Tempus Pro

User/Operator Manual

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A Philips company

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Manufacturer's address

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1 Introduction

This manual is for the Tempus Pro patient monitor.

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

- 00-1004-R: standard configuration with invasive pressure (2 channels), $ETCO_2$ and contact temperature (1 or 2 channels).
- 00-1007-R: standard configuration with invasive pressure (2 channels), $ETCO_2$, contact temperature (1 or 2 channels) and Bluetooth headset.
- 00-1024-R: standard configuration with printer, $ETCO_2$ and contact temperature (1 or 2 channels).
- 00-1026-R: standard configuration with printer, invasive pressure (2 channels), $ETCO_2$ and contact temperature (1 or 2 channels).

For a full list of Tempus Pro features, see “1.6 Features list”.

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

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

1.1 CE statement

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

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

A Declaration of Conformity in accordance with the above regulations has been made and is on file with RDT, see "RDT contact details".

The wireless portion of this equipment may be operated in GB, France, Italy, Switzerland, Germany, Holland, Portugal, Spain, Sweden, Norway, Denmark and Finland.

1.2 FDA prescription statement

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

1.3 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.

Tempus Pro, Corsium, Corsium Crew, RachBak, i2i and TempusNET are all 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.

The following trademarks are the property of Oridion Medical Ltd.: Oridion, Microstream, FilterLine, (FilterLine Set; FilterLine H Set, Nasal FilterLine), CapnoLine (Smart CapnoLine, Smart CapnoLine O2, Smart CapnoLine Plus, Smart CapnoLine Plus O2, Smart CapnoLine H Plus, Smart CapnoLine H Plus O) and Integrated Pulmonary Index (IPI).

The following trademarks are the property of Masimo Inc, SET, PVI, Rainbow, FastSAT.

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.

Masimo and the Masimo SET logo are the property of Masimo Inc.

1.4 Use of this manual

The instructions and safety precautions provided in this manual must be observed during all phases of the operation, usage, service or repair of the Tempus or its accessories. Failure to comply with the information contained in this manual e.g. warnings, precautions, instructions etc. will violate the safety standards of design, manufacture and intended use of the products. Remote Diagnostic Technologies Ltd. assumes no liability for customer failure to comply with the information contained in this manual.

WARNING 	**The Tempus is intended to be operated by clinically qualified personnel only. This manual, as well as accessory directions for use and all precautionary information and specifications should be read before use.**
CAUTION 	Separate manuals are provided for the setup and maintenance of the device. These manuals are intended for the communications engineers and Bio-medical engineers responsible for such activities and are available from RDT upon request.

Please check RDT's website regularly for new versions of this manual: https://www.rdtltd.com/support-and-resource-centre/.

To access the manual, you will need to enter the following details:

Username	TEMPUSPROnnnn	"nnnn" is the last four digits of your Tempus Pro serial number.
Password	w265nnnn	

1.5 Intended users

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

The Tempus Pro and this manual are intended to be used by such clinically-trained personnel. While the Tempus Pro has been designed as a good quality monitor; RDT reminds users that no monitor can replace good clinical judgment 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 manual, other associated labelling and on the equipment.

It is the user's responsibility to ensure they are properly prepared to use the product. No formal training should be required so long as the user reads this manual thoroughly and familiarises themselves with the product before use. RDT can provide direct training courses if preferred.

1.6 Features list

All Tempus Pro monitors come with the following items:

- Lithium-ion battery
- Non-invasive blood pressure hose
- Non-invasive blood pressure cuff
- Masimo patient cable
- Tempus Pro ECG cable
- Tempus mains power supply and mains cable
- Tempus Pro user manual set (CD-ROM)

The following additional items may be included:

- Configurations with a built in capnometer (optional) are provided with an Oridion Military and Air Medical Sample Pack.

Configurations can include an optional 2 Channel Invasive Pressure Module (part number 01-2017).

1.7 Patent and warranty

1.7.1 Patent claims

RDT has applied for patents covering the Tempus Pro and its communications technology in the following jurisdictions: Patents Pending (US No.2006/0287586 EP 1734458 A & other areas).

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

PATENT MARKING: This device is covered under one or more of the following U.S.A. patents:5,758,644, 5,823,950, 6,011,986, 6,157,850, 6,263,222, 6,501,975, 7,469,157and other applicable patents listed at http://www.masimo.com/patents.htm.

1.7.2 Limited warranty

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

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

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

1.7.3 Service support and returns

Repairs made under warranty to any Tempus must be made by the manufacturer. If the device requires repair or return for any reason, please contact your local distributor or Remote Diagnostic Technologies in order to first obtain a returns reference (RMA) number, see “RDT contact details”.

RDT reserves the right not to accept returns which have not first been provided with an RMA number. When calling, please be ready to quote the serial number of the device.

The Tempus Pro is designed to be as maintenance free as possible. The only user replaceable and user serviceable parts are those listed in section 11 of this manual.

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

2 Warnings and cautions

2.1 Safety and note icons

This manual uses 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:

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

2.2 EMC information

The Tempus Pro Patient Monitor has been tested and approved to IEC/EN60601-1-2:2014. This means that the Tempus meets or exceeds the requirements for electrical medical equipment in terms of its levels of emitted electromagnetic (EM) radiation and its susceptibility to electromagnetic radiation from other devices.

In addition, the Tempus Pro has been tested according to the requirements of RTCA DO-160-G section 21 category M.

It should be noted that the Tempus Pro may be affected by high levels of stray EM radiation from other electronic devices (even those which comply with relevant CISPR emission standards) that are being used in close proximity to it.

As required by international medical device standards, the Tempus Pro is intended for use in electromagnetic environments of ±8kV static contact (±15kV air discharge) and magnetic fields of 30 A/m (50/60Hz). The Tempus Pro is proof against radiated RF emissions from 80MHz to 2.7GHz to a level of at least 3V/m. In the event that the Tempus Pro will be used in environments with RF levels exceeding this, please contact RDT for further information.

WARNING 	**Operating high frequency electrosurgical equipment in the vicinity of the monitor can produce interference in the monitor and cause incorrect measurements.**
WARNING 	**Do not use the monitor with nuclear spin tomography (MRT, NMR, NMT) as the function of the monitor may be disturbed.**
WARNING 	**This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Tempus or shielding the location.**

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

2.3 Indications for use

The Tempus Pro is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel, for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for: 3-, 4- 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 CO2 (ETCO2) and respiration rate; pulse oximetry (SpO2); contact temperature; and invasive pressure and extended pulse oximetry capability including; carboxyhaemoglobin (SpCO), methaemoglobin (SpMet), total haemoglobin (SpHb) and total oxygen content (SpOC) measurements.

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

The device is indicated for adults, paediatrics and neonates.

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

* Not cleared for use with the Tempus Pro in Canada or the USA.

2.3.1 Contraindications

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

The Tempus Pro is not intended to be used in strong magnetic or electro-magnetic fields which are generated for medical purposes e.g. MRI.

2.4 General warnings, cautions and notes

DANGER	**ELECTRICAL SHOCK HAZARD when covers are removed. Do not remove covers. Refer servicing to qualified personnel authorised by RDT.**
DANGER	**Explosion Hazard: DO NOT use the Tempus Pro in the presence of flammable gasses such as fuels. Use of the Tempus Pro in such environment may present an explosion hazard.**
WARNING	**The FilterLine may ignite in the presence of O2 when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent flammability of the FilterLine or surrounding surgical drapes.**
WARNING	**The use of the or the or the symbols indicates that the user must read the user manual before using the product.**
WARNING	**When used with the mains power supply, to avoid the risk of electric shock the power supply must only be connected to a supply mains with a protective earth.**
WARNING	**Do not connect the Tempus Pro to an electrical outlet controlled by a wall switch or dimmer.**
WARNING	**To ensure patient electrical isolation, only connect Tempus Pro to other systems which are compliant with the relevant IEC standard e.g. IEC60950, and which employ suitably electronically isolated circuits. Signal input and output connectors are only for connection to equipment complying with relevant IEC safety standards and must be configured to comply with IEC60601-1-1 or IEC60601-1:2005.**
WARNING	**Attaching different medical systems together can cause increases in leakage currents. If the Tempus is connected to other medical devices, or if the patient has multiple devices attached to them at the same time, the cumulative effect of leakage currents must be considered.**
WARNING	**Do not touch the patient at the same time as touching the body or contacts of any of the medical or communications or power connectors.**
WARNING	**Many environmental variables, including patient physiology and clinical application, can affect the accuracy and performance of the monitor. The clinician must verify all vital-signs information prior to patient intervention.**
WARNING	**Do not autoclave, ethylene oxide sterilise, or immerse in liquid the Tempus or any of its cables or accessories as this may cause sensor damage which may result in inaccurate readings.**
WARNING	**Attention should be paid to the following EMC information prior to installing or using the device.**
WARNING	**The Tempus should not be stacked next to other equipment. If this is necessary verify normal operation if utilizing device adjacent to or stacked with other electrical equipment.**

WARNING 	**Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of the device.**
WARNING 	**Computers, cables and accessories not tested to IEC/EN60601-1-2 or equivalent IEC standards may result in increased emissions or decreased immunity of the device.**
WARNING 	**Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.**
WARNING 	**Only use Tempus Pro with the relevant cables and peripherals provided by RDT. Use of any other accessories could result in inaccurate measurements. Use of any other cables or accessories could affect defibrillator protection.**
WARNING 	**Exposure of the wireless communication features of the Tempus Pro or its accessories may be interfered with by other devices which operate at the same frequencies.**
WARNING 	**The sensors of the Tempus Pro are only for contact with intact and undamaged skin.**
WARNING 	**Any device or accessory that has been dropped, damaged or subjected to harsh usage or extreme environmental conditions should be inspected by qualified service personnel prior to use to ensure proper operation.**
WARNING 	**The ECG device is not intended for use in a sterile environment. Do not use for direct cardiac application.**
WARNING 	**Do not attempt to insert the ECG device (including patient cables) into an electrical outlet.**
WARNING 	**The ECG recorder and monitoring functions are for resting ECG and should not be used in stress testing environments.**
WARNING 	**Though false positive errors will intentionally outnumber false negative errors, both will occur, thus the necessity for over reading by a qualified physician of any computer-interpreted ECG. The computer interpretation does not produce a definitive diagnosis.**
WARNING 	**Ensure electrodes are connected only to patient.**
WARNING 	**Conductive parts of electrodes and connectors, including neutral electrode, should not contact other conductive parts including earth.**
WARNING 	**Always keep motion to a minimum. Motion artefact can potentially affect the accuracy of patient readings.**
WARNING 	**Do not connect more than one patient to a monitor. Do not connect more than one monitor to a patient.**

WARNING 	**Do not use the Tempus in a Magnetic Resonance Imaging (MRI) suite or a hyperbaric chamber.**
WARNING 	**Do not place the monitor or its accessories in locations where they could fall onto the patient. When moving the product take care that any connected leads and sensors are not jerked so that they become detached or damaged.**
WARNING 	**The Tempus Pro is protected against defibrillator discharge but rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.**
WARNING 	**During defibrillation, keep the defibrillator's paddles or electrodes away from the monitor's ECG wires, electrodes and any other sensors or conductive parts of the monitor.**
WARNING 	**Pacemaker signals can differ from one pacemaker to the next. The Association for Advancement of Medical Instrumentation (AAMI) cautions that "in some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. All pacemaker patients should be kept under close or constant observation."**
WARNING 	**Device may not operate effectively on patients who are experiencing convulsions or tremors.**
WARNING 	**Misuse or improper handling of the device or its sensors or cables can cause damage which may lead to equipment failure or inaccurate readings.**
WARNING 	**Do not apply excessive tension to any cable. Using a damaged patient sensor may cause inaccurate readings, possibly resulting in patient injury or death. Inspect each sensor. If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair centre for help.**
WARNING 	**The Tempus and all its cables and accessories should be inspected frequently to check for damage. Any worn or damaged items should be replaced. Failing to thoroughly and regularly inspect and maintain the product could result in hazards to patients or equipment failure.**
WARNING 	**Using a damaged patient cable may cause inaccurate readings, possibly resulting in injury or death. Inspect the patient cable. If the patient cable appears damaged, do not use it. Contact your authorized repair centre for help.**
WARNING 	**Ensure that close attention is paid to the alarm configuration settings of the product. If alarm volumes are turned down or if the product is used in noisy environments, then the alarm may not be audible. If alarms are muted this will be indicated on the screen. Always ensure the screen of the Tempus can be seen in case the audible alarms cannot be heard or are turned off.**
WARNING 	**Do not attempt to charge a non-rechargeable battery. Never over charge, crush, heat or incinerate, short-circuit, deform, puncture, dismantle or immerse the batteries in any liquid.**
WARNING 	**Only use rechargeable batteries and battery chargers specified by RDT.**

WARNING 	**Ensure patient cabling or tubing is carefully routed on device to reduce the possibility of patient entanglement or strangulation.**
WARNING 	**All numerical, graphical and interpretive data should be evaluated with respect to the patient's clinical and historical picture.**
WARNING 	**Do not attempt to insert any connections from the Tempus Pro (including patient cables) directly into an electrical outlet. (IEC60601-2-34:2011, 2011).**
WARNING 	**Failure of Operation: If the Tempus Pro fails to respond as described in this user guide; DO NOT use it until approved for use by qualified personnel.**
WARNING 	**Reuse, disassembly, cleaning, disinfecting or sterilizing of any single use items (such as the Capnometer cannula) may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labelled as single patient use is reused.**
WARNING 	**Do not touch the patient at the same time as touching the body or contacts of any of the medical or communications or power connectors.**
WARNING 	**The USB connection must only be connected to non-mains powered peripherals (such as a mouse or keyboard) or to interface accessories provided by RDT (such as the USB-Serial Cable part number 01-1022). Any connections made to the USB port must be to medical or IT peripherals or communications systems which comply with the applicable IEC safety standard (i.e. IEC60601-1 or IEC60950). Any connection arrangements must be made in a manner compliant with IEC60601-1-1 or IEC60601-1:2005.**
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 Centre 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 Centre is not equipped with alarm silencing or suspending controls.**
WARNING 	**When connected to a PC running the i2i application at a Response Centre, streamed data, such as the waveforms displayed on the Tempus Pro, will be transmitted and displayed automatically on that PC's display. Users are advised that streamed data are transmitted using the UDP protocol. The UDP protocol includes error checking but does not retransmit data. Therefore, any data that is dropped, lost or delayed during the streaming process will not be retransmitted. In the event that packets of waveform data are lost, they will appear as gaps in the waveform that is displayed on the i2i interface.**
WARNING 	**Medical data (vital signs data, photos, ECG recordings, patient details, TCCC cards etc.) are transmitted using TCP/IP, this includes error checking and retransmission so missing or dropped packets are therefore retransmitted.**

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

CAUTION 	The Tempus may be used on ambulances or on vehicles using radios. As detailed in section 14.5, it has been tested to determine operation in field strengths greater than 3V/m. Users are advised to maintain the best distance possible between radio antennas and the Tempus as best practice.
CAUTION 	This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.
CAUTION 	The Tempus Pro may not operate correctly if used or stored outside the relevant temperature or humidity ranges described in the performance specifications of this manual.
CAUTION 	Only use only approved accessories supplied by RDT. Conventional 4mm snap-on, pre-gelled ECG electrodes may be used so long as they comply with AAMI EC12. Users are reminded to read and adhere to the instructions for such electrodes including noting single use only status, maximum usage times and patient indications.
CAUTION 	Do not clean the Tempus or its accessories except as directed in this guide.
CAUTION 	In the event that the device displays an error that is not described within this manual e.g. applications errors, turn the device off and then on again. This should clear the error and allow normal operation to resume. Do not continue to use the device if such an error is displayed. If symptoms persist, please contact RDT.
CAUTION 	The Tempus records all data that it measures. In order to ensure that data from different patients is not confused, the device must be switched off between taking readings from different patients or the patient discharge function used.
CAUTION 	Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating. Take care to ensure that water or liquids are not spilt over the device or into its ventilation holes in the side corners.
CAUTION 	If the accuracy of any measurement is in question, verify the patient's vital sign(s) by an alternative method and then check the monitor for proper functioning.
CAUTION 	Follow local government regulations and recycling instructions regarding disposal and recycling of device and device components.
CAUTION 	The Tempus Pro and its accessories use different types of batteries which includes rechargeable and non-rechargeable types. If any battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly.

CAUTION 	Dispose of batteries in accordance with applicable regulations which vary from country to country. In most countries, the disposal of used batteries is forbidden in general domestic and commercial waste and the end-users are invited to dispose of them properly, typically through not-for-profit profit organisations, mandated by local governments or organised on a voluntary basis by professionals.
CAUTION 	Pressing buttons or the touch screen with sharp or pointed instruments may cause permanent damage. Only fingers should be used to press these keys.
CAUTION 	Do not reconnect the headset to its docking pin when the main battery is very low or flat (less than 10% charge – as represented by a single flashing LED on the battery charge indicator). Doing this could reduce the battery charge into a “deep discharge” state (where no battery lights come on).
CAUTION 	Use of monitoring during continuous nebulised medication delivery will result in damage to the device which is not covered by the warranty. Disconnect the Capnometer sample line from the device, or switch off the device, during medication delivery.
CAUTION 	Observe proper battery polarity (direction) when replacing batteries. The batteries slide easily into place when correctly oriented and should not be forced.
CAUTION 	The mobile RF communications equipment contained within the device and its accessories can affect other medical devices that are in close proximity to the device.
CAUTION 	Use of the RF communications equipment contained in the device and its accessories may be prohibited in a number of areas. These include: on aircraft in-flight (including during take-off and landing), near defibrillators (that are in use), near other electronic medical devices and in hospitals.
CAUTION 	In addition, the use of the RF communications equipment contained in the device and its accessories may be prohibited in explosive atmospheres e.g. in fuelling areas, near fuel or chemical transfer or storage areas and in areas containing chemicals or particles such as grain, dust or metal powders.

CAUTION

The use of the RF communications equipment contained in the device and its accessories may cause interference with implanted pacemakers and other medically implanted equipment.

A minimum distance of 2.3 m (7.5 ft) must be maintained between the device and its accessories (containing RF communications equipment) and other medical equipment (including implantable medical devices such as defibrillators and pacemakers). If such medical equipment has an electromagnetic interference immunity level of less than 3V/m (or 10V/m for implantable devices), this distance should be increased in line with the requirements of IEC60601-1-2:2014.

If the intended patient has an implantable device (e.g. pacemaker), do not use any of the Tempus Pro's RF communications equipment (e.g. Bluetooth® or WiFi) before using the device to record the patient's physiological data. After the data recording session is completed, move the device at least 2.3 m (7.5 ft) away from the patient, and then use it normally to communicate with the base station. Otherwise, radiofrequency radiation from the device (up to 63mW) may adversely impact the implantable pacemaker in the patient. If the patient's implantable device has an immunity level less than 10 V/m, the separation has to be greater than 2.3 m (7.5 ft).

If you suspect interference is being caused, disconnect from the Response Centre by pressing . Interference could include visible interference on equipment displays, audible interference e.g. buzzing, from speakers of other equipment, or equipment unexpectedly changing state e.g. functions starting or stopping.

Example of a PC display without interference:

Example of a PC display with interference:

CAUTION 	When using the device with GAN terminals, in order to avoid the risk of interference from the output beam from the antenna of the terminal with the operation of the device, ALWAYS ensure that the device is situated at least 6m behind the face of the antenna. Since the power of the GAN terminal's beam is high (25W approx.), care should be taken to ensure that the antenna remains fixed and to maintain the device away from the face (and therefore the beam) of the antenna.
CAUTION 	RF energy may affect some electronic systems in motor vehicles, such as car stereo, safety equipment, etc. Check with your vehicle manufacturer's representative to be sure that your product will not affect the electronic system in your vehicle.
CAUTION 	Do not use the Tempus Pro's Bluetooth® or WiFi communications on-board any aircraft where its use is prohibited.
CAUTION 	Take care to minimise the risk that trailing cables will be caught by passers by.
CAUTION 	Prior to deployment of Tempus Pro there are settings that user organisations need to configure. Carefully check all the relevant settings on each Tempus Pro before it is deployed. For more information, see "4.1 Before deployment".
CAUTION 	If you use mounting systems that are not supplied or approved by RDT, we cannot guarantee the performance of the Tempus Pro.

Note 	The Tempus has been tested and found to comply with IEC/EN 60601-1-2.
Note 	If all the battery lights remain off when the battery button is pressed, the battery may be in a "deep discharge" state. The battery is not damaged when in this state but will require an extended period on an external charger (additional 24 hours) in order to restore normal operation.
Note 	Important! The Tempus Pro is intended for use in the electromagnetic environment(s) specified in this manual. Users of this equipment should ensure that it is used in such environment(s).
Note 	After the life cycle of the Tempus Pro and its accessories have been met, disposal should be accomplished following national and/or local requirements.
Note 	Operation of the device may be adversely affected in the presence of conducted electrical transients or strong electromagnetic or radio frequency sources such as electrosurgery and electrocautery equipment, HF radio transmission antenna, x-ray machines and high intensity infrared radiation.
Note 	All user and patient accessible materials are non-toxic.
Note 	Hazards arising from software errors have been minimised. Hazard analysis was performed to meet the requirements of EN14971 and IEC60601-1-4.
Note 	Each external connection and part of the device is electrically isolated.
Note 	Performance and safety test data are available on request from RDT, see "RDT contact details".

Note	GSM usage is restricted by the network availability, roaming agreements and local provision of circuit mode connections.
Note	IP sealing is not guaranteed if the device is subject to rough handling, impact, improper use or rapid decompression.
Note	Device should be returned for service if it is subject to rough handling and IP sealing is needed to be relied upon.
Note	The device specifications are subject to change without notice.
Note	It is recommended that the device is connected to the Response Centre every month for a test patch.
Note	The iAssist help processes on your Tempus Pro may differ from the example iAssist help process used in this manual; however, the process always follows the same key elements.
Note	Always ensure that you read the complete iAssist help process in order and do exactly what it requires.
Note	For optimum performance of the wireless communications, please make sure that there is no metal surrounding the Tempus Pro.
Note	Over bending the folding foot or RapidPak clip could cause them to be damaged. Do not over-bend these items.
Note	Take care when repacking cables to ensure they cannot be snagged or damaged in the RapidPak clip and the folding foot.
Note	The Tempus Pro should be repacked following the relevant instructions. Lost or damaged cables and accessories should be replaced with spares ordered from RDT.

3 Introduction to the Tempus Pro

The Tempus Pro is a multi-parameter vital signs monitor designed for use in pre-hospital and remote locations. It provides the user with conventional patient monitoring parameters for use in measuring and monitoring patient's vital signs.

The device also provides the user with the ability to capture patient incident data in electronic format. This data can be passed from one Tempus to another to enable the patient's record to remain with them as they move from one caregiver to another.

In addition, the device also gives the user the ability to transmit all data in real-time to a Response Centre using a variety of integrated communications interfaces. If data is being transmitted, the device also allows the user to transmit still or moving pictures via an integrated digital camera and also to speak to the Response Centre using a wired or wireless headset.

The Tempus Pro is intended to be used by trained clinical staff.

The Tempus Pro can provide the following information about the patient from its sensors:

- ECG Monitoring;
- Real-time arrhythmia detection and alarming;
- Real-time ST and QT measurement and alarming;
- 12 Lead Diagnostic ECG Recording;
- 12 lead ECG recording interpretation;
- Impedance pneumography (respiration rate measured through ECG leads);
- Heart rate (from ECG) or pulse rate (from pulse oximetry);
- Non-invasive blood pressure;
- End tidal CO2 (ETCO2);
- Respiration rate;
- Pulse Oximetry including Oxygen saturation (SpO2) pulse oximetry (SpO2), Total Haemoglobin (SpHb), Methaemoglobin saturation (SpMet), Carboxyhaemoglobin (SpCO), Oxygen Content (SpOC), Pleth Variability Index (PVI);
- Temperature;
- Invasive pressure.

Tempus Pro is also able to display ultrasound and video laryngoscopy images on its large colour display utilising third party ultrasound probes and video laryngoscopy accessories. For more information, please refer to *Tempus Pro Ultrasound Supplement Guide* (Part number 42-2003) and *Tempus Pro Laryngoscope Supplement Manual* (Part number 42-2004).

To display anaesthetic agent gas vital signs on the Tempus Pro, you can use the Masimo ISA OR+ Anaesthetic Gas module (available from RDT). For more information, see the *Tempus Pro AA Gas Supplement Guide*.

3.1 Overview of the Tempus Pro

The Tempus Pro consists of a PC-ABS plastic enclosure which is over-moulded with TPU material to make it resistant to shock. The enclosure also includes the RapidPak™ clip which provides storage for the SpO_2 sensor, the adult NIBP cuff and hose and the ECG cable.

The unit has a clear window on the top which contains the alarm bar. This lights yellow or red for clinical alarms. The alarm bar can be configured by the user to light green in all non-alarm conditions. The alarm bar has a small aperture at the rear of the case which allows the alarm status to be seen from the rear. In addition, light from the alarm bar is distributed by the translucent handle which sits across the top of the device.

3.2 Key features of the unit

3.2.1 Tempus Pro front

On the front of the unit is a large, colour display which is fitted with a touchscreen. The touchscreen may be used with a gloved hand or plastic stylus. Around the touchscreen are two panels of membrane buttons (left/below and right).

Also on the front are grilles covering the alarm speaker. Care should be taken not to probe through the grilles with any sharp or pointed object.

The Tempus Pro

3.2.2 Tempus Pro base

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

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

3.2.3 Tempus Pro rear

Non-printer models

If the Tempus Pro is not fitted with an internal printer (part number 00-1004-R or 00-1007-R):

- The rear houses the RapidPak clip (discussed above).
- Also on the rear is the aperture for the camera and backlight.
- The clip carries a general product label for regulatory purposes and also two labels which help guide the user to repack the SpO_2 sensor and the ECG cable.

If the Tempus Pro is a non-printer model with Bluetooth headset (part number 00-1007-R):

- The Bluetooth headset is docked onto a connector which enables the Tempus Pro to top its charge up automatically on a regular basis, thus ensuring the headset is always ready to use.
- The Bluetooth headset is a Sennheiser Presence or Sennheiser VMX200.

The Rear of the Tempus Pro (non-printer model)

Printer models

If the Tempus Pro is a printer model (part number 00-1022-R, 00-1024-R or 00-1026-R):

- The rear houses the internal thermal printer.
- Also on the rear are the camera, backlight and moveable foot.
- The RapidPak clip is absent.
- The ECG cables, SpO2 sensor and NIBP cuff are stored in the bag.

(1) Rear alarm light

(2) Camera and backlight

(3) Printer

The Rear of the Tempus Pro (printer model)

3.2.4 Tempus Pro left side

The left side of the device contains seven connectors for:

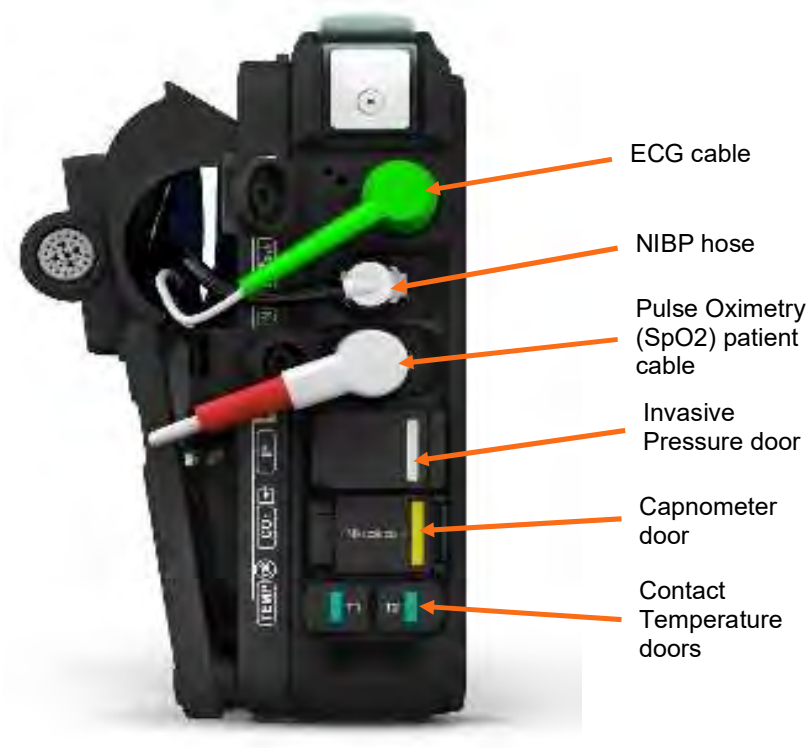
- ECG monitoring and Diagnostic ECG - green;
- NIBP - white latching connector;
- Pulse oximeter (SpO2 and pulse rate) – light grey
- Invasive pressure – white;
- Capnometer (ETCO2 and respiration rate) - yellow;
- Contact temperature (2 sockets marked T1 & T2) - turquoise.

WARNING	**Do not touch the patient at the same time as touching the body or contacts of any of the medical or communications or power connectors.**
CAUTION	Consideration needs to be made to the potential for leakage currents to be created if the Tempus or its connectors are made wet or dusty. In the event that any connectors (but particularly patient leads i.e. ECG, Invasive Pressure, SpO_2, contact temperature) or their respective sockets become wet or contaminated with sand or dust, they should be cleaned and dried before use – see "10.2.4 Cleaning the NIBP cuffs and hose". Connectors and their immediate surrounding areas should be clean and dry at all times.

Normally the ECG, NIBP and SpO_2 connectors will have their sensor cables attached at all times.

The Tempus' connectors are rated IP66 in their own right and are therefore water proof and sand proof against ingress of water or particulate into the device's enclosure without the covers. The covers provide

additional protection to prevent nuisance ingress of sand into the connectors in the event that a cable or sensor is not in place.



