Tempus IC

User/Operator Manual

Part number 41-1001

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Contents

1 Introduction

1.1 Manufacturer's Address

The **Tempus IC** is designed and manufactured by:

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1.2 CE Statement

Marking by the CE symbol indicates compliance of this device to the Medical Devices Directive 93/42/EEC and the Radio and Telecom Terminal Equipment Directive 1995/5/EC. The CE mark is accompanied by the number 0473 which is the reference number for the Notified Body who certify RDT's quality system.

A Declaration of Conformity in accordance with the above regulations has been made and is on file at Remote Diagnostic Technologies Ltd at the address in section 1.1.

1.3 FDA Prescription Statement

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

1.4 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 IC. 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. Tempus IC™ is a registered trademark of RDT Ltd.

1.5 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, precaution, instructions etc. will violate the safety standards of design, manufacture and intended use of the product. RDT Ltd assumes no liability for customer failure to comply with the information contained in this manual.

Users of **Tempus IC** and its accessories are advised to convey the following safety information to operating personnel and to incorporate applicable information into their own internal literature where necessary.

1.6 Patent Claims

RDT has applied for patents covering **Tempus IC** and its communications technology in the following jurisdictions:

Patents Pending (US No.2006/0287586 EP 1734458 A & other areas).

1.7 Limited Warranty

Remote Diagnostic Technologies Limited ('RDT') warrants each new **Tempus IC** 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 **Tempus IC** is in any way modified or if it is 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.

1.7.1 Service Support and Returns

Repairs made under warranty to **Tempus IC** must be made by the manufacturer. If **Tempus IC** requires repair or return for any reason, please contact your local distributor or Remote Diagnostic Technologies at the address in section 1.1 in order to first obtain a returns reference (RMA) number. RDT reserves the right not to accept returns which have not first been provided with an RMA number. When calling, please be ready to quote the serial number of **Tempus IC**.

The Tempus IC is designed to be as maintenance free as possible. The only user replaceable and user serviceable parts in the Tempus IC are those listed in section 10 of this manual.

In the event that the device fails to operate correctly or in a way that is not described in this manual, stop using the device immediately and switch the device off immediately. Contact the manufacturer or distributor at once. Do not attempt any kind of corrective action and do not connect the device to a patient.

2 Warnings and Cautions

2.1 EMC Statement

Tempus IC remote patient monitor has been tested and approved to IEC/EN60601-1-2:2007. This means that **Tempus IC** meets or exceeds the requirements for electrical medical equipment in terms of its levels of emitted electromagnetic radiation and its susceptibility to electromagnetic radiation from other devices.

In addition, **Tempus IC** has been tested according to the requirements of RTCA DO160-E section 21 category M.

It should be noted that **Tempus IC** 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, **Tempus IC** is intended for use in electromagnetic environments of ±6kV static contact (±8kV air discharge) and magnetic fields of 3A/m (50/60Hz). **Tempus IC** is proof against radiated RF emissions from 80MHz to 2.5GHz to a level of 3V/m. In the event that **Tempus IC** will be used in environments with RF levels exceeding this, please contact RDT for further information.

2.2 Indications for Use

Tempus IC is intended to aid with the diagnosis of a person presenting as unwell or sick when they are in a location remote from immediate medical assistance. The device allows the User to take vital signs data from a patient and to transmit that data to medical professionals located at the response centre elsewhere. Typical examples are remote land, sea or air locations.

Tempus IC is intended primarily to be used by medically unqualified people who have received basic training in the use of the device. Medical expertise is provided through communication with the Response Centre which would be staffed by physicians who would advise the operator on the nature of the medical incident.

Tempus IC is intended to be used where a physician or other medically trained staff may or may not be present but where remote physician support is required.

A trained medical professional such as a physician or paramedic may also use **Tempus IC**.

Tempus IC is suitable for use on adults or children (over 10 years old and over 20kg in weight).

2.3 Contraindications

Tempus IC is not intended to be used on extremely small or extremely large patients; this limit is set by the physical limits of the ECG harness.

Tempus IC does not replace a physician's care. The device is not intended for neonatal use. The device is not an apnoea monitor.

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

Tempus IC is not intended to allow a lay user to make any clinical decision for treatment or diagnosis.

Tempus IC ECG is not intended to be used on patients with prosthetic limbs.

