recorded are immediately transmitted to the i2i. If ECGs or video images have been recorded whilst the Tempus was not connected to the i2i, but during the current incident, then these ECGs and Video pictures are placed in a queue ready for later transmission to the i2i. They are not automatically transmitted when the connection is established because an unknown and potentially large number could have been recorded. Transmitting a large number of ECGs or Video pictures would hog the communication line and may delay the transmission of newer more important data, such as an ECG that has just been recorded.

For this reason the boxes shown below are displayed on the Video and ECG tabs. These boxes show if any ECGs or video images are in the queue awaiting transmission. It would normally be expected that the Tempus operator would tell you if they had recorded any ECGs or video pictures whilst not connected. However it is very simple for you to check by looking at the relevant area on the ECG and Video tab.

In this case there are 3 ECG files to upload. To upload the next ECG click **Upload Next**. The ECG will then be transferred and displayed in the normal manner. The same is true for a Video picture except that all off line video images are low resolution. When the transfer has been completed the outstanding data area will show that there are now only two ECGs left to upload.

This approach to off-line Video pictures and ECGs allows you decide the most appropriate point at which to upload the information.

Please also see "4 Off-line monitoring" for instructions on recording and transmitting off-line data.

3.6 Using the tabs for the patient notes, video images, chart data and ECG views

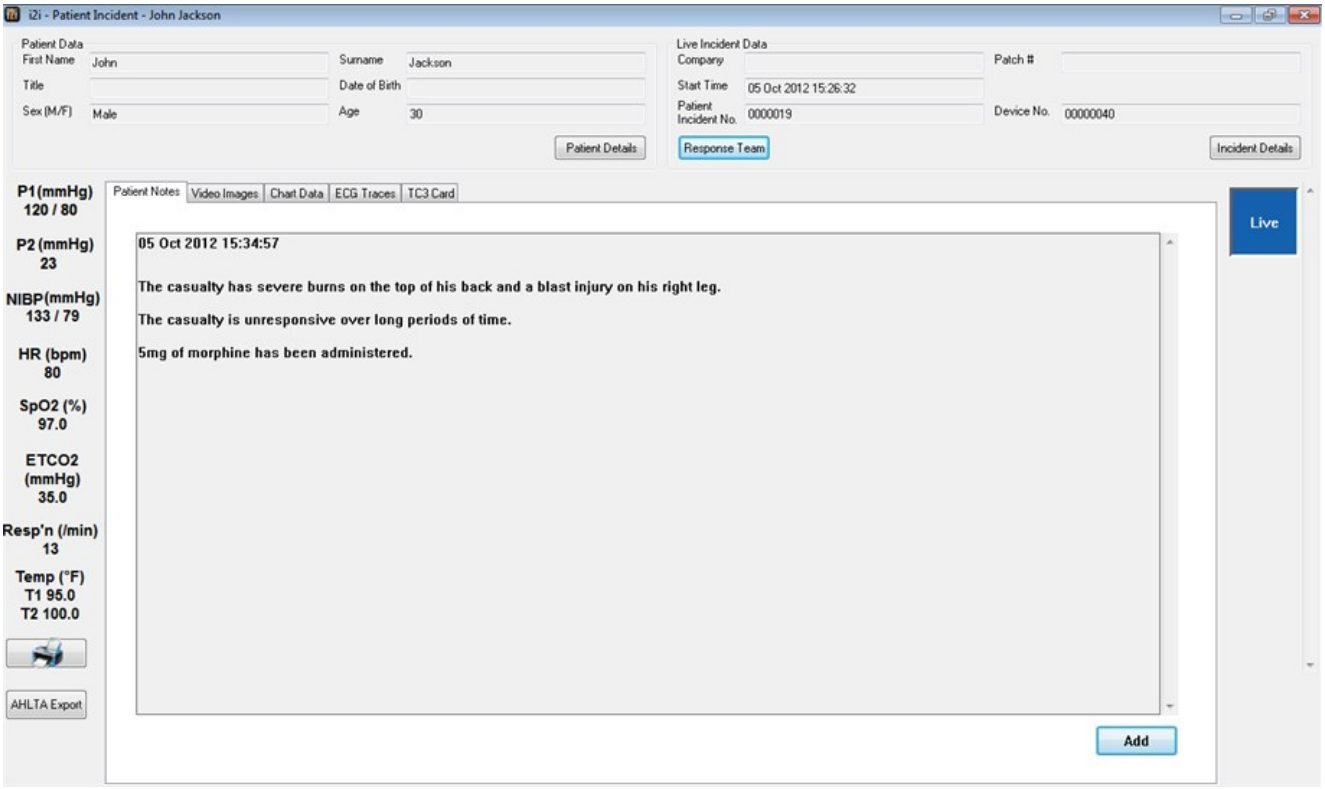
The Patient Record Display has tabs that provide access to each of the following:

- Patient Notes
- Video Images
- Chart Data
- ECGs
- TCCC Card or Summary Record of Care

Each of these views will be discussed in detail below:

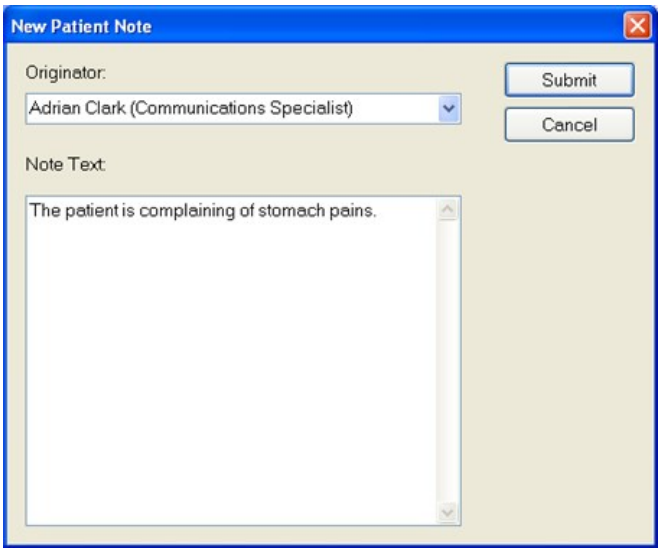
3.6.1 Patient Notes tab

Selecting the **Patient Notes** will display the following window:



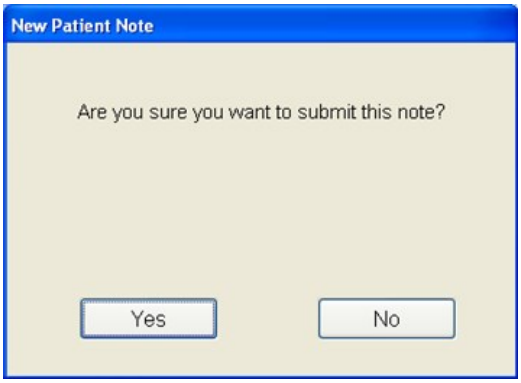
Patient Notes tab

In this case a note has already been entered. It should be noted that notes can only be added. For audit trail purposed they cannot be edited or deleted. To add a new note click **Add**. This will display the following dialogue:



Entering patient notes

Type in the name of the originator or select it from the drop down list. Enter the note in the “Note Text” area. You can exit without saving changes by pressing **Cancel**. When you are finished press **Submit** to save the note. This will bring up the following confirmation dialogue:



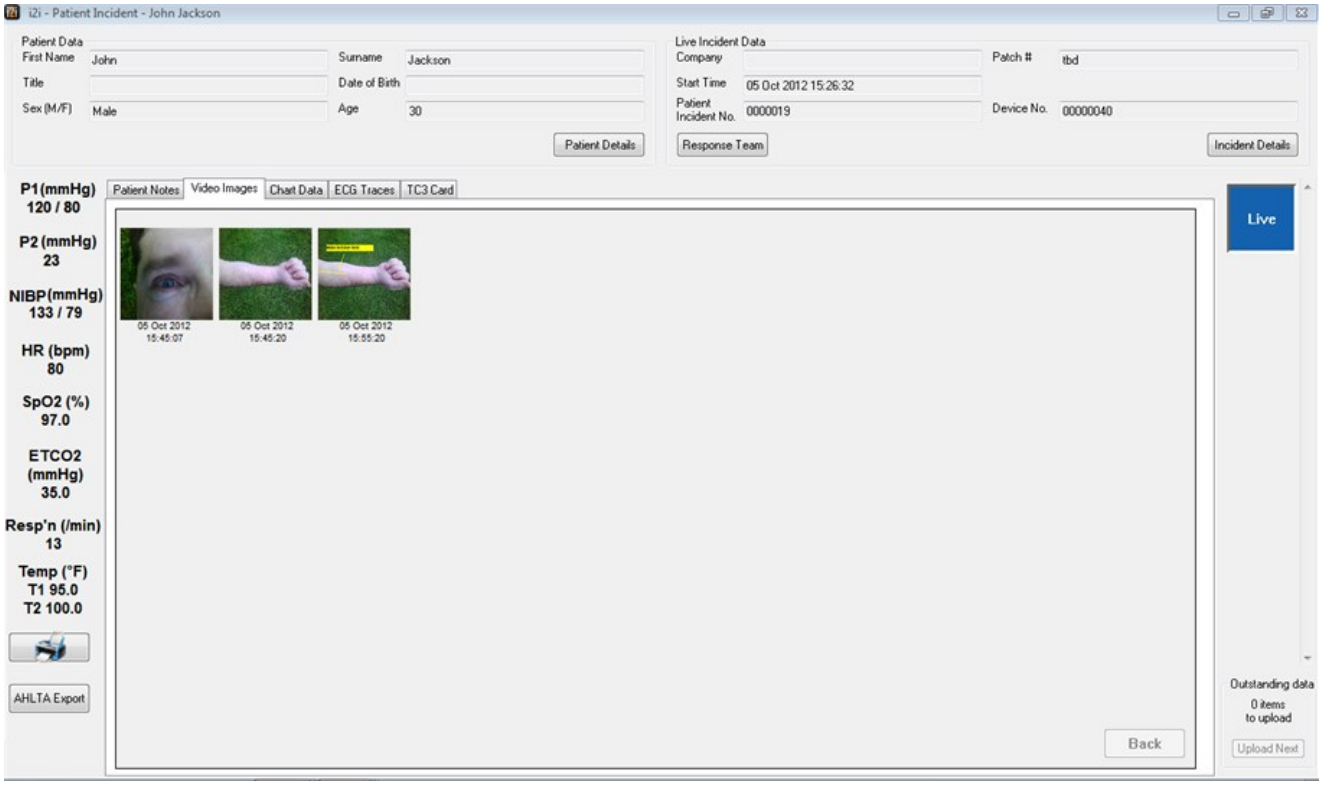
Confirming notes

Press **Yes** to submit the note or **No** to return to the previous dialogue.

Notes are displayed with the last note entered at the top of the list.

3.6.2 Video Images tab

Selecting the “Video Images” tab will display the following window:



Video Images tab

You can see that there is a thumbnail with a date and time stamp for each Video image. Annotated Video Images have a separate thumbnail. To view an image double click on it with the mouse. Images include camera photos and laryngoscope captures.

3.6.3 Chart Data tab

Selecting the Chart Data tab will display the following window:

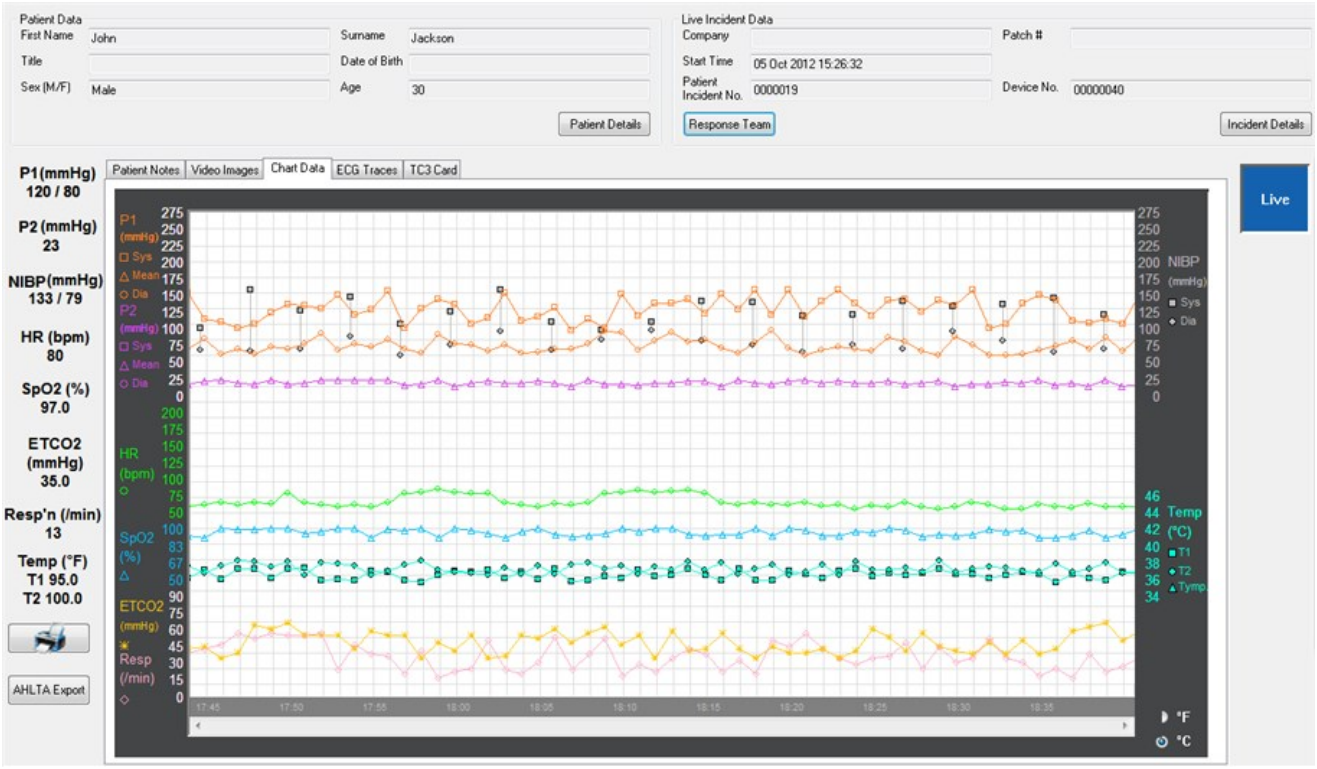


Chart Data tab

The patient record chart mimics a hospital style end of bed chart. The scales are clearly marked and color coded for each medical parameter. The time scale is marked along the bottom of the window, the horizontal scroll bar can be used to scroll through the chart.

The °F and °C radio buttons can be used to switch the temperature units between Fahrenheit and Celsius.

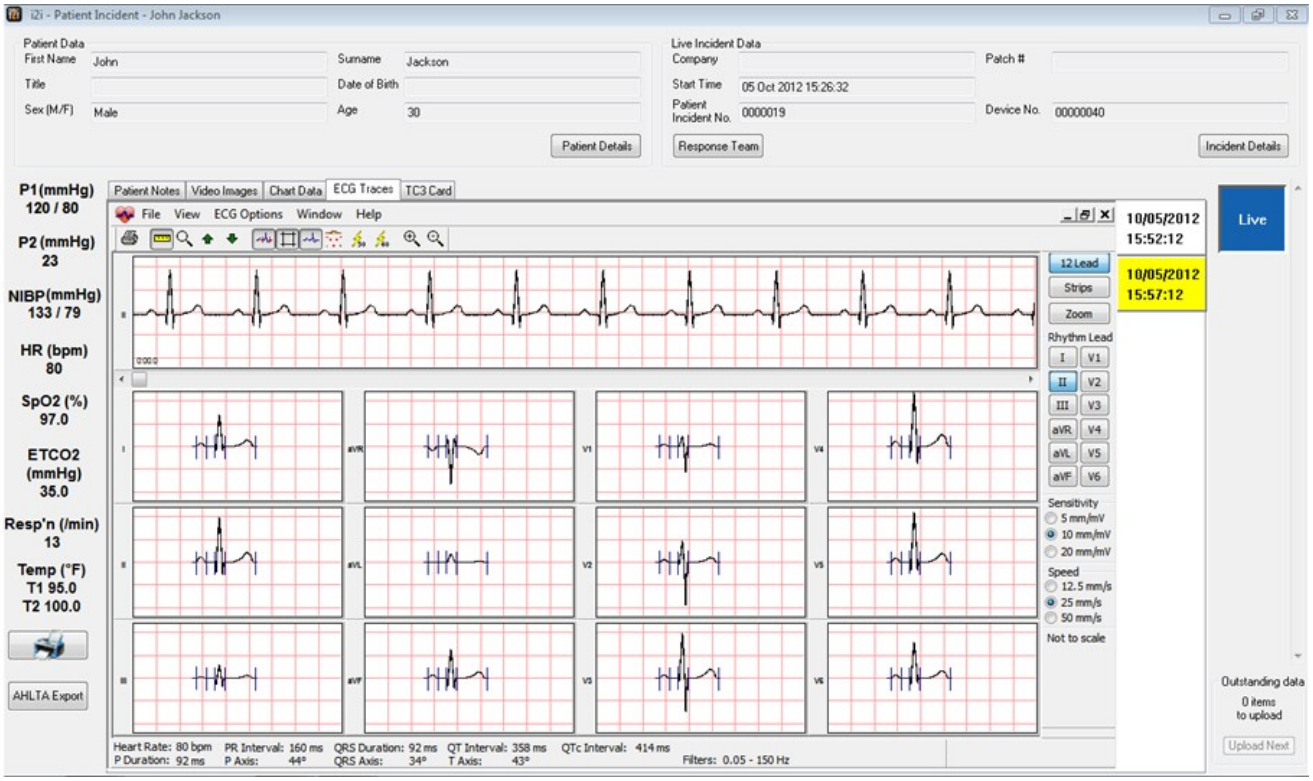
The vertical bar on the chart shows that two device incidents have been joined to make up this patient incident.

The sample rate for each parameter is shown in the table below.

