Ultrasound Supplement Guide

English

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Tempus Pro

Patient Monitor

PHILIPS

Manufacturer's address

Tempus Pro is designed and manufactured by:

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EC REP

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Table of Contents

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About this guide

This guide is to support the user in displaying ultrasound images on the Tempus Pro utilising third party ultrasound probes. The Tempus Pro accessory range includes the following ultrasound probes from Interson Corporation:

- 01-2008 – Tempus Pro USB 3.5 MHz General Abdominal Probe (Interson's reference number: 99-5553)
- 01-2042 – Tempus Pro USB 7.5 MHz Vascular Ultrasound Probe (Interson's reference number: 99-5554)

These ultrasound probes can be used with Tempus Pro patient monitors. To be compatible with the ultrasound probes, the Tempus Pro must be installed with software version 4.02 or higher.

Tempus Pro ultrasound users must be clinically trained in patient vital signs monitoring, vital signs interpretation, ultrasound examination and ultrasound interpretation.

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 observer all warnings, cautions and safety markings in this supplement guide, the *Tempus Pro User /Operator Manual* from RDT and the *Interson User Guide USB Ultrasound Imaging Probes* from Interson Corporation.

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.

Purpose of this manual

The purpose of this document, which is to be read in conjunction with *Tempus Pro User/Operator Manual* and the *Interson User Guide USB Ultrasound Imaging Probes* (supplied with the probes), is to provide the user with adequately detailed information to efficiently use Interson Ultrasound Imaging probes with the Tempus Pro.

It is not intended to provide information on cleaning and disinfection, or care and handling of the ultrasound probes, as reference should be made to the *Interson User Guide USB Ultrasound Imaging Probes* from Interson Corporation.

Failure to comply with the information contained in this guide, the *Tempus Pro User/Operator Manual* and the *Interson User Guide USB Ultrasound Imaging Probes*, such as warnings, precautions, instructions etc. will violate the safety standards of design, manufacture and intended use of the product. Remote Diagnostic Technologies Ltd. assumes no liability for customer failure to comply with the information contained in this guide and the applicable supporting manuals.

The USB ultrasound probes are designed and manufactured by Interson Corporation. Please refer to the *Interson User Guide USB Ultrasound Imaging Probes* for all warnings and cautions in relation to the USB ultrasound probes.

1.1 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:

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. 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 and EDS are trademarks of RDT.

SeeMore USB probe® and Interson® are trademarks of Interson Corporation.

Restrictions on use

EMC statements

EMC compliance statements for the Tempus Pro and ultrasound are available in the following documents:

- For the Tempus Pro, please refer to the *Tempus Pro User /Operator Manual*.
- For the Ultrasound probes, please refer to the *Interson User Guide USB Ultrasound Imaging Probes* from Interson Corporation.

Indications and contraindications for use

For indications and contraindications for use of the Tempus Pro, refer to the *Tempus Pro User/Operator Manual*.

FDA prescription statement

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

Acoustic Energy

The effects of acoustic energy on human tissue are currently under investigation.

Therefore, it is recommended that diagnostic ultrasound output power be set to the lowest possible levels in accordance with the principle of ALARA (As Low As Reasonably Achievable).

The diagnostic ultrasound output power is pre-set to the optimal minimal level on the Tempus Pro patient monitor. The Pulse Frequency is the only user adjustable setting which can change the acoustic energy. The maximum possible MI value for the probe selected is displayed on the screen.

See the *Interson User Guide USB Ultrasound Imaging Probes* for details of the acoustic measurements.

CE statement

Marking by the CE symbol indicates compliance of this medical device to the Medical Device Regulation (EU) 2017/745.

General warnings, cautions and notes

Remote Diagnostic Technologies Ltd. assumes no liability for customer failure to comply with the information contained in this manual and its supporting manuals.

WARNING
Failure to comply with the information contained in this manual, the *Tempus Pro User/Operator Manual* and the *Interson User Guide USB Ultrasound Imaging Probes* from Interson Corporation (e.g. warnings, precautions, instructions etc.) will violate the safety standards of design, manufacture and intended use of the product.

WARNING
The Tempus is intended to be operated by clinically qualified personnel only. This supplement guide, *Tempus Pro User/Operator Manual* and the *Interson User Guide USB Ultrasound Imaging Probes* manual, as well as accessory directions for use and all precautionary information and specifications should be read before use.