2.4 Warnings, Cautions and Notes

KEYWORD	DEFINITION
WARNING	Indicates a potentially harmful condition that can lead to personal injury.
CAUTION	Indicates a condition that may lead to equipment damage or malfunction.
NOTE	A point of particular interest or emphasis intended to provide more effective or convenient.

2.4.1 Tempus IC Warnings, Cautions and Notes

WARNING

It is essential to switch off the Tempus IC between applying it to different patients in order to ensure patient records remain separate.

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

WARNING: The Tempus IC is not intended for unsupervised patient monitoring. There are no audible or visible alarms.

WARNING: Do not use device in the presence of flammable anaesthetics or fuels.

WARNING: Do not autoclave, ethylene oxide sterilise, or immerse in liquid or immersing the sensors in liquid as it may cause sensor damage which may result in inaccurate readings.

WARNING: ELECTRICAL SHOCK HAZARD when covers are removed. Do not remove covers. Refer servicing to qualified personnel authorised by RDT.

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

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

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

WARNING: The Tempus IC is not for use on neonates.

WARNING: The device should not be used on patients undergoing defibrillation. The Tempus IC is protected against defibrillator discharge but rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.

WARNING: There is no defibrillator synchronisation output on the device. Make no connections between the device and a defibrillator.

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

WARNING: Device is not for apnoea detection. Device has not been tested or validated for use in apnoea detection.

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

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

WARNING: Only use rechargable 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: Verify normal operation if utilizing device adjacent to or stacked with other electrical equipment.

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 IC (including patient cables) directly into an electrical outlet

WARNING: Attention should be paid to the following EMC information prior to installing or using the device.

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

WARNING: Device has been tested and found to comply with IEC/EN 60601-1-2.

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 device.

WARNING: Explosion Hazard: DO NOT use the Tempus IC in the presence of flammable anesthetics or other flammable gasses. Use of the Tempus IC in such environment may present an explosion hazard.

WARNING: Electrical Shock Hazard: Always disconnect the LoFlo sidestream Capnometer before cleaning. Do NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.

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

WARNING: Failure of Operation: If the Tempus IC 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 apply excessive tension to any cable.

WARNING: Electrical Shock Hazard; No user serviceable parts inside

WARNING: Before use, carefully read the Operator's Guide and these operating instructions.

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

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

WARNING: **Do not use Tempus IC stacked with or adjacent to other equipment.**

WARNING: **Only use Tempus IC with the relevant cables and peripherals provided by RDT.**

WARNING: **Only connect Tempus IC to IT and communications systems which are compliant with the relevant IEC standard e.g. IEC60950.**

WARNING: **Exposure of the wireless communication features of the Tempus IC may be interfered with by other devices which operate at the same frequencies.**

CAUTION: Do not disassemble the device. There are no user-serviceable parts inside. Refer servicing to the manufacturer. Changes or modifications not expressly approved by RDT could void the user's authority to operate the equipment.

CAUTION: Repairs or service activity not detailed in this manual or in accompanying documents must only be undertaken by personnel trained or authorized by RDT.

CAUTION: Autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause sensor damage which may result in inaccurate readings.

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 IC 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.

CAUTION: DO NOT clean the IC or its accessories except as directed in this guide.

CAUTION: DO NOT apply excessive tension to any of the Tempus IC cables.

CAUTION: Read all instructions for use and specifications provided prior to use.

CAUTION: Device is intended for use by persons trained in its operation. The operator must be thoroughly familiar with the information in this manual before using the device.

CAUTION: The device is not intended to, and does not, sound alarms for physiological parameters.

CAUTION: In the event that the device displays an error that is not described within this manual e.g. Windows 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: Device must be switched off between taking readings from different patients.

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 IC and its accessories uses both rechargeable and non-rechargeable batteries. 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. RDT cannot dispose of used batteries. Dispose of batteries in accordance with applicable regulations which vary from country to country.

(In most countries, the trashing of used batteries is forbidden and the end-users are invited to dispose them properly, eventually through not-for-profit profit organisations, mandated by local governments or organised on a voluntary basis by professionals).

CAUTION: Pressing buttons and touch screen with sharp or pointed instruments may permanently damage the buttons and touch screen. 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 red 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: Only connect the device to communications systems which are compliant with relevant international safety standards e.g. IEC60950 for IT and telecommunications equipment. Only connect the device to communications systems which it is intended to be used with.