Parameter	Sample rate
Temperature	Once per minute
Blood pressure	Every reading
Pulse rate	Once per minute
SpO_2	Once per minute
Respiration rate	Once per minute
$ETCO_2$	Once per minute
Invasive pressure	Once per minute

3.6.4 ECG Traces tab

Selecting the ECG Traces tab will display the following window:



ECG Traces tab

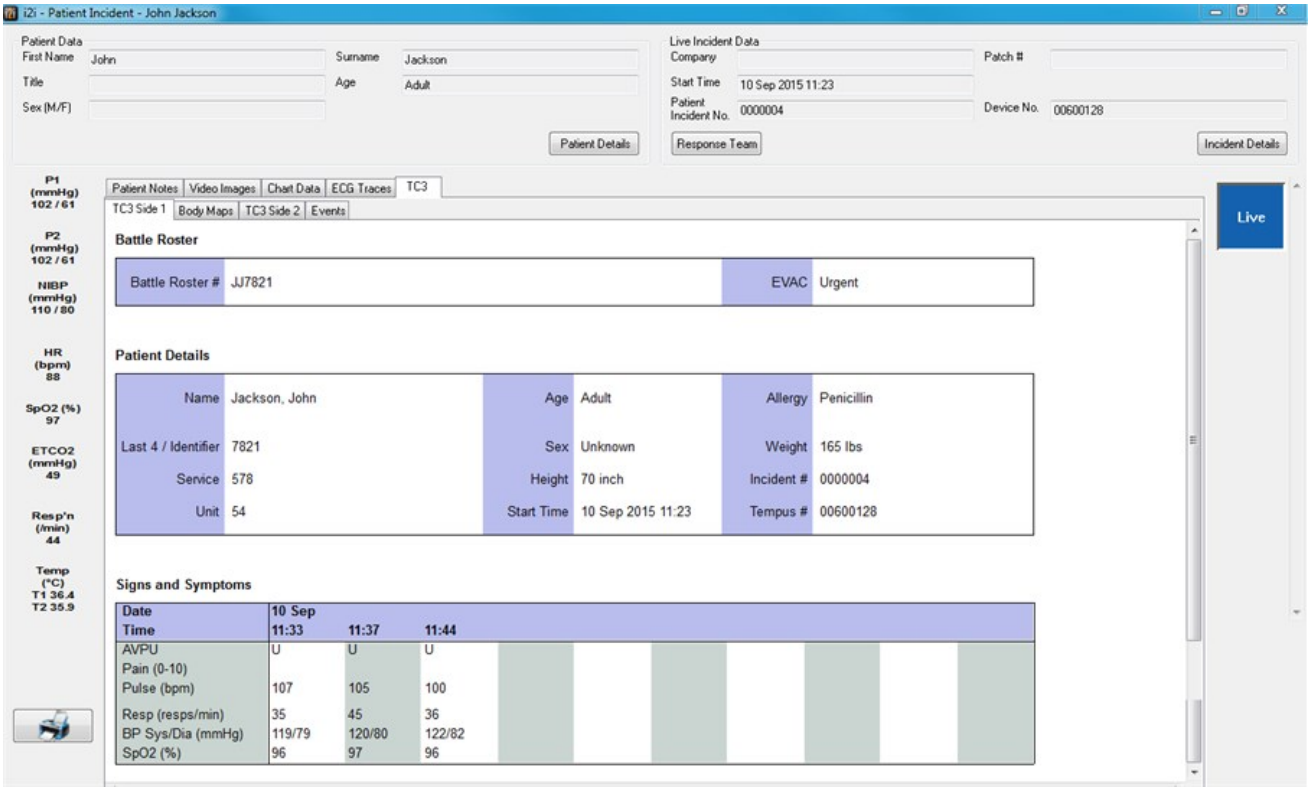
The ECG view allows you to view, manipulate and overlay ECGs. The ECG functions are discussed in more detail in "3.7 Functions of the ECG".

3.6.5 TCCC card tab

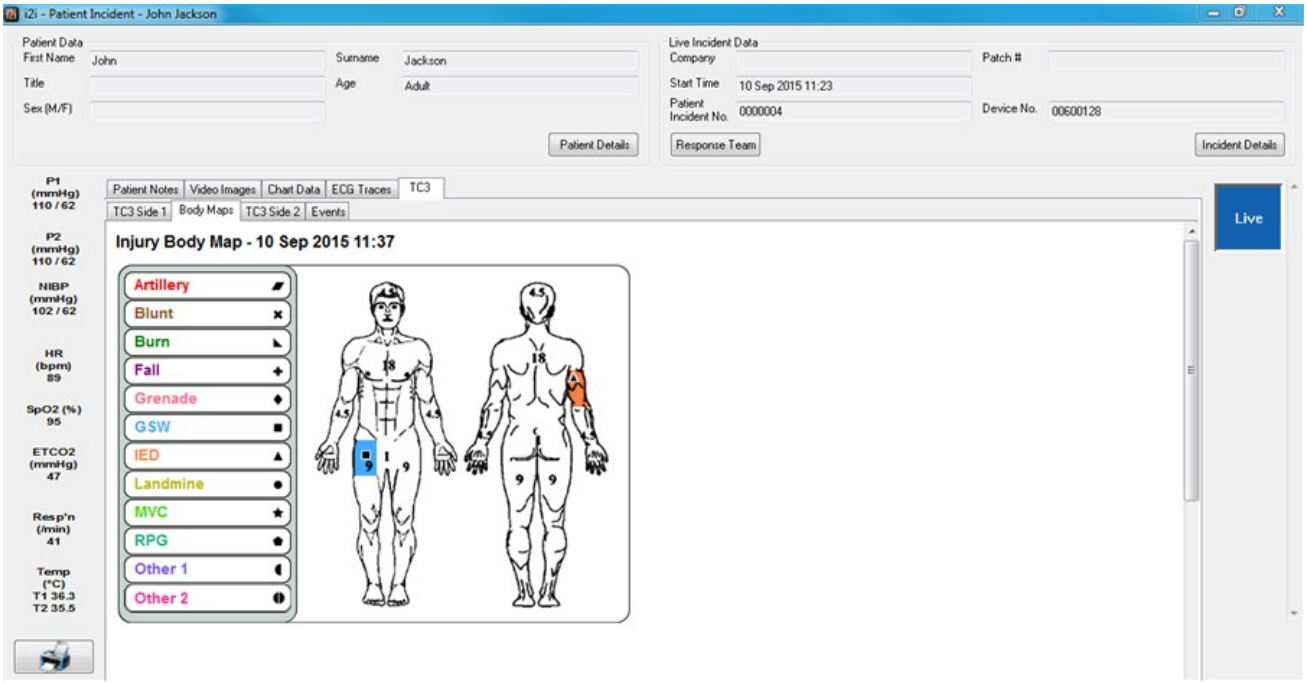
If the i2i patient record includes the “TC3” tab, this indicates that the Tempus Pro patient report type is Tactical Combat Casualty Care (TCCC). The TCCC card is a record card format used by the military to capture patient incident and treatment information (primarily relating to battlefield trauma).

Users of i2i should note that they are not able to edit the TCCC or see it being edited on their Tempus window. To view the created TCCC card, i2i users should press the “Patient Information” button on the Tempus window and then click on the TCCC tab.

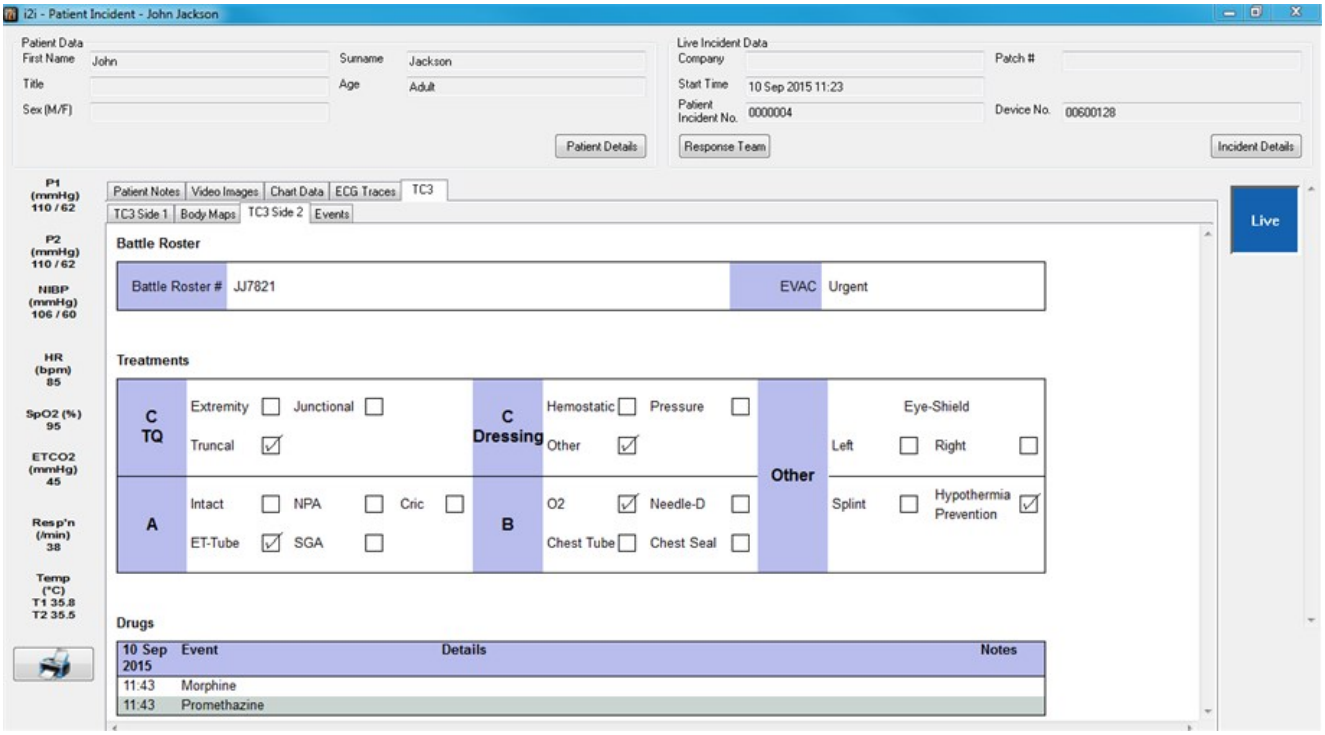
The TCCC tab has four sub-tabs labelled “Side 1”, “Body Maps”, “Side 2” and “Events”. These correspond to the sides of the card on the military form. The i2i updates the TCCC card every 2 minutes, users should note therefore that what they see on the i2i may not be the latest information that the Tempus operator has entered.