Left side of the Tempus – medical connectors

3.2.5 Tempus Pro right side

The right side of the Tempus houses the data communication and power connections. These comprise:

- Two USB 1.0 & 2.0 sockets – these are reserved ONLY for non-mains powered radios (or other communications devices), non-mains powered USB peripherals (such as keyboards) or non-mains powered medical accessories. Any accessory or peripheral attached to the Tempus MUST be approved for use with the Tempus Pro by RDT.
- Mains Power – only use the Tempus Pro approved mains power supply part number 01-2049 provided by RDT.
- Audio – this is only for use with the Wired Headset (part number 01-1019) supplied by RDT or for use with the Tactical Headset Adaptor Cable (part number 01-2041) supplied by RDT (this cable adapts to Peltor® or similar military-style headsets).
- Tactical Switch – this switch allows the user to switch the Tempus' visual and audible outputs to a minimal setting and is described in section 4.3.2.

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

WARNING 	**Always use a Baaske MI 1005 isolation device when connecting from the Ethernet socket to any mains-powered communications device (e.g. router, access point, hub, communications terminal etc.).**
WARNING 	**The Ethernet connection must only be connected to battery powered (non-mains-powered) communications devices such as laptop computers or satellite communications terminals such as BGAN or VSAT terminals. Any connections made to the Ethernet port must be to medical or IT peripherals or communications systems which comply with the applicable IEC safety standard (i.e. IEC60601-1 or IEC60950). Any connection arrangements must be made in a manner compliant with IEC60601-1:2005 or IEC60601-1-1:2001. Users must ensure that they maintain the communications device 1.5 m away from the patient and also must ensure the user does not touch the communications device while touching the patient. If such devices require mains power then the device must be powered using a power supply compliant with the electrical isolation requirements IEC60601-1.**
WARNING 	**The audio connector must only be connected to unpowered microphone headsets or battery powered microphone headsets (such as Peltor® or Bose®). Further details can be obtained from RDT upon request.**
WARNING 	**Do not touch the patient at the same time as touching the body or contacts of any of the medical or communications or power connectors.**

CAUTION 	Do not use USB hubs (powered or unpowered) with the Tempus. This could cause the USB sockets to cease operating.
CAUTION 	Consideration needs to be made to the potential for leakage currents to be created if the Tempus or its connectors are made wet or dusty. In the event that any or their respective sockets become wet or contaminated with sand or dust, they should be cleaned and dried before use – see “10.2.3 Cleaning connectors”. Connectors and their immediate surrounding areas should be clean and dry at all times. Ensure the communications connectors are securely covered with their dust covers (if fitted) at all times.

Right Side of the Tempus – Communications Connectors

3.3 Theory of operation

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

3.3.1 Pulse rate and oxygen saturation (SpO_2)

Pulse oximetry measures functional oxygen saturation.

Pulse oximetry is based on the following:

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

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

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

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

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

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

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

3.3.2 Non-invasive blood pressure

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

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

3.3.3 Electrocardiograph (ECG)

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

- a 3-lead cable to monitor ECG leads I-III;
- a 4-lead cable to monitor ECG leads I-III, AvR, AvL and AvF;
- a 5-lead cable to monitor ECG leads I-III, AvR, AvL, AvF and a user-placeable V lead.

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

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

3.3.4 Impedance pneumography

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

The impedance method is an indirect measurement of respiration and is also subject to muscle noise and electrode placement and therefore is inferior to the respiration rate measurement provided through capnography.

3.3.5 End tidal CO_2 ($ETCO_2$) and respiration rate

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

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

The Microstream® $EtCO_2$ consumables deliver a sample of the inhaled and exhaled gases from the ET tube adaptor or directly from the patient (via an oral/nasal cannula) into the monitor for CO_2 measurement.

Moisture and patient secretions are extracted from the sample, while maintaining the shape of the CO_2 waveform.

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

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

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

3.3.6 Temperature

Two channels of contact temperature are measured through two sockets on the Tempus. These sockets are compatible with YSI type 400 probes only. A range of third-party YSI 400 series compatible transducers may be used with the Tempus. These transducers may be re-usable or disposable.

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

The thermometer’s reading can be presented in ºC or ºF.

3.3.7 Invasive pressure

Two channels of invasive pressure are measured through a socket on the Tempus. An interface cable is required to be attached to this socket, the interface cable splits into two ends, each of which can be connected to a third-party pressure transducer (with a sensitivity of 5 µV/V/mmHg). A range of third-party transducers (both reusable and disposable) are available. A list of compatible sensors is provided in section 14.8. A different interface cable is required to adapt the Tempus’ socket to the specific connectors of each type of transducer.

The Tempus measures pressure by measuring the changing resistance in the transducer. When a transducer is correctly attached to the Tempus and to the patient’s blood stream e.g. in the pulmonary artery, the Tempus obtains a constant reading of resistance that equates to the systolic and diastolic pressure. From this mean arterial pressure and heart rate are also calculated.

The option to use two additional channels invasive pressure measurement is provided by an external USB IP Module. The 2 Channel IP Module can be located adjacent to the Tempus Pro or clipped onto a new feature on the rear clip. There is no setup required to connect the USB device to the Tempus Pro, other than plug the USB cable in. The Tempus Pro will automatically recognise that the module is attached.

3.3.8 Controls and indicators

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

Note	Touchscreen and membrane buttons should be pressed once. As with all touchscreens if your finger wavers or quivers, the Tempus Pro may register it as more than one press.
Note	To display ultrasound and video laryngoscopy images on the Tempus Pro's large colour display, you can use third-party ultrasound probes and video laryngoscopy accessories. For more information, see the *Tempus Pro Ultrasound Supplement Guide* and *Tempus Pro Laryngoscope Supplement Guide*.

3.3.9 Summary Record of Care / Tactical Combat Casualty Care

The Tempus contains an electronic patient record card known as a Summary Record of Care (SRoC). This is completed semi-automatically through the collection of vital signs and the use of the Event button. SRoC allows the user to record patient trauma details and to review historic events and trends.

SRoC is automatically augmented with patient encounter data when:

- An arrhythmia alarm is triggered. The Tempus Pro automatically logs an event. You can also store a snapshot of the waveform at the same time, see the All Alarms menu.
- A waveform snapshot is manually captured. To capture a waveform at any time, press and release the Camera & Waveform Snapshot button.
- A 12 Lead ECG is recorded.
- A camera or laryngoscope image is recorded. For laryngoscope details refer to *Tempus Pro Laryngoscope Supplement Guide*.
- An ultrasound image is recorded. Images can be taken during general and FAST exams. Refer to *Tempus Pro Ultrasound Supplement Guide*.

Tempus Pro can also be configured to record a Tactical Combat Casualty Care (TCCC) card (this feature only applies to Tempus units configured with the TCCC patient report type); for details see “9.3.2 Updating the TCCC card”.

3.3.10 Previous activity button

The Previous Activity button allows the user to return to the last non-monitoring function that they were using i.e.:

- TCCC card
- Summary Record of Care
- Enter patient details
- Discharge patient

3.3.11 Trends

All vital signs are captured on the device. These can be easily viewed as a graphical or tabular trend. Also included in the trends are all alarm states and Events.

3.3.12 Data handover

The Events, Trauma Record and Trend data (as well as photos and 12 Lead ECGs) are automatically collated together to form a Summary Record of Care patient report. This can be exported from the Tempus via USB and handed to the next caregiver within the care path. Should the next caregiver have a Tempus Pro, the data may then be viewed and augmented on that unit. Alternatively, the data may be viewed on any computer that is capable of reading .PDF files.

3.3.13 Email

An encrypted PDF formatted Summary Record of Care can be shared using email. Encryption and data transfer are performed using FIPS- 140-2 compliant technology.

3.3.14 ePCR export

Summary Record of Care data can be exported to an electronic Patient Care Reporting system (ePCR). Encryption and data transfer are performed using FIPS- 140-2 compliant technology. This feature is optional.

3.3.15 Communications

GPS

The Tempus contains a Global Positioning Satellite (GPS) receiver. This can be used to detect signals from multiple geostationary satellites to obtain a location (expressed in terms of longitude and latitude). The GPS receiver needs a clear view of the sky to work and so must be used outside.

Digital camera & waveform snapshot

A miniature digital camera is mounted in the unit. Still photos of the patient can be taken which are then automatically added to the patient record.

Photos can be transmitted to a Response Centre at the time (if the device is connected to a Response Centre) or transmitted later. In addition, if the Tempus is connected then live moving video can be transmitted (one way from the Tempus to the Response Centre). This enables the user to show to colleagues the patient and what is happening to them.

The Camera & Waveform Snapshot button is a two function key. Pressing the button will record the previous ten seconds and the following ten seconds of the waveforms for review. Pressing and holding the button will take you to the Camera & Video Options Menu.

Long range voice and data communications

In addition to being able to operate as a vital signs monitor, the Tempus Pro can optionally transmit all of its measurements via a communications link to a Response Centre. The device allows the Response Centre to see exactly what is on the Tempus' display in real time. Therefore, the Response Centre user can see what the patient's vital signs are, if they are in an alarm condition etc. In addition, the Response Centre user can control the device remotely (except for the alarm controls on the membrane keypad which are not provided to the Response Centre user).

The Tempus also allows the user to talk to the Response Centre user via a wired or wireless headset.

The user at the Response Centre is able to receive still photos from the device and is also able to annotate these pictures (with words, symbols and markings) and send back to the Tempus device to better illustrate the verbal instructions being given to the operator at the remote location. The Response Centre user can also receive moving video from the Tempus.

The Tempus Pro can connect over either wired or wireless (WiFi) Ethernet networks.

All data, voice and video that is transmitted can be secured using FIPS- 140-2 compliant encryption technology.

If the device is connected to a Response Centre, then all the readings are transmitted via a communications link to a computer at a Response Centre which enables the user there to see exactly the same information that is being displayed on the device in real time. The only exceptions to this are when a 12 Lead ECG is being monitored or recorded and when a still photo is being taken – in both cases the data (ECG or picture) is first recorded and then transmitted to the Response Centre.

ECG data and digital pictures take the following amount of time to send to the Response Centre:

- 12 lead ECG recordings – 1 minute
- Digital picture – up to 30 seconds

Note 	These times are for guidance only and are based on the use of a 64kbaud or greater connection. Real time data and waveforms are transmitted with up to a 5 second delay.
Note 	RDT recommends that users perform a test connection to the Response Centre every month in order to verify that their communications remain open for the Tempus to use.

Bluetooth® communications

The Tempus is fitted with a Bluetooth® radio. This enables it to communicate with other Bluetooth® enabled devices. The Tempus can be provided with an optional Bluetooth headset for providing voice communications.

3.3.16 On-screen user instructions

The Tempus provides the user with a conventional vital signs monitoring user interface. It can also be set to provide additional on-screen instructions in the form of text and graphics. This is called iAssist mode. It is intended for use by a trained healthcare professional, who may benefit from additional instructions on how to attach the monitor to a patient. It is assumed that a more skilled or experienced user will turn the iAssist feature on before handing the device to the more junior colleague.

iAssist is intended to make the device easier to use, provide on-screen instructions and provide context sensitive errors in order to help the user apply the device. It does not change the behaviour of the patient or technical alarms except to provide more on-screen and graphical instructions in some cases.

Using iAssist means that the format of the results (Home Screen) changes from a 4 channel (2 ECG, Plethysmogram and Capnogram) layout to a 3 channel (1 ECG, Plethysmogram and Capnogram) layout.

iAssist instructions are available for ECG monitoring, Non-Invasive Blood Pressure, Pulse Oximetry, Contact Temperature and Capnography. iAssist instructions are not available for invasive pressure as this process requires specific training and is surgically invasive. Instructions are not included for use of a 10-wire ECG cable as this requires specific training.

4 Setting up

4.1 Before deployment

Prior to deployment of Tempus Pro there are settings that user organisations need to configure. Carefully check all the relevant settings on each Tempus Pro before it is deployed. When deploying multiple units, you may set up a single unit and export the configuration from one unit to the others (cloning the settings).

Three types of configuration are exporting and imported:

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

Summary record of care events include:

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

New patient defaults include:

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

Settings include:

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

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

4.2 Unpacking the Tempus Pro

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

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

Users should ensure that all expected items are received with the Tempus when first opening the delivery case.

The Tempus Pro

As detailed in section "1.6 Features list", the Tempus Pro is supplied in a number of configurations. Confirm that all items ordered have been received.

4.3 Starting and stopping the Tempus Pro and selecting a patient

4.3.1 Switching on

WARNING	**Ensure the latches on both sides of the battery are fully engaged prior to using the Tempus - an incorrectly fitted battery could result in the Tempus losing power during use.**
CAUTION	Do not press any of the controls until the Tempus has started.

To switch on the Tempus Pro, press and hold the  button on the front panel for 1 second. The LED on the  button will flash green. The device is ready for use when the LED shines green constantly.

When the Tempus starts it will briefly light the alarm bar and sound the patient alarm. This is to demonstrate that these functions are operational and must be checked by the user (with the tactical switch off).

4.3.2 Tactical mode (optional)

WARNING	**To ensure that the Tempus Pro is safe to use when colleagues are using NVGs (night vision goggles), use only the settings in the green shaded NVG areas of the Tactical Menu: LED Indicators set to off, Brightness set to Min, Low or Mid.**
WARNING	**The Tactical Switch is intended for use by military and civilian pre-hospital care users for scenarios where low emitted light and low emitted sound is required or desired. Users are reminded that while these functions are enabled, the device will not emit visual alarms from the alarm bar, will not emit audible alarms from the speaker and may present a display that may be too dim to see in daylight conditions. Users should therefore ensure that they use these features only when required and recognise that greater levels of patient care and supervision will be required.**

It should be noted that the Tempus may be started in a low emitted light and silent state by using the Tactical switch on the right hand side of the device.

Tempus Pro Tactical Switch

When the switch is set closest to the  symbol the Tempus will start in the following configuration:

- All alarm LEDs off;
- All audible signals off;
- Wireless functions (if enabled by configuration) off;
- Display set to mid brightness and standard contrast mode.

In this condition, the following menu of display options will be shown:

Tempus Pro Display Tactical Menu

Note	To toggle high contrast, press and hold the Display button  for two seconds.

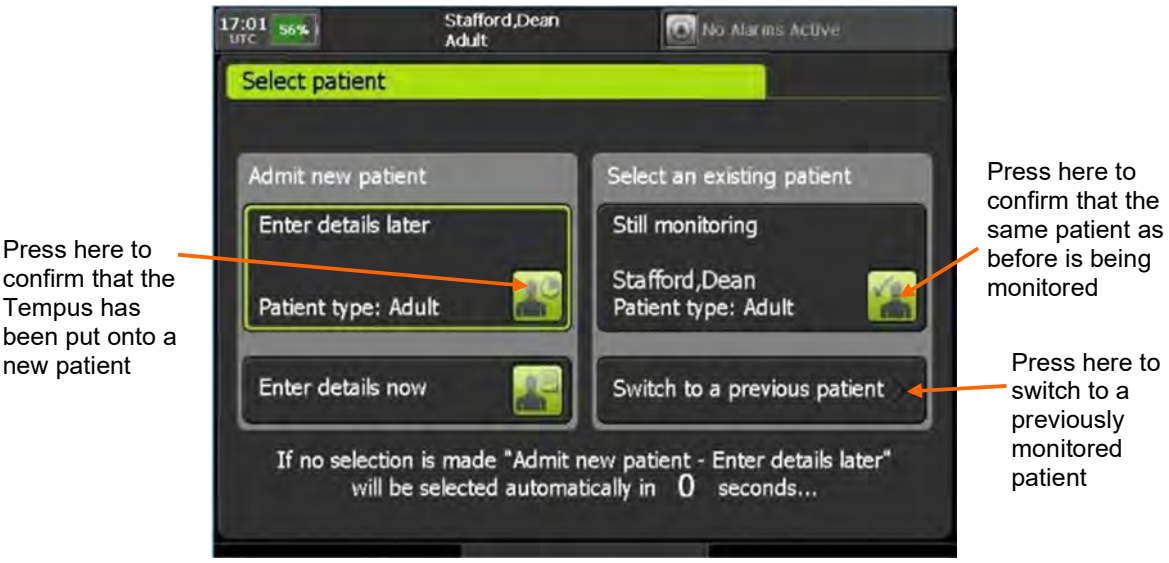
Note	Toggling the Tactical Switch will immediately return the display settings to their previous configuration i.e. display brightness, all LEDs active, alarms set to the default level and high contrast off.
Note	The Tactical Switch disables the ac power and charging LEDs; these are only re-enabled using this switch.
Note	The battery charge LEDs are not disabled using the Tactical Switch.

4.3.3 Setting the patient

WARNING	**Ensure that you select the correct patient record. Records can be identified by patient name (last and first), ID number, or incident start time. If you are not sure if the record you wish to select is the correct one, then select new patient. Mixing different patient's records could lead to confusion and misdiagnosis.**

When the Tempus is turned on, it will ask if it is monitoring a new or previous patient. If the Select Previous Patient option is pressed, the Tempus will show all patients monitored in the last 72 hours i.e. any patients whose monitoring started within the last 72 hours.

If any patients have been monitored in the last 72 hours, then the dialog will also include (shown below) an option to select the last patient that was monitored.



Patient type is defined as Adult, Child (paediatric) or Neonate. For more information on these groups and how to select them, see "9.3.5 Entering patient details".

4.3.4 Starting and stopping iAssist

The iAssist function gives additional on screen instructions for:

- Using the ECG
- Taking non-invasive blood pressure readings
- Taking blood oxygen readings
- Taking $C0_2$ readings
- Taking temperature readings

To switch it on or off:

1. Press the Main Menu button  .
2. Slide the iAssist switch to On or Off. When switched on, iAssist buttons appear at the bottom of the home screen.

4.3.5 Switching off

Before switching the Tempus Pro off, you should make sure that it is not in use.

To power off quickly with no countdown or confirmation:

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

To power off with countdown and confirmation:

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

Power Off Dialog

Note	Before removing the battery, you must switch off the Tempus Pro by pressing the power button. Do not remove the battery when the Tempus is on (unless there is a power supply attached to the device).
Note	If necessary, you can force a hard shut-down by pressing and holding the power button for 10 seconds.
Note	Remember that the battery cannot be removed until the lamp on the front panel has gone out.

5 Using the Tempus Pro

The Tempus can be used laying on its back or standing on its foot.

5.1 Controlling the Tempus Pro

Tempus Controls

The Tempus can be controlled through two different control interfaces. These are:

- The touchscreen;
- The graphically labelled membrane buttons.

5.1.1 The touchscreen

Note	Take care to press the touchscreen once for any control. Users should press the controls firmly with a finger (gloved or bare skin can be used). Pressing the touchscreen lightly can lead to "double presses" if the user's finger wavers or quivers. If the touch screen is pressed twice in quick succession and there is a control in the same area where the finger pressed *after* the first control would have disappeared (if the screen changes etc.) then the Tempus will register the second press as activating the second control before the control appears.

When the device is started it will present as follows:

4 parameter channels are provided. These are labelled and colour coded to the patient connectors on the side

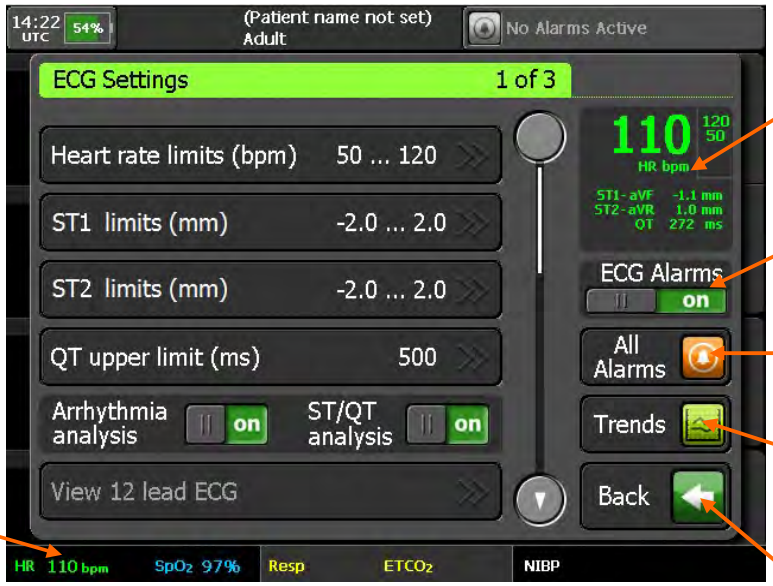
No patient sensors have been connected yet so this is indicated for each parameter

Vital signs readings are displayed in these areas alongside alarm limits (if applicable)

Each parameter area is a button which can be pressed to access the settings for that parameter

The Home Screen at Start up

Pressing any of the parameter areas will access the controls and settings menu for that parameter. For example, if the ECG area is touched, the following menu will be shown:



Real-time vital signs are shown across the bottom

The current measurement is always shown here

The parameter alarms can be turned off and on here

All alarm settings can be accessed here

Graphical and tabular trends can be accessed here

Press here to return to the results screen

ECG Settings Menu 1 of 2

5.1.2 Membrane buttons and LED indicators

The Tempus can be controlled through the following membrane buttons:

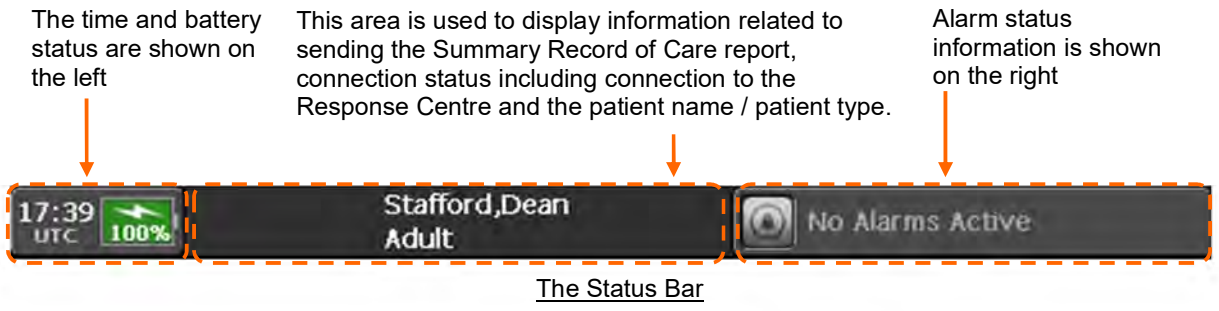
	The **On/Off** button – pressing and holding down this starts and stops the Tempus – see "4.3.1 Switching on".
	The **Alarm Suspend** button – pressing this latches all alarms off for 2 minutes (factory default – this is configurable by the operating institution) – see "7.6 Silencing or suspending alarms".
	The **Alarm Silence** button – pressing this stops any audible alarm signals for 2 minutes (factory default – this is configurable by the operating institution) from monitoring parameters (and clears alarm signals from discrete measurements such as non-invasive blood pressure – see "7.6 Silencing or suspending alarms".
	The **Home** button - this returns the unit to the results screen
	The **Data Input/Output** button – pressing this launches a menu which offers options on outputting data to peripherals such as printers or USB memory sticks – see "9.1 Data input and output". Note that pressing and holding the Data Input/Output button for 2 seconds will automatically launch the function that is shown at the top of the Data Input / Output menu. This acts as a short cut to make activating this function easier.
	The **Display** button – pressing this launches a menu which offers a range of display options – see "9.2 Display options". Note that pressing and holding the Display button for 2 seconds will automatically switch the display mode into a high contrast mode (black on white) for use in strong daylight conditions. This acts as a short cut to make activating the high contrast display easier.
	The **Patient** button – pressing this allows the user to manage the patient information – see "9.3 Patient information". Note that pressing and holding the Patient Information button for 2 seconds will automatically launch the function that is shown at the top of the Patient Information menu. This acts as a short cut to make activating this function easier.
	The **Connect** button – pressing this will bring up instructions on how to connect the device to a Response Centre to transmit voice, data and images in real time – see "9.6 Connecting to an alternate location".
	The **Disconnect** button – if the device is connected to a Response Centre (i2i ReachBak only), pressing this will bring up a 10 second countdown after which the voice and data connection will be dropped – see "9.6 Connecting to an alternate location".

	The **Camera & Waveform Snapshot** button – pressing and releasing this starts the waveform capture, pressing and holding will start the camera – see “8 Summary Record of Care”. Note that certain events will cause the Tempus to capture a waveform automatically – see “8.1.4 Automatic event capture”. Note for devices with software revisions earlier than v4 this button will only perform the camera function. Please contact RDT for software updates.
	The **Main Menu** button – pressing and releasing this will take you to a full menu to access all features of the product – see “5.2.1 The main menu”.
	The **Event** button – brings up the Summary Record of Care (SRoC) and provides access to trend graphs, trend tables and the TCCC card (if configured).
	The **Previous Activity** button – pressing this will take you back to whatever non-monitoring function you were last performing. For example, this button could be pressed to take you back into the trauma card if you had been editing it and a patient alarm had gone off – see “3.3.10 Previous activity button”.
	The battery gas gauge button – pressing this will light the power status LEDs on the battery – see “11.1.1 The battery”.
Also on the membrane are two LEDs, these are indicators and not a button, their function is described below:	
	**Mains power** LED – lights solid green when the mains charger is attached
	**Battery charger** LED – flashes green for up to 20 seconds when a battery is first connected and the device is being run from mains power, then lights solid green as long as mains power is attached and the battery is not fully charged – see “11.1.3 Charging the battery”.

5.1.3 Status bar

The status bar at the top of the screen shows the time, battery status, communications status and alarms status – see “7 Alarms”.

The current patient name and patient type appears in the centre of the status bar until any wired or wireless communications devices are being used then this will be shown in the centre of the status bar.



The Status Bar

Battery status indicator

The battery status indicator in the status bar shows the percentage of battery charge remaining:

Icon	Status	Indication/Action
	Green, no flash	Battery charge remaining: 51% - 100%. Tempus Pro battery is not currently charging.
	Green with flash	Battery charge remaining: 51% - 100%. Tempus connected to mains power (charging in progress).
	Orange, no flash	Battery charge remaining: 26-50%. Tempus Pro battery is not currently charging.
	Orange with flash	Battery charge remaining: 26-50%. Tempus connected to mains power (charging in progress)...
	Red, no flash	Battery charge remaining: 0% - 25%. Tempus Pro battery is not currently charging: connect it immediately!
	Red with flash	Battery charge remaining: 0% - 25%. Tempus connected to mains power (charging in progress).
	Unknown battery status	Tempus cannot communicate with battery. Check the following: • Is the battery fitted? • Are the battery clips fully engaged? • Are the battery contacts clean and undamaged? • Is the battery in deep discharge state? For more information, see “11.1.1 The battery”.

Note 	The battery charge can always be checked by pressing the battery gas gauge button, even when the Tempus is switched off – see “11.1.1 Checking the charge of the battery”.

5.1.4 Status bar for communications

The centre section of the status bar shows if any communications features are being used. If any Bluetooth® devices are in use, then the Bluetooth® symbol will be shown and along with the number of peripherals that are connected to the device.

Note	It does not identify the specific peripheral connected to the Tempus Pro.

If a WiFi connection is in use, then this will be shown.

If an external Invasive Pressure module is attached, then this will be shown.

The information displayed in the communications area of the status bar is based on the following priorities:

- Email – highest priority
- Response Centre communication
- Patient name & type – lowest priority

Email status bar messages

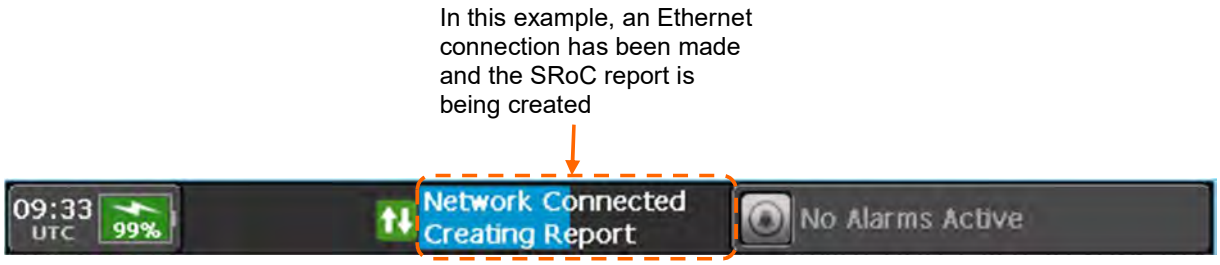
When the Summary Record of Care is being shared using email, the upper part of the status area is used to display the connection progress whilst the lower part of the status area is used to indicate the progress related to the Summary Record of Care report creation and sending.

The connection progress messages (upper part) may be:

- Network Connecting
- <Carrier name> e.g. Vodafone UK (only in GSM mode)
- Network Connected (only in Wi-Fi or Ethernet modes)

The SRoC report progress messages (lower part) may be:

- Creating Report
- Sending Report
- Report Sent (displayed for 30 seconds after completion)



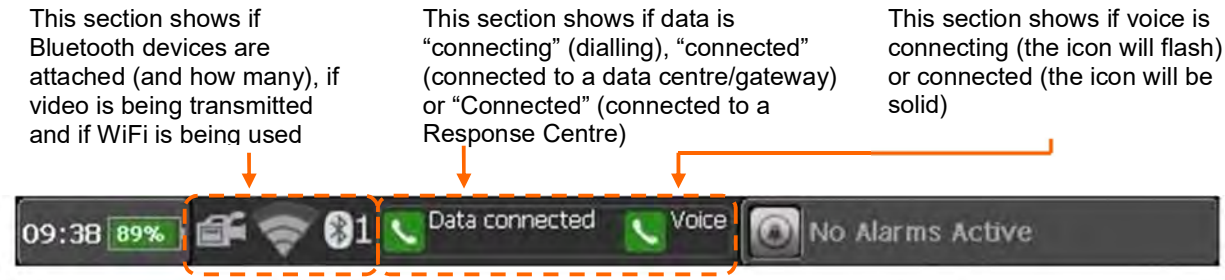
Status bar when SRoC report is shared via email

Response Centre (i2i) communication

If a data connection is in progress this will be shown. The green icon will flash when the connection is in being established and the text will read “Data connecting”. When a link to the data centre (gateway) has been made the icon will stop flashing and the text will read “Data connected”. At this time the Tempus will be connected to the data centre (gateway) but will not be transmitting any patient data until a Response Centre user initiates the connection from their terminal. Once they have done this the text will read “Data Connected”.

Note	To transmit data, you must have a manned Response Centre who have the i2i software installed and who have familiarised themselves with its operation. Full installation instructions are provided with the i2i software and support is available from RDT, see “RDT contact details”.