CAUTION: Do not touch electrically live parts of other electrical systems while touching the patient.

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: Do not transport or store the device with flammable gas, liquids or explosives.

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

A minimum distance of 2.3m (7.5 feet) must be maintained between the device and its accessories (containing RF communications equipment) and other medical equipment (including implantable medical devices such as defibrillators and pacemakers). Note that if such medical equipment has an electromagnetic interference immunity level of less than 3V/m (or 10V/m for implantable devices), this distance should be increased in line with the requirements of IEC60601-1-2:2007.

If the intended patient has an implantable device (e.g. implantable pacemaker), do not use any of the Tempus IC'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 CCm 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

If you suspect interference is being caused, disconnect the connection to the response centre by pressing  . Examples of interference could include visible interference on equipment displays, audible interference e.g. buzzing from speakers of other equipment, or equipment unexpectedly changing state e.g. functions starting or stopping. Examples of visible interference on a PC display are shown below:

<u>Example of a PC display with no interference</u>

Example of a PC display with interference

A minimum distance of 20cm (8”) must be maintained between the device and the body of the User or Patient.

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

CAUTION: 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 apx), 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: 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 red 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: 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 IC's Bluetooth or WiFi communications on-board any aircraft where its use is prohibited.

CAUTION: Do not use the Tempus IC during take-off or landing

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 a charger (additional 2-3 hours) in order to restore normal operation.

NOTE: Important! The Tempus IC 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: The Tempus IC or its accessories contain no user serviceable parts except as detailed by this manual or accompanying documents. Refer service to qualified service personnel.

NOTE: This product and its accessories are latex free.

NOTE: After the life cycle of the Tempus IC 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 the address in section 1.1.

NOTE: Device complies with Part 68 of the US FCC Rules and the requirements adopted by ACTA . The device is labelled with, among other information, a product identifier in the format US:AAAEQ###TXXXX. If requested, this number must be provided to the telephone company.

NOTE: A plug and jack used to connect the device to the premises wiring and telephone network must comply with the applicable FCC Part 68 rules and requirements adopted by ACTA. A compliant telephone cord and modular plug is provided with this product. It is designed to be connected to a compatible modular jack that is also compliant.

NOTE: The REN is used to determine the number of devices that may be connected to a telephone line. Excessive RENs on a telephone line may result in the devices not ringing in response to an incoming call. In most but not all areas, the sum of RENs should not exceed five (5.0). To be certain of the number of devices that may be connected to a line, as determined by the total RENs, contact the local telephone company. For products approved after July 23, 2001, the REN for this product is part of the product identifier that has the format US:AAAEQ##TXXXX. The digits represented by ## are the REN without a decimal point (e.g., 03 is a REN of 0.3). For earlier products, the REN is separately shown on the label.

NOTE: If the device causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice isn't practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it is necessary.

NOTE: The telephone company may make changes in its facilities, equipment, operations or procedures that could affect the operation of the equipment. If this happens the telephone company will provide advance notice in order for you to make necessary modifications to maintain uninterrupted service.

NOTE: If the equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.

NOTE: Connection to party line service is subject to state tariffs. Contact the state public utility commission, public service commission or corporation commission for information.

NOTE: If your home or area of installation has specially wired alarm equipment connected to the telephone line, ensure the installation of the device does not disable your alarm equipment. If you have questions about what will disable alarm equipment, consult the supplier as described in section 1.7.1.

NOTE: This equipment is not hearing aid compatible.

NOTE: **ALWAYS** ensure that any satellite terminals e.g. GAN or Mini-M terminals, used with the device are powered from mains power supplies which are earthed. Using a non-earthed power supply with satellite terminals will cause interference on the ECG trace. Earthed power supplies will always have a three pin connector to plug the mains lead into, non-earthed power supplies will always have the following symbol on their label  . In addition, when purchasing any replacement power supplies for satellite terminals, always ensure that the replacement has the same input and output voltage (V), current (A) and power (W) ratings, the same type and polarity of output connector and is approved to EN/IEC60950 (safety standard). Advice on this matter may be sought from RDT if needed.

NOTE: GSM usage is restricted by the network availability, roaming agreements and local provision of circuit mode connections.

NOTE: Users who own multiple device units should note that their device are likely to be pre-configured for different aircraft, yachts or other locations according to the customer's needs. Consequently different device units owned by one User may not necessarily be compatible with all of the customer's different aircraft, yachts etc. Users should refer to RDT's delivery notes which will detail if specific device is configured for specific applications. Alternatively please check with a technical contact at RDT for confirmation.