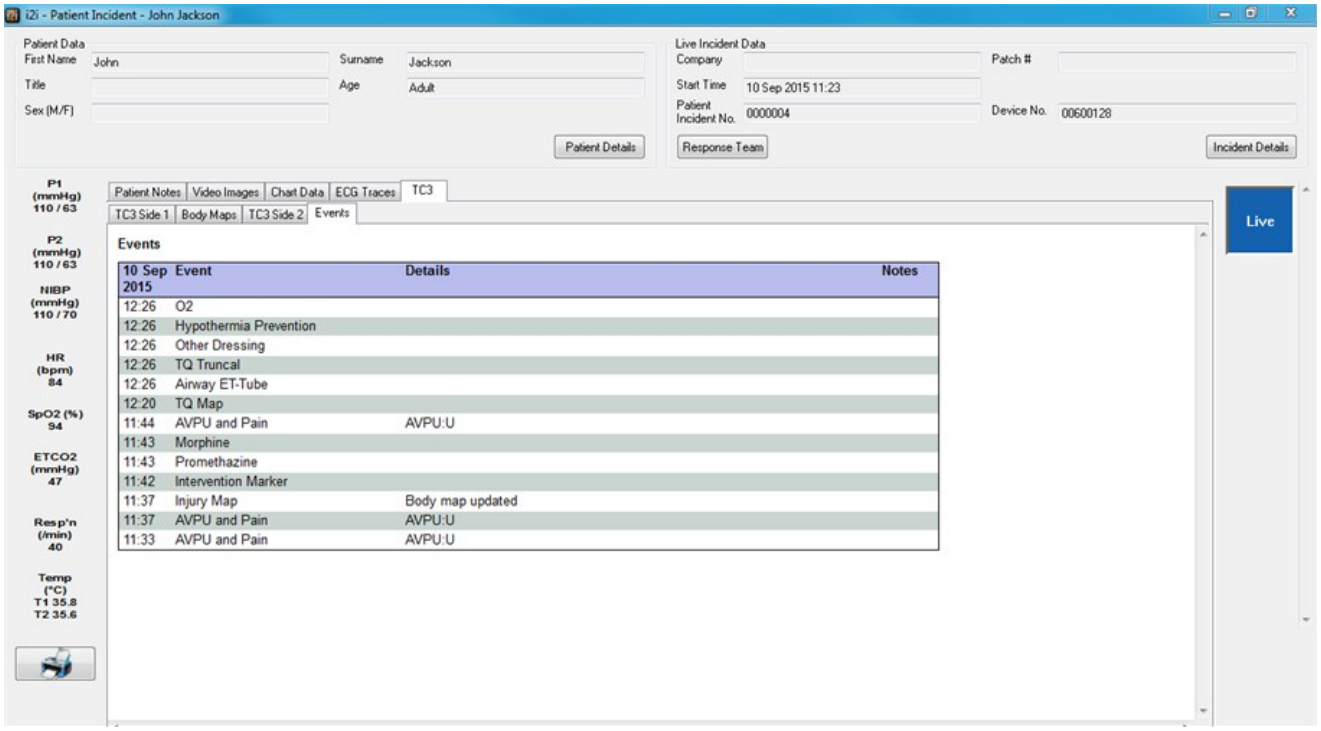
TCCC Card Tab Side 1



TCCC Card Tab Body Map



TCCC Card Tab Side 2



TCCC Card Tab Events

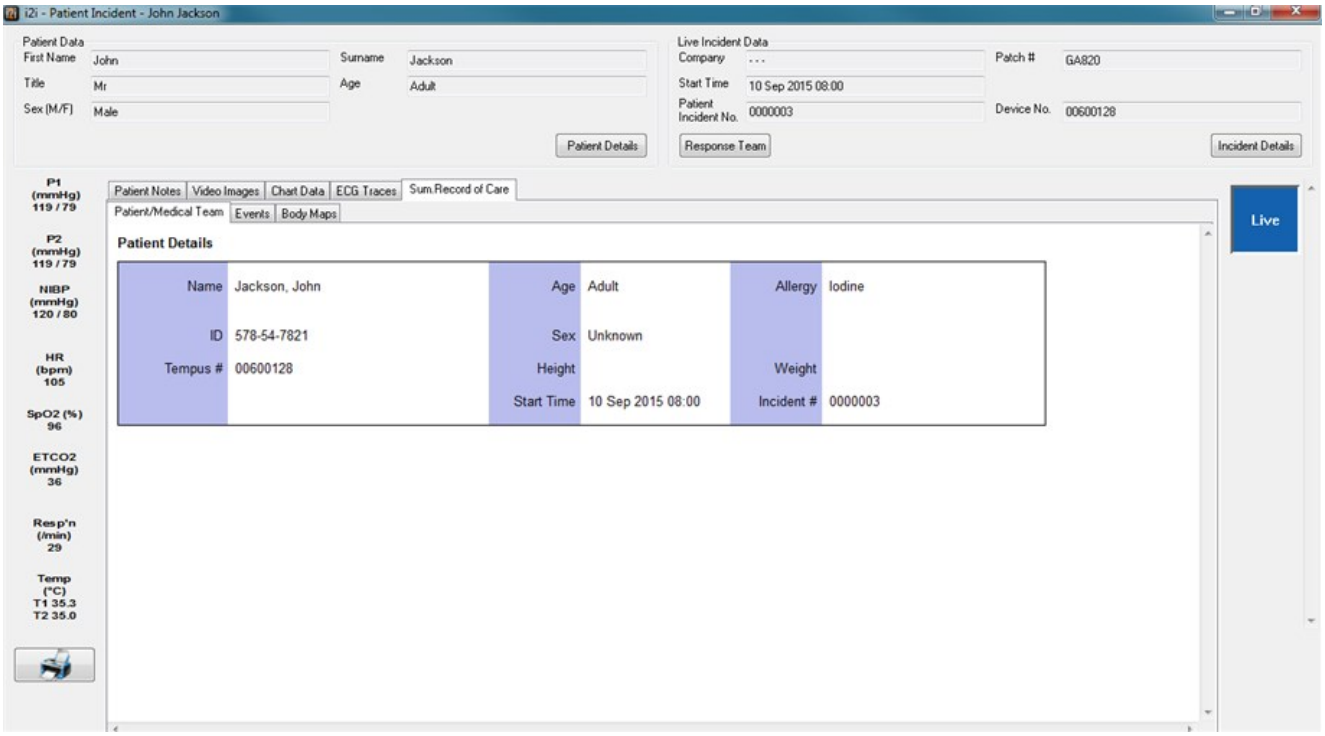
The TCCC Card will be included in any printed reports that the i2i creates – see "3.8 Printing".

3.6.6 Summary Record of Care tab

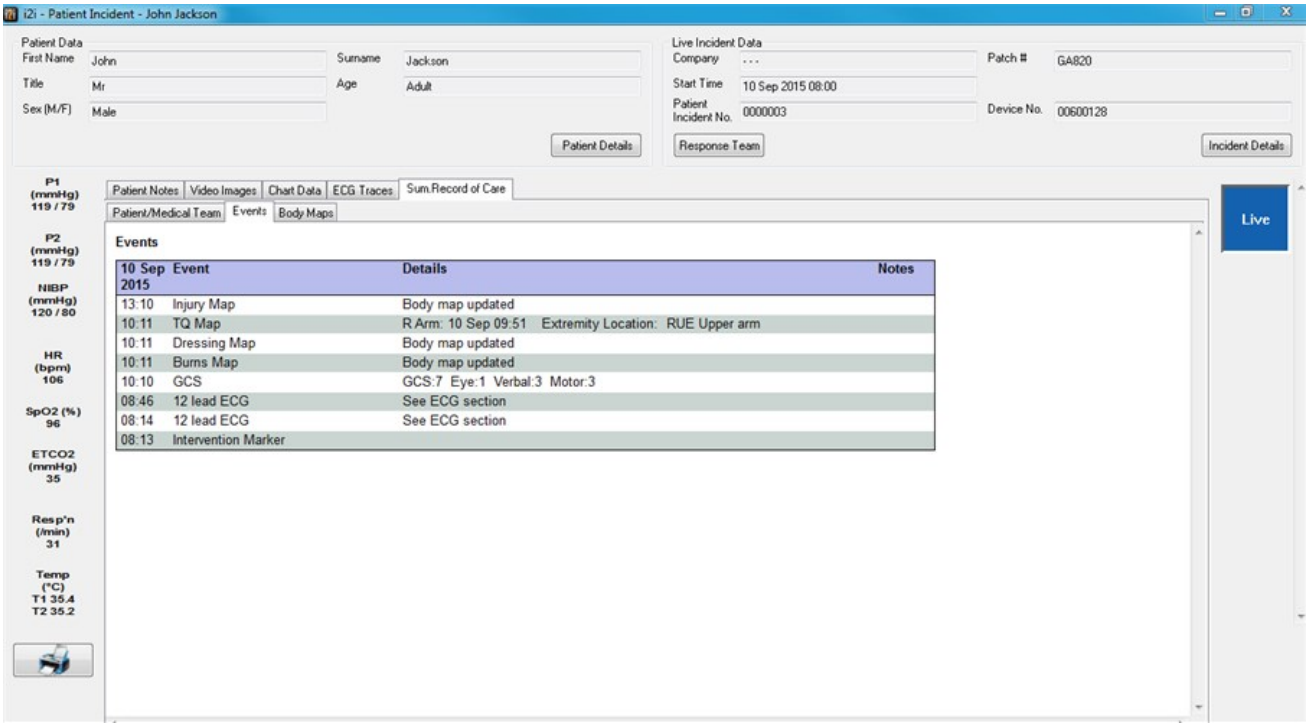
If the i2i patient record includes the “Sum. Record of Care” tab, this indicates that the Tempus Pro patient report type is Standard. Summary Record of Care is used to capture patient incident and treatment information consisting of assessments, interventions, fluids, drugs and body maps.