If a voice connection has been initiated, then an additional green icon will appear with the text “Voice” next to it. The icon will flash while the voice connection is being established and will stop flashing once the call has been picked up by the Response Centre. If video is being transmitted this will be shown.



Status bar when response centre communication is established

5.1.5 Instrument readings

When the Tempus is in use each area will become populated with data. For ECG, Pulse Oximetry, Contact Temperature, Invasive Pressure or Capnography the data will begin to appear on the display as soon as the parameter is connected i.e. there is no start control or button for these parameters.

Since the non-invasive blood pressure measurements are single readings this requires the user to both attach the cuff to the patient **and** start the reading. These readings are therefore time-stamped with the time that they were recorded.

5.2 Menus

5.2.1 The main menu

If ever you are unsure of what to do, press one of the following membrane buttons:

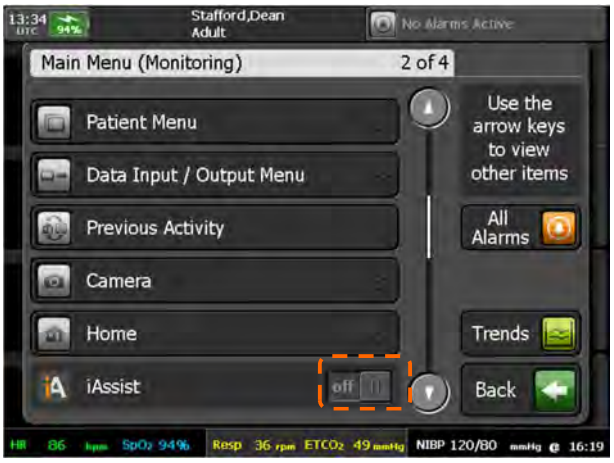
The **Main Menu** button - this will take you to a full menu to access all features of the product.

The **Home** button - this returns the unit to the results screen.

Structure of the Main Menu

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

The Main Menu allows access to the following features and controls:

Menu option	Menu screen
TDL Settings – for use with the Tempus ALS system. **Quick Start Guide** – pressing each numbered button will take you through a series of graphics which explain the features of the device. **Medical Parameter Settings** – open a menu from which all medical parameter settings can be accessed, see "6 Taking medical readings". **Summary Record of Care** - performs the same function as the **Event** membrane button, see "3.3.9 Summary Record of Care / Tactical Combat Casualty Care". **Waveform Snapshot** - performs the same function as pressing and releasing the membrane button, see "5.1.2 Membrane buttons". **Display Menu** – performs the same function as the membrane button, see "9.2 Display options".	 **Note:** The **All Alarms** and **Trends** buttons are present on all pages of the Main Menu, see: "7 Alarms" "8 Summary Record of Care"
Patient Menu – performs the same function as the membrane button, see "9.3 Patient information". **Data Input / Output Menu** – performs the same function as the membrane button, see "9.1 Data input and output". **Previous Activity** - performs the same function as the membrane button, see "3.3.10 Previous activity button". **Camera** – performs the same function as pressing and holding the membrane button, see "9.4 Digital camera". **Home** – performs the same function as the membrane button. **IAssist** – turn iAssist on or off, see "9.7 iAssist processes".	 **Note:** Switches are provided to turn functions on and off, e.g. iAssist here.

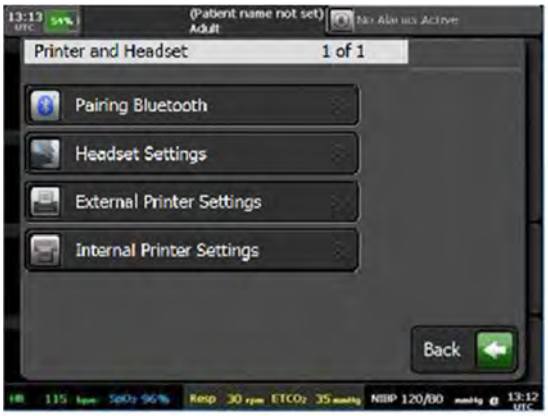
Menu option	Menu screen
Communication Modes – configure the modes, see “9.6.4 Communications modes”. **Wireless Enabled** – disable or enable all wireless communications. If any of these features are not enabled (either not purchased or disabled in the device’s maintenance settings) then they will be greyed out. **Connect** – performs the same function as the membrane button, see “9.6 Connecting to an alternate location”. **Manage Wi-Fi Networks** – provides access to the Manage Wi-Fi Networks menu. **GPS Location** – obtain a fix on the device’s location (using the built-in GPS module), see “9.5 GPS location”.	
Power and Clock Settings – provides access to screen brightness, time, date and power saving settings, see “5.2.3 Power and clock settings”. **Maintenance and Settings** – open the Maintenance and Setting Menu. This allows unit name and mode network settings to be modified, see the *Tempus Pro Maintenance Manual* (available from RDT). **Demonstration and Training** – review and update the demonstration settings, see “13.1 Demonstration and training”. **About Tempus Pro** – view device identification data and a list of features installed on Tempus Pro, see “9.8 View installed features”. **Printer and Headset** – open the settings for the communications interfaces of the product, see “5.2.2 Printer and Headset menu”.	

5.2.2 Printer and Headset menu

The current unit configuration can be viewed by accessing the Configuration screen from the Printer and Headset menu – see "5.2.1 The main menu".

The Printer and Headset menu allows access to settings and controls that the user may occasionally need to access. Note that the primary communication settings are designed only to be controlled by maintenance staff so these settings are only available behind the maintenance menu function in the main menu.

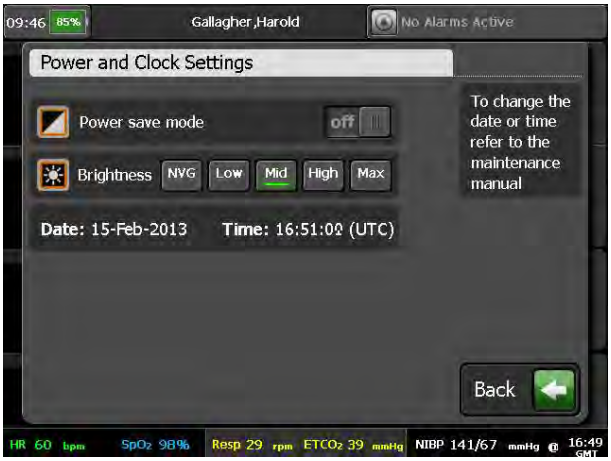
The menu allows access to the following functions:

Menu option	Menu screen
Pairing Bluetooth – provides step-by-step instructions on pairing the device. **Headset Settings** – update the headset's noise filter setting (applicable only to the Bluetooth headset) and change the default headset between wired and wireless. **External Printer Settings** – choose the default printer paper - either US Letter (8.5 x 11") or A4 - and switch between PCL3 & PCL3-GUI printer types. **Internal Printer Settings** – only available if the Tempus Pro is fitted with a printer. Change internal printer settings, for example paper type (plain or grid) and auto print snapshots (on or off). See "9.9 Printer maintenance".	

5.2.3 Power and clock settings

Using this menu, you can set the power save mode and the screen brightness level. For details relating to the brightness setting, see "9.2.5 Brightness control".

This menu is accessed using the **Power and Clock Settings** button on the Main Menu – see "5.2.1 The main menu".

Menu option	Menu screen
Power save mode – turn power saving on or off. **Brightness** – select the screen brightness level. **Note**: The current time and date are also displayed.	

6 Taking medical readings

Note	When a medical module is first started the word “initialising” may appear for a few seconds in the results area associated to the medical parameter being started.

6.1 Electrocardiography (ECG)

The Tempus Pro allows the user to either monitor the patient’s ECG or take a diagnostic recording of their ECG (this is an optional feature). This section will explain how to use both features. The device defaults to ECG monitoring with either a 3-lead, a 4-lead or a 5-lead cable.

WARNING	**The ECG device is not intended for use in a sterile environment. Do not use for direct cardiac application.**
WARNING	**The ECG device is reusable, other than disposable single-use electrodes.**
WARNING	**Do not attempt to insert the ECG device (including patient cables) into an electrical outlet.**
WARNING	**The ECG is for resting recordings and should not be used in stress testing environments.**
WARNING	**Ensure electrodes are connected only to the patient.**
WARNING	**Conductive parts of electrodes and connectors, including neutral electrode, should not contact other conductive parts including earth.**
WARNING	**During ECG recordings, ECG alarms are not active and will only be reactivated once monitoring is resumed.**
WARNING	**The Tempus Pro is rated as being proof against the effects of a defibrillator discharge. Follow these warnings if using an AED or defibrillator with the Tempus Pro:** Follow the instructions of the defibrillator or AED when using it with the Tempus Pro. • Do not touch the patient during defibrillation. • Do not touch the defibrillator’s paddle-electrode surface when discharging the defibrillator. • Keep defibrillation electrodes well clear of other electrodes or metal parts in contact with the patient.

	• Do not touch the patient, bed, or any conductive material in contact with the patient during defibrillation.

WARNING 	**The Tempus Pro is protected against defibrillator discharge but rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.**
WARNING 	**The Tempus Pro may not operate effectively on patients who are experiencing convulsions or tremors, or who are moving or are in motion (transport) environments. In such cases remember to use best practise for electrode site selection (torso rather than limbs), site preparation (cleaning/scrubbing with an alcohol wipe) and cable securement at the sensor site and as much as possible along the cable's length. In motion environments the Tempus should be secured using a clamp or strap and to obtain the best possible readings the device should be damped to reduce shocks or vibrations if possible.**
WARNING 	**The Tempus is not for direct cardiac application.**
WARNING 	**Do not use electrodes of dissimilar metals.**
WARNING 	**Always set the Tempus Pro to the correct patient age to ensure the QRS detector is set to detect appropriate R wave amplitudes. Per AAMI EC 13, the Tempus uses the definitions of patient age provided as follows:** • **Neonate –** Children 28 days old or less if born at term (based on 37-week gestation), otherwise up to 44 gestational weeks. • **Paediatric (Child) –** Children of 29 days up to and including 12 years old. • **Adult** – Individuals 13 years old or older. **Failure to set the correct age may result in the Tempus mis-detecting R waves and providing incorrect heart rate values.** **Setting the patient age to 8 years or less will mean that the ECG monitor will be set to detect paediatric R waves per AAMI EC13.** **If you do not set the patient age, the Tempus will use the default patient age group (see the *Tempus Pro Maintenance Manual*). Ensure that the patient age/type is always entered for non-adult patients – see "9.3.5 Entering patient details".**

CAUTION 	As the following sections will explain, the Tempus Pro will present results in a different layout depending on whether the device is set to ECG monitoring or Diagnostic ECG. The alarm functions will be the same in either case.
CAUTION 	Certain line-isolation monitors may cause interference on the ECG display and may inhibit heart rate alarms. Users should ensure electrodes are placed correctly, with the skin prepared in advance as instructed.
CAUTION 	The electrodes of the ECG apron must be applied carefully. Follow the electrode manufacturer's instructions in the storage, removal and application of the electrodes to the patient to ensure the electrode is placed optimally.
CAUTION 	Care must be taken to ensure that the electrodes do not contact live (electrical) parts or earthed metal parts of local systems or structures.

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

Note	The leads and cables of the ECG should be checked for fraying, tears, knots or other signs of damage before and after use.
Note	Ensure that all labelling including instructions for use, printed warnings and use-by dates associated with third-party ECG electrodes are adhered to.

6.1.1 Getting started

1. To measure correct R wave values, make sure that the right age group is selected in the patient details. For instructions, see “9.3.5 Entering patient details”.
2. Make sure that you have read the monitoring standards in "14.1.1 ECG monitoring".
3. Ensure that the ECG cable is properly inserted into the green connector on the Tempus Pro:

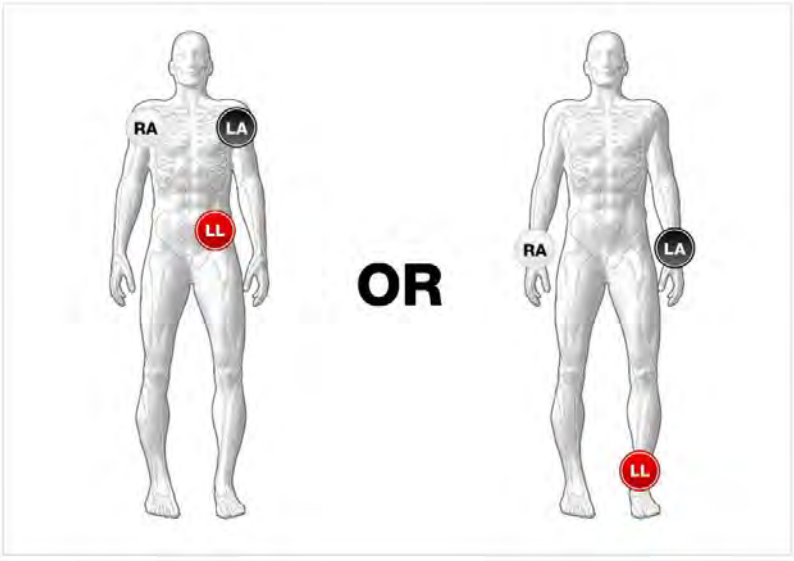
4. Prepare the patient's skin at the electrode sites:
   - Shave or clip excess hair.
   - Clean the skin thoroughly with an alcohol wipe.
   - Rub the skin to dry.
5. If the patient has a pacemaker, turn on pacemaker indication:
   - Press the ECG area of the touchscreen or navigate to the medical parameter setting in the Main Menu.
   - Switch **Pacemaker indication** on.
6. Make sure that the frequency setting matches the frequency of the mains you are using:
   - Press the ECG area of the touchscreen.
   - Select the correct **Mains power frequency**.

6.1.2 Monitoring ECG with a 3-lead cable

By default, the Tempus Pro will be set to ECG monitoring when it is supplied.

ECG monitoring with a 3-lead cable allows the user to monitor Leads I, II or III of the patient's ECG. ECG monitoring requires the use of a 3-lead/electrode cable – see "12 Accessories list of the Tempus Pro".

The 3-lead cable may be pre-attached to the Tempus in the green connector. The Tempus Pro will automatically detect which cable type is in use. With a 3 electrode cable one lead waveform (I, II, or III) is available for display at a time.



Electrode Positions for 3-lead ECG Monitoring

The cable terminates in conventional 4 mm snap connections which can be used with various commonly available disposable ECG electrodes. Two types of cables are provided for compliance with AAMI and IEC guidelines. For details of cable part numbers, see "12 Accessories list of the Tempus Pro".

These are labelled:

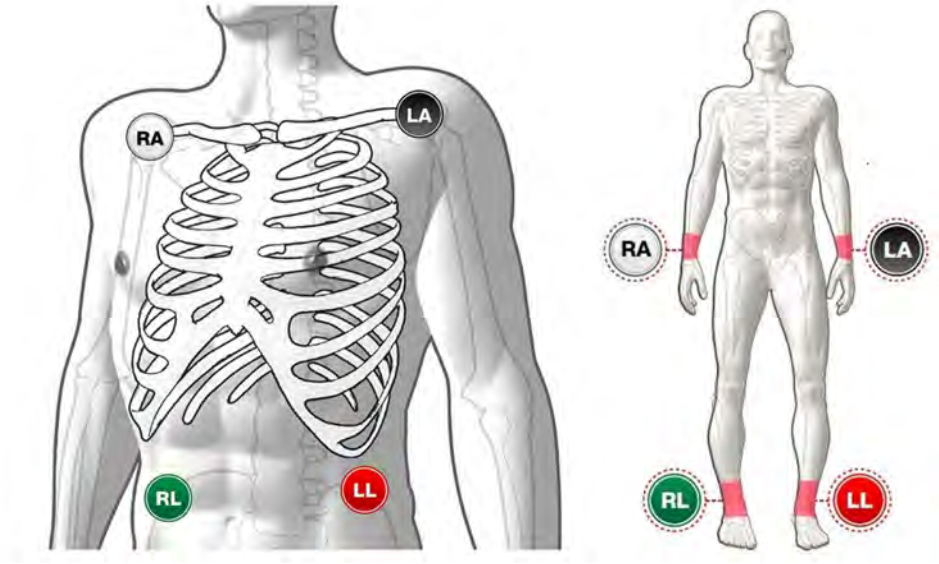
Position	AAMI Label/Colour	IEC Label/Colour
Right mid-clavicular line under clavicle / right wrist	RA White	R Red
Left mid-clavicular line under clavicle / left wrist	LA Black	L Yellow
Left hip / left ankle	LL Red	F Green

Once the electrodes are connected to the patient, the Tempus will begin to display the ECG signals immediately.

6.1.3 Monitoring ECG with a 4-lead cable

ECG monitoring with a 4-lead cable allows the user to monitor Leads I, II, III, AvL, AvR and AvF. Up to two leads can be displayed at any time. Four wire ECG monitoring requires the use of a 4-lead/electrode cable – see "12 Accessories list of the Tempus Pro".

The 4-lead cable should be pre-attached to the Tempus in the green connector.



Electrode Positions for 4-lead ECG Monitoring (torso or limbs)

The cable terminates in conventional 4 mm snap connections which can be used with various commonly available disposable ECG electrodes. Two types of cables are provided for compliance with AAMI and IEC guidelines. For details of cable part numbers, see "12 Accessories list of the Tempus Pro".

These are labelled:

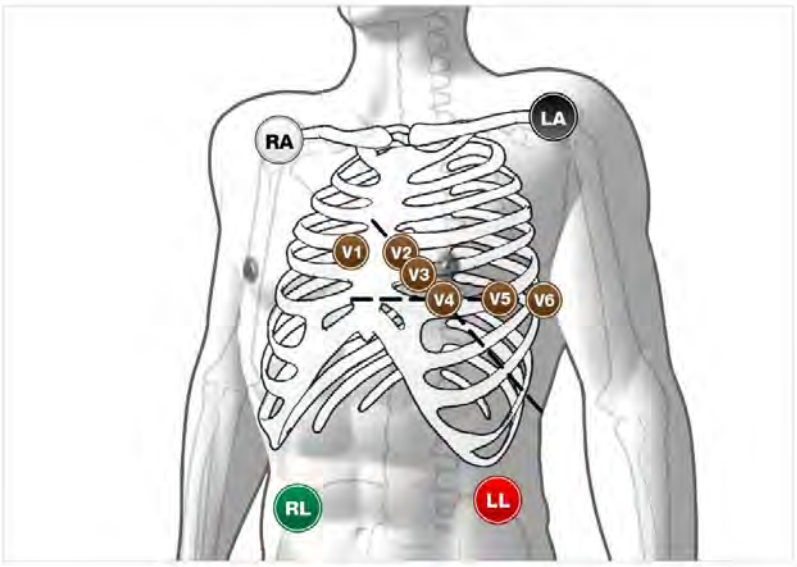
Position	AAMI Label/Colour	IEC Label/Colour
Right mid-clavicular line under clavicle / right wrist	RA White	R Red
Left mid-clavicular line under clavicle / left wrist	LA Black	L Yellow
Left hip / left ankle	LL Red	F Green
Right hip / right ankle	RL Green	N Black

If the ECG is inoperable then the ECG will either show a "Leads off" error for the specific Lead that is unavailable or will show a technical error as described in section "7.4 Technical alarms".

6.1.4 Monitoring ECG with a 5-lead cable

ECG monitoring with a 5-lead cable allows the user to monitor Leads I, II, III, AvL, AvR, AvF or a user-placeable V Lead. Up to two leads can be displayed at any time. Five wire ECG monitoring requires the use of a 5-lead/electrode cable – see "12 Accessories list of the Tempus Pro".

The 5-lead cable should be pre-attached to the Tempus in the green connector.



Electrode Positions for 5-lead ECG Monitoring

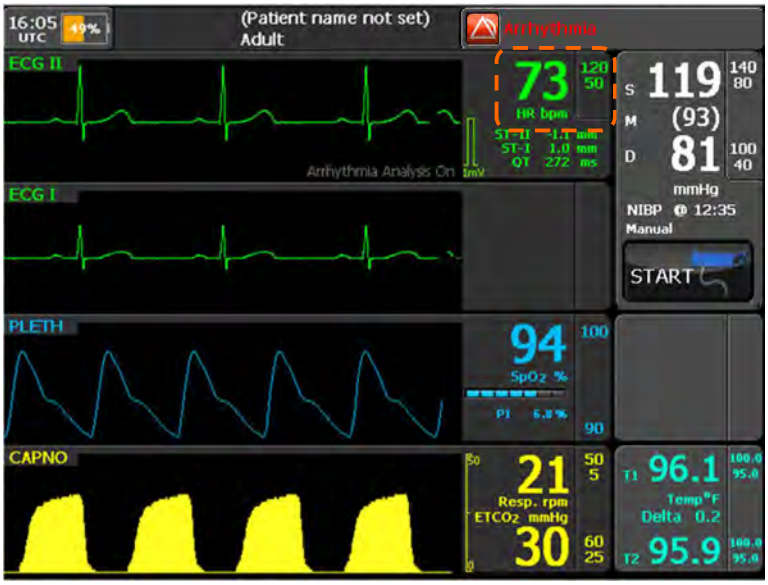
The cable terminates in conventional 4 mm snap connections which can be used with various commonly available disposable ECG electrodes. Two types of cables are provided for compliance with AAMI and IEC guidelines. For details of cable part numbers, see "12 Accessories list of the Tempus Pro".

These are labelled:

Position	AAMI Label/Colour	IEC Label/Colour
Right mid-clavicular line under clavicle / right wrist	RA White	R Red
Left mid-clavicular line under clavicle / left wrist	LA Black	L Yellow
Left hip / left ankle	LL Red	F Green
Right hip / right ankle	RL Green	N Black
This is a moveable pre-cordial electrode. Place it in any position from V1-6 as follows: V1 - 4th intercostal space at right sternal margin. V2 - 4th intercostal space at left sternal margin. V3 - Midway between V2 and V4 leads. V4 - 5th intercostal space at mid-clavicular line. V5 - Same transverse level as V4 at left anterior-axillary line. V6 - Same transverse level as V4 at left mid-axillary line.	V Brown	C White

If the ECG is inoperable then the ECG will either show a "Leads off" error for the specific Lead that is unavailable or will show a technical error as described in section "7.4 Technical alarms".

The picture below shows the Tempus monitoring Lead II and Lead I (using a 5-lead cable). Each ECG trace is labelled in the top left. The heart rate is shown on the right hand side for the uppermost trace.



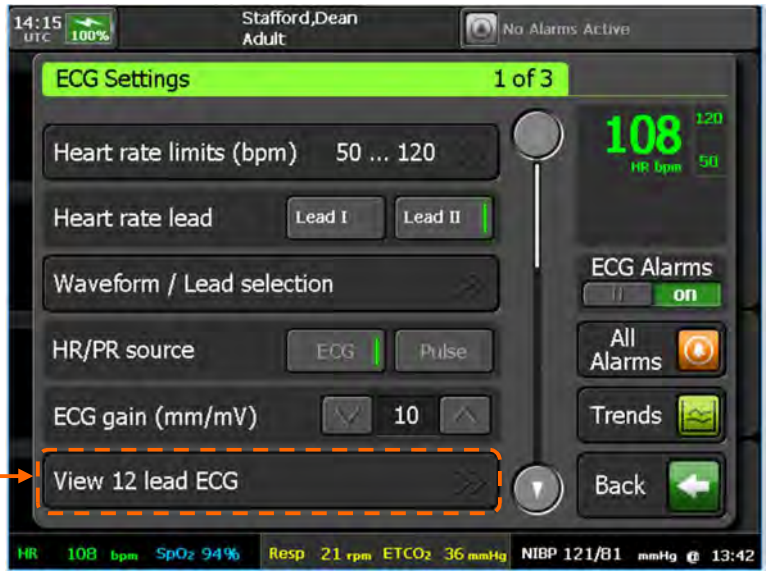
Tempus monitoring Lead II and Lead I (using a 5-lead cable)

6.1.5 Monitoring ECG with a 12-lead cable

Diagnostic 12 lead ECG is an option on the Tempus Pro. You can use a standard 12-lead ECG cable or a 12-lead modular cable (a 4-lead cable connected to an additional 6-lead cable). The cable terminates in a 4 mm snap style connector for use with normal disposable electrodes – see "12 Accessories list of the Tempus Pro".

To view a 12-lead ECG, the ECG settings must be changed as shown below.

With the 12 Lead cable connected, press here to activate the 12 Lead view



ECG Settings Menu – 12 Lead ECG Selected

If the 12-lead ECG Cable is attached but the 12-lead View is not selected on the screen, then the Tempus will remain in standard ECG monitoring mode and will continue to show two waveforms on screen.

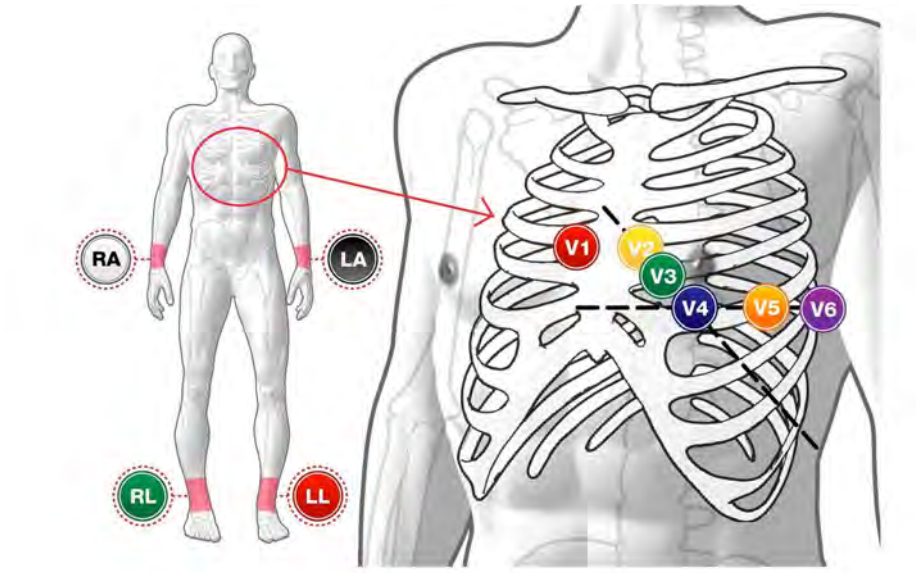
Two types of cables are provided for compliance with AAMI and IEC guidelines. For details of part numbers of cables, see "12 Accessories list of the Tempus Pro".

These are labelled:

Position	AAMI Label/Colour	IEC Label/Colour
Right mid-clavicular line under clavicle / right wrist	RA White	R Red
Left mid-clavicular line under clavicle / left wrist	LA Black	L Yellow
Left hip / left ankle	LL Red	F Green
Right hip / right ankle	RL Green	N Black
This is a moveable pre-cordial electrode. Place it in any position from V1-6 as follows:		
V1 - 4th intercostal space at right sternal margin.	V1 Red	C1 Red
V2 - 4th intercostal space at left sternal margin.	V2 Yellow	C2 Yellow
V3 - Midway between V2 and V4 leads.	V3 Green	C3 Green
V4 - 5th intercostal space at mid-clavicular line.	V4 Blue	C4 Brown
V5 - Same transverse level as V4 at left anterior-axillary line.	V5 Orange	C5 Black
V6 - Same transverse level as V4 at left mid-axillary line.	V6 Violet	C6 Violet

The electrodes should be attached to the patient as shown below. Before attachment the patient's skin should be prepared according to the instructions of the electrodes e.g. cleaning the skin with alcohol and shaving if necessary.

Remember only to use electrodes which are compliant with AAMI EC12 and to read and follow the instructions for the electrodes.



Electrode Placement for 12 Lead ECG Monitoring

Once in 12 Lead ECG Mode, the ECG will monitor 12 Leads of ECG.

If the ECG is inoperable then the ECG will either show a "Leads off" error for the specific lead that is unavailable or will show a technical error as described in section 7.4.

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

In 12 Lead mode, the other vital signs data remain displayed across the bottom of the display. All 12 ECG Leads are shown in the main display (each Lead is labelled).

12 Lead ECG Monitoring Screen

If no signal or a poor signal is seen on one or more leads, the following steps should be reviewed:

- Has the correct cable been used, is it connected properly?
- Is the patient still?
- Is the equipment setup properly (all electrodes attached)?
- Could there be interference from other electrical equipment?
- Is the mains filter set correctly (see ECG Settings)?
- Are the 12 lead filters set correctly (see ECG Settings)?
- Was skin sufficiently well prepared?
- Could the electrodes be dry or poorly attached?

6.1.6 Performing a diagnostic ECG

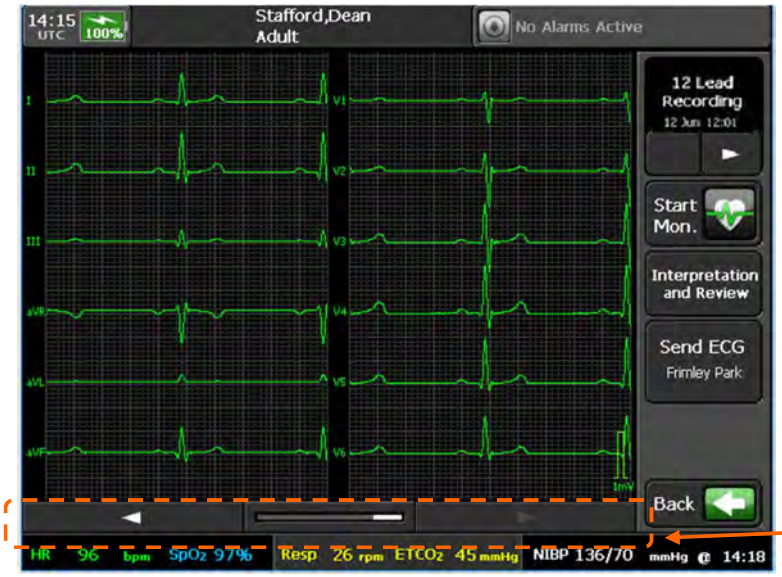
The 12 Lead function enables users to record a 10 second trace for immediate or subsequent analysis and interpretation.