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

NOTE: IP sealing is not guaranteed if the device is subject to rough handling, impact, improper use, 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 Tempus IC's water ingress seals are warranted for 1 year from the date of manufacture.

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 IC** 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 IC.

NOTE: Overbending the folding foot or RapdiPak 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 IC should be repacked following the relevant instructions. Lost or damaged cables and accessories should be replaced with spares ordered from RDT.

2.4.2 LoFlo Sidestream Capnometer - Warnings, Cautions, & Notes

WARNING: Do not operate the LoFlo sidestream Capnometer if it fails to operate properly, if it appears to have been damaged or when it is wet or has exterior condensation.

WARNING: DO NOT use device on patients that can not tolerate the withdrawal of 50 ml/min +/- 10 ml/min from the airway or patients that can not tolerate the added dead space to the airway.

WARNING: Do not connect the exhaust tube to a ventilator circuit.

CAUTION: DO NOT sterilize or immerse the LoFlo sidestream Capnometer in liquids.

CAUTION: DO NOT store the LoFlo sidestream Capnometer at temperatures less than -40º F (-40º C) or greater than 158º F (70º C).

CAUTION: DO NOT operate the LoFlo sidestream Capnometer at temperatures less than 32º F (0º C) or greater than 104º F (40º C).

CAUTION: Remove the LoFlo sampling kit sample cell from the receptacle when not in use.

CAUTION: DO NOT stick appendage into sample receptacle.

NOTE: Recommended operating temperature is 32º F (0º C) to 104º F (40º C).

NOTE: Nitrous oxide, elevated levels of oxygen, helium , Xenon, halogenated hydrocarbons, and barometric pressure can influence the CO_2 measurement..

2.4.3 Pulse Oximeter Sensor - Warnings, Cautions, & Notes

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

WARNING: Prolonged use 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: Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the SpO_2 reading.

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 using the wipe provided before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

WARNING: Significant levels of dysfunctional hemoglogins, such as carboxyhemoglogin or methhemoglobin, 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: Ethylene oxide sterilizing the sensor may lead to tissue damage when the sterilized sensor is placed on a patient.

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 display dashes if unable to 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.

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

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: Use proper disposal guidelines when discarding the device.

2.4.4 ECG Recorder Sensor - Warnings, Cautions, & Notes

WARNING: The computerized interpretation is only valid when used in conjunction with clinical findings. All computer generated tracings and interpretations must be confirmed by a qualified physician. Test interpretations are intended for the physician's use only. All ECG numerical and graphical data should be evaluated with respect to the patient's clinical and historical picture.

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

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: Though false positive errors will intentionally outnumber false negative errors, both will occur, thus the necessity for over reading by a qualified

physician of any computer-interpreted ECG. The computer interpretation does not produce a definitive diagnosis.

WARNING: Ensure electrodes are connected only to the patient

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

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

− Follow the instructions of the defibrillator or AED when using it wih the Tempus IC.

− 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

CAUTION: The ECG is designed and tested to AAMI EC11

CAUTION: Electrocardiography – The suggested maximum electrode duration is 8 hours

2.4.5 The Blood Pressure Monitor - Warnings, Cautions, & Adverse Reactions

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

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.

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.

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, which 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.

3 Introduction to the Tempus IC

3.1 Product Description and List of Features

Colour iAssist help processes are provided to assist the user in every stage of use.

Everything that is displayed on **Tempus IC** screen is simultaneously seen at **Tempus Net** in the Response Centre, enabling the medical expert to fully interact with the operator. The medical expert can, in fact, fully control **Tempus IC** if required, giving added comfort to the operator and patient at the remote location.

Tempus IC in Use

Tempus IC sends all of its measurements and displays via the telephone connection to **Tempus Net**, where the displays are duplicated. The medical expert at the **Tempus Net** is also able to annotate (with words, symbols and markings) and send back the still video picture to better illustrate the verbal instructions being given to the operator at the remote location. If necessary, the expert can take control of most functions of **Tempus IC**, giving added comfort to both the user and patient.

4 Introduction to the Tempus IC

4.1 Tempus IC Device

Tempus IC is a multi-paramater vital signs monitor which connects to a dedicated Response Centre. Connection is achieved using different communications technologies, refer to the Modes Menu on your Tempus for details of what communications systems it can be used with.