Users of i2i should note that they are not able to edit the Summary Record of Care or see it being edited on their Tempus. To view the created Summary Record of Care, i2i users should press the “Patient Information” button on the Tempus window and then click on the “Sum. Record of Care” tab.

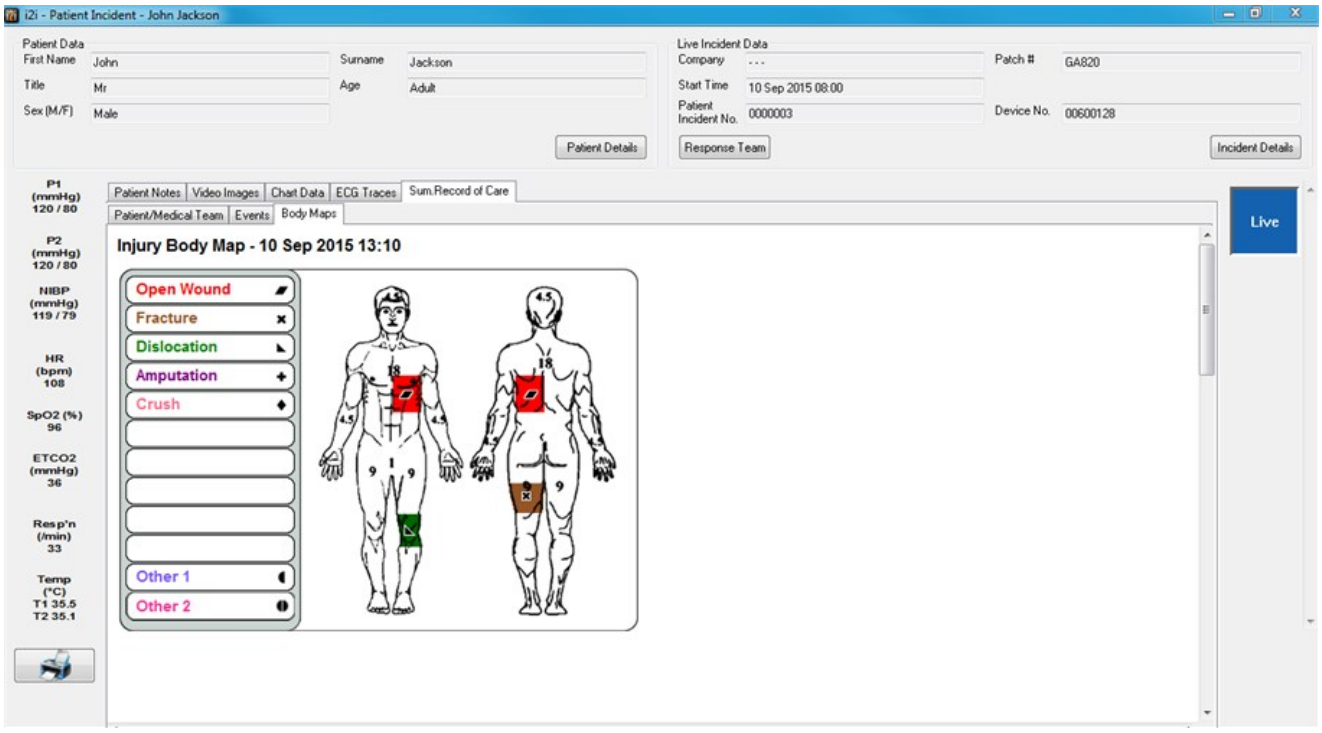
The “Sum. Record of Care” tab has three sub-tabs labelled “Patient/Medical Team”, “Events” and “Body Maps”. The i2i updates the “Sum. Record of Care” tab every 2 minutes, users should note therefore that what they see on the i2i may not be the latest information that the Tempus operator has entered.



SRoC Patient/Medical Team tab



SRoC Events tab



SRoC Body Map tab

The Summary Record of Care will be included in any printed reports that the i2i creates – see "3.8 Printing".

3.7 Functions of the ECG

It will not normally be necessary to adjust any of the ECG software settings.

3.7.1 Drop-down menus

As shown above, the ECG Traces view contains a number of drop-down menus. Clicking on these will cause a number of options to be produced that can then be selected.

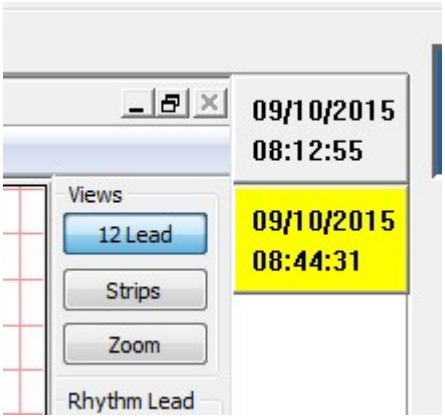
File menu

The printer set-up is available from this menu.

ECG View menu

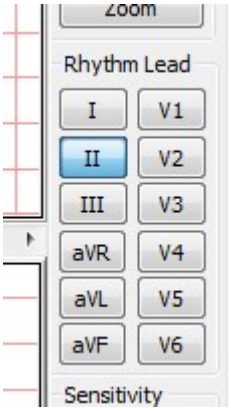
Through the ECG View menu can be selected:

- Type of view – either 12 lead, strips or zoomed in. This is the same as pressing on the buttons on the top right of the display.



- The rhythm lead position (either placed at the top or bottom of the screen).
- All displayed leads can be zoomed in or out. This is the same feature as pressing on the magnifying glass icons on the top of the display.

- The rhythm lead can be changed. This is the same feature as pressing on the buttons on the right of the display.

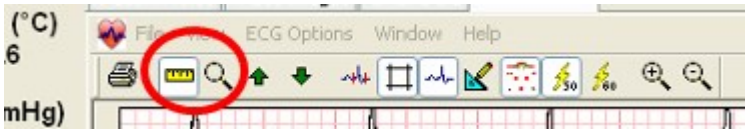


- The on-screen display settings can be turned off and on such as the toolbar, the grid etc.

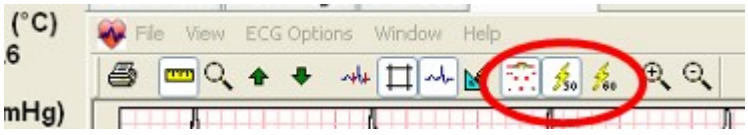
ECG Options menu

Through the ECG Options menu you can change the settings of how the ECG is shown such as:

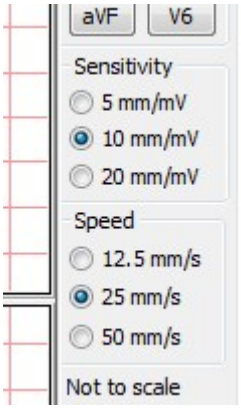
- ECG cursor – toggling between the two settings enables the mouse to be used to either zoom in or make measurements on the leads. This is the same feature as pressing on the ruler/magnifying glass icons on the top of the display.



- Measurement units can be set to microvolts or millimetres.
- The ECG can be filtered for muscle noise or mains (50 Hz or 60 Hz). This is the same feature as pressing on the filter buttons on the top of the display.



- The sensitivity of the trace can be set to 5 mm/mV, 10 mm/mV or 20 mm/mV and the speed of the trace can be set to 12.5 mm/s, 25 mm/s or 50 mm/s. This is the same feature as pressing on the radio buttons on the right of the display.