The 10 second recording will be added to the patient record and therefore can be exported by USB stick to another Tempus or to a computer to be read as a .PDF file. The ECG can also be transmitted to a Response Centre if this option is in use – see “9.6 Connecting to an alternate location”.

Making a 12 lead ECG recording

Pressing the **Start Record** button will initiate a 10 second recording. If the Tempus is connected to a Response Centre then this will be transmitted as soon as the recording is complete. The Response Centre has tools for measuring the ECG. Otherwise, the recording can be viewed on screen by using the left and right arrow keys.

Note	If you inadvertently press **Stop Record**, you can press **Start Record** to immediately restart the recording.



12 Lead ECG Recording Screen

If an internal printer is fitted to the Tempus, you can print the 10 second recording using the **Print** button. For printer instructions see "9.9.2 Internal printer configuration (optional)".

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

ECG interpretation

WARNING	**All numerical, graphical and interpretive data should be evaluated with respect to the patient's clinical and historical picture.**
WARNING	**ECG interpretation performed by software is not a substitute for review and evaluation of ECG recordings by a qualified clinician.**
WARNING	**Motion artefact or noise in the ECG recording could result in erroneous interpretations.**

Note	Interpretations are unconfirmed and need to be reviewed by a clinician.
Note	ECG interpretation is only available for patients aged 18 years and over. If age is not set, interpretation will be based on an adult patient type.

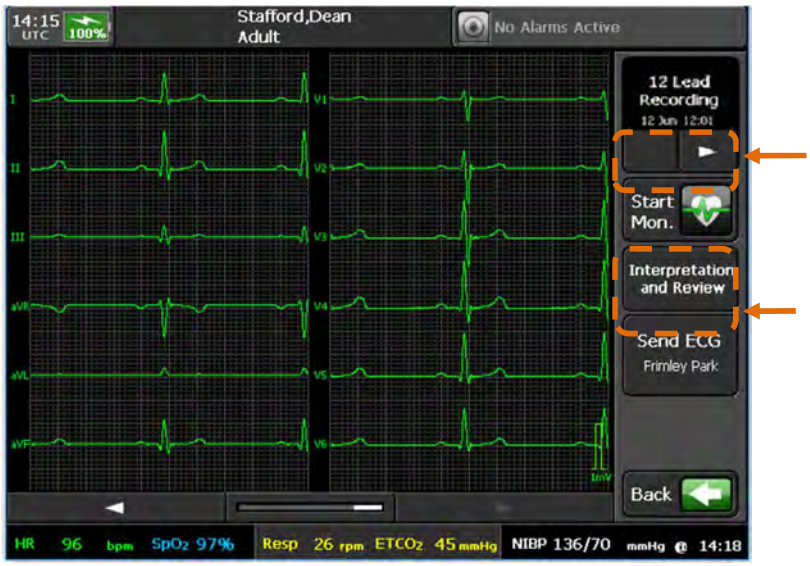
The Tempus Pro provides ECG interpretation of the 12 lead ECG recordings. This interpretation includes:

- **Rhythm statements** – there are 69 different statements this includes the reporting of detected Arrhythmias such as Ventricular Tachycardia, Atrial Fibrillation, Extreme Bradycardia, and AV Block (please see *QRS Diagnostic Physician's Guide ECG Analysis for Resting 12-lead ECG* for further information, Part number 630000-00).
- **Morphology statements** – there are 121 different statements including ST analysis which includes over 20 Ischemic ST change statements such as: "Ischemic ST-T changes in posterolateral leads" and

"Ischemic ST-T changes in lateral leads" (please see *QRS Diagnostic Physician's Guide ECG Analysis for Resting 12-lead ECG* for further information, Part number 630000-00).

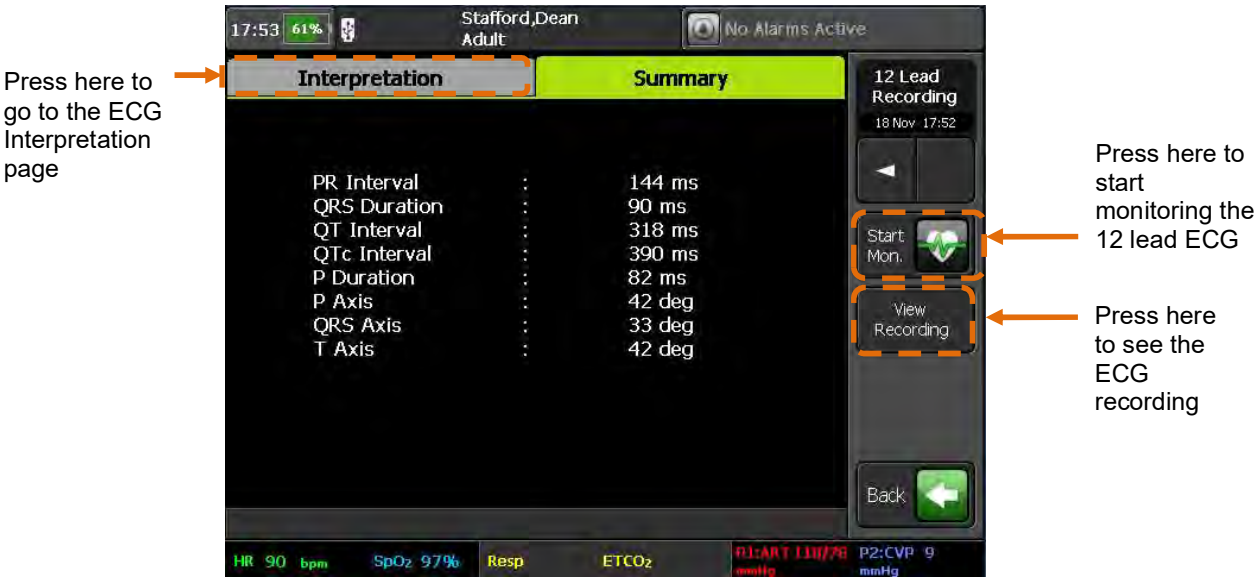
- **Waveform summary measurements** – this includes; QT and QTc interval measurements, PR interval, QRS duration, P duration, P axis, QRS axis and T axis.

Once a 12 lead ECG has been recorded you can view the ECG interpretation.



View ECG Recordings Screen

ECG Interpretation Screen



ECG Summary Screen

6.1.7 ECG specifications

ECG monitoring specifications

The following disclosures are made in accordance with the requirements of AAMI EC13 and IEC60601-2-27:

- The ECG's display includes the isoelectric segments of the QRS.
- For leads off detection, the ECG device applies a 1 kHz triangular wave of approximately 6 mV p-p between the R/RL and L/LL electrodes
- The Heart Rate Detection of the ECG monitor is accurate to +/-10% or +/-5 bpm for a T Wave of amplitude: up to 1.0 mV.
- The heart rate is calculated from the average of the 8 most recent RR intervals. Intervals are logged as "invalid" if the detections are unreliable, or if detections are absent over the maximum RR interval of 2.4 s. Invalid intervals are counted but not included in the average. If there are no valid intervals in the most recent 8, then no heart rate is reported. Heart rate is updated with every new valid or invalid interval.
- Further to clause 4.1.2.1e) of AAMI EC13: the system's response to Fig 3a is 40 bpm ±10% (inverted QRS are counted). The system's response to Fig 3b is 30-100 bpm (small QRS are intermittently counted). The system's response to Fig 3c is 120 bpm± 10% (all QRS are counted). The system's response to Fig 3d is 60-100 bpm (bipolar QRS are intermittently counted).
- Electrical noise such as power line transients can cause false heart beat detection which may inhibit alarms. The problem may be minimized by ensuring good electrode contact. Power system noise may be reduced by running the monitor from its battery.
- The system's typical response time to change from 80 to 120 bpm is ~7 s, for a change from 80 to 40 bpm is the typical response time is ~7.5 s.
- The system heart rate alarm will respond to the specified tachycardia signals of Figures 4a and 4b of AAMI EC13 within 5-7 s. In some cases, an out of range alarm may be given, with an indication of no valid heart rate.
- The heart rate limit alarm will respond to an out of range condition 0-10 seconds after being activated.

- Per EC13, 4.1.4.1, heart rate is accurately indicated in the presence of effective pacemaker single pulses without overshoot, having width of up to 2 ms and amplitude up to 700 mV, and such pulses alone do not cause heart rate detection. In the case of ineffectively paced QRS, erratic readings may result for single pulses above 2 mV. Overshoot is specified according to EC13 4.1.4.1 Method B.
- Per EC13 4.2.9.12, the muscle filter will make pacemaker pulses appear smaller than 2mm. Switch muscle filters off (Diagnostic filter setting) to see pacemaker pulses more clearly.
- Measurements of the ECG waveform should be normalized against the scale provided. The scale presents 1 mV as 8 mm with a gain setting of 10mm/mV.
- Note that in the 4 waveform view the channel height of the ECG is 24 mm and thus permits a maximum input signal of ±2.2 mV when using a gain of 5 mm/mV. In the large ECG view a maximum input signal of ±5 mV is achieved using a gain of 5 mm/mV. Large ECG view is described in "9.2 Display options".
- Compliance with EC12 clause 4.2.9.8 b) (and relevant clause of IEC60601-2-25:2011) requirements for frequency response are achieved only with the muscle filters switched off (i.e. using the Diagnostic filter setting).
- For leads off detection, the ECG applies a 1 kHz triangular wave of approximately 6 mV p-p between the R/RL and L/LL electrodes.
- The slew rate of the ECG as per AAMI EC13 4.1.4.3 is 3.7 V/s (all filters off).

ECG recording specifications

The following disclosures are made in accordance with the requirements of AAMI EC11 and IEC60601-2-25:

- Frequency and impulse response has been evaluated according to methods A, B and C of EC11:1991 3.2.7.2/4.2.7.2. All EC11 tests have been performed using SCP files generated by the i2i software as an acquisition system. Compliance requires that all optional filters be switched off.
- ECG data in this system are contained in computer files, using a proprietary format based on the SCP-ECG standard. The ECG data are digitized using a sample rate of 500sps and a resolution of 2995nV/bit with 12 bit (4096 level) dynamic range.
- Automated measurements of amplitude and duration of QRS complexes generated from the ECG recording are only valid for adult patients. For younger patients the values should be measured using the electronic calipers within i2i.
- Per clause 201.12.1.101.3 automated measurements of the S segment duration of CAL waveforms are ±15 ms. The automated value can be confirmed using the electronic calipers within i2i
- Per clause 201.12.4.107.3 The skew rate is 0
- Automated measurements are only able to distinguish T-waves of amplitudes greater than >50 µV

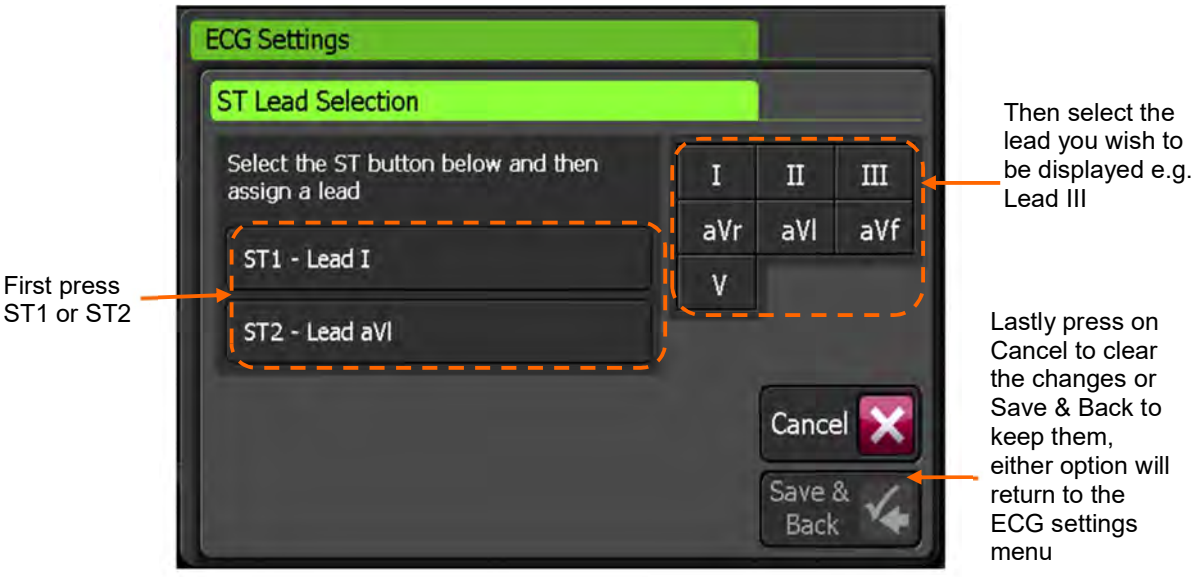
6.1.8 ECG settings

Pressing either of the ECG trace areas will bring up the ECG settings menu:

Menu option	Menu screen
Heart rate limits (bpm) – open the the alarm limits editor (described below). **Heart Rate Lead** – (4-, 5- and 12-lead ECG only) change which lead the heart rate is taken from. **Waveform / Lead selection** - when using 4-, 5- or 12-lead ECG, press here to customise the selection of waveforms on the four waveform display, see "9.2.4 Waveform and lead selection". **HR/PR source** –select **ECG** or **Pulse** oximeter as the heart/pulse rate source (see also **HR/PR beat volume** below). **ECG Gain (mm/mv)** –select the desired gain (or size) of the waveform. **View 12 lead ECG** – if the 10 wire (12 Lead) ECG cable is selected, this option will be available. Pressing it will bring up a different display interface that shows all 12 ECG leads.	 **Note:** When using a 3-lead ECG, the heart rate is derived from the waveform displayed: 
Arrhythmia analysis and **ST/QT analysis** (on/off) – enable or disable these measurements. **ST lead selection** - when ST monitoring is active, change the ST leads that are displayed, see "ST lead selection". **ST1 limits (mm)** – open the editor to change the ST alarm limits. **ST2 limits (mm)** – open the editor to change the ST alarm limits. **QT upper limit (ms)** – open the editor to change the QT alarm upper limit. **Cardiac wave speed (mm/s)** – select the desired speed of the waveform.	

Menu option	Menu screen
HR/PR beat volume – volume of the audible tone that the Tempus emits every time a heartbeat is detected. Use the up and down arrows to adjust the volume from zero (no tone) to 100%. The tone is based on the **HR/PR source** setting (see above): when set to **ECG**, QRS beats trigger a single tone at 1 kHz. When set to **Pulse**, pulse beats trigger pulse tones – see "6.3.6 Pulse oximeter settings". **Pacemaker indication** – turning this on will show a vertical dotted line on the ECG waveform when the ECG is connected to a patient wearing a pacemaker. **Monitoring filter** – use the arrows to select a filtering option. **12 lead filter** – use the arrows to select a filtering option. **ECG Power Filter** – this is set to ON by default, switch it off if you wish the ECG to be presented without the Power noise being filtered out.	

ST lead selection screen



ST Lead Selection

Note	The ECG waveforms displayed on the home screen will change to match the selected ST leads.

Note	In order to reduce noise and artefact the Monitoring filter should be set to **Monitor** or **Filtered diagnostic** and the Mains filter should be switched on. When attached to a mains power supply noise may be observed on the ECG if these filters are switched off. Consequently, they should be left switched on when operating under mains power or mains power should be disconnected if the filters need to be switched off.
Note	Users are reminded to have the mains filter frequency set to the correct value (50 Hz or 60 Hz) in order for it to be effective. This should be checked before use.

Mains frequency setting. Hz means Hertz, or cycles per second. In North America, mains electricity supplies operate at 60 Hz; most of the rest of the world uses 50 Hz. In aircraft the filter should normally be set to 50 Hz. In remote land and maritime applications, the local voltage could be either 50 Hz or 60 Hz. ECG systems can pick up interference from mains electricity supplies. This interference appears on the screen as regular interference patterns.

6.1.9 Detecting arrhythmias during ECG monitoring

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

WARNING	**ECG monitoring arrhythmia analysis is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times.**
WARNING	**The Automated ECG Arrhythmia Analysis software is designed to be used by qualified medical personnel.**
WARNING	**The clinician and/or medically qualified personnel are responsible for determining the clinical significance of each detected arrhythmia event or alarm.**
WARNING	**The arrhythmia detection feature on the Tempus Pro is not a diagnosis tool and is an additional tool to support the clinician in their own diagnosis only. The classification performance of the arrhythmia feature has been tested using the FDA recognised consensus standard. The analysis algorithm has also been tested and approved in other products. The monitor cannot be relied upon to detect all arrhythmias. Do not rely solely on the displayed arrhythmia data and alarms to assess the patient's condition. Always observe the patient closely and monitor all of their vital signs carefully.**
WARNING	**The arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect atrial or supraventricular arrhythmias. The program may incorrectly identify the presence or absence of an arrhythmia. A physician must analyse the arrhythmia information with other clinical findings.**
WARNING	**The system can filter out some interference but corrupted or excessively noisy signals may cause artefacts. If the ECG waveform is too noisy, Noise is displayed on screen. If no arrhythmias are detected and there is no noise in the signal, Arrhythmia Analysis On is displayed to ensure the operator is aware arrhythmia analysis is running.**
WARNING	**Heart parameters can be affected by the use of drugs. Patient drug use history should be reviewed when reviewing detected arrhythmia.**

WARNING 	**For patients with pacemakers, ensure pacemaker indication is turned on.**
WARNING 	**Arrhythmia analysis is sourced from the ECG signal (including detection of extreme bradycardia, extreme tachycardia), this is independent of the heart rate display source selection (ECG or pulse).**

CAUTION 	Only start arrhythmia learning during periods of predominantly normal rhythm, and when the ECG signal is relatively noise-free. If arrhythmia learning takes place during ventricular rhythm, the ectopics may be incorrectly learned as the normal QRS complex. This may result in missed detection of subsequent arrhythmias.
CAUTION 	If arrhythmia analysis is not restarted when a template changes: • Inaccurate arrhythmia alarms can be triggered. • Inaccurate heart rates can be recorded.

To optimise arrhythmia detection, select leads with the largest amplitude and the least amount of noise to be analysed:

1. Turn on arrhythmia analysis in the ECG menu. Arrhythmia detection starts up and performs a learning period.
2. To change the waveforms being analysed, press **Lead waveform selection** on the ECG menu and select the lead required.
3. If a patient's ECG template changes dramatically, turn arrhythmia analysis off and on.

Arrhythmia detection performs a relearning period based on the new template.

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

- Change patients
- Change **Lead waveform selection** or **Heart rate lead** options

The following arrhythmia events are detected and recorded:

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

A medium priority alarm is triggered when:

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

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

A 20 second waveform snapshot is captured for all arrhythmia events that trigger an alarm – see "8.1 Event capture".

6.1.10 Measuring ST elevation and QT interval (optional)

WARNING 	**ST measurements should always be verified by the clinician and/ or medically qualified personnel.**
WARNING 	**Some clinical conditions may make it difficult to achieve reliable ST monitoring. For best results, consider the following: the ability of the patient to cooperate and be relaxed. Patients who are restless can produce noisy physiological signals. Noisy signals which can result in inaccurately high or low data measurements.**
WARNING 	**QT measurements should always be verified by the clinician and/ or medically qualified personnel.**
WARNING 	**The ST and QT measurements have <u>not</u> been qualified for use on paediatric or neonate patients and are therefore switched off when an age <18 is entered on the Tempus Pro.**
WARNING 	**The QT algorithm has been tested for accuracy. The significance of the QT segment however needs to be determined by a clinician. This feature is to aid the clinician in monitoring the change in QT only.**
WARNING 	**The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes however needs to be determined by a clinician. This feature is to aid the clinician in monitoring the change in ST and not diagnosing STEMI or Ischemic events.**
WARNING 	**During the 10 seconds of an ECG recording ST and QT measurements will stop and therefore there may be an additional delay before an ST or QT alarm is triggered if the alarm limit is breached during a recording.**
WARNING 	**For very high heart rates (>250 bpm) no ST value will be reported.**
WARNING 	**Some arrhythmia conditions may make it difficult to reliably produce ST measurements.**
WARNING 	**With ECG waveforms with T-waves smaller than 0.1 mV, the accuracy of the QT measurement may be reduced, therefore select leads with large T-waves.**

Note 	When using a 3-lead ECG cable only 1 ECG waveform is produced. Therefore, only 1 ST measurement value can be produced by the Tempus Pro. For optimum monitoring of ST, a 4- or more lead cable should be used so both ST measurements can be reported.

The Tempus Pro presents the user ST elevation (+) and depression (-) measurements as well as QT duration measurements for the electrocardiogram (ECG) monitoring waveform and displays it in numeric format on the results screen.

The Tempus makes ST and QT measurements on the 2 waveforms which are viewed on the home screen. These waveforms can be changed using the Lead Waveform selection option on the ECG menu. These measurements can be performed on any of the lead types available from the ECG cable being used. An ST measurement for each of the 2 waveforms is reported along with a single global QT measurement value.

The ST measurement is taken between the ECG isoelectric line (PR segment) and a point in the ST segment. The point taken for measurement is 80 milliseconds after the J point if the heart rate does not exceed 115 bpm and 60 milliseconds after the J point if the heart rate exceeds 115 bpm. The ST measurement value is updated every 10s. If the measurement is not available, the display will show “- - - “.

The ST value measured is a voltage; by convention the value is displayed as the equivalent measurement height for a standard ECG gain of 10mm/mV. In this convention 0.1mV will be displayed as 1.0mm. The ST measurement height gain is fixed at 10mm/mV and does not depend on the ECG gain setting.

A medium priority alarm will be triggered if the ST alarm limit is exceeded for more than 1 minute and the value will flash to indicate it is in alarm.

The QT interval is a measurement of the time between the start of the Q wave and the end of the T wave in the heart’s electrical cycle. The Tempus Pro shows this measurement on the results screen. The QT value is reported in milliseconds (ms).

A medium priority alarm will be triggered if the QT alarm limit is exceeded for more than 1 minute and the value will flash to indicate it is in alarm.

6.1.11 Monitoring respiration rate with ECG cable

The Tempus Pro allows the user to monitor the patient's respiration through the ECG cable by measuring the change in the patient's impedance as their chest wall moves (impedance pneumography). This section will explain how to use this feature. The device defaults to impedance respiration being off. By turning Impedance Respiration on, it can be measured through one ECG lead on 3-, 4-, 5- or 12-lead cables, unless the Capnometer is in operation.

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

Respiration rate from ECG leads

By default, the Tempus Pro will be set to monitor respiration rate through the ECG leads when it is supplied.

WARNING 	**If capnography is used, the Tempus will always obtain its respiration rate measurement from this parameter. If capnography is not available, then respiration will be derived from the ECG leads using an impedance-based method. In this case, users are reminded that the reading represents a cyclic change in measured impedance which is interpreted to be the change of impedance as the chest moves out and in. Users should note that this is therefore an indirect reading of respiration.**
WARNING 	**Impedance pneumography detects respiratory effort through changes in chest volume. However, No Breath episodes with continued respiratory effort may go undetected. Always monitor and set alarms for SpO_2 when using impedance pneumography to monitor respiratory function.**
WARNING 	**With any monitor that detects respiratory effort through impedance pneumography, artefact due to patient motion, apnoea mattress shaking, or electrocautery use may cause apnoea episodes to go undetected. Always monitor and set alarms for SpO_2 when using impedance pneumography to monitor respiratory function.**
WARNING 	**When using impedance pneumography, don't use the Tempus with another respiration monitor on the same patient, because the respiration measurement signals may interfere with one another.**
WARNING 	**Impedance pneumography is *not* recommended for use on paced patients, because pacemaker pulses may be falsely counted as breaths.**
WARNING 	**Impedance pneumography is not recommended for use with high frequency ventilation.**
WARNING 	**Since impedance pneumography uses the same leads as the ECG channel, the Tempus unit determines which signals are cardiovascular artefact and which signals are the result of respiratory effort. If the breath rate is within five Percent of the heart rate, the monitor may ignore breaths and trigger a respiration alarm.**

CAUTION ⚠	Users should note that in the case of supine patients, breathing may involve relatively greater movement of the abdomen (and consequently less expansion of the chest) during breathing. In this case chest impedance changes may not be significant to produce reliable readings.
CAUTION ⚠	If impedance respiration is being used, the ECG electrodes should be placed on the torso and not the limbs.
CAUTION ⚠	Impedance respiration measurements are highly subject to patient movement. The impedance changes across the chest during breathing can be easily masked by patient movement or muscle noise during movement.
CAUTION ⚠	In motion environments care should be taken to observe best practise on electrode site preparation, electrode and cable securement, securement of the Tempus and securement of the patient. RDT recommends using capnography to measure respiration in motion environments.

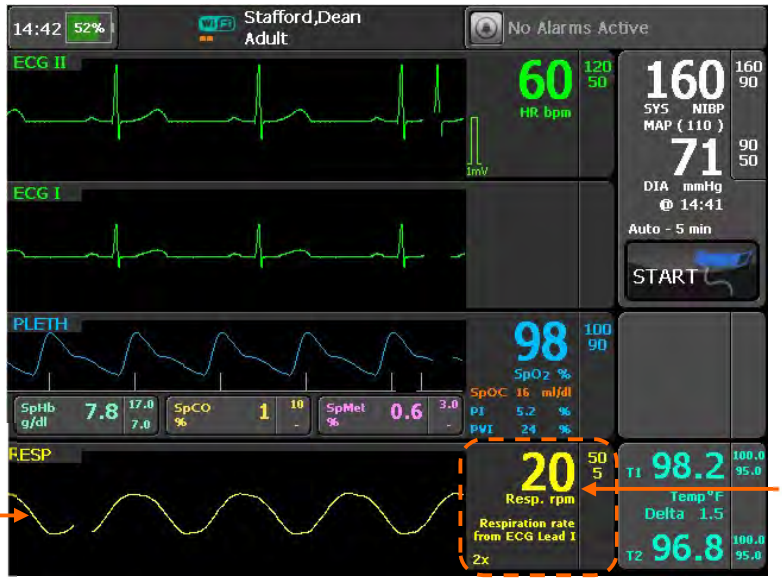
Impedance-based respiration monitoring is performed through the Lead II wires (RA-LL) by default. This can be changed to use Lead I (RA-LA). For the most reliable respiration measurement, users should select the lead which has the largest R-wave. Your choice depends on the ECG cable type connected and the lead chosen for ECG waveform monitoring:

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

Note	If capnography is in use, the waveform will automatically change to “CAPNO” and will display the end tidal CO_2. The results will change to additionally display the $ETCO_2$ reading.

Once the ECG cable is attached, respiration measurements will be started. The device will produce a reading once an average of 3 readings has been obtained. Consequently, with very low respiration rates (e.g. 5 per minute), a reading may not be obtained for 30 seconds or more. The product will as a consequence also have a slower level of responsiveness to marginal changes in respiration rates with patients with such low breathing rates.

The pneumography (respiration) waveform is shown here



The respiration rate is shown here

Impedance respiration settings

Pressing anywhere on the Respiration area brings up the Respiration Settings Menu.

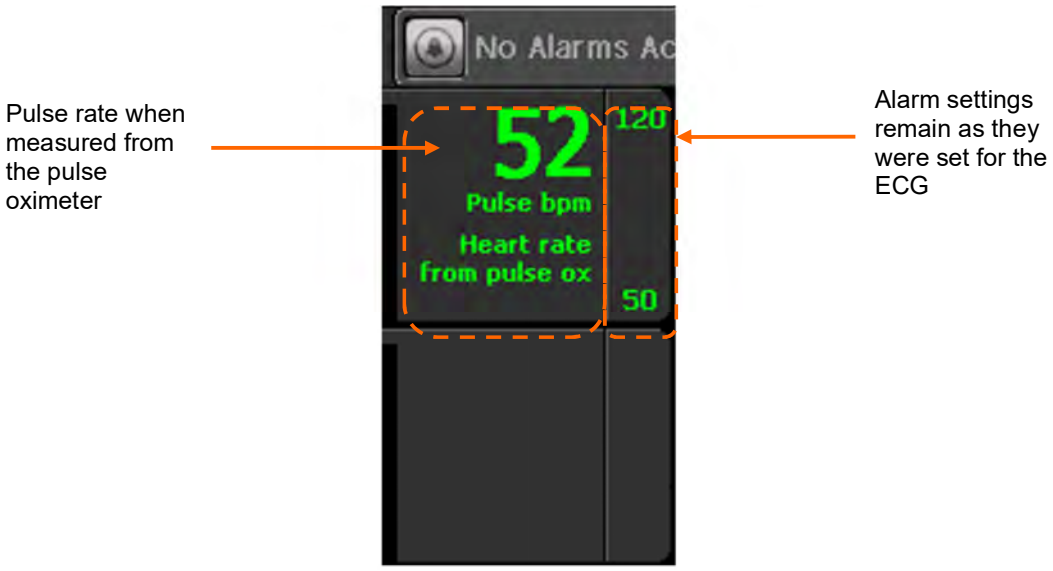
Note	If capnography is in use, the waveform shown will be labelled “CAPNO” and will display the end tidal CO_2. In this state pressing on the waveform will bring up the Capnometer Settings Menu.

Menu option	Menu screen
Respiration limits (rpm) – set the upper and lower alarm limits for respiration. **Respiration wave speed (mm/s)** – set wave speed to **3.1**, **6.25** or **12.5**. This setting is independent of other waveforms. **Respiration lead** – select which ECG lead will measure respiration rate. **Respiration wave gain** – use the up and down arrows to adjust wave height (gain). **Respiration monitoring** – turn impedance respiration off or on. Use this, for example, where patient movement is too great to allow stable impedance measurements to be taken.	

6.1.12 Monitoring heart/pulse rate with no leads

If the ECG is not attached to the patient, then the heart rate will be taken from the pulse oximeter if this is attached to the patient. Otherwise no heart rate will be shown.

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



Pulse Rate Measured from the Pulse Oximeter

If the ECG is inoperable then the ECG will either show a “Leads off” error for the specific Lead that is unavailable or will show a technical error as described in section “7.4 Technical alarms”.