A physician may use **Tempus IC** as a stand-alone diagnostic device (without it being connected to the Response Centre).

Tempus IC provides the following information about the patient from its sensors:

- Pulse rate
- Oxygen saturation (SpO_2)
- Blood pressure
- 12 lead Electrocardiograph (ECG)
- End tidal CO_2 ($ETCO_2$)
- Respiration rate

These readings are transmitted via telephone to the **Tempus Net** (which is a computer that enables the physician to see all the vital signs data).

Additionally, **Tempus IC** includes a colour video camera which is capable of sending colour still images to **Tempus Net**.

The following sections describe how each of the sensors, the camera and communications systems work.

Tempus IC consists of a enclosure which is overmoulded with rubber to make it resistant to shock. The enclosure also includes a rear clip which provides storage for the SpO_2 sensor, the NIBP cuff and communications cable.

4.1.1 Tempus IC Front

The front of **Tempus IC** has a large screen (6.5” transflective daylight readable) which is fitted with a touch-screen.

The front panel houses two membrane keypads which are graphically labelled with their function. Also present is a jog wheel.

Note that the markings on the top of the unit (Bluetooth, GPS, GSM & WiFi) are illustrative only and do not indicate the technical capabilities of any particular unit.

4.1.2 Tempus IC Base

The base of **Tempus IC** has a space for the battery to attach. In the panel behind the battery is a removable panel which allows access to the GSM SIM card and a removable memory card.

The base of the device also has a docking connector to allow the unit to be docked to a cradle in future applications.

4.1.3 Tempus IC Rear

The rear of **Tempus IC** houses the RapidPakTM clip (discussed above) and the Bluetooth Headset. This item is docked onto a connector which enables the VSM to top the charge of the headset up automatically on a regular basis, thus ensuring the headset is always ready to use.

Also on the rear is the aperture for the camera and backlight, this aperture is labelled for aesthetic purposes. The clip carries a general product label for regulatory purposes and also two labels which help guide the user to repack the SpO2 sensor and the comms cable. The top of the clip carries a product-specific brand also.

4.1.4 Tempus IC Sides

The left side of the VSM houses the medical connections. These are colour-coded and are rated IP67. Connections are provided for ECG, NIBP, SpO_2 and $ETCO_2$. Normally the NIBP and SpO_2 connectors will have their mating half attached at all times.

The right side of the VSM houses the non-medical connections. These comprise:

- USB – this is reserved for non-mains powered USB peripherals (such as mouse and keyboards) to be specified by RDT
- RJ-45 Ethernet – use only the Ethernet cable supplied by RDT
- Power – this is reserved for a power supply to be provided by RDT
- Audio – this is only for use with the backup wired headset supplied by RDT

The RJ-45 connector provides the Ethernet connection (the Ethernet cable is normally fitted).

Communications Connection Panel

5 Using the Tempus IC

NOTE: The iAssist help processes on your **Tempus IC** may differ from this example iAssist help process in the following sections. 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.

5.1 Controlling the Tempus IC

Tempus IC is graphically rich and provides audio feedback from the device in the form of beeps, tones and error messages. The feedback differs depending on if the user presses active or inactive parts of the touchscreen.

At any time, if the user is unsure of what to do they may press either of the following two buttons on the front of the device:

the Help button - this will take you to a set of menus.