WARNING
When not in use, always disconnect the USB probe from the Tempus Pro.

WARNING
Always maintain a charge level of at least 10% in the Termpus Pro's battery. If the Tempus Pro's battery charge is below 10%, the USB interfaces (and therefore the ultrasound probe) will not work.

WARNING
To ensure high quality images, all patient images must be obtained by personnel trained in performing ultrasound examinations.

WARNING
Check the ultrasound probes prior to each use to ensure that they function correctly and have been properly cleaned and disinfected.

WARNING
Before you attempt to use Tempus Pro's ultrasound capability, you should be trained in ultrasonography or be under the supervision of someone who is trained in ultrasonography.

WARNING
To prevent misdiagnosis or harm to the patient, you must understand the Tempus Pro's ultrasound capabilities prior to use.

WARNING
Service and repair of RDT's patient monitor and/ or Interson's ultrasound probes must be carried out only by the manufacturer or its authorized representatives. RDT and Interson reserves the right to disclaim all responsibility, including but not limited to responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.

CAUTION
This manual is intended for the clinical operator of the device. Separate manuals are provided for the setup and maintenance of the Tempus Pro.

CAUTION
Cleaning and disinfection of the ultrasound probes is important. Please refer to the probe manufacturer's instructions for the best method of cleaning and disinfecting the ultrasound probes.

CAUTION
Follow all instructions from the manufacturer of the ultrasound probes. Any deviation from the manufacturer's instructions or use of agents may impact the performance or durability of the ultrasound probes.

Some Tempus Pro units provide a FAST exam feature. This takes you through each of the FAST views in sequence and allows you to save ultrasound images and record notes for each view. If you wish to use this feature but it is not available in the Ultrasound menu, please contact your technical support team. The feature may be installed but not enabled, in which case it can be enabled by following the instructions in the *Tempus Pro Maintenance Manual*.

If the FAST exam feature is not available on your Tempus Pro, you can still perform FAST exams using the general ultrasound scan, but the Tempus does not guide you through the process and does not provide note recording screens.

The SeeMore USB ultrasound probes are designed and manufactured by Interson Corporation. Please refer to the *Interson User Guide USB Ultrasound Imaging Probes* for all warnings and cautions in relation to the USB ultrasound probes.

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1 Ultrasound imaging with the Tempus Pro

The Tempus Pro can be used to perform ultrasound examinations through the use of two plug-in USB Ultrasound Probes. The use of these probes allows ultrasound examinations without the need for additional equipment beyond the monitor and the small, portable probes.

Tempus Pro continues monitoring vital signs data whilst the ultrasound feature is being used. The Tempus Pro status bar, alarm display and medical summary bars can be seen at all times during ultrasound use. Status and monitoring information is displayed at the top and bottom of the screens. Alarms will continue to sound and will appear in the alarm display. The parameter in alarm will flash at the bottom of the screen and the alarm LEDs on the top of the Tempus Pro will light.

1.1 Preparing for an ultrasound exam

1.1.1 Selecting a probe

Two ultrasound probes are available for use with the Tempus Pro. The two probes provide different focal depths and resolutions and can be interchanged depending on the examination being performed. Use the appropriate probe for the depth you are trying to scan:

- The 3.5 MHz ultrasound probe (part number 01-2008). This device is a hand-held, single element, mechanical sector probe intended to be used as an accessory to the Tempus Pro monitor. The nominal operating frequency is 3.5 MHz. In B-mode the transducer operates over a 35 mm^2 area as an end-firing probe. This device can be used with the Tempus Pro vital signs monitor for the transcutaneous imaging of neonatal, abdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc.
- The 7.5 MHz ultrasound probe (part number 01-2042). This device is a hand-held, single element, mechanical sector probe. The nominal operating frequency is 7.5 MHz. In B-mode the transducer operates over a 29 mm^2 area as an end-firing probe. This device can be used with the Tempus Pro vital signs monitor for the transcutaneous imaging of peripheral vessels and small organs.

WARNING
The 7.5 MHz probe is not cleared for foetal clinical applications. Please refer to *Interson User Guide USB Ultrasound Imaging Probes* for details of clinical application for both probe types.