6.2 Non-invasive blood pressure (NIBP)

WARNING 	**This device should not be used when oscillometric pulses may be altered by other devices or techniques such as External Counter pulsation (ECP) or Intra-Aortic Balloon Pump Counter pulsation.**
WARNING 	**DO NOT use the Blood pressure monitor for any purpose other than specified in this manual.**
WARNING 	**DO NOT attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to the patient.**

WARNING 	**You must use the right size of blood pressure cuff to suit the patient. The cuff's bladder length should be at least 80% of the limb's circumference which the cuff width should be equal to 40% of the limb's circumference. Selecting a cuff that is too small will result in measurements higher than the patient's actual blood pressure. Conversely using too large a cuff will result in too low a reading.** **The appropriate cuff sizes are:** • Disposable neonate cuff size 1 (3-6 cm), • Disposable neonate cuff size 2 (4-8 cm), • Disposable neonate cuff size 3 (6-11 cm), • Disposable neonate cuff size 4 (7-13 cm), • Disposable neonate cuff size 5 (8-15 cm), • Disposable infant cuff (8-13 cm), • ORANGE infant cuff (8-13 cm), • GREEN child (12-19 cm), • GREEN child LONG (12-19 cm), • ROYAL BLUE small adult (17-25 cm), • ROYAL BLUE small adult LONG (17-25 cm), • NAVY BLUE normal adult (23-33 cm), • NAVY BLUE normal adult LONG (23-33 cm), • BURGUNDY large adult (31-40 cm), • BURGUNDY large adult LONG (31-40 cm), • BROWN adult thigh (38-50 cm).

WARNING 	**Always set the Tempus Pro to the correct patient age to ensure the initial inflation pressure is set correctly. The Tempus uses the definitions of patient age provided in IEC80601-2-30 as follows:** • **Neonate – Children 28 days old or less if born at term (based on 37-week gestation), otherwise up to 44 gestational weeks.** • **Paediatric (Child) – Children of 29 days up to and including 12 years old.** • **Adult – Individuals 13 years old or older.** **Failure to set the correct age will result in the Tempus using an inappropriate cuff inflation pressure which could cause serious harm to a neonate or infant. For pressures, see "14.1.5 Non-invasive blood pressure".** **Setting the patient age to 2 years or less will mean that inflation pressures, alarm defaults and alarm ranges will be set to those for a neonate (per IEC80601-2-30).** **If you do not set the patient age, the Tempus will use the default patient age group (see the *Tempus Pro Maintenance Manual*). Ensure that the patient age/type is always entered for non-adult patients – see "9.3.5 Entering patient details".**

WARNING 	**The Tempus Pro non-invasive blood pressure monitor is not for use with pregnant, including pre-eclamptic, patients.**
WARNING 	**The Tempus Pro may not operate effectively on patients who are experiencing convulsions or tremors, or who are moving or are in motion (transport) environments.**
WARNING 	**Prolonged or repetitive use of the blood pressure cuff may harm skin integrity and circulatory status. Observe the limb concerned to check that circulation is not impaired.**
WARNING 	**Do not attempt to take NIBP readings from patients undergoing cardiopulmonary bypass.**
WARNING 	**If you suspect a non-invasive blood pressure measurement is invalid, repeat the measurement. If you remain unsure about the validity of the reading, then take another measurement using another piece of equipment or a different method.**
WARNING 	**Do not apply the cuff over a wound, as this can cause further injury.**
WARNING 	**Do not apply and pressurize the cuff on any limb where intravascular access or therapy such as an IV line, saline lock or an arterio-venous (A-V) shunt, is present as it may cause temporary interference with blood flow and result in injury to the patient.**
WARNING 	**Do not apply and pressurize the cuff on the arm on the side of mastectomy.**
WARNING 	**Application of continuous cuff pressure due to kinking of the blood pressure hose can interfere with blood flow and result in harmful injury to the patient.**

CAUTION 	Accuracy of any blood pressure measurement may be affected by the position of the subject, his or her physical condition and use outside of the operating instructions detailed in

	this manual. Interpretation of blood pressure measurements should be made only by a physician or trained medical staff.
CAUTION 	Hoses of a certain material and/or durometer may cause the module to perform in an improper fashion. Only use hoses provided by RDT.
CAUTION 	Incorrectly sized cuffs may cause measurement inaccuracy or errors.
CAUTION 	If the blood pressure cuff is on the same limb as a pulse oximeter probe, the oxygen saturation results will be altered when the cuff occludes the brachial artery.
CAUTION 	To obtain accurate blood pressure readings, the cuff must be the correct size, and also be correctly fitted to the patient. Incorrect size or incorrect fitting may result in incorrect readings.
CAUTION 	When a cuff is going to be positioned on a patient for an extended length of time, be sure to occasionally check the limb for proper circulation.
CAUTION 	Allergic exanthema (symptomatic eruption) in the area of the cuff may result, including the formation of urticaria (allergic reaction including raised edematous patches of skin or mucous membranes and intense itching) caused by the fabric material of the cuff.
CAUTION 	Petechia (a minute reddish or purplish spot containing blood that appears in the skin) formation or Rumple-Leede phenomenon (multiple Petechia) on the forearm, following the application of the cuff, may lead to Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions), or phlebitis (inflammation of a vein) may be observed.

CAUTION 	Blood pressure readings can be affected by patient movement, speech, incorrect sizing and placement of the cuff and environmental factors (vibration, motion, noise etc.). Care should be taken to ensure that motion and other artefacts are removed or reduced when taking blood pressure readings.
CAUTION 	Do not place the cuff on the same limb as the pulse oximeter sensor as the cuff may prevent the pulse oximeter sensor from reading reliably during NIBP measurement cycles.
CAUTION 	Ensure the cuff is wrapped firmly around the arm; a loosely applied cuff can result in artificially high readings.

Note 	Compression or restriction of the blood pressure hose or cuff, or induced movement or vibration or very low pulse volumes may prevent the monitor from taking a reading or may influence the accuracy of the reading obtained.
Note 	The Tempus Pro non-invasive blood pressure monitor is designed to work with the cuffs and hoses supplied. Use of other cuffs and hoses may compromise performance and accuracy.
Note 	The Tempus Pro non-invasive blood pressure monitor does not provide any specific burns protection parts for non-invasive blood pressure (in accordance with IEC80601-2-30 cl 201.7.9.2.101).

6.2.1 Getting started

The Tempus is intended to be used to take non-invasive blood pressure readings from neonates, children, small adults, adults and large adults. Blood pressure measurements can be affected by the position, physiologic condition, or activity level of the patient, who should be seated, standing or lying down depending on the usage model for the device or procedure being performed on the patient. If the patient is seated, they should have legs uncrossed, feet flat on the floor and back and arms supported. If the patient is lying (supine) they should not have their legs crossed.

The patient should be comfortable, relaxed as much as possible and not talking during the NIBP measurement. Before taking the first measurement, a period of at least 5 minutes should elapse to give time for blood pressure stabilization. When the pressure in the cuff increases, the patient should avoid excess movement during measurements. Let the cuffed arm hang or lay loosely, slightly away from the body. Avoid flexing the muscles or moving the hand and fingers of the cuffed arm. Avoid having the cuff or the hose next to vibrating surfaces.

The patient should be advised to relax as much as possible and not talk during the measurement procedure.

The operator should be positioned in their normal operating position.

To take a non-invasive blood pressure reading, remove the cuff from the rear of the device. If a cuff is not attached to the hose, or the hose is not attached to the Tempus then make the necessary connections (twist and lock for the cuff and push/latch to attach the hose).

Ensure the cuff is wrapped firmly around the limb with the cuff placed centrally between the two joints of the limb i.e. 2-5 cm above the elbow joint or 5-10 cm above the knee. Ensure the end of the cuff wraps around within the two range lines – if it does not then use a different cuff. Ensure the cuff's artery marker is placed over the position of the artery e.g. between the bicep and the tricep for the brachial artery on the arm.

Ensure the hose is not kinked, crushed or damaged.

Remember to place the middle of the cuff at the same level as the right atrium of the heart. Placing the cuff substantially higher or lower than the heart will result in incorrect readings.

Remember that there may be differences in results between arms and legs, left and right side and can be affected by the patient's position (sitting, standing, lying down), exercise or their physiologic condition.

Once the cuff is attached, press the start button shown within the Blood Pressure area. The reading can be stopped at any time by pressing the button again (it will be labelled STOP).

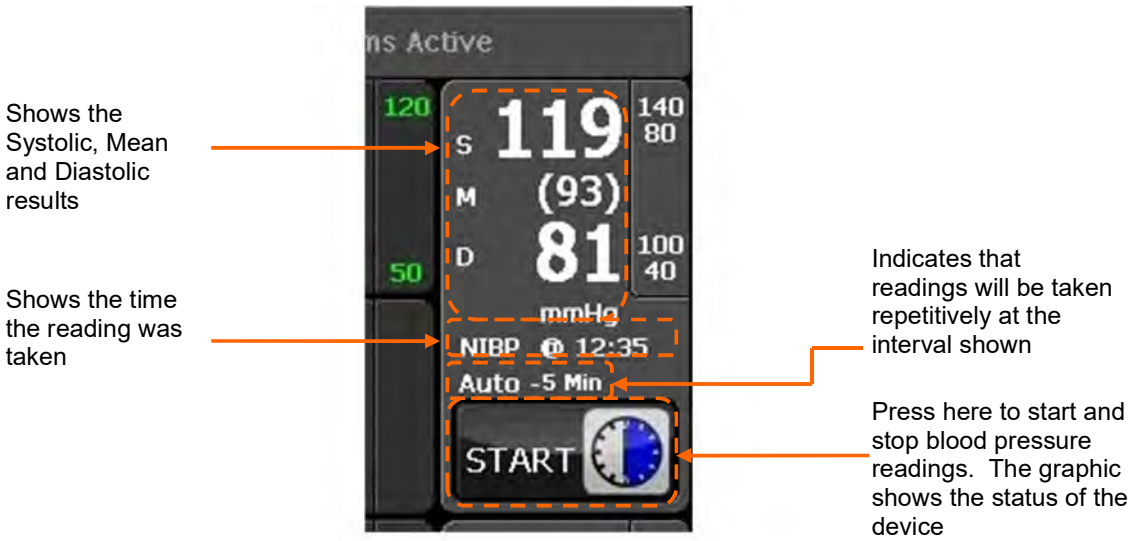
If an unexpected reading is obtained, wait for a brief period and then take the reading again having checked the hose for leaks and kinks, the correct placement of the cuff and the patient's orientation.

Remember that the pressure reading can be affected by common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arteriosclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling, shivering etc.

6.2.2 Taking readings

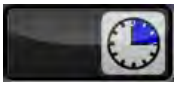
While the cuff is inflating and deflating, the icon in the start button will change to reflect the status of the reading i.e.:

-  Cuff is inflating;
-  Cuff is deflating.



The Non-Invasive Blood Pressure Section of the Home Screen

Once the measurement has been taken, the icon will change to indicate that the device is on timer as shown below:

-  Cuff is on timer;
-  Cuff is on timer;
-  Cuff is on timer;
-  Reading is about to start.

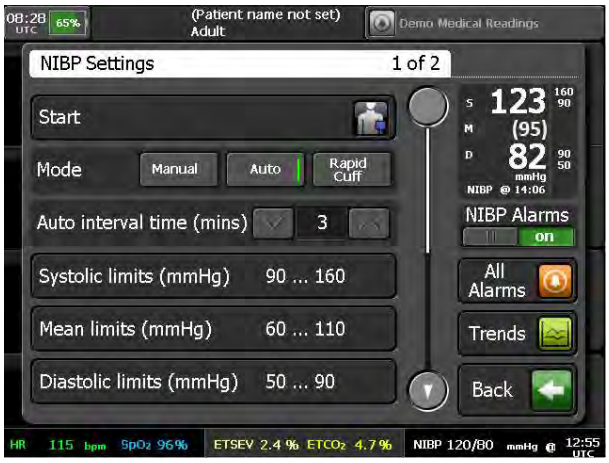
If the device is not set to take readings automatically then it will show the following:

-  Blood pressure monitor is idle.

6.2.3 NIBP settings

Pressing anywhere on the non-invasive blood pressure area brings up the NIBP settings menu:

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

Menu option	Menu screen
Start – start or stop NIBP readings. **Mode** – select **Manual**, **Auto** or **Rapid Cuff**. **Auto interval time (mins)** – when in **Auto** mode, set the time between NIBP readings. **Systolic limits**, **Mean limits** and **Diastolic limits (mmHg)** – set the lower and upper alarm limits.	
Initial inflation (mmHg) – change the initial inflation pressure. The default value is set by Tempus depending on patient age group. **Reading format** – change the format of displayed NIBP readings.	

NIBP mode

The NIBP can be set to read in three different modes:

- **Auto** – allows the user to set the Tempus to take readings automatically on a cycle (3 mins default, can be set to 2 mins, 3 mins, 5 mins, 10 mins, 15 mins, 30 mins and 60 mins).
- **Manual** – allows the user to take a single reading only every time the NIBP button is pressed.
- **Rapid Cuff** – where the Tempus will take as many readings as it can in 10 minutes and will then reset to Auto. If an NIBP technical alarm occurs while in Rapid Cuff mode, the alarm will be reported and the mode will reset to Auto.

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

Initial inflation

The user can adjust the initial NIBP inflation pressure. The default is set by the Tempus depending on patient age group – see “9.3.5 Entering patient details”.

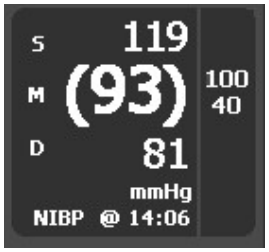
NIBP adjusts its inflation pressure dynamically between readings so this setting only applies to the first reading and when it is manually adjusted.

Patient Type	Default initial inflation	Range
Adult	160 mmHg	120 to 280 mmHg
Paediatric (29 days to 12 years)	140 mmHg	80 to 280 mmHg
Neonate (<29 days)	90 mmHg	60 to 140 mmHg

NIBP reading format

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

NIBP reading format S/D (M)



NIBP reading format (M) S/D

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

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

6.3 Pulse oximetry

WARNING 	**Do not use this device in the presence of high EMI/RFI radiation. High EMI/RFI radiation may cause induced current to the SpO_2 sensor resulting in patient injury.**
WARNING 	**This device may give inaccurate readings in the presence of strong electromagnetic sources, such as electrosurgery equipment.**
WARNING 	**This device may give inaccurate readings in the presence of computed tomography (CT) equipment.**
WARNING 	**Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours. Prolonged use may cause blisters, skin deterioration, and discomfort.**
WARNING 	**Incorrectly applied sensors may give inaccurate readings.**
WARNING 	**SpO_2 measurements may be inaccurate in the presence of high ambient light. Shield the sensor area (with a towel, for example) if necessary.**
WARNING 	**Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO_2 readings.**
WARNING 	**Remove fingernail polish or false fingernails before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.**
WARNING 	**Significant levels of dysfunctional haemoglobins, such as carboxyhaemoglobin or methaemoglobin, will affect the accuracy of the SpO_2 measurement.**
WARNING 	**Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes or inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.**
WARNING 	**Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with opaque material. Optical cross-talk may adversely affect the accuracy of the SpO_2 readings.**
WARNING 	**Obstructions or dirt on the sensor's red light or detector may cause a sensor failure or inaccurate readings. Make sure there are no obstructions and the sensor is clean.**
WARNING 	**Under certain clinical conditions, pulse oximeters may not display SpO_2 and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.**

WARNING 	**Do not use the pulse oximeter for any other purpose than specified in this manual. It should NOT be used as an apnoea monitor.**
WARNING 	**Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.**
WARNING 	**A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analysed by a laboratory co-oximeter to completely understand the patient's condition.**
WARNING 	**Tissue damage can be caused by incorrect application or use of the sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor *Directions for Use* to ensure skin integrity and correct positioning and adhesion of the sensor.**
WARNING 	**Interfering Substances: Carboxyhaemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhaemoglobin present.**
WARNING 	**Reposition the oximeter probe at least once every hour to allow the patient's skin to respire. This time should be reduced in ambient temperatures over 41 °C. No other special actions are required for use in such ambient temperatures although users are advised to check the sensor site frequently in high temperatures to avoid skin damage.**
WARNING 	**The SpO_2 sensor should snugly fit the finger without straining it and if not alternative fingers should be tried. The probe is sized for patients who weigh 20 kg /44 lbs or more. The probe can be used either on patient's fingers, thumbs or largest toe.**
WARNING 	**The plethysmogram may become unstable on patients who are experiencing convulsions or tremors, who are moving or are in motion (transport) environments.**
WARNING 	**Always read and follow the instructions on the packaging of SpO_2 sensors regarding their storage, use and disposal. In particular take into account any information regarding toxicity.**
WARNING 	**For measurements of high or low SpHb readings, blood samples should be analysed by laboratory instruments to completely understand the patient's condition.**
WARNING 	**A pulse oximeter cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO2 measurement.** **For increased COHb: COHb levels above normal tend to increase the level of SpO2. The level of increase is approximately equal to the amount of COHb that is present.** **For increased MetHb: the SpO2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.**
WARNING 	**Haemoglobin synthesis disorders may cause erroneous SpHb readings.**
WARNING 	**Elevated levels of Total Bilirubin may lead to inaccurate SpO2, SpMet, SpCO, SpHb, and SpOC measurements.**

WARNING 	**Motion artefact may lead to inaccurate SpMet, SpCO, SpHb, and SpOC measurements.**
WARNING 	**Severe anaemia may cause erroneous SpO2 readings.**
WARNING 	**Very low arterial Oxygen Saturation (SpO2) levels may cause inaccurate SpCO and SpMet measurements.**
WARNING 	**With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.**
WARNING 	**Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings.**
WARNING 	**Use of additional tape can cause skin damage or damage the sensor.**
WARNING 	**If the sensor is wrapped to tightly or supplemental tape is used, venous congestion/pulsations may occur causing erroneous readings.**
WARNING 	**Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).**
WARNING 	**Venous pulsations may cause erroneous low readings (e.g. tricuspid valve regurgitation).**
WARNING 	**Loss of pulse signal can occur when:** • The sensor is too tight. • The patient has hypotension, severe vasoconstriction, severe anaemia, or hypothermia. • There is arterial occlusion proximal to the sensor. • The patient is in cardiac arrest or is in shock.
WARNING 	**The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display.**
WARNING 	**Verify patient's pulse rate against the ECG heart rate.**
WARNING 	**Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.**
WARNING 	**Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.**

WARNING 	**Before use, carefully read the sensor's *Directions for Use*.**
WARNING 	**To avoid cross contamination only use Masimo single use sensors on the same patient.**
WARNING 	**Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide.**
WARNING 	**See the cleaning instructions in the directions for use for the Masimo re-useable sensors.**

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

CAUTION 	Users are reminded that because pulse oximeter measurements are statistically distributed, only about two-thirds of measurements can be expected to fall within ±Arms of the value measured by a co-oximeter. Information on the clinical desaturation trials performed to validate the oximeter is available on request.
CAUTION 	Use only Masimo oximetry sensors for SpO_2 measurements. Other oxygen transducers (sensors) may cause improper results.
CAUTION 	Do not use the Pulse CO-Oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Pulse CO-Oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
CAUTION 	Exercise caution when applying a sensor to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.
CAUTION 	Circulation distal to the sensor site should be checked routinely.

Note 	SpO_2 averaging is the number of pulse beats over which the SpO_2 value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.
Note 	DESAT trails were performed in the normal sensitivity mode.

Note 	The plethysmogram is not normalised.
Note 	The pulse oximeter probe is for use with intact skin only. The probe used is not sterile and contains no latex. Patient contact materials have undergone extensive biocompatibility testing; further information is available on request.

Note	Any condition that restricts blood flow, such as use of a blood pressure cuff (other than the Tempus Pro cuff used in accordance with the instructions herein) may cause an inability to determine accurate pulse and SpO_2 readings.
Note	SpO_2 measurements may be adversely affected in the presence of high ambient light levels (e.g. strong sunlight). This may be more noticeable with disposable probes. If necessary, shield the sensor area (e.g. with a towel) or a Masimo® light shield.
Note	Remove fingernail polish or false fingernails before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.
Note	Performance and safety test data are available on request from RDT, see "RDT contact details".
Note	The graphical displays of pulse rate, SpO_2 and pulse strength are not proportional to the pulse volume. The amplitude of the waveform is adjusted on an on-going basis to provide the largest size waveform possible. Do not attempt to normalise the waveform to any scale.
Note	The SpO_{2_2} sensor should be on the opposite arm to the blood pressure cuff. The arm of the patient must be kept still and either be horizontal to the shoulder (if the patient is lying down) or below the shoulder (if the patient is sitting upright). If the finger selected does not give good results, this could be due to poor perfusion of blood. Ensure that the finger is inserted all way into the clip, or try taking a reading on another finger.
Note	If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and the check the MS board pulse oximeter for proper functioning.
Note	NO IMPLIED LICENSE - Possession or purchase of this device does not convey any express 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.

Note	Inaccurate measurements may be caused by: • Incorrect sensor application or use • Significant levels of dysfunctional haemoglobins. (e.g., carboxyhaemoglobin or methaemoglobin) • Intravascular dyes such as indocyanine green or methylene blue. • Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material) • Excessive patient movement. • Venous pulsations. • Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

Note	Loss of pulse signal can occur in any of the following situation: • The sensor is too tight. • There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight. • A blood pressure cuff is inflated on the same extremity as the one with a SPO_2 sensor attached. • The patient has hypotension, severe vasoconstriction, severe anaemia, or hypothermia. • There is arterial occlusion proximal to the sensor. • The patient is in cardiac arrest or is in shock.
Note	High levels of COHb may occur with a seemingly normal SpO2. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.

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

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

WARNING 	• As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
	• Do not place the pulse co-oximeter or accessories in any position that might cause it to fall on the patient.
	• Do not start or operate the pulse co-oximeter unless the setup was verified to be correct.
	• Do not use the pulse co-oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
	• Do not use the pulse co-oximeter if it appears or is suspected to be damaged.
	• Explosion hazard: Do not use the pulse co-oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
	• To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
	• To protect against injury, follow the directions below:
	  ○ Avoid placing the device on surfaces with visible liquid spills.
	  ○ Do not soak or immerse the device in liquids.
	  ○ Do not attempt to sterilize the device.
	  ○ Use cleaning solutions only as instructed in this operator's manual.
	  ○ Do not attempt to clean the device while monitoring a patient.
	• To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.
	• If any measurement seems questionable, first check the patient’s vital signs by alternate means and then check the pulse co-oximeter for proper functioning
	• Inaccurate SpCO and SpMet readings can be caused by:
	  ○ Improper sensor application
	  ○ Intravascular dyes such as indocyanine green or methylene blue
	  ○ Abnormal hemoglobin levels
	  ○ Low arterial perfusion
	  ○ Low arterial oxygen saturation levels including altitude induced hypoxemia
	  ○ Elevated total bilirubin levels
	  ○ Motion artifact

WARNING

- Inaccurate SpHb and SpOC readings may be caused by:
  - Improper sensor application
  - Intravascular dyes such as indocyanine green or methylene blue
  - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
  - Elevated PaO2 levels
  - Elevated levels of bilirubin
  - Low arterial perfusion
  - Motion artifact
  - Low arterial oxygen saturation levels
  - Elevated carboxyhemoglobin levels
  - Elevated methemoglobin levels
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Vasospastic disease such as Raynaud's
  - Elevated altitude
  - Peripheral vascular disease
  - Liver disease
  - EMI radiation interference
- Inaccurate SpO2 readings may be caused by:
  - Improper sensor application and placement
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Elevated levels of bilirubin
  - Elevated levels of dyshemoglobin
  - Vasospastic disease, such as Raynaud’s, and peripheral vascular disease
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Severe anemia
  - Very low arterial perfusion
  - Extreme motion artifact
  - Abnormal venous pulsation or venous constriction
  - Severe vasoconstriction or hypothermia
  - Arterial catheters and intra-aortic balloon
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
  - Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
  - Skin color disorders

WARNING

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

CAUTION

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

CAUTION

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

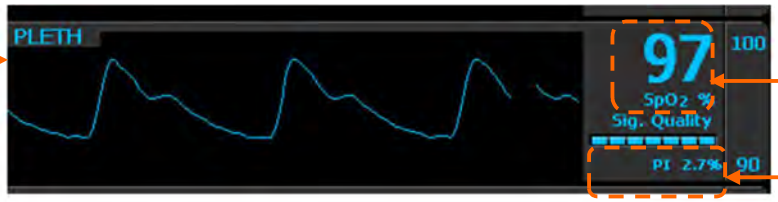
Note

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

6.3.1 Getting started

To use the pulse oximeter, remove the soft finger probe from the back of the device. Attach it to a well-perfused finger of the patient taking care to ensure it is not the same arm which has a blood pressure cuff attached. The readings will begin a few seconds after the probe is attached to the patient.

The plethysmogram is shown continuously



The SpO_2 reading is provided shown here

The signal strength and perfusion index of the site are shown here

The Pulse Oximetry Section of the Home Screen

The SpO_2 section gives the oxygen saturation of the blood and shows the plethysmogram, signal strength (in bar graph form) and the perfusion index.

The Signal Quality bar graph shows how well the pulse sensor is detecting the pulse. The amplitude of the indication indicates the quality of detection. If the indication on the Signal Strength meter is low, or becomes low, then the finger sensor should be repositioned. Similarly, the Perfusion Index gives a numerical indication of the level of arterial pulsatile blood at the sensor site.

The Pulse Rate displayed on the Tempus Pulse Oximeter may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can cause the pulse rate displayed on the Tempus to be significantly different than the ECG heart rate.

The perfusion index (PI) indicator provides a relative numeric indication of the pulse strength at the monitoring site. It is a calculated percentage between the pulsatile signal and non-pulsatile signal of arterial blood moving through the site. PI may be used to find the best perfused site and to monitor physiological changes in the patient. It displays an operating range of 0.02 % to 20.00 %. A percentage greater than 1.00 % is desired. Extreme changes in the display number are due to motion artefact and changes in physiology and blood flow.

The device indicates perfusion on a 7-bar LED indicator. The lower two segments of the bar will turn red when the amplitude of the arterial pulsations is very low (low perfusion). It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation. This “localized hypoxemia” may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

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

6.3.2 Pleth variability index

Pleth Variability Index or PVI® helps users to discern between patients who may respond to fluid from those who may not.

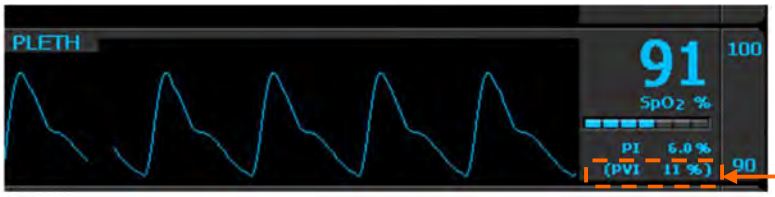
PVI has been shown to help clinician to predict fluid responsiveness in mechanically ventilated patients under general anaesthesia, defined as a significant increase in cardiac output after fluid administration. PVI is an automatic measure of the dynamic change in Perfusion Index (PI) that occurs during the respiratory cycle.

$PVI = ((PI_{max}-PI_{min})/PI_{max}) \times 100$.

The greater the PVI, the more likely the patient will respond to fluid administration. Typically, a PVI of >14% prior to volume expansion is predictive that a mechanically ventilated patient will respond to fluid

administration (81% sensitivity). A PVI prior to volume expansion is predictive that a mechanically ventilated patient will not respond to fluid administration (100% specificity).

PVI® is an option for Tempus Pro.



The Pulse Oximetry Section with PVI

6.3.3 Taking readings

Note	Depending on which of the features have been purchased, some of the features shown below may not be available on your Tempus Pro device.

1. Remove the patient cable from the RapidPak area of the Tempus.
2. Connect the SpO_2 cable to the Tempus Pro.
3. Attach the chosen sensor to the patient cable:

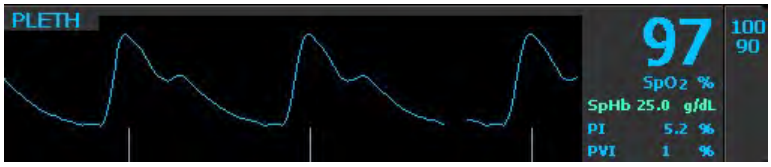
   SpO2 sensor - SpO2, PI and PVI

   SpCO sensor - SpCO, SpMet, Sp02, PI and PVI

   SpHb sensor - SpHb, SpMet, SpOC, Sp02, PI and PVI

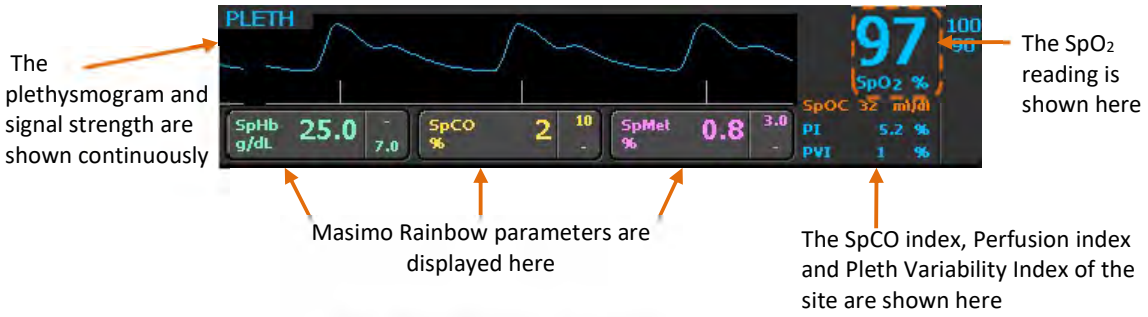
Attach it to a well-perfused finger of the patient taking care to ensure it is not the same arm which has a blood pressure cuff attached. The measurement will begin as soon as the probe is attached to the patient but different values take different lengths of time to appear on the screen.

Standard Waveform view



Large Waveform view

6.3.4 Features



The Pulse Oximetry section of the home screen

Depending on which features have been purchased for your Masimo Rainbow Pulse OX and which sensor you are using will depend on which of the following features the Tempus Pro can monitor.

Masimo® SET® measurements supplied as standard:

- **SpO_2** - Intended for non-invasive measurement of arterial blood saturation and also provides pulse rate when ECG is not attached.
- **Pulse Rate (PR)**.
- **Perfusion Index (PI)** - Gives a numerical indication of the level of arterial pulsatile blood at the sensor site.