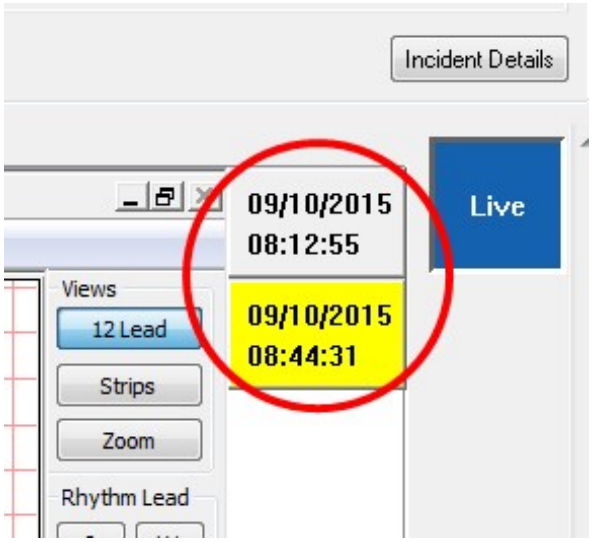


- The presentation of the lead order can be changed.

Window menu

The Window menu enables you to view the different ECGs for the incident.

This is the same feature as pressing on the time-stamped buttons on the right of the display.



Help menu

The Help menu gives you on-line links to this manual.

ECG interpretation

See the Tempus Pro user manual for details of the ECG recording interpretation.

The ECG recording interpretation can be accessed by selecting ‘view’ and then ‘details’. The Interpretation will then appear below the ECG waveforms. The ECG Interpretation Physician’s Guide is available from the help menu.

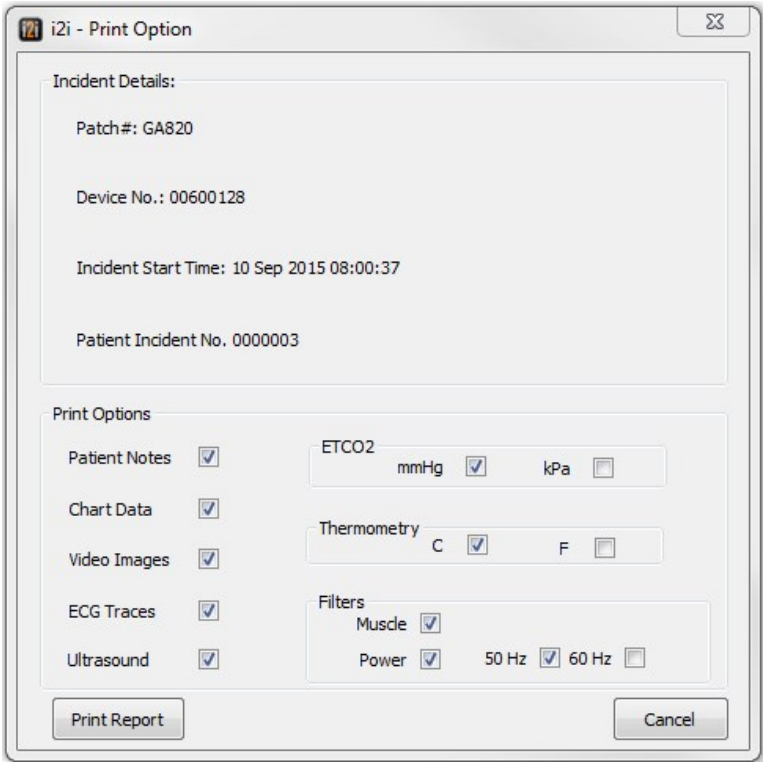
3.8 Printing

The i2i software allows the operator to print out the patient record at any time. To do this, click on the print icon at the bottom left of the database window.

Print icon

The i2i will then show a dialog which allows you to select different parts of the patient record to print (i.e. Notes, Chart data, Video Images, and ECG traces). All features will be selected by default.

You can also configure thermometer units and ECG muscle filter for 50 Hz or 60 Hz. ECG muscle and power filters can also be enabled – these should always be selected.

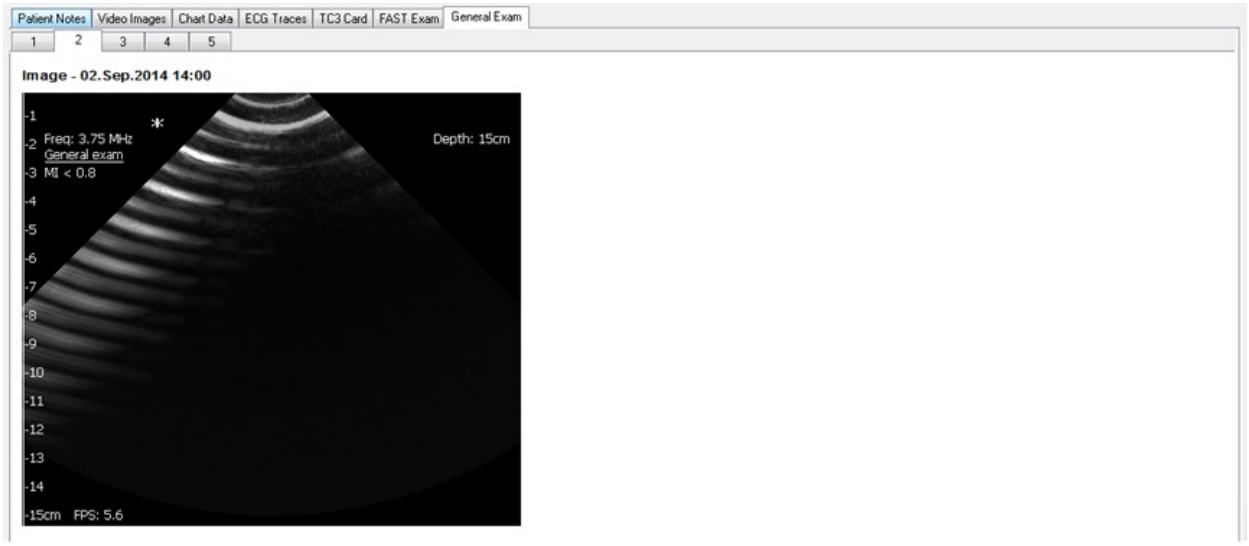


Print option

3.9 Ultrasound images

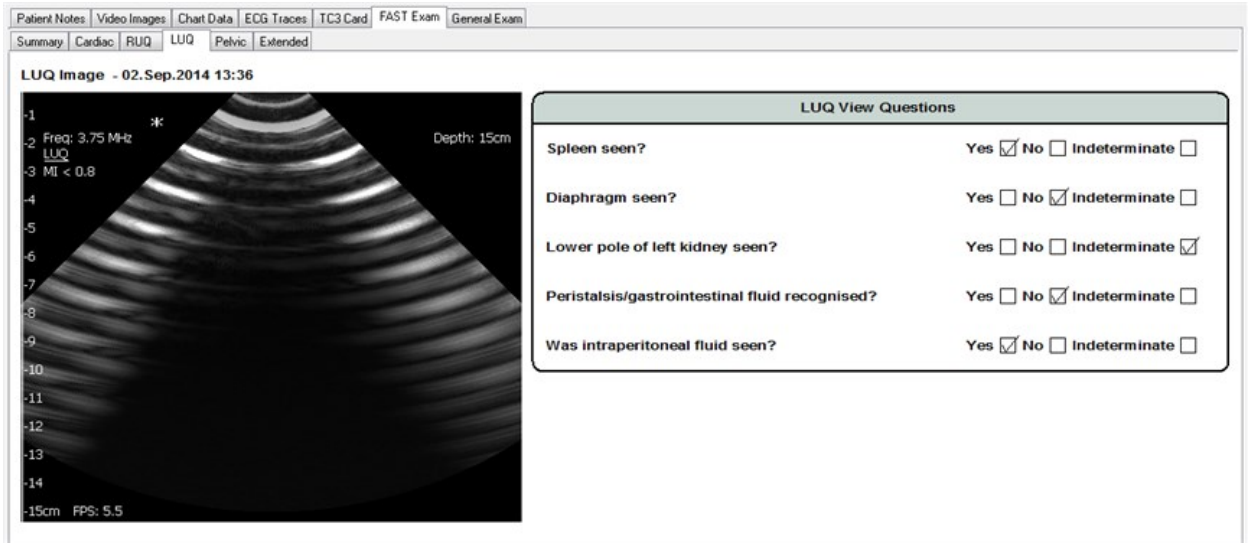
When ultrasound images have been saved on the Tempus Pro ultrasound tabs will be displayed in the patient data management area. FAST Exam report images (optional on Tempus Pro) and General Exam images can be uploaded using the historic data upload button (refer to "3.5 Outstanding data area").

Up to 5 general ultrasound exams may be uploaded.



General ultrasound exam

FAST Exam images (optional feature on Tempus Pro) will be displayed with the exam record when uploaded: the FAST Exam has sections for the exam: summary, cardiac, RUQ, LUQ, pelvic and optional extended exam.



FAST ultrasound exam

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4 Off-line monitoring

4.1 Parameter sampling

As discussed in section "3.5 Outstanding data area", ECGs and Video images can be recorded off line for later transmission in the same device incident. When running in this mode, real time measurements such as pulse rate and blood oxygen level are stored on the Tempus for later transmission when the Tempus is connected to an i2i during the same device incident. The sample rate for each parameter is shown below:

Parameter	Sample rate
Temperature	Once per minute
Blood pressure	Every reading
Pulse rate	Once per minute
SpO_2	Once per minute
Respiration rate	Once per minute
$ETCO_2$	Once per minute
Invasive pressure	Once per minute

4.2 Using off-line monitoring

Examples of using off-line monitoring are:

- The Tempus has been connected to the i2i, the Doctor has reviewed the data and thinks all is OK. However, the Doctor has requested that the patient has their pulse rate monitored for the next two hours but does not feel the Tempus needs to remain connected to the i2i. This avoids tying up a connection to the Response Center and saves the customer money on satellite phone bills.
- The Tempus is disconnected but the pulse oximeter is left on the patient for the next two hours. The pulse readings will be sampled once a minute and stored on the Tempus for later transmission to the i2i.