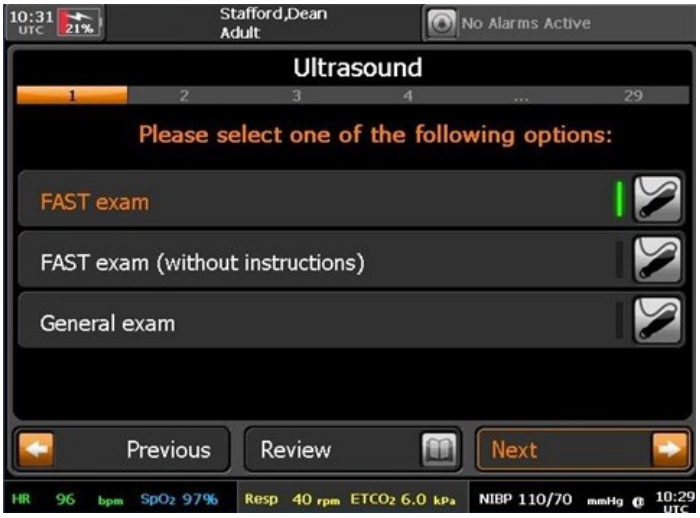
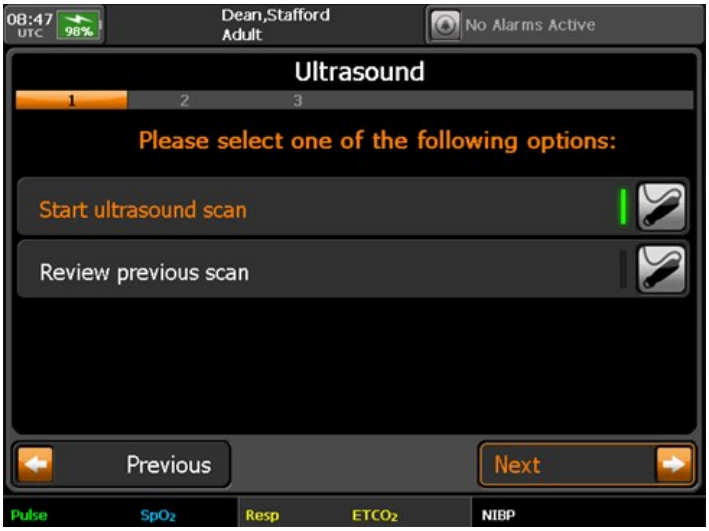
Only one probe will work at a time on the Tempus Pro, so you must change probes by disconnecting one and connecting the other.

Prior to patient evaluation, inspect the USB ultrasound probe for any physical damage such as leaking fluid and cracks in the membrane, housing, strain relief or USB cable. If physical damage exists, do not use the probe for patient evaluation, just return it to the manufacturer for service evaluation.

For more general information, cleaning instructions, warnings and cautions about the probes you must read the *Interson User Guide USB Ultrasound Imaging Probes*.

1.1.2 Starting the examination

To start ultrasound examination, proceed as follows:

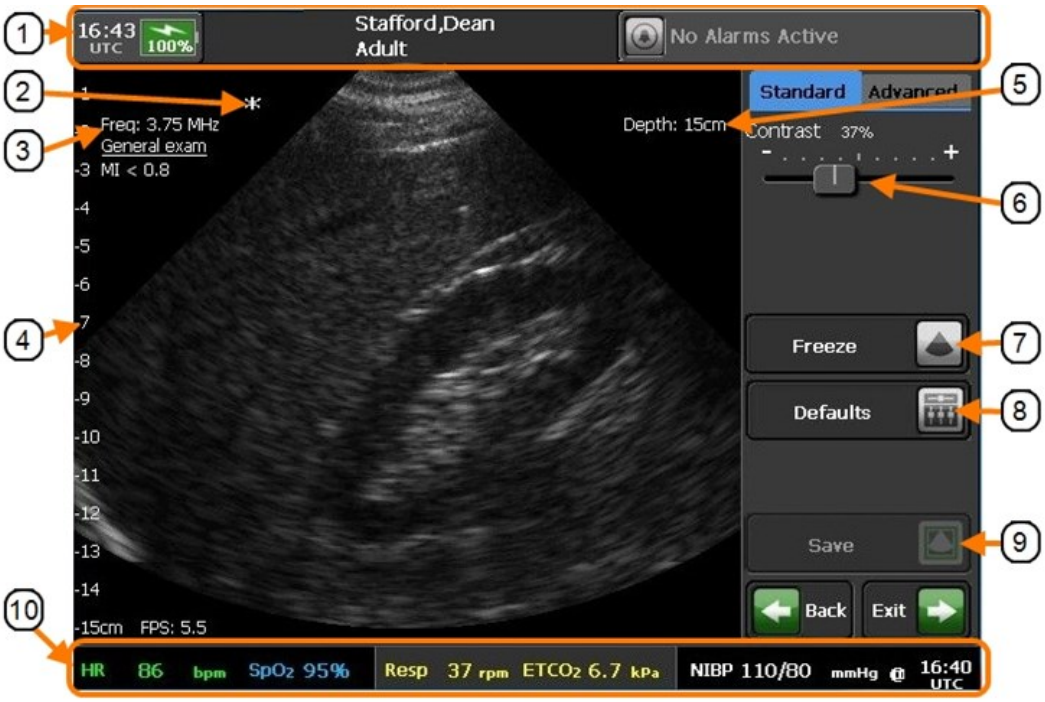
Step	Description	Photos and notes
1.	Plug the USB ultrasound probe into either of the two latched USB ports on the right hand side of the Tempus Pro.	**Important** Ultrasound cannot be used while the Tempus Pro is connected in ReachBak communications modes.
2.	The Tempus Pro displays the Ultrasound menu. If FAST exam is available, the options are: • **FAST exam**: described in "2 FAST exam". • **FAST exam (without instructions)**: described in "2 FAST exam". • **General exam**: described in "1.2 Ultrasound scan". • **Review**: review previous saved scans. If FAST exam is not available, the options are: • **Start ultrasound scan**: described in "1.2 Ultrasound scan". • **Review previous scan**: review previous saved scans.	If FAST exam is available:  If FAST exam is not available: 
3.	Once ultrasound imaging is complete, either remove the ultrasound USB plug or press the **Home** button on the front of the Tempus Pro.	

1.2 Ultrasound scan

The Tempus Pro Ultrasound screen contains two tabs: Standard and Advanced. The Standard tab is displayed by default.

1.2.1 Standard tab

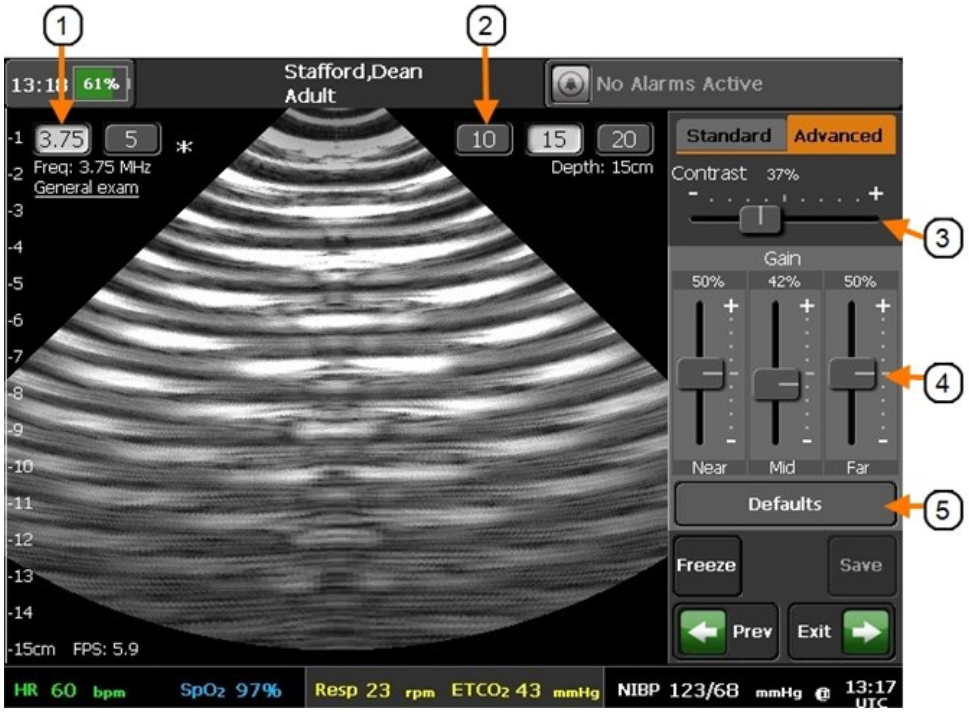
Press the probe capture button and move the probe over the patient, observing the position of the reference spot (*) on the screen.