Masimo® SET® Rainbow measurements purchased as optional upgrades:

- **SpCO** - Allows clinicians to noninvasively and immediately detect elevated levels of carbon monoxide.
- **SpMet** - Allows clinicians to noninvasively and immediately detect elevated levels of methaemoglobin in the blood.
- **SpHb Index** - Gives continuous monitoring of the haemoglobin levels in blood.
- **SpOC** - Gives the patient's oxygenation status by calculating the haemoglobin and oxygen saturation.

PVI purchased as an optional upgrade:

- **Pleth Variability Index (PVI)** - Helps clinicians noninvasively and continuously assess fluid status of patients.

The Signal Quality waveform (underneath the plethysmogram) shows how well the pulse sensor is detecting the pulse. The height of the peak indicates the strength of the signal, if the peaks are short the finger sensor should be repositioned.

The Pulse Rate displayed on the Tempus Pulse Oximeter may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can cause the pulse rate displayed on the Tempus to be significantly different than the ECG heart rate.

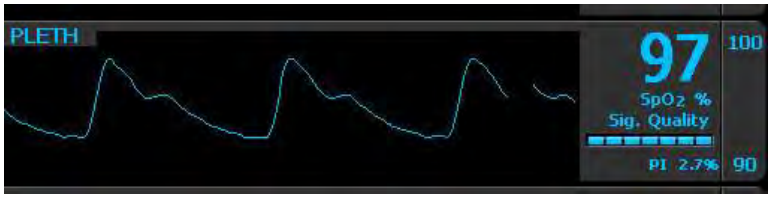
The device indicates perfusion. It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation. This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate).

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

6.3.5 Pulse oximetry probes

The following pulse oximetry sensors may be used with the Tempus Pro: standard, SpCO or SpHb. Each sensor shows a different range of parameters. There is no single sensor that shows all parameters.

The standard adult SpO2 reusable sensor reads SpO2, PI and PVI



The Standard adult SpO2 section

The SpCO sensor reads SpCO, SpMet, SpO2, PI and PVI

The Pulse Oximetry section with SpCO

The SpHb sensor reads SbHb, SpMet, SpOC, SpO2, PI and PVI

The Pulse Oximetry section with SpHb

Note	Depending on which sensor is used the Tempus will display only the available parameters.

6.3.6 Pulse oximeter settings

Pressing anywhere in the plethysmogram area brings up the Pulse Oximeter Settings menu:

The SpCO, SpMet, SpHb and SpOC limits are only activated when their Masimo licenses have been installed and the appropriate probes are plugged in.

Note	PI and PVI alarms are only available in Tempus Pro devices with part numbers ending in "-R".

Menu option	Menu screen
SpO2, SpCO and SpMet limits (%) – set the upper and lower alarm limits for SpO2, SpCO and SpMet. **SpHb limits and settings** – open the SpHb Settings menu, see "6.3.7 SpHb settings". **HR/PR source** – select **ECG** or **Pulse** oximeter as the heart/pulse rate source. **Large pleth waveform** – turn the large pleth waveform display on and off.	
Sensitivity mode – adjust sensitivity by pressing **Max**, **Norm** or **APOD**. **Averaging time (s)** – use the up and down arrows to adjust averaging time in seconds. **FastSAT** – turn FastSAT on or off. **Cardiac wave speed (mm/s)** – change wave speed. This setting is common to ECG, Sp02 and IP. **HR/PR beat volume** - volume of the audible tone that the Tempus emits every time a heartbeat is detected. **SpOC limits (ml/dl)** – set the upper and lower alarm limits for SpOC.	

Menu option	Menu screen
PI limits (%) – set the upper and lower alarm limits for Perfusion Index. **PVI limits (%)** – set the upper and lower alarm limits for Pleth Variability Index.	

Pulse tones

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

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

When pulse tones are turned on Tempus Pro emits a beep for each pulse beat detected. The beep tone (frequency) depends on the value of pulse ox saturation (SpO2). Higher SpO2 values mean that each beat is emitted with a higher tone beep and vice-versa. So the tone drops as SpO2 (%) falls, with the lowest frequency tone at values of SpO2 = 80% or below.

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

Averaging time

The pulse oximeter can be set to average its heart rate reading over different time periods. By default, this is 8 seconds. This can be adjusted to make the reading more or less responsive. The available settings are: (2-4 seconds, 4-6 seconds, 8 seconds, 10 seconds, 12 seconds, 14 seconds and 16 seconds).

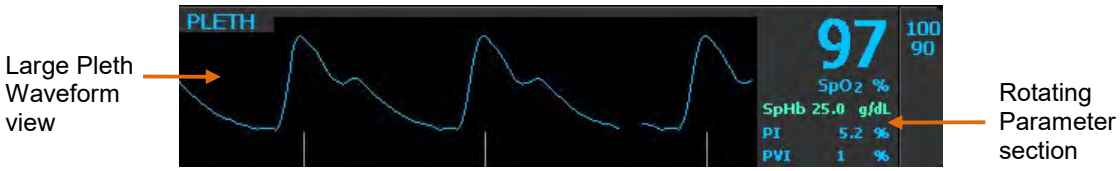
Sensitivity mode

The Pulse Oximeter is equipped with 3 different sensitivity modes. Each mode allows the clinician to change the sensitivity settings of the device to meet the increased demands of the patient's physiological condition or enable it to work during periods of low perfusion and/or motion. They are as follows:

- **Normal Sensitivity (Norm)** – This is the recommended mode for patients that are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).
- **Adaptive Probe Off Detection (APOD)** – This is the recommended start-up monitoring mode for most patients with acceptable perfusion or where a more robust sensor off detection is desired. It is the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient.
- **Maximum Sensitivity (Max)** - This mode is recommended for patients with low perfusion or when the low perfusion or low signal quality message is displayed on the screen in APOD or normal sensitivity mode. This mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings. Also, after a power off and on cycle, the sensitivity will change from the MAX to the factory default or user configured default setting of APOD or NORM.

Large pleth waveform

Large pleth waveform changes the display to show a bigger waveform. This will remove the Rainbow measurement parameters from the waveform section of the home screen and move them to the tile on the right. The parameters will then rotate every 5 seconds.



Large Pleth Waveform section of the home screen

FastSAT

FastSAT enables rapid tracking of arterial oxygen saturation changes. Arterial oxygen saturation data is averaged using pulse oximeter averaging algorithms to smooth the trend. When FastSAT is "On" the averaging algorithm evaluates all the saturation values providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With FastSat, the averaging time is dependent on the input signal. For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds, respectively.

6.3.7 SpHb settings

Pressing the SpHb settings button (if activated) brings up the SpHb settings page:

Menu option	Menu screen
SpHb limits (g/dL) – set the upper and lower alarm limits for SpHb. **SpHb mode** – select **Arterial** or **Venous**. **SpHb averaging** – select **Short, Medium or Long**. **Sensor life remaining** – shows the remaining life of the pulse ox sensor.	

Sensor life remaining

'**Sensor life remaining**' shows the life of the sensor. A tech alarm will sound to warn when the remaining life is low. If the patient is still being monitored when the sensor life reaches zero, it will continue to monitor the patient but must be changed once monitoring has finished. A further tech alarm will sound once monitoring of patient has finished.

Note	If monitoring is complete, remember to disconnect the sensor from the patient cable as this may impact the life expectancy of the sensor.

6.4 Capnography

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

NO IMPLIED LICENSE

Possession or purchase of this device does not convey any express or implied license to the device with unauthorized consumable CO_2 sampling consumable products, which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device and/or CO_2 sampling consumable products.

WARNING 	**To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.**
WARNING 	**To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, such as rain.**
WARNING 	**The monitor is a prescription device and is to be operated by qualified healthcare personnel.**
WARNING 	**The Tempus Pro is not for apnoea detection. The Tempus Pro is not an apnoea monitor and does not provide apnoea alarming.**
WARNING 	**If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternative means, and then make sure the monitor is functioning correctly.**
WARNING 	**Carefully route the FilterLine to reduce the possibility of patient entanglement or strangulation.**
WARNING 	**Do not lift the monitor by the FilterLine, as it could disconnect from the monitor, causing the monitor to fall on the patient.**
WARNING 	**The use of accessories, transducers, sensors and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system.**
WARNING 	**CO_2 readings and respiratory rate can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.**
WARNING 	**The FilterLine may ignite in the presence of oxygen if exposed to high heat.**
WARNING 	**When using a sampling line for intubated patients with a closed suction system, do not place the airway adapter between the suction catheter and endotracheal tube. This is to ensure that the airway adapter does not interfere with the functioning of the suction catheter.**
WARNING 	**Do not cut or remove any part of the sample line. Cutting the sample line could lead to erroneous readings.**

WARNING 	**If too much moisture enters the sampling line (i.e., from ambient humidity or breathing of unusually humid air), the message *Clearing FilterLine* will appear in the message area. If the sampling line cannot be cleared, the message *FilterLine Blockage* will appear in the message area. Replace the sampling line once the FilterLine Blockage message appears.**
WARNING 	**Loose or damaged connections may compromise ventilation or cause an inaccurate measurement of respiratory gases. Securely connect all components and check connections for leaks according to standard clinical procedures.**
WARNING 	**Always ensure the integrity of the patient breathing circuit after insertion of the airway adapter by verifying a proper CO2 waveform (capnogram) on the monitor display.**
WARNING 	**Do not lift the Tempus by the FilterLine as it could disconnect from the monitor causing the monitor to fall on the patient.**
WARNING 	**Do not use the FilterLine H Set Infant/Neonatal during magnetic resonance imaging (MRI) scanning. Using the FilterLine H Set Infant/Neonatal during MRI scanning could harm the patient.**

CAUTION 	During MRI scanning, the module must be placed outside the MRI suite. When the module is used outside the MRI suite, EtCO2 monitoring can be implemented using the FilterLine XL.
CAUTION 	Use of a CO_2 sampling line with H in its name (indicating that it is for use in humidified environments) during MRI scanning may cause interference. The use of non H sampling lines is advised.
CAUTION 	Microstream® EtCO2 sampling lines are designed for single patient use, and are not to be reprocessed. Do not attempt to clean, disinfect, sterilize or flush any part of the sampling line as this can cause damage to the monitor.
CAUTION 	Dispose of sampling lines according to standard operating procedures or local regulations for the disposal of contaminated medical waste.
CAUTION 	Before use, carefully read the Microstream $ETCO_2$ sampling line's *Directions for Use*.
CAUTION 	In high-altitude environments, $ETCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high-altitude environments, it is advisable to consider adjusting $ETCO_2$ alarm settings accordingly.
CAUTION 	Use of monitoring during continuous nebulised medication delivery may result in damage to the Tempus Pro which is not covered by the warranty. Disconnect the Capnometer sample line from the Tempus Pro or switch off the Tempus Pro during medication delivery.
CAUTION 	Do not use on patients that cannot tolerate the removal of 50 ml/min from their total minute ventilation.

Note	The following conditions can potentially cause a change in the flow rate: • Water, mucous or other patient contaminate has entered the sample tubing. • The sample tubing is crimped or pinched so that the sample flow rate has decreased. • Damage to the sample line. • The sample line has been cut, or split, causing the flow rate to increase.
Note	The Capnometer will require warming up if it is started from cold. The warm up time is specified in section 14.1.4. Once the Capnometer is warmed up, the capnogram will appear on the display.
Note	In order to avoid moisture build-up and sampling line occlusion during nebulisation or suction for intubated patients, remove the sampling line luer connector from the Tempus.

The Tempus uses the Oridion® Microstream® FilterLine® and CapnoLine® systems to monitor CO_2.

Before using the Capnometer, select the appropriate cannula taking into account the patient age and the use of ventilation/intubation.

NSN	Oridion PN	Description	Application
6515-01-596-6547	015016	FilterLine H Set, Adult / Paediatric	Intubated sampling line and airway adapter for humid environments
6515-01-586-3075	015018	Smart CapnoLine Plus O_2	Non-Intubated Oral/ Nasal sampling with O_2 delivery for Adults
6515-01-596-7270	015021	FilterLine Set, Adult / Paediatric	Intubated sampling line and airway adapter for short term monitoring
6515-01-596-6391	015026	VitaLine H Set, Adult / Paediatric	Intubated sampling line and airway adapter for high ambient humidity
6515-01-596-7077	015027	Smart CapnoLine O_2 Paediatric	Non-Intubated Oral/ Nasal sampling with O_2 delivery for Paediatrics
6515-01-596-6387	015028	FilterLine H Set, Infant / Neonate	Intubated sampling line and airway adapter for humid environments, Infant/neonatal use

6.4.1 Getting started

To use the Capnometer, lift the door covering the Capnometer connector. The door will either be resting or will be pushed closed (in which case it will be latched). Lift the door by gently pressing on the latch end of the door and then levering the door up. The door is spring-loaded and will provide a gentle resistance to your finger. Letting go of the door will allow it to snap-shut. The door can be latched shut by applying gentle pressure to the latch end of the door to push it in – you will feel a click as the door latches.

CAUTION	The Capnometer door must be shut at all times when a cannula is not fitted. This is important to prevent dust, fluids or foreign objects from entering the Capnometer. Ensure the door is only kept open for the minimum time necessary to plug and unplug a cannula into the Tempus.
CAUTION	If the door snaps shut this will only provide functional protection against dust/fluids etc. to the Capnometer. For IP66 sealing the door must be pushed closed to engage the door's latch. If the Capnometer door is open the device has an IPX1 rating.
CAUTION	If the door is broken it must be replaced as soon as possible. The door and spring assembly can be removed and replaced with spare items by an appropriate technician without the unit being returned to RDT.

CAUTION ⚠	Allowing dust, fluids or foreign objects to enter the Capnometer can cause permanent damage to the device.

With the door open, attach a suitable patient airway adaptor (cannula) to the Capnometer socket of the Capnometer. An adult nasal cannula is typically supplied but a range of cannulas and other adaptors are available. Twist the cannula clockwise to insert and counter clockwise to remove. When inserting, ensure the cannula is fully inserted by twisting it until it is finger-tight.

CAUTION ⚠	Always ensure the cannula is fully inserted and fully tightened. Failing to tighten the cannula may result in the sample being diluted and an artificially low reading being produced.
CAUTION ⚠	Below the hole for the cannula inlet is a small hole for the Capnometer exhaust. Take care not to block this hole (an error will be caused if it becomes blocked) and ensure that dust, fluids or foreign objects do not enter it. Note that the Capnometer is not suitable for connection to a gas scavenging system.

Attach the cannula or airway adaptor to the patient following the instructions printed onto the pack of the adaptor. The Capnometer will start as soon as the probe is attached to the patient.

Applying a FilterLine set

The FilterLine set is intended for the CO_2 monitoring of intubated patients.

Before attaching the airway adapter to the breathing circuit, verify that the adapter is clean, dry and undamaged. Replace if necessary.

Place the airway adapter at the proximal end of the airway circuit between the elbow and the ventilator circuit wye. Do NOT place the airway adapter between the ET tube and the elbow as this may allow patient secretions to accumulate in the adapter.

If pooling does occur, the airway adapter and sampling line must be replaced.

Applying a Smart CapnoLine oral/nasal cannula

The oral/nasal cannulas are intended for monitoring CO_2 in non-intubated patients.

Oral/nasal sampling cannulas are especially valuable for patients who are prone to mouth breathing, since most (if not all) of the CO_2 is exhaled through the mouth. If a standard nasal CO2 sampling cannula is used on such patients, the $ETCO_2$ values and capnogram displayed will be substantially lower than the actual CO_2 levels present in the patient's expired breath.

Remove the cannula from the package. Verify that the cannula is clean, dry, and undamaged.

Replace if necessary.

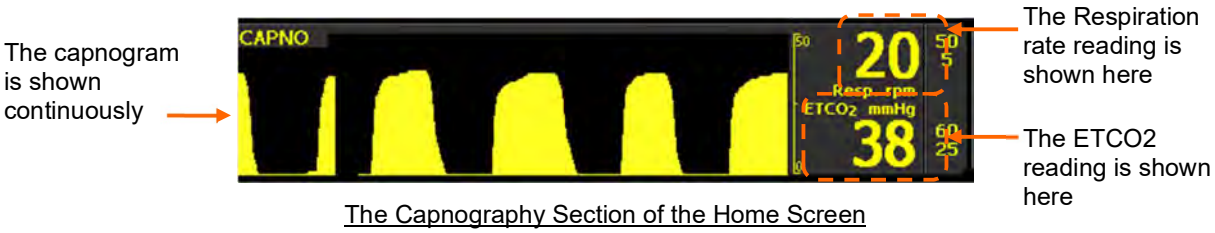
6.4.2 Taking readings

Place the oral/nasal cannula onto the patient with two hands by first placing the prongs of the cannula into the patient's nostrils, then extend the lengths of the cannula around both sides of the patient's face routing the cannula tubing up to and then over both the patient's ears.

Proceed to loop the tubing around the back of the ears and bring the tubing under the ears and back towards where the patient's chin and throat meet.

Holding the tubes together with one hand under the chin, slide the collar around the cannula up so it secures both tubes of the cannula together firmly but comfortably under the patient's chin

CAUTION ⚠	Dispose of Microstream $ETCO_2$ consumables according to standard operating procedures or local regulations for the disposal of contaminated medical waste.



The Capnography Section of the Home Screen

Once the Capnometer is active it will run until the cannula is unplugged from the Tempus. Note that the wave speed of the capnogram is slower that the ECG and Pleth by default.

Once the Capnometer is started it will display the message “Warming up” for approximately 30 seconds. $ETCO_2$ readings will then display immediately and respiration readings will appear 2 breath cycles after the $EtCO_2$ readings appear. If the Capnometer is sufficiently warm, it can take as little as 7 seconds to return an $ETCO_2$ reading and 12 seconds to return a respiration rate reading (assuming a rate of >10 rpm).

Once the Capnometer has started, check that the connections have been made properly by confirming the capnogram waveform appears correctly.

Note	If impedance respiration was in use, the waveform will automatically change to “CAPNO” and will display the end tidal CO_2 as soon as the cannula is connected. As soon as the cannula is disconnected (and the consequent error is cleared) the device will resume monitoring using impedance respiration.

After the Capnometer has started, it should draw a steady flow of breath gas down the cannula. If the cannula becomes blocked, the Capnometer will attempt to free the blockage by forcing low pressure air into the cannula. While this is occurring the waveform and readings will not be displayed and a message saying “Capnometer filter line purging” will be displayed in the waveform area. If the purging is successful then operation will resume automatically, if the blockage cannot be cleared (45 seconds approx.) then an error will be posted instructing to replace the cannula and the Capnometer will cease operation until the cannula is removed and replaced.

6.4.3 Capnometer settings

Pressing anywhere in the capnogram area brings up the Capnometer settings menu:

Menu option	Menu screen
Respiration limits (rpm) – set the upper and lower alarm limits for respiration. **No breaths (sec)** – set the time that elapses after detection of no breaths until the alarm sounds. **ETCO2 limits** – set the upper and lower alarm limits for ETCO2. **ETCO2 units** – select **mmHg** or **kPa**. **Wave range** – adjust respiration wave height and amplitude. **Respiration wave speed (mm/s)** – set wave speed to **3.1**, **6.25** or **12.5**.	

Menu option	Menu screen
Operating mode – to switch off the pump (for suction or lavage), select **Pause 5 mins** or **Pause 10 mins**.	

Note	
	The ETCO2 units can be presented on the home screen in either mmHg or kPa but measurements in the Trends table and at i2i are only available in mmHg.

6.5 Contact temperature

WARNING	**The thermometer is only intended for use with YSI series 400 sensors. Disposable and reusable 400 series sensors may be used. Do not use series 700 sensors with the Tempus.**
WARNING	**Application and use of metal-jacketed temperature sensors that come into contact with conductive objects or clinical personnel during electrocautery may cause burns at the patient-probe/electrode contact points.**
WARNING	**Always read and follow the instructions on the packaging of temperature sensors regarding their storage, use and disposal. In particular take into account any information regarding toxicity.**

Note	The contact temperature probes must be attached to the parts of the body which their labelling shows they are indicated for.
Note	A single temperature channel (T1) is provided on the Tempus as standard. The second channel may be activated as an option using a software update.

6.5.1 Getting started

To use the thermometer, plug a YSI series 400 temperature sensor into the Tempus' ¼" socket marked "T1".

6.5.2 Taking readings

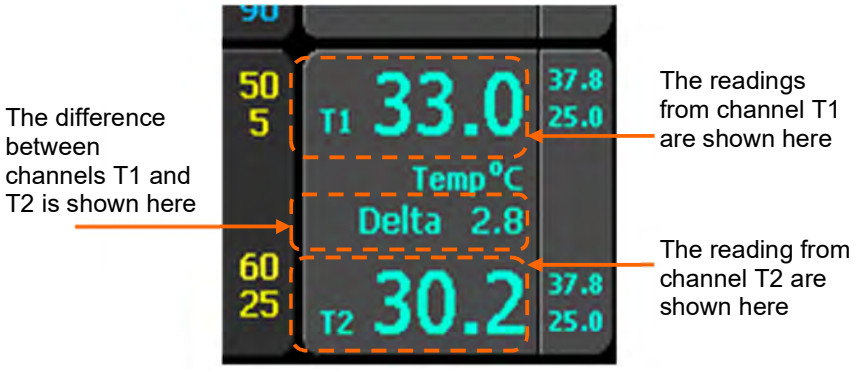
Attach the sensor to the patient following the instructions on the sensor's packaging.

The device will start to provide readings as soon as the sensor is connected (typically <10 seconds but up to 35 seconds according to IEC80601-2-56).

Users should monitor the temperature to observe when the reading settles (settling time will be dependent on environmental and patient factors).

Change the setting of the Tempus to °C or °F as required.

Note	Ensure the probe is suitably secured to the patient'



6.5.3 Contact temperature settings

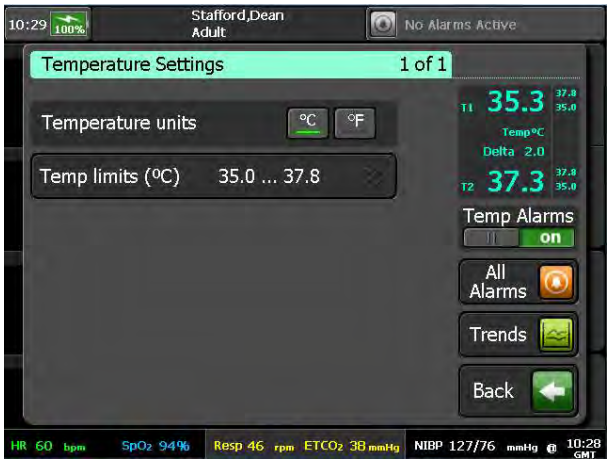
Pressing anywhere on the contact temperature area brings up the contact temperature settings menu.

Note	The thermometer performs a self-check to 38.8 °C ±0.1 °C constantly to ensure that its readings are accurate and within specification.

If the Tempus Pro is configured to support only one temperature channel:

- The values in the Temperature Settings screen apply regardless of whether the temperature sensor is connected to socket T1 or T2.
- The maintenance user can still configure default alarm limits for two channels (T1 and T2), but the T2 default alarm limits are ignored and the initial temperature limits in the Temperature Settings screen are equal to the T1 default alarm limits.

The single channel Temperature Settings screen looks like this:

Menu option	Menu screen
Temperature units – set the measurement units to **°C** or **°F**. **Temp limits** – set the lower and upper temperature alarm limits.	

If the Tempus Pro is configured to support two channels of contact temperature:

- There are separate configured alarm limits for the T1 and T2 channels.
- There is a configured alarm limit for the difference between T1 and T2 (Delta).

The two-channel Temperature Settings screen looks like this:

Menu option	Menu screen
Temperature units – set the measurement units to **°C** or **°F**. **T1 limits** and **T2 limits** – set the lower and upper temperature alarm limits for each channel. **Delta limits** – set the delta temperature alarm limits, based on the difference between T1 and T2.	

6.6 Invasive pressure

WARNING 	**DO NOT use the Invasive Pressure monitor for any purpose other than specified in this manual.**
WARNING 	**If electrocautery is used, always avoid using any transdducer with a conductive (metal) case connected to its ground shield. Using a conductive transducer that is connected to its cable shield risks high-frequency burns at the ECG electrodes if the transducer case becomes grounded to earth.**
WARNING 	**Normal alarm functions will detect complete disconnections of invasive pressure transducers and faulty cables / transducers. Use only approved transducers and ensure that they are connected properly.**

WARNING 	**Invasive Pressure is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times.**
WARNING 	**Do not touch metal parts of the transducer while it is in contact with the patient.**
WARNING 	**Do not reuse any components that are labelled for single use only.**
WARNING 	**Although complete disconnections of invasive pressure transducers will be detected by the normal alarm functions, partial disconnection will not be detected, nor will the use of some incompatible transducers. The user must exercise reasonable measures to ensure that approved transducers are used and that pressure transducers are connected properly.**
WARNING 	**If electrocautery is used, always avoid using any transducer with a conductive (metal) case that is electrically connected to its cable shield. Using a conductive transducer case with such a shield connection risks high-frequency burns at the ECG electrodes if the transducer case becomes earth grounded.**
WARNING 	**Always read and follow the instructions on the packaging of transducers regarding their storage, use and disposal. In particular take into account any information regarding toxicity.**
WARNING 	**Remember to follow instructions provided with the transducers relating to use in defibrillation.**
WARNING 	**Remember to differentiate the different transducers that are connected to the Tempus. The adaptor cables are labelled P1 & P2. The Tempus provides features to additionally label these channels with their site description on the display.**

CAUTION 	Do not attempt to clean, disinfect, sterilize or in any way re-use transducers, catheters or other patient connected tubing which are labelled as single use only.
CAUTION 	Dispose of all single use items according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

Note	The invasive pressure meter will require warming up if it is started from cold. The warm up time is specified in section "14.1.6 Invasive pressure". Once the Tempus is turned on and the invasive pressure parameter functional, the pressure waveform will appear on the display.
Note	Check all cables and connections before use. Request that an appropriate service technician check the function of the device (including operation of all audible and visual alarms) on a regular basis.

The Tempus is compatible with a range of invasive pressure sensors – see "12.1.2 Invasive pressure accessories"

Always use the correct adaptor cable for the desired transducer to connect it to the Tempus.

The Tempus provides two channels of invasive pressure which can be extended to four channels via a USB IP Module. The Tempus Pro can then be used with one, two, three or four transducers.

6.6.1 Getting started

To measure invasive pressure, open the transducer packaging and inspect the transducer cable. If the cable shows signs of damage or wear, then replace it.

Attach the transducer to the patient following the instructions supplied with the device's packaging.

Attach the appropriate adaptor cable for the transducers you wish to use to the Tempus (white socket). Then connect the transducers to the cable, taking care to note and understand which transducer is attached to channel P1 and which to channel P2.

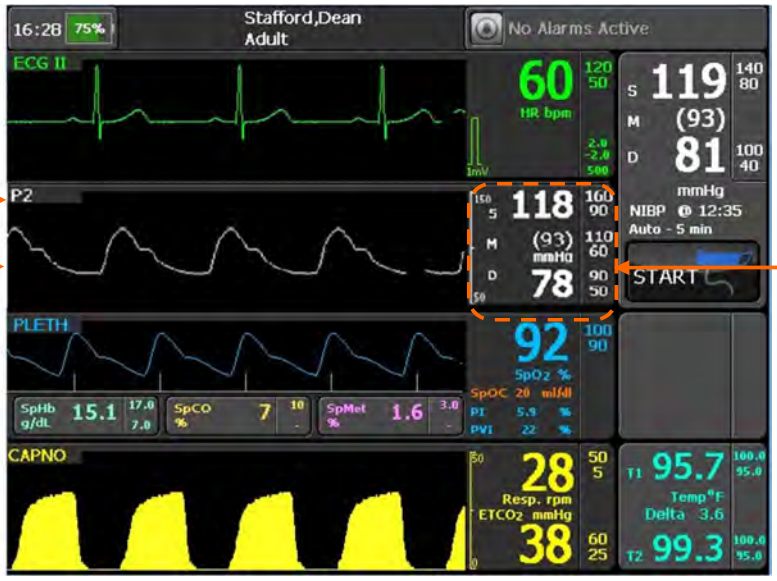
6.6.2 Taking readings

Then zero the transducers using the process described in section "6.6.5 Zeroing transducers".

WARNING	**Always zero the transducer before using it.**

Then attach the transducer to the patient following the instructions on the transducer's packaging.

Note	The invasive pressure feature can be used to monitor a single channel at a time. In this case, either channel P1 or P2 can be used. See the example shown below where channel P2 is being used in isolation.

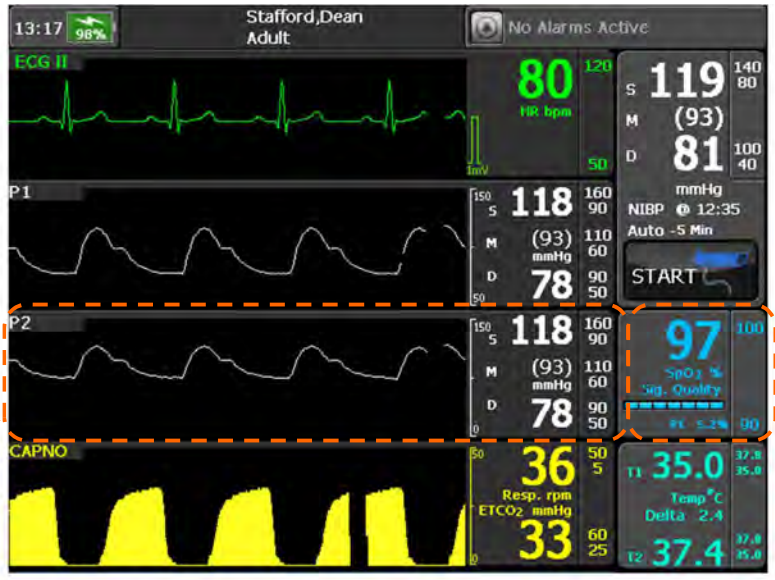


The channel label is shown here

The pressure waveform is shown here

The Systolic, Diastolic and Mean measurements are shown here

Once a second channel of invasive pressure is in use, it will appear as shown below.