After two hours the Tempus operator re-connects to the Tempus and the stored data is transmitted and a live incident is set up.

The same situation can occur if the satellite phone system fails and the connection is lost. In this case the Tempus operator will want to re-connect as soon as possible. During the time there is no connection, the Tempus will still be monitoring: it is important that this information is stored for later transmission when the connection is re-established.

4.3 Uploading after off-line monitoring

As discussed previously, ECG and Video data is placed in a queue ready for upload when required by the i2i operator. Real-time data is automatically uploaded in background as soon as a connection is made to the i2i. The historic real-time data will be available for viewing on the patient record chart a few minutes after the connection is established.

4.4 Viewing incidents off-line

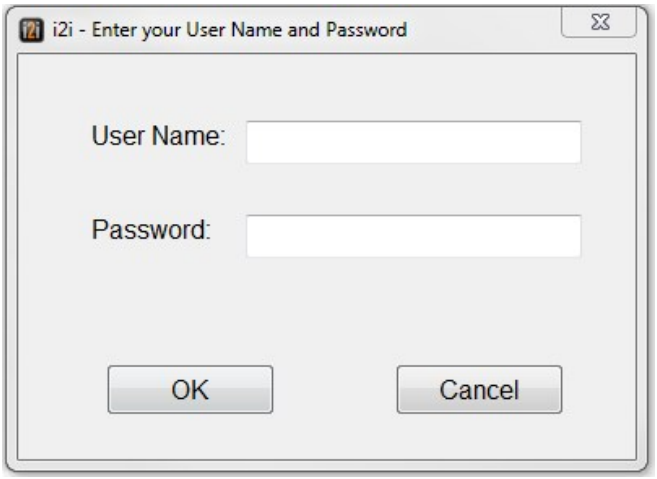
The i2i can be used to view and edit certain details for incidents that have previously been downloaded to the i2i. Medical parameters and notes may not be edited. However, it is possible to complete or edit incident details such as patient address or incident location.

4.4.1 Viewing historic incidents

To view incidents off-line select **View Historic Incidents** on the i2i window when it has no live connections.

View historic incidents button

This facility is password protected. The following log on dialogue will be displayed:

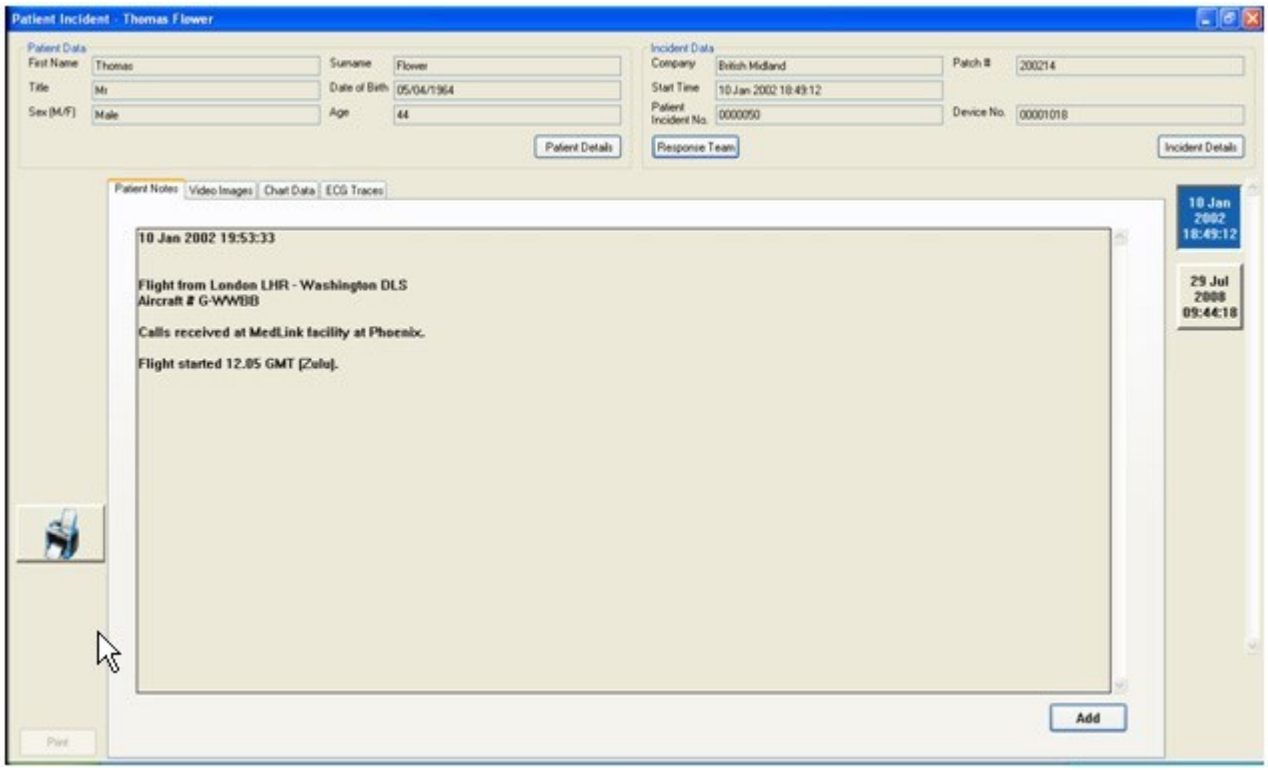


User name and password entry

Type in your User Name and Password and select **OK**. The following dialogue will be displayed:

Selecting an incident

Select the incident that you want to view by picking it from the list and pressing **Select**. The following window will then be displayed:



Viewing a historic incident

This is the same patient database window that has been discussed through this manual. The only difference is that there is no live incoming data connection.

You will find that some functions such as annotation are not available when viewing patient records off-line. This is normal.

4.4.2 Viewing historic records – a new incident connects

If a connection to a Tempus is established whilst you are viewing or editing an old incident the Patient Record Display will automatically be closed so that the i2i is ready to handle the new incident.

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Annex A : System requirements

A.1 Hardware requirements

To maintain compliance with the applicable local device regulations, all PCs and other hardware used to run the i2i application must be supplied locally to the site of the Response Center. All hardware must meet the minimum requirements given below and must be approved for use by RDT Ltd. before the software can be installed. In the event that the server hardware is procured by the user, RDT will require that all hardware being used as the platform for the i2i be shown to meet all applicable local regulations.

For example, this will mean that in Europe, all hardware must be CE marked to the provisions of the Low Voltage Directive 73/23/EEC, the EMC Directive89/336/EEC and, where applicable, the relevant national legislation for approval of telecommunications devices being attached to the PSTN or the provisions of the Radio and Telecommunications Terminal Equipment Directive 99/5/EC. Monitors will be shown to meet the requirements of the MPR II standard.

CAUTION
i2i software is not suitable for use on Mac hardware or operating systems.

The requirements for Response Centers running i2i are as follows:

- Workstations must use Windows 10.
- Workstations must have a minimum of a 1.8G MHz processor, 1 GB RAM, 20 GB hard disk and a SVGA (1024x768) minimum size screen with keyboard and mouse.
- Backup power should be provided.
- An appropriate means of local data backup should be provided.
- At least two workstations should be setup with at least one additional provided for redundancy.
- At least 2 MB (uncontended) IP bandwidth should be provided. All workstations should be on fixed IP addresses.

All equipment for the i2i will be provided by the Response Center and will not be the responsibility of RDT.

It is the user's responsibility to ensure that the i2i application is installed on PCs which meet these minimum requirements and which are reliable and provided with suitable power and access to the internet.

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Annex B : Configuring i2i

B.1 Changing the configuration

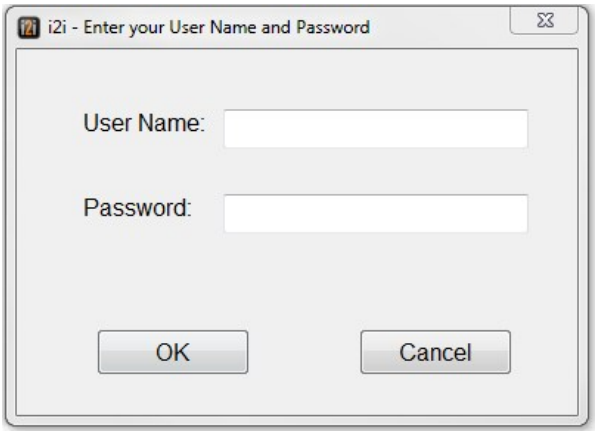
The i2i window gives a constant indication that it is able to receive data connections from Tempus Pro units. Ensuring that access remains unaffected requires that the initial internet access settings (including the settings of firewalls or other security provisions) should not be changed after the initial installation of the system.

If changes are required to be made, the system can be reconfigured by pressing on the **Configuration** button on the i2i window while there are no incoming connections, or by re-installing the Response Center software.