- (1) Status bar and alarm display - displayed throughout the ultrasound process.
- (2) Reference spot (*) - moves over the screen image as you move the probe.
- (3) **Freq** - the pulse frequency cannot be adjusted in the Standard tab.
- (4) Depth range (cm) - scale depends on probe being used and depth setting.
- (5) **Depth** - the scan depth (cm) cannot be changed in the Standard tab.
- (6) **Contrast** - slide bar to adjust image contrast as needed.
- (7) **Freeze**- capture the last 32 frames.
- (8) **Defaults**- return all settings to their defaults.
- (9) **Save** - save the chosen frame.
- (10) Medical summary bar - displayed throughout the ultrasound process.

1.2.2 Advanced tab

The probe settings have been automatically optimized to give a good quality picture scan in most cases. If these default settings are not suitable, select the **Advanced** tab on the Ultrasound screen. The Advanced tab provides touchscreen controls for you to adjust the pulse frequency, scan depth and gain settings. For example, image quality may be improved by adjusting pulse frequency (resolution) and scan depth.

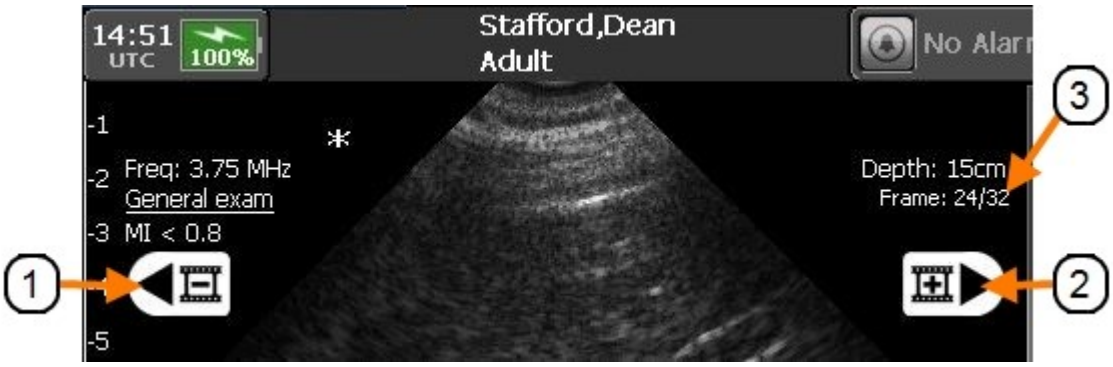


:

- (1) Pulse frequency contro.;
- (2) Depth control.
- (3) **Contrast** - use slide bar to adjust contrast.
- (4) **Gain** - use slide bars to adjust **Near**, **Mid** and **Far** gain settings.
- (5) **Defaults** - use to return all settings to their defaults.

1.2.3 Capturing and saving images

Once you have a suitable image on the display, capture it by pressing either the button on the probe or the **Freeze** button on the screen. The Tempus Pro will store the last 32 frames captured by the probe and will freeze the screen on the last frame.



- (1) Previous frame button (‘-’).
- (2) Next frame button (‘+’).
- (3) Number to identify the frame being viewed.

Use the minus and plus buttons to step through the 32 stored frames. Find the most suitable image, then press **Save** to save it.

- The saved frame can be reviewed again under the review tab in the ultrasound menu screen.
- Captured images are part of the patient record and can be transferred to the i2i PC application or exported from the Tempus Pro. See the *Tempus Pro User/Operator Manual* for details of patient records.

To unfreeze and continue scanning, press the button on the probe or the **Freeze** button on the display. If you unfreeze before saving, your last capture will not be saved.