The second channel will appear here

Note that the pulse oximetry readings move to here

Monitoring two channels of invasive pressure

Note	If a second channel of invasive pressure is used, this channel will replace the pulse oximeter's results and plethysmogram in the results layout. The pulse oximeter results will move to the right into the previously unoccupied area. As soon as the either of the invasive pressure channels stop being used (when the transducer is disconnected from the adaptor cable and the alarm ceased), the pulse oximeter results and plethysmogram will return to their original location.

6.6.3 Invasive pressure settings

Pressing anywhere on the invasive pressure area brings up the invasive pressure settings menu.

CAUTION ⚠	The settings of each invasive pressure channel can be set differently. Press on the area of the relevant channel to access its settings. Changes in settings made to one channel are never automatically made to any other channel.

Menu option	Menu screen
The title bar shows the channel being configured (P1 in this example). **Channel configuration** – label and reconfigure the channel, see "6.6.4 Configuring the transducer / channel". **Zero transducer** – zero the transducer, see "6.6.5 Zeroing transducers". **Systolic limits**, **Mean limits** and **Diastolic limits** – set the lower and upper alarm limits. **Cardiac wave speed (mm/s)** – change wave speed. This setting is common to ECG, Sp02 and IP.	

Various conditions can affect the performance and accuracy of the invasive pressure measurement. These include:

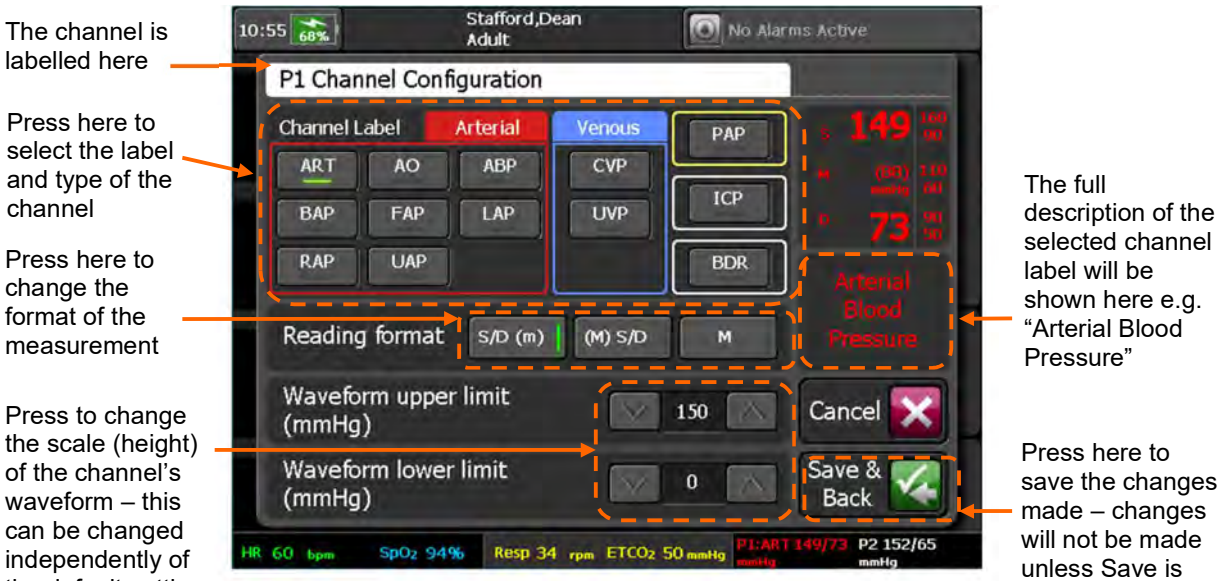
- Clogging of the catheter.
- The placement of the catheter in the vasculature. Artefact such as catheter whip should be managed according to whatever clinical protocols are in place locally.
- The position of the transducer stopcock, catheter and flush port.
- The position of the transducer with respect to the patient's haemostatic axis or the catheter tip.
- Patient movement.
- Saline line flushes which may temporarily interrupt accurate pressure measurement.
- Air bubbles in the catheter or in the transducer dome.

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

6.6.4 Configuring the transducer / channel

Each channel can be configured according to its application. By default, both channels will appear in white, with results configured as "S, M and D" with a default scale (height) of the channel waveforms being 0-150 mmHg.

Accessing the Channel Configuration menu allows the channel labels to be individually named, the results format to be re-configured and the channel height to be adjusted.



Configuring an Invasive Pressure Settings Menu

CAUTION	The settings of each invasive pressure channel can be set differently. Changes in settings made to one channel are never automatically made to any other channel.

The menu allows the user to pick pre-set labels for the channel. These are grouped by colour and application with RED being for arterial labels, BLUE being for venous labels, PALE YELLOW for pulmonary arterial pressure and WHITE being for other application labels.

Simply picking a label and then pressing Save will change the channel label and the colour of the waveform and results. It will also change the waveform height and the Reading format and alarm limits. If a label is changed from one 'type' to another (e.g. from an arterial to a venous pressure), the reading format and waveform upper and lower limits will be set to defaults for the selected label. If a label is changed but stays within the same type (e.g. from ART to AO), any non-default reading format or waveform upper / lower limits will persist. The default settings are detailed below. For default alarm limits and alarm ranges, see "7.3 Patient alarms".

Note	Labelled channels will keep their labelling until either the patient is discharged, switched to previous patient or if the user manually changes the channel label.
Note	If an invasive pressure channel is labelled as Arterial and the critical alarm sounds pressing the alarm buttons will automatically set that channel to zero required.

Label	Application	Colour	Reading format	Waveform height
ART – Arterial Blood Pressure	Arterial	Red	S/D (m)	0-150 mmHg
BAP – Brachial Artery Pressure	Arterial	Red	S/D (m)	0-150 mmHg
RAP – Radial Artery Pressure	Arterial	Red	S/D (m)	0-150 mmHg
AO – Aortic pressure	Arterial	Red	S/D (m)	0-150 mmHg
FAP – Femoral Artery Pressure	Arterial	Red	S/D (m)	0-150 mmHg
UAP – Umbilical Artery Pressure	Arterial	Red	S/D (m)	0-150 mmHg
ABP – Abdominal Aorta Pressure	Arterial	Red	S/D (m)	0-150 mmHg
LAP – Left Atrial Pressure	Arterial	Red	S/D (m)	0-150 mmHg

Label	Application	Colour	Reading format	Waveform height
CVP – Central Venous Pressure	Venous	Blue	(M) S/D	0-30 mmHg
UVP – Umbilical Venous Pressure	Venous	Blue	(M) S/D	0-30 mmHg
PAP – Pulmonary Artery Pressure	Pulmonary artery	Pale yellow	S/D (m)	0-50 mmHg
ICP – Intra-Cranial Pressure	Intra-cranial	White	M	0-50 mmHg
BDR – Bladder Pressure	Bladder	White	M	0-30 mmHg

The reading format can be changed independently of the default settings. The reading can be formatted to read Systolic, Mean and Diastolic readings in the following orders:

S/D (m) – where Systolic and Diastolic are shown in larger font and the mean is shown in brackets in a smaller font.

(M) S/D – where Mean is shown first in brackets and the Systolic and Diastolic are then shown in a similar font.

M – where only the Mean is shown. When this setting is chosen ("M" only), Systolic and Diastolic alarming will be disabled for that channel.

The scale (height) of the channel waveform can be changed independently of the default settings. The scale can be formatted to read from -99 mmHg to 310 mmHg in pre-set levels.

Note	Users should review the default alarm and parameter settings and decide if these are compatible with the clinical protocols in place locally for attended and unattended monitoring of patients and make any procedural changes required in light of this review.

6.6.5 Zeroing transducers

WARNING	**Always zero the transducer before using it.**

Note	You can re-zero the transducer as often as required.
Note	If the transducer is disconnected from the cable, ensure a pause of at least 5 seconds is maintained before reconnecting the transducer (or before connecting a new transducer). Always zero a transducer after it has been it is connected to the Tempus (before use).

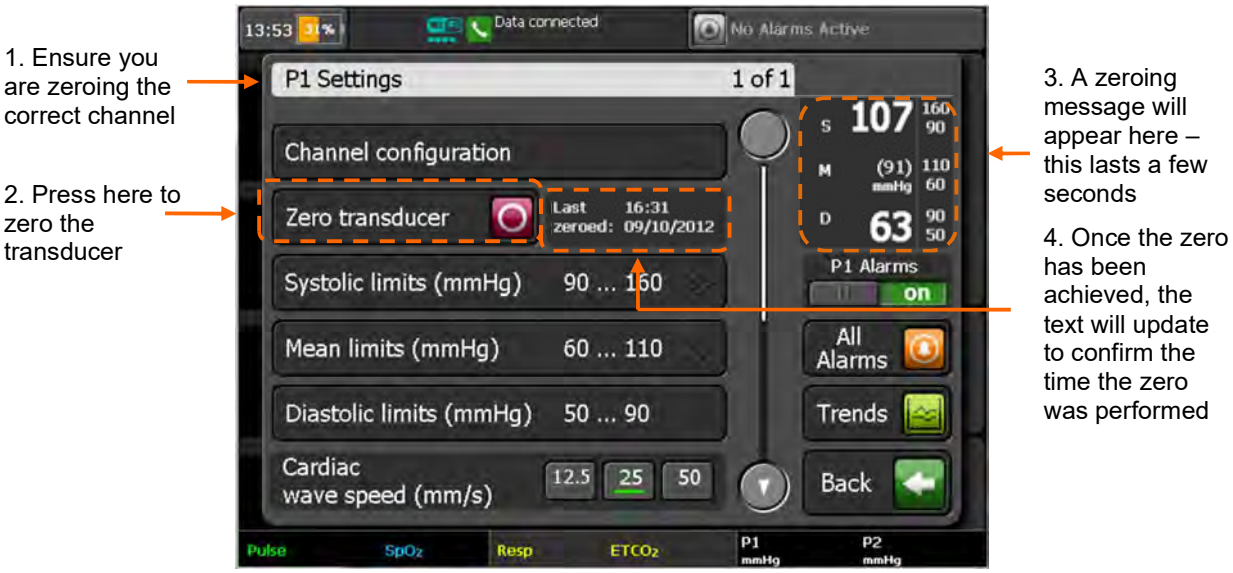
The invasive pressure transducers must be zeroed to ensure they provide accurate measurements. If a transducer is changed or moved, it must be zeroed again.

Follow the instructions on the transducer's packaging while following the zeroing process detailed below.

The transducer should be placed at the same height as the patient's left atrium before and during the zeroing process.

To zero, first close the transducer stopcock to the patient.

Then open the transducer's venting stopcock to atmosphere. Allow the transducer a few seconds to settle.



Zeroing the transducer

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

If the process fails to measure a valid zero reading, check the transducer stop cock is open to atmospheric air and correctly connected to the Tempus. Then repeat the process. Replace the transducer if the error recurs.

6.6.6 Two channel USB invasive pressure module

2 Channel USB IP Module Connected to the Tempus Pro

2 Channel IP Module

When the 2 channel USB IP Module is plugged into the Tempus Pro USB socket and a patient cable and transducers are connected, channels 3 and 4 of will appear as shown below.

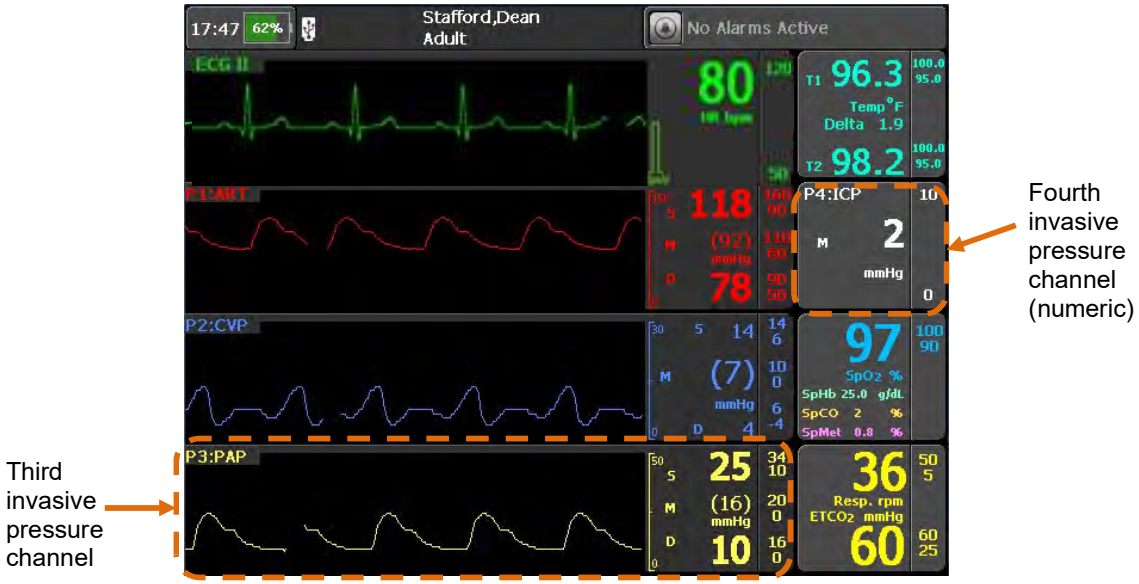
For part number details, see “12 Accessories list of the Tempus Pro”.

For specification details for the module, see “14 Specifications and standards”.

The USB module employs the same technology as the Tempus Pro’s internal Invasive Pressure measurement technology and therefore the same warnings, cautions and notes should be adhered to.

Four channel invasive pressure display

If four channels of invasive pressure are used, the third invasive pressure channel replaces the capnometer waveform and the fourth invasive pressure channel replaces the NIBP display:

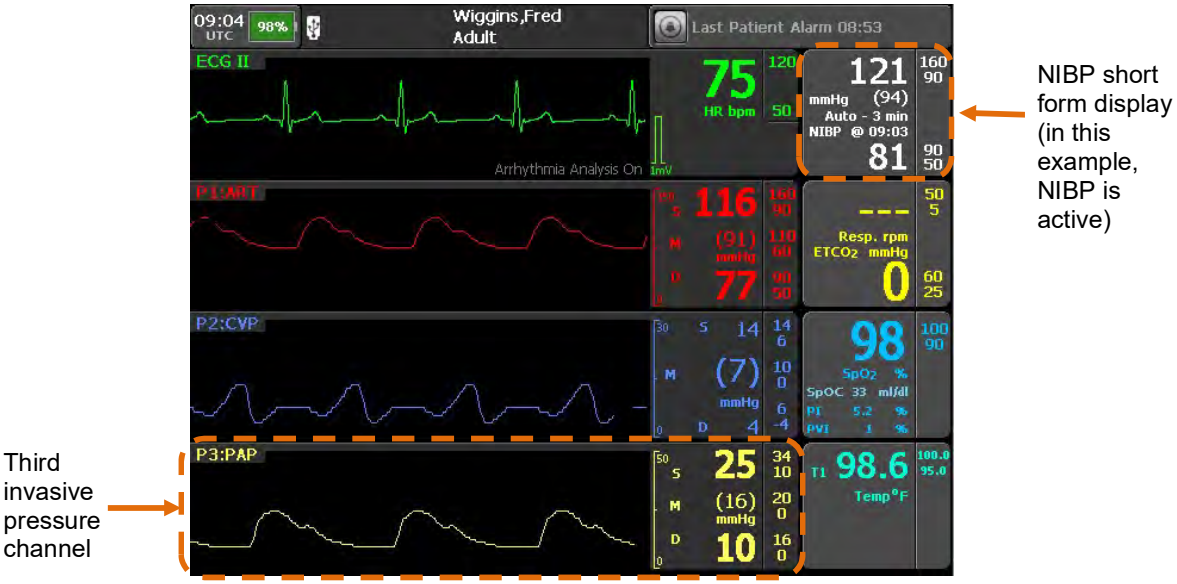


Four Channels of Invasive Pressure results page

Note	If a fourth channel of invasive pressure is used, NIBP becomes unavailable and measurements are stopped.
Note	If you disable one of the four invasive pressure channels, the display reverts to three channel format (see below). If you disable two of the four channels, the capnometer waveform and NIBP results will return to their original location.
Note	The invasive pressure channels will always be displayed in numerical order on the results page, even if you plug in channel three and four before one and two. You can change which 3 of the 4 channels are displayed as waveforms by selecting if a waveform is required or not for that channel in the channel settings.

Three channel invasive pressure display

If three channels of invasive pressure are used, the third invasive pressure channel replaces the capnometer waveform and the NIBP is displayed in short form:



Three Channels of Invasive Pressure results page

Note	If NIBP is active, the short form display does not include a Start button or a timer icon. To take a new NIBP reading without waiting for the auto-timer period, or to take a reading when in manual mode, press the NIBP display area and use the Start button at the top of the NIBP Settings menu.
Note	If you disable one of the three invasive pressure channels, the capnometer waveform and NIBP results will return to their original location.

7 Alarms

The Tempus produces both patient (physiological) alarms and technical alarms. Patient alarms are user configurable but technical alarms are not. Patient alarm settings are reset to factory defaults when a new patient is admitted or if you switch back to monitor a previous patient. If you turn the Tempus off and on and select to continue monitoring, the alarm settings will be retained (if the off period is less than 30 seconds) and the Tempus will revert to currently used settings.

Default alarm values will differ across different patient ages (adult, paediatric, and neonate) – see “7.3 Patient alarms”.

Note that default alarms are configurable by the operating institution.

WARNING 	**Do not silence the audible alarm if patient safety may be compromised.**
WARNING 	**Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.**
WARNING 	**Before each use, verify that the alarm limits are appropriate for the patient being monitored.**
WARNING 	**Check the audible alarm silence duration before temporarily silencing the audible alarms.**
CAUTION 	In high-altitude environments, EtCO2 values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high altitude environments, it is advisable to consider adjusting EtCO2 alarm settings accordingly.

All alarms are “non-latching” i.e. the audible and visual alarm indicators will cease when the alarm condition ceases to exist. For example, if the heart rate goes from 80 to 105 and the alarm threshold has been set to 100, then both visual and audible alarms will be generated, when the heart rate drops below 100 the visual and audible alarms will cease automatically.

Alarms are audible in a 360° direction from the Tempus, however users should note that alarm volume will be loudest when the user is positioned facing the Tempus. Moving to the side or rear of the Tempus will produce quieter alarm volumes. Alarm volumes are specified at 1m from the front of the device.

The visual alarms are visible in a 360° direction around the Tempus. However, users should note that alarms will be most visible from the front of the device. While the alarms are visible from the sides (via light dispersed in the handle) and the rear, the visibility of the alarms is reduced in these positions.

The normal operating position of the operator should take into account the ability to see and hear the alarm signals taking into account local light and noise levels.

The alarm bar and the audible alarm will operate briefly soon after start up. Ensure both functions are operating before using the device.

WARNING 	**If relying on the alarms, ensure that the display and alarm bar are viewable from the user's operating position. Ensure the handle and rear alarm light remain clean and unobstructed. Ensure the alarm speaker remains unobstructed and alarm volume is set to a level appropriate to the level of background noise expected.**
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 Centre 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 Centre is not equipped with alarm silencing or suspending controls.**
WARNING 	**When connected to a PC running the i2i application at a Response Centre, streamed data, such as the waveforms displayed on the Tempus Pro, will be transmitted and displayed automatically on that PC's display. Users are advised that streamed data are transmitted using the UDP protocol. The UDP protocol includes error checking but does not retransmit data. Therefore, any data that is dropped, lost or delayed during the streaming process will not be retransmitted. In the event that packets of waveform data are lost, they will appear as gaps in the waveform that is displayed on the i2i interface.**
WARNING 	**Medical data (vital signs data, photos, ECG recordings, patient details, TCCC cards etc.) are transmitted using TCP/IP, this includes error checking and retransmission so missing or dropped packets are therefore retransmitted.**
WARNING 	**Too many of the same or similar pieces of equipment in an area, with different alarm pre-sets, may make it difficult for the operator to know how the alarm system will operate.**
WARNING 	**Users should check to ensure that any alarm setting is appropriate prior to use.**

CAUTION 	Ensure alarm values are not changed to extreme levels simply to disable the alarms system. Ensure alarm levels are brought into a more sensitive state for severe or critical patients or for patients who will be left unattended.
CAUTION 	The Tempus' alarms are intended to alert attendant users. They are not intended to alert users who remove themselves from the patient's vicinity. Users should consider the levels of background ambient noise and light if they will not be in close proximity to the patient. The alarms provided by the system do not replace user care.

Note 	Users are reminded to ensure the alarm speaker is working every time they use the product. This can be verified by simply using the touchscreen – if the speaker is working then audible feedback will be given for each press of the screen.
Note 	The Tempus will not report any alarm for the first 10 seconds after a sensor is attached. This is to prevent false positive alarms being generated due to patient/user/sensor artefact that can be commonly caused while a parameter's sensor is first fixed to the patient.

7.1 Audible alarm characteristics

The Tempus provides audible alarm indications through a speaker mounted on the front of the device.

WARNING	**If relying on the alarms, ensure that the display and alarm bar are viewable from the user's operating position. Ensure the handle and rear alarm light remain clean and unobstructed. Ensure the alarm speaker remains unobstructed and alarm volume is set to a level appropriate to the level of background noise expected.**
CAUTION	Do not attempt to clean beneath the grille with a sharp or rough implement; this can damage the water-proof sealing that is present beneath the grille and cause reduction or impairment of the ingress protection barrier.

Audible alarms are separated into either patient (physiological) alarms or "inop" (technical) alarms. These alarm signals are specified as follows:

Nominal Characteristics	Patient Alarm (Red)	Patient Alarm (Yellow)	Technical Alarm
Pulse sequence	10 x 175 ms pulses	3 x 125 ms pulses at 440 Hz (with 4 harmonics under 4 kHz)	2 x 250 ms pulses
Repetition rate	Every 10 seconds	Every 5 seconds	Every 15 seconds
Duration of gap between pulse sequences	50 ms silence between pulses 1 and 2, 2 and 3, 4 and 5, 6 and 7, 7 and 8, 9 and 10. 170 ms silence between pulses 3 and 4, 8 and 9. 625 ms silence between pulses 5 and 6	250 ms silence between pulse sequences	250 ms silence between pulse sequences
Volume (dBA at 1 m)	85 dBA (default) – the volume may be reduced using the All Alarms menu **Alarm Volume** settings: Min, Low, Mid and High.		

7.2 Visual alarm characteristics

When alarms occur, the Tempus Pro indicates their presence in the following ways:

Visual Alarm Manifestations

7.2.1 Alarm bar LEDs

The alarm bar LEDs illuminate in one of the following ways:

- Flashing yellow LED (for patient alarms);
- Solid yellow (for technical alarm);
- Flashing red (for specific high priority alarms).

CAUTION	The alarm bar can also be user-configured to show a solid green LED to indicate no active alarms (this feature is enabled and disabled in the Maintenance Menu, refer to the *Tempus Pro Maintenance Manual* for details).

7.2.2 Alarm status area

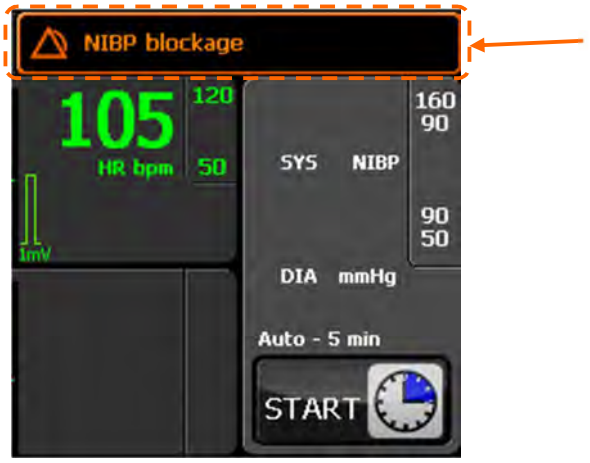
For both patient and technical alarms, the Tempus shows the alarm symbol and a description of the alarm in the alarm status area at the top right of the display.

CAUTION	In strong daylight users should ensure that the alarm status area is visible.

Note	If multiple alarms occur, they will be displayed in rotation in the alarm status area.

Press the alarm status area to view a list of all active alarms and to select technical alarms for clearing – see "7.7 Viewing and clearing alarms".

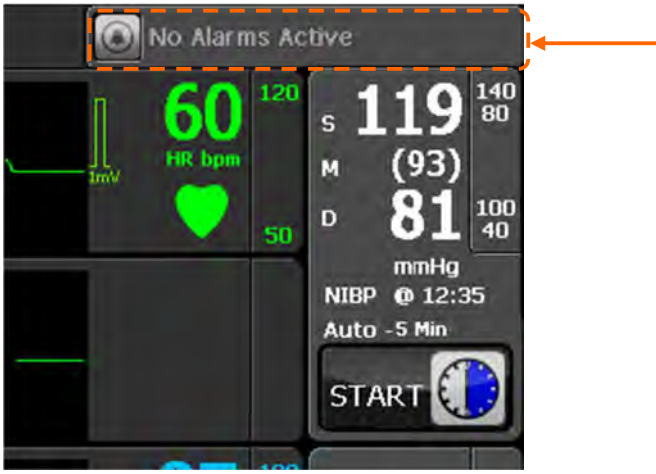
Alarm Status Area – Patient Alarm



Active technical alarms look like this

Alarm Status Area – Technical Alarm

When there is no alarm state, the alarm bar will display the time of the last patient alarm or “No Alarms Active” if there have not been any alarms.



This shows that no alarms are active

Alarm Status Area with no alarms active

7.2.3 Alarm limits bar

For patient alarms only, on the Home screen, the Tempus highlights the alarm limits bar for the parameter that is alarming. It is highlighted in a solid (not flashing) yellow.

Alarm Limits Bar

7.2.4 Bottom status bar

For patient alarms only, on screens that have a bottom status bar, the Tempus highlights the parameter that is alarming in flashing white text on an orange background.