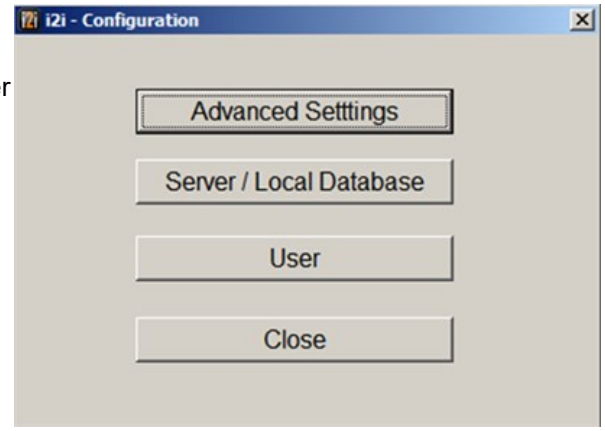
The i2i Configuration button

- Changing the configuration of the i2i could prevent it from receiving data connections from Tempus Pro units. Only suitably qualified IT personnel should use these features and then only with support from RDT.
- User name and password settings are preset by RDT. User's IT departments should contact RDT for the user name and password.

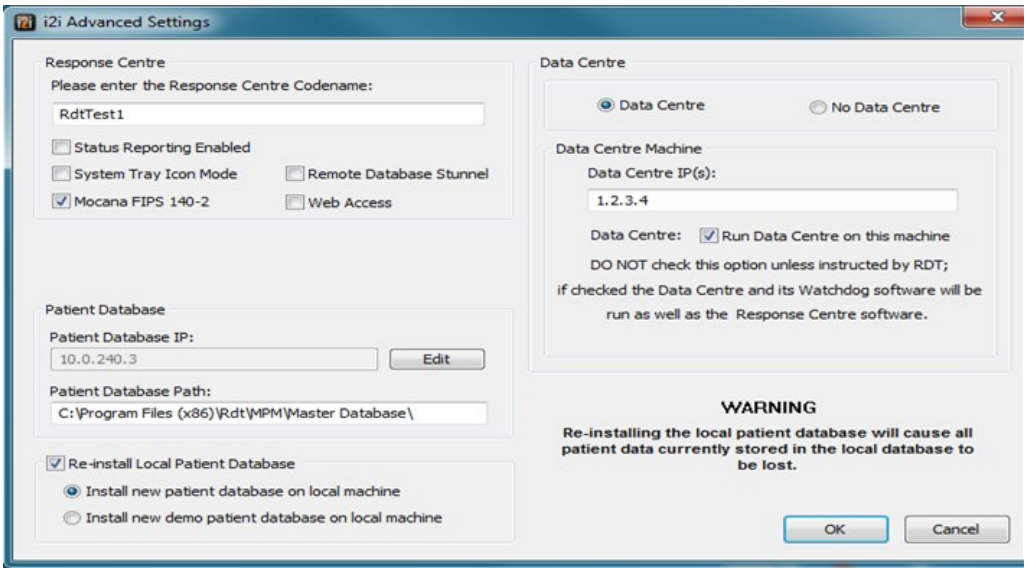
Entering the **User Name** and **Password** for configuration access.



The **Advanced Settings** button will only be displayed for an administrator user; the **Server / Local Database** button will be greyed out if there is no server database setup.



B.2 Advanced settings



The database IP address is stored in a default directory C:\Program Files\rdt\MPM\Master Database. In Response Centers where the i2i application is installed on multiple PCs **in the same office**, RDT recommends that the database file structure is moved to a separate server which remains switched on at all times.

Important

It is the user's responsibility to ensure that their database or databases are suitably secure and backed up.

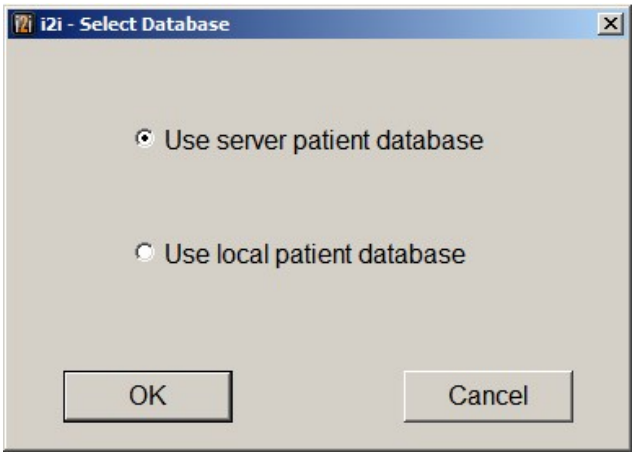
Users should keep the Data Transfer Sockets setting as **Data Center**.

B.3 Server/local database

This allows you to change between a Central Database (Server) or a Local database.

This dialog is not available if a server database is not setup.

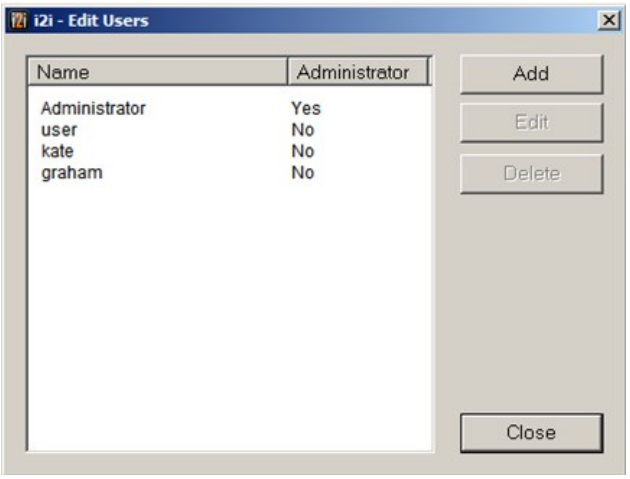
Users should always have this set to **Use server patient database**.



B.4 User

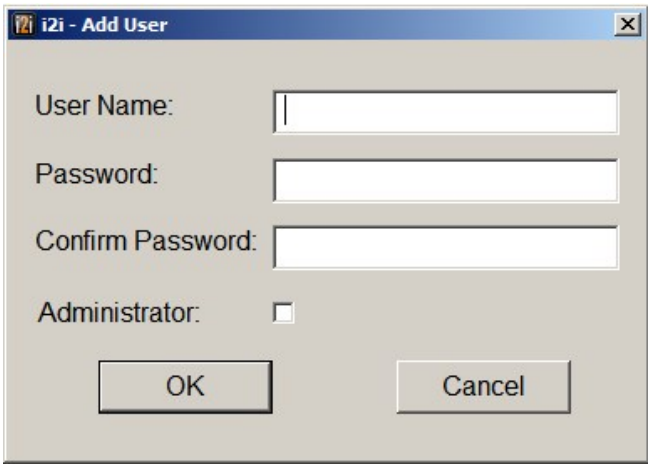
This option is to allow users to have different user names and passwords for different staff.

Clicking on **Add** brings up the dialog below.



Type in the name and password of users that you wish to add. Note that adding users will enable people to have their own user name and password for viewing historic incidents.

When adding user names, if you set the “Administrator” box then these users will additionally be able to access the Configuration settings as described in this section.



Annex C : Software license

i2i software license

This license covers RDT's i2i software (incorporating QRS Office Medic 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.

License:

- You may use this program on up to 15 single computers.

- You may make a backup copy of this software in support of your use of this software.

- You may not transfer the program and license to another party. 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 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 i2i. RDT gives you a personal, revocable, non-assignable, and non-exclusive license to use i2i.

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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 them.

You acknowledge that you are installing the software for the purpose of receiving data from Tempus patient monitors. These monitors will send their data via the internet, for which you will maintain a connection to the Internet of at least 2MB. You will also maintain voice (telecoms) lines with which to receive the voice calls from the Tempus units. You will maintain both IP and voice lines and will inform RDT of any changes to them e.g. change to IP address, telephone numbers, area codes etc. You will also ensure that your firewalls and other network security systems continue to allow the software to receive and transmit data. You will use your best endeavours to inform RDT of any changes to this infrastructure that could affect Tempus connectivity in advance of the change. Failure to do this may result in you being unable to receive data from Tempus units.

i2i and RDT is not a "covered entity" under the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated there under ("HIPAA"). As a result, HIPAA does not apply to the transmission of health information by RDT or i2i to any third party.

Acceptance of these terms and conditions is acknowledged by installation of the i2i software.

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While the Mocana FIPS security algorithm is provided as an option in Tempus Pro devices, it is standard to all installations of i2i.

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Annex D : Symbols used

The following symbols are used either on this product or on the accessories and packaging provided with it:

	Consult the instructions for use. These are provided in electronic format in the Philips Document Library.
	Consult the instructions for use (for an electronic IFU). These are provided in electronic format in the Philips Document Library.

	Name and address of the European Union Authorized Representative.
	Indicates the medical device manufacturer.
 YYYY - MM	Date of manufacture. The year that the item was manufactured is represented by the year and then the month e.g. 2019 06 is June 2019.
 **YYYY - MM**	The manufacturer's batch code. The year that the item was manufactured as a part of a larger batch is represented by the year and then the month e.g. 2019 06 is June 2019.
	Catalogue Number Indicates the manufacturer's catalogue number
	Unique Device Identifier Indicates a carrier that contains unique device information
	The entity importing the medical device into the locale.
	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.
CE **0413**	Signifies European technical conformity for a device/accessory, CE marked by notified body number 0413

CE	Signifies European technical conformity for a device/accessory. For class I devices.

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