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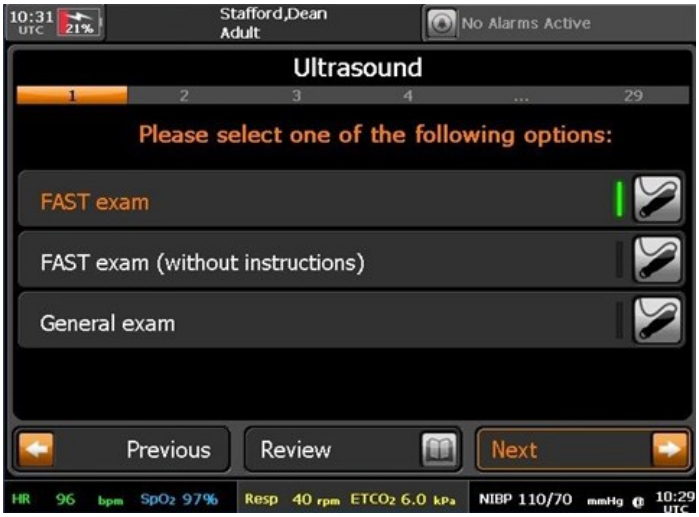
2 FAST exam

If the FAST exam feature is available, you can use it to step through each of the FAST views in sequence, save ultrasound images and record notes for each view. The FAST views are: Cardiac, RUQ, LUQ, Pelvic and Extended.

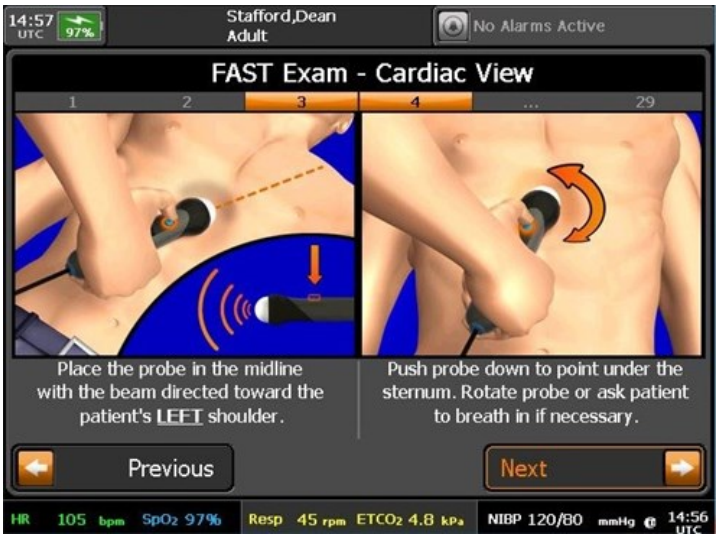
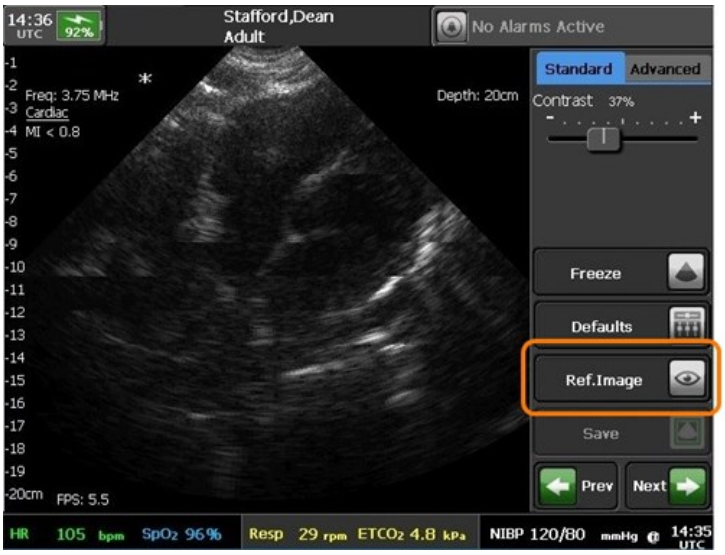
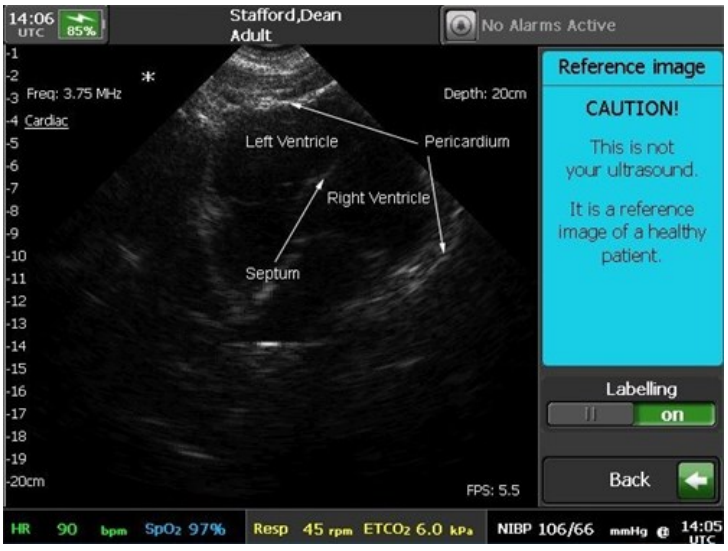
The Extended view is optional and requires a 7.5 Mhz probe.