Reading outside Limits

7.3 Patient alarms

The table below lists all patient alarms:

Parameter	Measurement Range	Patient type	Default Alarm Low	Alarm Low Range	Default Alarm High	Alarm High Range
ECG Heart rate	30-300 bpm	Adult	50 bpm	30-238 bpm	120 bpm	32-239 bpm
	30-300 bpm	Paediatric	50 bpm	30-238 bpm	150 bpm	32-239 bpm
	30-300 bpm	Neonate	100 bpm	30-238 bpm	200 bpm	32-239 bpm
ST	-50 - +50 mm	Adult	-2.0 mm	-10 – +2 mm	+2.0 mm	-2 – +10.0 mm
	N/A	Paediatric	N/A	N/A	N/A	N/A
	N/A	Neonate	N/A	N/A	N/A	N/A
QT	1 – 2000 ms	Adult	N/A	N/A	500 ms	10 – 1990 ms
	N/A	Paediatric	N/A	N/A	N/A	N/A
	N/A	Neonate	N/A	N/A	N/A	N/A
PI	0-20%	Adult	OFF	Off, 0.1 to 18	OFF	0.2 to 19, Off
	0-20%	Paediatric	OFF	Off, 0.1 to 18	OFF	0.2 to 19, Off
	0-20%	Neonate	OFF	Off, 0.1 to 18	OFF	0.2 to 19, Off
PVI	0-100%	Adult	5%	Off, 1 to 98	40%	2 to 99, Off
	0-100%	Paediatric	5%	Off, 1 to 98	40%	2 to 99, Off
	0-100%	Neonate	5%	Off, 1 to 98	40%	2 to 99, Off
SpOC	0 to 35 ml/dl	Adult	10 ml/dl	Off, 1 to 33	25 ml/dl	2 to 34, Off
	0 to 35 ml/dl	Paediatric	10 ml/dl	Off, 1 to 33	25 ml/dl	2 to 34, Off
	0 to 35 ml/dl	Neonate	10 ml/dl	Off, 1 to 33	25 ml/dl	2 to 34, Off
SpO_2 pulse rate	25-239 bpm	Adult	50 bpm	30-238 bpm	120 bpm	32-239 bpm
	25-239 bpm	Paediatric	50 bpm	30-238 bpm	150 bpm	32-239 bpm
	25-239 bpm	Neonate	100 bpm	30-238 bpm	200 bpm	32-239 bpm
Impedance respiration	3-150 rpm	Adult	5 rpm	3-145 rpm	30 rpm	5-149 rpm
	3-150 rpm	Paediatric	5 rpm	3-145 rpm	30 rpm	5-149 rpm
	3-150 rpm	Neonate	12 rpm	3-145 rpm	80 rpm	5-149 rpm
SpO_2	0-100%	Adult	90%	50-98%	100%	52-100%
	0-100%	Paediatric	90%	50-98%	100%	52-100%
	0-100%	Neonate	85%	50-98%	95%	52-100%
SpCO	0-99%	Adult	OFF	1-97%	10%	2-98%
	0-99%	Paediatric	OFF	1-97%	10%	2-98%
	0-99%	Neonate	OFF	1-97%	10%	2-98%
SpHb	0-25 g/dl	Adult	7.0 g/dl	1.0-23.5 g/dl	17.0 g/dl	2.0-24.5 g/dl
	0-25 g/dl	Paediatric	7.0 g/dl	1.0-23.5 g/dl	17.0 g/dl	2.0-24.5 g/dl

Parameter	Measurement Range	Patient type	Default Alarm Low	Alarm Low Range	Default Alarm High	Alarm High Range
	0-25 g/dl	Neonate	7.0 g/dl	1.0-23.5 g/dl	17.0 g/dl	2.0-24.5 g/dl
SpMet	0.0-99.9%	Adult	OFF	0.1-99.0 %	3.0%	1.0-99.5 %
	0.0-99.9%	Paediatric	OFF	0.1-99.0 %	3.0%	1.0-99.5 %
	0.0-99.9%	Neonate	OFF	0.1-99.0 %	3.0%	1.0-99.5 %
Capnometer respiration	1-149 rpm	Adult	5 rpm	2-145 rpm	30 rpm	5-149 rpm
	1-149 rpm	Paediatric	5 rpm	2-145 rpm	30 rpm	5-149 rpm
	1-149 rpm	Neonate	12 rpm	2-145 rpm	80 rpm	5-149 rpm
Capnometer respiration – no breaths detected	-	Adult	30 seconds	10-60 seconds	-	-
	-	Paediatric	30 seconds	10-60 seconds	-	-
	-	Neonate	30 seconds	10-60 seconds	-	-
Capnometer $ETCO_2$	0-150 mmHg 0-20 kPa	Adult	25 mmHg 3.3 kPa	0-145 mmHg 0-19.3 kPa	60 mmHg 8 kPa	5-150 mmHg 0.7-20 kPa
	0-150 mmHg 0-20 kPa	Paediatric	25 mmHg 3.3 kPa	0-145 mmHg 0-19.3 kPa	60 mmHg 8 kPa	5-150 mmHg 0.7-20 kPa
	0-150 mmHg 0-20 kPa	Neonate	25 mmHg 3.3 kPa	0-145 mmHg 0-19.3 kPa	60 mmHg 8 kPa	5-150 mmHg 0.7-20 kPa
Non-Invasive Blood Pressure - Systolic	40-260 mmHg	Adult	90 mmHg	40-255 mmHg	160 mmHg	45-260 mmHg
	40-230 mmHg	Paediatric	70 mmHg	40-155 mmHg	120 mmHg	45-160 mmHg
	40-130 mmHg	Neonate	40 mmHg	40-125 mmHg	90 mmHg	45-130 mmHg
Non-Invasive Blood Pressure - Diastolic	20-200 mmHg	Adult	50 mmHg	20-195 mmHg	90 mmHg	25-200 mmHg
	20-160 mmHg	Paediatric	40 mmHg	20-155 mmHg	70 mmHg	25-160 mmHg
	20-100 mmHg	Neonate	20 mmHg	20-95 mmHg	60 mmHg	25-100 mmHg
Non-Invasive Blood Pressure - Mean	26-220 mmHg	Adult	60 mmHg	26-215 mmHg	110 mmHg	30-220 mmHg
	26-183 mmHg	Paediatric	50 mmHg	26-155 mmHg	90 mmHg	30-160 mmHg
	26-110 mmHg	Neonate	24 mmHg	26-155 mmHg	70 mmHg	25-160 mmHg
Contact temperature	20-45 °C / 68-113 °F	Adult	35°C / 95°F	20-44 °C / 68-111 °F	37.8 °C / 100 °F	21-45 °C / 69.8-113 °F
	20-45 °C / 68-113 °F	Paediatric	35°C / 95°F	20-44 °C / 68-111 °F	37.8 °C / 100 °F	21-45 °C / 69.8-113 °F
	20-45 °C / 68-113 °F	Neonate	35°C / 95°F	20-44 °C / 68-111 °F	37.8 °C / 100 °F	21-45 °C / 69.8-113 °F

Parameter	Measurement Range	Patient type	Default Alarm Low	Alarm Low Range	Default Alarm High	Alarm High Range
Invasive Pressure – Systolic Arterial	-99 – 310 mmHg	Adult	90 mmHg	-99 – 310 mmHg	160 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	70 mmHg	-99 – 310 mmHg	120 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	40 mmHg	-99 – 310 mmHg	90 mmHg	-99 – 310 mmHg
Invasive Pressure – Diastolic Arterial	-99 – 310 mmHg	Adult	50 mmHg	-99 – 310 mmHg	90 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	40 mmHg	-99 – 310 mmHg	70 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	20 mmHg	-99 – 310 mmHg	60 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean Arterial	-99 – 310 mmHg	Adult	60 mmHg	-99 – 310 mmHg	110 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	50 mmHg	-99 – 310 mmHg	90 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	24 mmHg	-99 – 310 mmHg	70 mmHg	-99 – 310 mmHg
Invasive Pressure – Systolic Venous	-99 – 310 mmHg	Adult	6 mmHg	-99 – 310 mmHg	14 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	2 mmHg	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	2 mmHg	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
Invasive Pressure – Diastolic Venous	-99 – 310 mmHg	Adult	-4 mmHg	-99 – 310 mmHg	6 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	-4 mmHg	-99 – 310 mmHg	2 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	-4 mmHg	-99 – 310 mmHg	2 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean Venous	-99 – 310 mmHg	Adult	0 mmHg	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	0 mmHg	-99 – 310 mmHg	4 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	0 mmHg	-99 – 310 mmHg	4 mmHg	-99 – 310 mmHg
Invasive Pressure – Systolic PAP	-99 – 310 mmHg	Adult	10 mmHg	-99 – 310 mmHg	34 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	24 mmHg	-99 – 310 mmHg	60 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	24 mmHg	-99 – 310 mmHg	60 mmHg	-99 – 310 mmHg
Invasive Pressure –	-99 – 310 mmHg	Adult	0 mmHg	-99 – 310 mmHg	16 mmHg	-99 – 310 mmHg

Parameter	Measurement Range	Patient type	Default Alarm Low	Alarm Low Range	Default Alarm High	Alarm High Range
Diastolic PAP	-99 – 310 mmHg	Paediatric	-4 mmHg	-99 – 310 mmHg	-4 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	-4 mmHg	-99 – 310 mmHg	-4 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean PAP	-99 – 310 mmHg	Adult	0 mmHg	-99 – 310 mmHg	20 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	12 mmHg	-99 – 310 mmHg	26 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	12 mmHg	-99 – 310 mmHg	26 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean ICP	-99 – 310 mmHg	Adult	0 mmHg	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	0 mmHg	-99 – 310 mmHg	4 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	0 mmHg	-99 – 310 mmHg	4 mmHg	-99 – 310 mmHg
Invasive Pressure – Mean BDR	-99 – 310 mmHg	Adult	-	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Paediatric	-	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg
	-99 – 310 mmHg	Neonate	-	-99 – 310 mmHg	10 mmHg	-99 – 310 mmHg

All patient alarms are medium priority alarm states as defined by IEC60601-1-8 with the exception of ECG arrhythmias and “catheter disconnected” for invasive pressure (mean arterial pressure **only**). In this event if the catheter pressure drops from a value of greater than 10 mmHg to less than 10 mmHg and remains there for a period longer than that specified in the table in section 7, then the red alarm bar LED will flash and a high priority alarm tone will be emitted.

7.4 Technical alarms

Technical alarms can relate to the state of the Tempus itself or its connection to the patient. Technical alarms are low priority alarm states as defined by IEC60601-1-8.

The majority of technical alarms are self-explanatory and should be addressed by following the on-screen instructions. Additional information is provided below for certain technical alarm conditions.

Technical alarms can be cleared by the operator – see “7.7 Viewing and clearing alarms”.

Condition	On-Screen Error Text	Comment
Bluetooth linking error	Attention - Bluetooth Unable to initialize Bluetooth. If the problem persists, use a wired headset.	Repeat the process taking care to follow on-screen and written instructions
Communications error – cable not plugged in	Attention - Data Cable The data cable is not plugged in correctly.	Repeat the process taking care to follow on-screen and written instructions
Communications notification	Attention - Data Connecting Initialising data encryption engine.	No action – initialisation process lasts <15 seconds

Condition	On-Screen Error Text	Comment
Communications error – connection failed	Attention - Data Connection The data link was unable to connect at this time.	Repeat the process taking care to follow on-screen and written instructions
Data export option	Attention - Data Export There is patient record data from other devices/times. Do you want to over-write it?	Respond to instruction by pressing the appropriate on-screen button option
GPS error	Attention - GPS A GPS location has not yet been obtained; leave the GPS on and check this screen again in a few minutes.	Repeat the process taking care to follow on-screen and written instructions
Bluetooth headset linking error	Attention - Headset The headset has not linked to the Tempus. Repeat step 3 of the instructions.	Repeat the process taking care to follow on-screen and written instructions
Low battery	Attention - Low Battery Battery charge 25%, please connect the charger.	Temporary notice – follow onscreen instructions. Find another power source if available.
Low battery	Attention - Low Battery Battery charge 10%, please connect the charger. USB devices are disabled.	Temporary notice – follow onscreen instructions. Find another power source if available.
Low battery	Attention - Low Battery The battery is almost empty, USB devices are disabled.	Temporary notice – follow onscreen instructions. Find another power source if available.
Patient switching error	Attention – Switch To A Previous Patient To switch patient you must first stop monitoring the current patient.	Disconnect leads from the current patient before discharging/admitting a new patient
Voice connection not possible, a data connection must be made first	Attention - Voice Connection Headset voice connection will be started after connecting data.	Repeat the process taking care to follow on-screen and written instructions
Voice connection error	Attention - Voice Connection The voice link was unable to connect at this time.	Repeat the process taking care to follow on-screen and written instructions
WiFi connection error	Attention - WiFi WiFi was unable to connect at this time. If the problem persists restart the Tempus and attempt the connection again.	Repeat the process taking care to follow on-screen and written instructions
WiFi not activated	Warning - WiFi WiFi is not activated on this device	Refer to the maintenance manual.
GSM not activated	Warning – GSM (Cell-phone) GSM is not activated on this device	Refer to the maintenance manual.
Bluetooth pairing error	Bluetooth Pairing Error The required Bluetooth device not found	Repeat the process taking care to follow on-screen and written instructions

Condition	On-Screen Error Text	Comment
Bluetooth pairing error	Bluetooth Pairing Error Entered PIN is incorrect	Repeat the process taking care to follow on-screen and written instructions
Bluetooth pairing error	Warning - Bluetooth Bluetooth is not activated on this device.	Repeat the process taking care to follow on-screen and written instructions
System error	Internal Fault Detected A fault has been detected. Reason: exception. The Tempus will need to restart. If this problem persists please contact your supplier.	Log the exact details of the fault so they can be communicated to the supplier.
System error	Internal Fault Detected A fault has been detected. Reason: file open error. The Tempus will need to restart. If this problem persists please contact your supplier.	Log the exact details of the fault so they can be communicated to the supplier.
System error	Internal Fault Detected A fault has been detected. Reason: file read error. The Tempus will need to restart. If this problem persists please contact your supplier.	Log the exact details of the fault so they can be communicated to the supplier.
System error	Internal Fault Detected A fault has been detected. Reason: file write error. The Tempus will need to restart. If this problem persists please contact your supplier.	Log the exact details of the fault so they can be communicated to the supplier.
System error	Internal Fault Detected A fault has been detected. Reason:cOS exception. The Tempus will need to restart. If this problem persists please contact your supplier.	Log the exact details of the fault so they can be communicated to the supplier.
IP address error	Invalid IP Address Please check the IP Address is in the format x.x.x.x and multiple addresses (maximum of 3) are separated by ';'.	Correct the format of the IP address
Network Settings Error	Network Settings Error There are no network settings in this mode.	Enter network settings
Software update error	Options Key Check Failed One or more option key checks have failed. Some features may be disabled. If the problem persists contact the service representative.	A software upgrade may have occurred incorrectly. Log the exact details of the fault so they can be communicated to the supplier.
Low ambient temperature warning	Temperature Warning The device temperature is low, Tempus may shutdown.	Attempt to warm the device and then restart

Condition	On-Screen Error Text	Comment
USB connection error	USB - Connection The USB memory stick is not plugged into the Tempus USB socket, please plug in. If plugged in, check it's the USB and not the RJ45 socket.	Remove and re-insert the stick into the USB socket
USB error	USB - Connection Failed to connect with USB, please retry.	Remove and re-insert the stick into the USB socket
USB error	USB - Import The USB memory stick is empty; there is no handover data on it.	Use the correct stick or ensure the files are on the stick you have
USB error	USB - Import The data on the USB memory stick was exported for the current patient. You cannot re-import this data.	You are attempting to re-write the current patient record with itself, this cannot be done
Maintenance notification	Warning - Settings Settings were not saved at power down and have been reset to defaults.	Reset settings as required

iAssist and Technical alarms are low priority alarm states as defined by IEC60601-1-8.

7.5 Setting alarms

Alarm limits are set in either the individual parameter settings menu (accessible by pressing on that parameter area on the touchscreen) or through the All Alarms Menu (accessible from the main menu and parameter settings menus).

7.5.1 Default alarm settings

It should be noted that all patient alarms have a user configurable delay of 0-8 seconds (4 seconds default, 0 seconds minimum) to help prevent spurious alarms being generated – see “7.5 Setting alarms”.

In addition to this user-configurable time, the Tempus will produce alarms after the durations specified below.

Alarm	Nominal Time to Delay (Excluding User Configurable Delay)
ECG heart rate high	2 seconds
ECG heart rate low	2 seconds
ECG heart rate out of range (low)	4 seconds (*)
Pulse rate (from Oximeter) high	3 seconds
Pulse rate (from Oximeter) low	3 seconds
Pulse rate (from Oximeter) out of range (low)	4 seconds
Pulse rate (from Oximeter) out of range (high)	4 seconds
SpO_2 high	3 seconds
SpO_2 low	3 seconds
SpHb low	2 seconds

Alarm	Nominal Time to Delay (Excluding User Configurable Delay)
SpHb high	2 seconds
SpMet low	2 seconds
SpMet high	2 seconds
SpCO low	3 seconds
SpCO high	4 seconds
PI low	2 seconds
PI high	2 seconds
PVI low	2 seconds
PVI high	2 seconds
SpOC low	2 seconds
SpOC high	2 seconds
$ETCO_2$ high	4 seconds
$ETCO_2$ low	4 seconds
Respiration rate (from Capnometer) high	4 seconds
Respiration rate (from Capnometer) low	4 seconds
Respiration rate (from ECG) high	4 seconds
Respiration rate (from ECG) low	4 seconds
Capnometer no breaths detected	10 - 60 seconds (depending on delay setting)
Non-invasive blood pressure systolic high	0 seconds at end of measurement
Non-invasive blood pressure systolic low	0 seconds at end of measurement
Non-invasive blood pressure mean high	0 seconds at end of measurement
Non-invasive blood pressure mean low	0 seconds at end of measurement
Non-invasive blood pressure diastolic high	0 seconds at end of measurement
Non-invasive blood pressure diastolic low	0 seconds at end of measurement
Contact temperature low	4 seconds
Contact temperature high	4 seconds
Invasive pressure systolic high	4 seconds
Invasive pressure systolic low	4 seconds
Invasive pressure diastolic high	4 seconds
Invasive pressure diastolic low	4 seconds
Invasive pressure mean low	4 seconds
Invasive pressure mean high	4 seconds
ECG monitoring arrhythmia - Extreme Brady	6 seconds (*)
ECG monitoring arrhythmia - Extreme Tachy	7 seconds
ECG monitoring arrhythmia - Vent Tachy	5 seconds
ECG monitoring arrhythmia - Vent Fib	9 seconds
ECG monitoring arrhythmia - Asystole	6 seconds

Alarm	Nominal Time to Delay (Excluding User Configurable Delay)
QT Alarm	60 seconds
ST Alarm	60 seconds

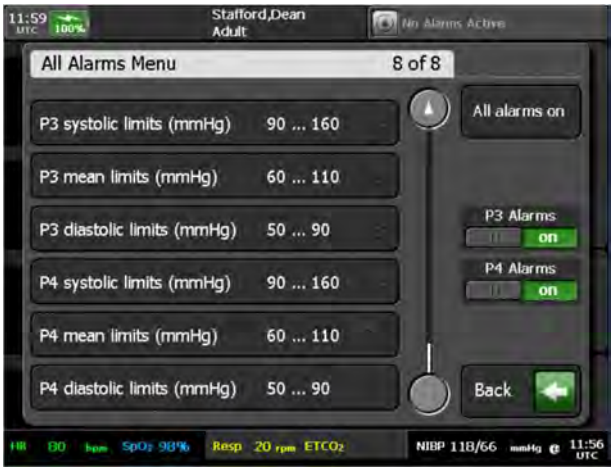
(*) The user configurable delay is not applicable to this alarm

7.5.2 All alarms menu

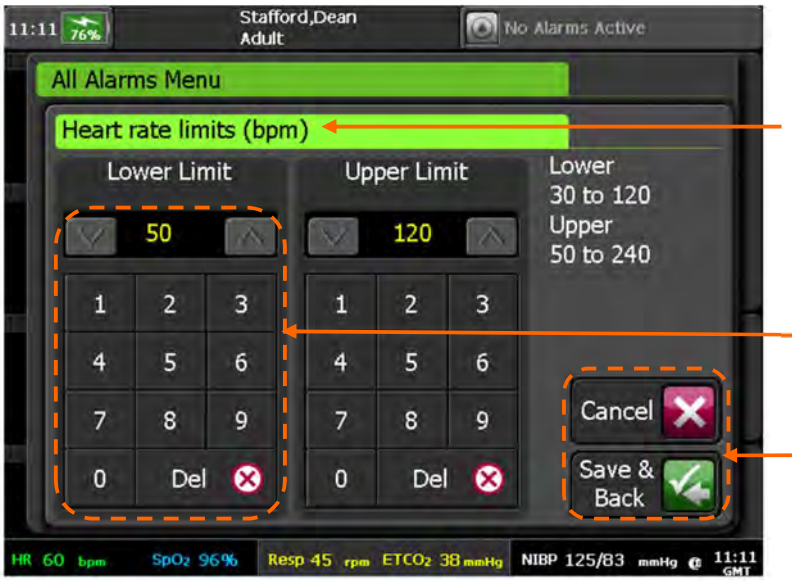
CAUTION	The **Reset to defaults** button resets the following to their new patient default values: all alarm limits, Alarm trigger delay (Alarm suspend time), Alarm silence time, NIBP mode, NIBP adult inflation, NIBP paediatric inflation, NIBP neonate inflation, HR/PR source, Pacemaker indication, Arrhythmia analysis, ST/QT analysis, Monitoring filter, 12-lead filter and ECG power filter.

Menu option	Menu screen
Alarm trigger delay – set a delay time to help prevent spurious alarms. Range is 0-8 seconds (4 seconds default, 0 seconds minimum). **Alarm volume** – select **Low**, **Mid** or **High** volume. **Waveform snapshot on alarm** – turn this feature on or off. **Alarm silence time** – set the time period in which audible alarms will be silenced when the Alarm Silence button is pressed. The available range is from 30 seconds up to the maximum value set in the Maintenance Menu. **All alarms on** – activate all alarms (present on all pages of this menu). **Reset to defaults** - reset all alarm limits and other parameters to their new patient default values.	
Heart rate limits – set alarm limits. **ST1 limits** – set alarm limits. **ST2 limits** – set alarm limits. **QT upper limit** – set alarm limit. **ECG Alarms** – turn ECG alarms off or on.	

Menu option	Menu screen
SpO2 limits – set alarm limits. **SpHb limits** – set alarm limits. **SpCO limits** – set alarm limits. **SpMet limits** – set alarm limits. **SpOC limits** – set alarm limits. **Pulse ox. Alarms** – turn pulse ox. alarms off or on.	
PI limits – set alarm limits. **PVI limits** – set alarm limits.	
ETCO2 limits – set alarm limits. **Capno no breaths** – set alarm limit. **Respiration limits** – set alarm limits. **T1 limits** and **T2 limits** – set the lower and upper temperature alarm limits for each channel. **Delta limits** – set the delta temperature alarm limits, based on the difference between T1 and T2. **Capno Alarms** – turn capnometer alarms off or on. **Resp Alarms** – turn respiration alarms off or on. **Temp Alarms** – turn temperature alarms off or on.	 **Note:** If there is only one contact temperature channel, the **Temp limits** control replaces **T1 limits**, **T2 limits** and **Delta limits**.

Menu option	Menu screen
NIBP systolic limits – set alarm limits. **NIBP mean limits** – set alarm limits. **NIBP diastolic limits** – set alarm limits. **NIBP Alarms** – turn NIBP alarms off or on.	
P1 systolic limits – set alarm limits. **P1 mean limits** – set alarm limits. **P1 diastolic limits** – set alarm limits. **P2 systolic limits** – set alarm limits. **P2 mean limits** – set alarm limits. **P2 diastolic limits** – set alarm limits. **P1 Alarms** – turn P1 alarms off or on. **P2 Alarms** – turn P2 alarms off or on.	
P3 systolic limits – set alarm limits. **P3 mean limits** – set alarm limits. **P3 diastolic limits** – set alarm limits. **P4 systolic limits** – set alarm limits. **P4 mean limits** – set alarm limits. **P4 diastolic limits** – set alarm limits. **P3 Alarms** – turn P3 alarms off or on. **P4 Alarms** – turn P4 alarms off or on.	

Simply press on the alarm that you wish to set and an editor will appear. This will allow you to edit both upper and lower limits of the alarm. The editor shows the range of the alarm settings. You change the alarm settings by simply typing in the desired value using the keypad or the up and down arrows. You can save the changes you have made or cancel them by pressing the relevant buttons at the bottom right.



The alarm being edited is shown in the title

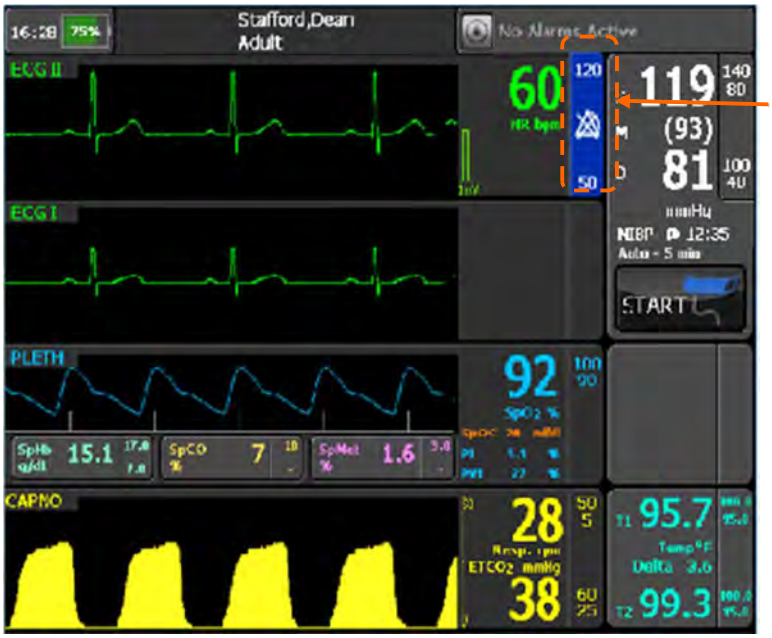
Change the upper or lower limits by typing the desired value into the keypad or use the arrows

Press here to cancel changes and go back or save changes and go back

Editing Heart Rate Alarm Limits

Note	The alarm limit shown is the number that the Tempus will display before the alarm is activated i.e. in the example shown above the tempus will display when the heart rate is less than 50 (49 or less) or greater than 120 (121 or more). The Tempus will not alarm at 50-120 inclusive. Therefore, it is possible to have the lower and upper limits set to the same value.

If any alarms are turned off, this will be shown on screen by the relevant parameter highlighted in blue.



The ECG Alarm bar shows the symbol for alarms inactive and is highlighted in blue

Alarms Suspended

It should be noted that other system configuration changes e.g. ECG lead selection, QRS beat volume, gain or waveform speed changes, communications mode and communications settings, iAssist mode etc. are all settings which are stored by the Tempus. Therefore, any changes to the Tempus configuration **other than alarm settings** will remain set even after the Tempus has been switched off and on again (for periods less than 72 hours).

7.6 Silencing or suspending alarms

The audible alarm can be silenced by pressing the Alarm Silence button  on the front panel.

For most patient alarms, the Alarm Silence button mutes the audible alarm for 2 minutes (factory default), after which the alarm will sound again if the alarm state is still present. During this time the visual indications of the alarm will remain (the alarm LED will remain lit and the on-screen indications will remain).

Note	The maximum (and default) alarm silence time is configurable via the maintenance menu. For instructions, see the *Tempus Pro Maintenance Manual*. The factory default is 2 minutes with an available range from 1 to 5 minutes.
Note	The alarm silence time may be adjusted by the user from the All Alarms menu. The adjustment is limited in the range 30 seconds up to the value of alarm silence time set via the maintenance menu. The alarm silence time will reset to the preset maintenance value when a new patient is admitted, or when switching patients.
Note	During the alarm silence period, if a new alarm occurs (patient or technical) the alarm will sound as normal.

For certain patient alarms, pressing the Alarm Silence button ceases the alarm permanently until the condition is experienced again. This applies to the following alarms:

- Capnometer No Breaths Detected;
- NIBP patient alarms;
- Catheter Disconnected.

For technical alarms, the Alarm Silence button acknowledges and silences all active technical alarms and causes them to be displayed with this symbol:

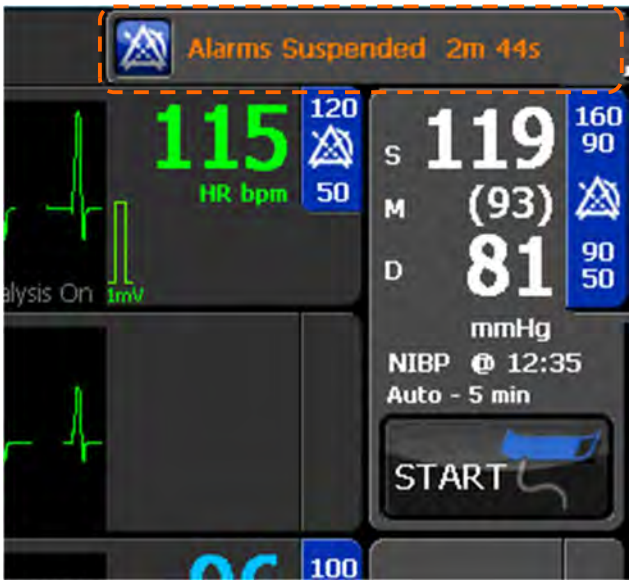
Alarm Suspend and Silence Buttons

Alarms can also be silenced before they occur using the Alarm Suspend button  . This enables users to prevent alarms from occurring for two minutes due to intentional intervention with the patient e.g. removing or moving a patient sensor such as an ECG electrode or pulse oximeter probe.

The Alarm Suspend button is positioned above the Alarm Silence button and has a different function. Pressing it will disable all audible **and** visual alarm indications for **both** technical and patient alarms for two minutes. During this time the yellow LED above the button will remain lit and the alarm bars on the display will indicate that alarms are paused and show a countdown for when they will be resumed.

Note	If a new technical alarm condition occurs during an alarms suspended period, once that period has expired there may be a delay of up to 15 seconds before the technical alarm audio is sounded.

The Alarm Suspend state can be deactivated at any time during the countdown by pressing the button again.



The alarm bar shows that alarms have been suspended

Alarm Bar Showing Alarms are Suspended

When a patient alarm is silenced the visual indication will remain on screen until the condition has passed i.e. the patient's vital signs have returned to a level within the alarm thresholds.

The non-invasive blood pressure is a periodic measurement. For this reason, an NIBP alarm is cleared by pressing the Alarm Silence or Alarm Suspend button. The alarm may then return when the next periodic reading is taken.

7.7 Viewing and clearing alarms

A list of active patient and technical alarms can be viewed on a screen, from which technical alarms can be selected to display more information and to clear them.

Note	Patient alarms cannot be cleared in this way.

To display the Alarm Status screen, press the touch screen in the alarm status area. The example screen shown below shows two patients and five technical alarms including three already silenced and acknowledged – see "7.6 Silencing or suspending alarms".

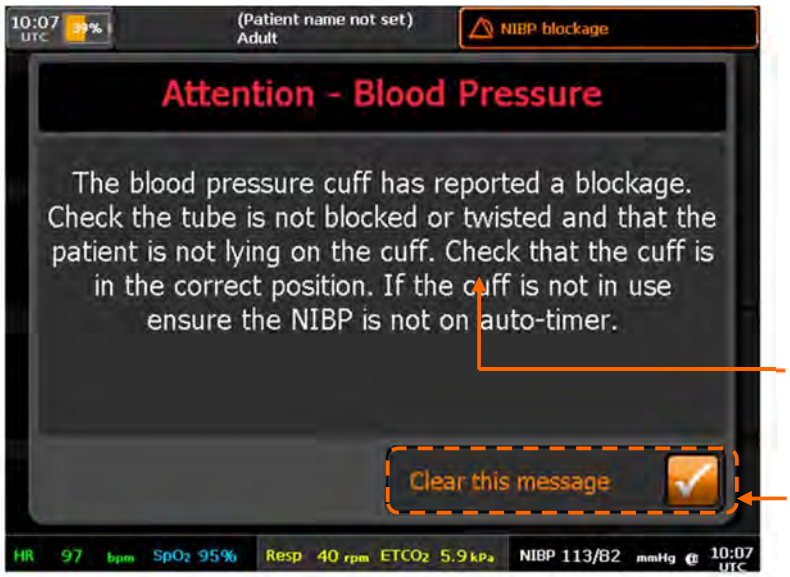
Alarm Status Screen with multiple active alarms

Alarms are shown on the Alarm Status screen in the following priority order:

- Patient alarms are shown before technical alarms.
- Technical alarms are shown on a first in-first out basis.

Note	The following technical alarm conditions take priority over patient alarms: Battery Empty (lasts for 10 seconds or so before automatic shutdown occurs) and Ambient Temperature High or Low.

Press any technical alarm in the Status Screen to display a dialog which describes the nature of the condition alarm state (as shown below).



Clearing a technical alarm

To clear technical alarms, use one of the following methods:

- Either: press the “Clear this message” button on the Alarm Description Dialog screen;
- Or: correct the error that caused the alarm to be raised, for example refit a patient sensor that has been disconnected.

7.8 Tactical mode warning

If the Tempus is set to Tactical (Silent) Mode, then all audible alarms will be ceased (visual alarm indications will remain) – see “4.3.2 Tactical mode (optional)”.

Setting Tactical Mode to ON will give the following warning:

Tactical Mode Warning

Once set, Tactical Mode can be turned off by switching the physical switch back to its original position – see "4.3.2 Tactical mode (optional)".

WARNING 	**Do not leave a unit in tactical mode without careful observation for alarm conditions on the screen.**

7.9 Testing alarms

RDT recommends that visual and audible alarms are tested before use.

The alarm bar will light and the audible alarm will sound on switch on (unless the tactical switch is enabled). If users do not perceive this test occurring, they should provoke a test to check that the visual and audible alarms are working before they begin to use the device. A simple way to do this would be to insert a finger into the pulse oximeter probe, wait for a reading to appear and then remove the finger. This will provoke a technical alarm which will test the alarm bar (will light solid yellow) and the alarm tone.