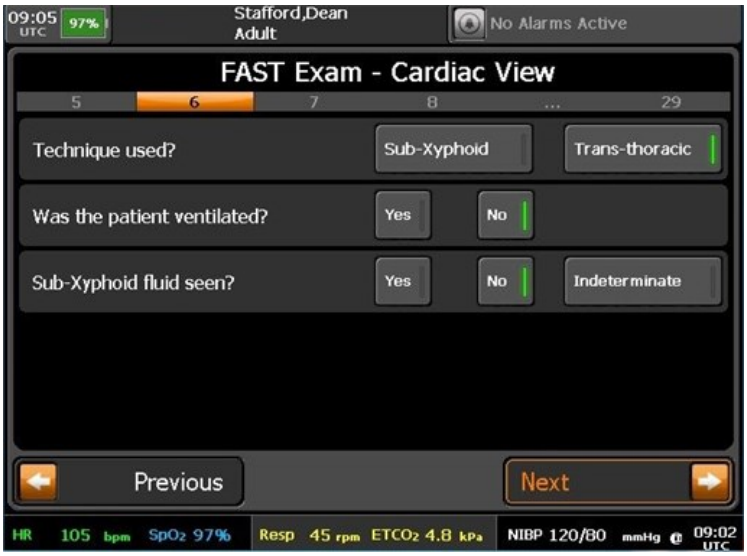
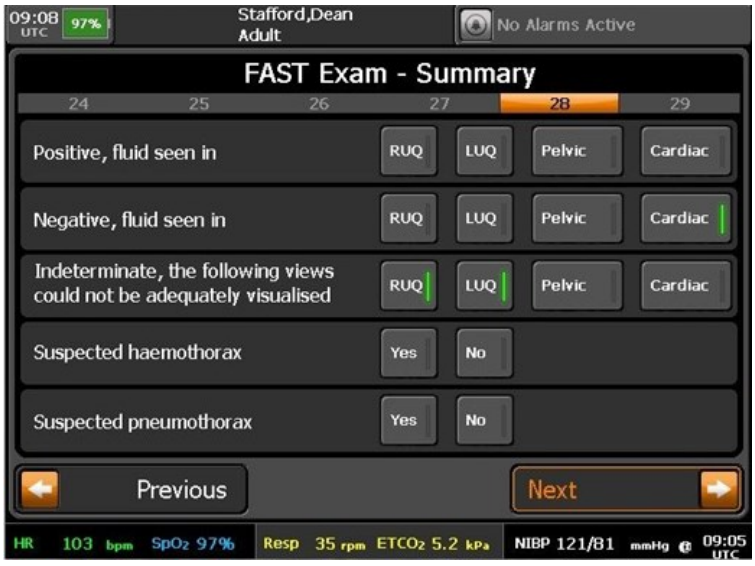
CAUTION
The guided FAST exam is not a substitute for FAST training. It should only be used by trained operators who need to be reminded of the correct procedure. It should not be used if the FAST exam needs to be performed quickly.

To start a FAST exam, proceed as follows:

Step	Description	Photos and notes
1.	On the Ultrasound menu, press one of the following buttons: • For an unguided FAST exam, press **FAST exam (without instructions)**. • For a guided FAST exam, press **FAST exam**.	
2.	The Tempus Pro displays the Ultrasound FAST menu. Decide which view you wish to start with, then select either **Start with cardiac** or **Start with RUQ** and press **Next**.	

For each view (Cardiac, RUQ, LUQ, Pelvic and Extended), the Tempus Pro takes you through the following sequence of screens:

Step	Description	Photos and notes
1.	In a guided FAST exam, the Tempus Pro displays one or more instruction screens before the Ultrasound screen. Read the instructions and then press **Next**. If you selected the **FAST exam (without instructions)**, instruction screens are not displayed.	
2.	The Tempus Pro displays the Ultrasound screen. For instructions, refer to "1.2 Ultrasound scan". In FAST exam mode, there is an extra button: **Ref.Image**.	
3.	In each FAST exam view, there is a reference image that shows a typical ultrasound display. To see this, press **Ref.Image**. Reference images display a blue **CAUTION!** panel. Use the **Labelling** switch to toggle reference image labelling **on** or **off**. To return to the Ultrasound screen, press **Back**.	

Step	Description	Photos and notes
4.	Scan the patient, capture and save images, then press **Next**.	In guided FAST exam mode, captured images are stored with a labelled title.
5.	The Tempus Pro displays a note capture screen for the current FAST exam view. Select the appropriate options in the screen and then press **Next** to proceed to the next FAST exam view.	
6.	After the last FAST exam view, the Tempus Pro displays the **FAST Exam - Summary** screen. This contains all information captured in the exam. Press **Next** to review the summary and complete the exam.	

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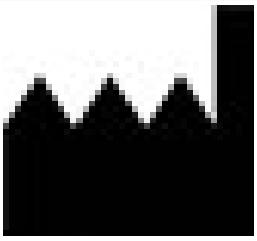
Annex A : Symbols Used

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

	Consult the instructions for use. These are provided in electronic format in the Philips Document Library.
	Consult the Instructions for use.
CE 0413	Signifies European technical conformity for a device/accessory, CE marked by notified body number 0413
	Indicates the medical device manufacturer
EC REP	Name and address of the European Union Authorized Representative.

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Annex B : Acoustic output reporting table

Table 1: Acoustic output reporting table: reportable mode 1 (B-Mode:3.5 MHz GP)

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.50	0.61		0.61		0.29
Index component value				0.61	0.61	0.61	0.61	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.90					
	P	(mW)		38.84		38.84		38.84
	P_{1x1}	(mW)		38.84		38.84		
	z_s	(cm)			N/A			
	z_b	(cm)					N/A	
	z_{MI}	(cm)	5.43					
	$z_{pii,\alpha}$	(cm)	5.43					
	f_{awf}	(MHz)	3.30	3.30		3.30		3.30
Other information	prr	(Hz)	3840.0					
	srr	(Hz)	15.0					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm2)	68					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm2)	3.98					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm2)	13.50					
	p_r at z_{pii}	(MPa)	1.66					
Operating control conditions	90 degree scan angle							
	15 Hz scan rate							
	256 lines per scan							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for a TRANDSDUCER ASSEMBLY not indended for transcranial or neonatal cephalic uses,

NOTE 4 If the requirements of IEC60601-2-37 clause 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.

NOTE 5 If the requirements of IEC60601-2-37 clause 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 6 Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 2: Acoustic output reporting table: reportable mode 3 (B-Mode:SR 7.5 MHz)

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.04	0.30		0.30		0.25
Index component value				0.30	0.30	0.30	0.30	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.27					
	P	(mW)		17.65		17.65		17.65
	P_{1x1}	(mW)		13.38		13.38		
	z_s	(cm)			N/A			
	z_b	(cm)					N/A	
	z_{MI}	(cm)	1.30					
	$z_{pii,\alpha}$	(cm)	1.30					
	f_{awf}	(MHz)	4.75	4.75		4.75		4.75
Other information	prr	(Hz)	4608.0					
	srr	(Hz)	18.0					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm2)	360					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm2)	36.15					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm2)	55.36					
	p_r at z_{pii}	(MPa)	2.80					
Operating control conditions	90 degree scan angle							
	15 Hz scan rate							
	256 lines per scan							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for a TRANDSDUCER ASSEMBLY not indended for transcranial or neonatal cephalic uses,

NOTE 4 If the requirements of clause 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.

NOTE 5 If the requirements of clause201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 6 Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

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