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

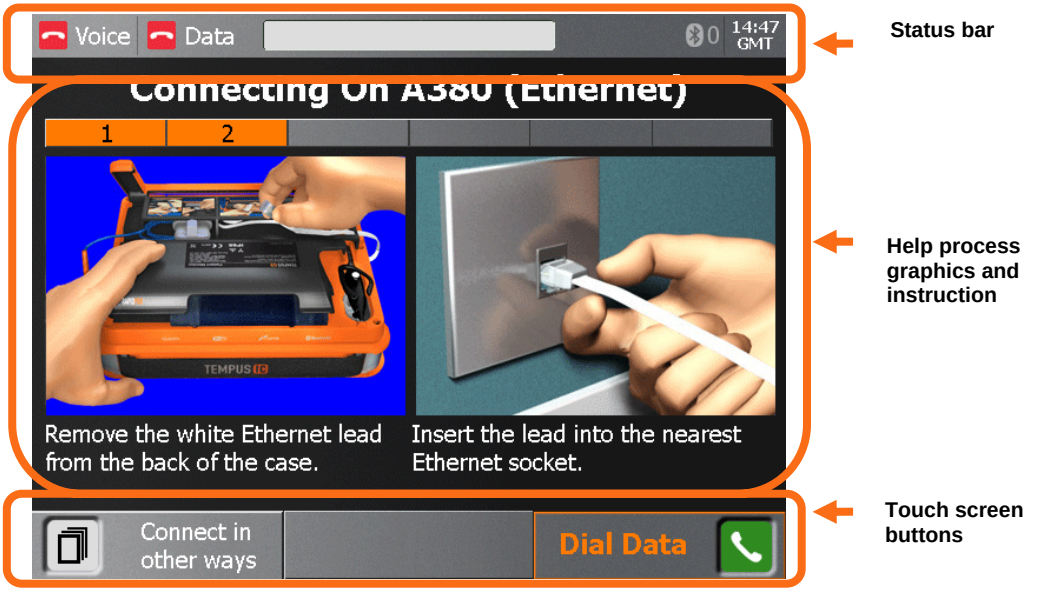
5.1.1.1 Layout of Instructions on the Tempus IC

Tempus IC provides the user with complete instructions on how to use it. Every step is detailed in pictures with accompanying text instructions. There are instruction processes for everything the user will need to do with the device:

- from obtaining a voice and data connection to the GMS,
- through applying all the medical devices;
- and then cleaning, repacking and replenishing the device.

The help screen shows a typical screen from **Tempus IC**. It shows that there are three distinct areas on the screen that give different types of information.

1. Status Bar — This shows if the voice and data links are connected, if ECGs or pictures are being transmitted and what the time is when recorded.
2. Process Instructions — This area contains the graphical pictures and text instructions that show you how to use the device. This takes the user through each activity one or two steps at a time.
3. Touch Screen Buttons — In this example there are two buttons at the bottom of the touchscreen. In all cases the user will press the button on the **bottom right** of the screen to progress onto the next step in the process.

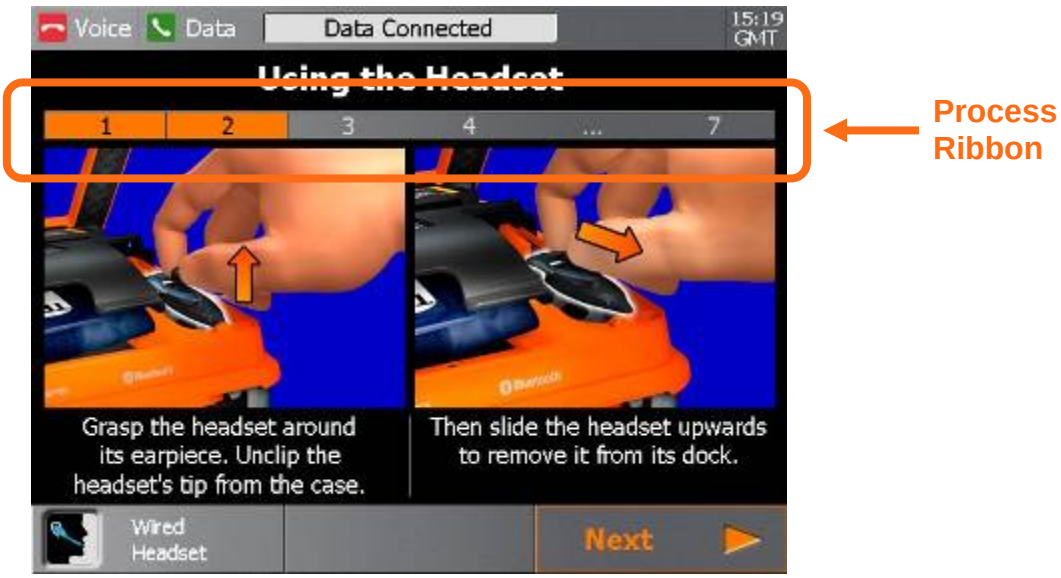


Example of the **Tempus IC** Screen Layout

5.1.1.2 Progressing through Help Processes

As mentioned above, **Tempus IC** breaks all processes down into small steps. These steps are shown on the screen in one or two at a time.

The user can see how many steps there are in any process by looking at the Process Ribbon near the top of the screen.



Example of the Process Ribbon

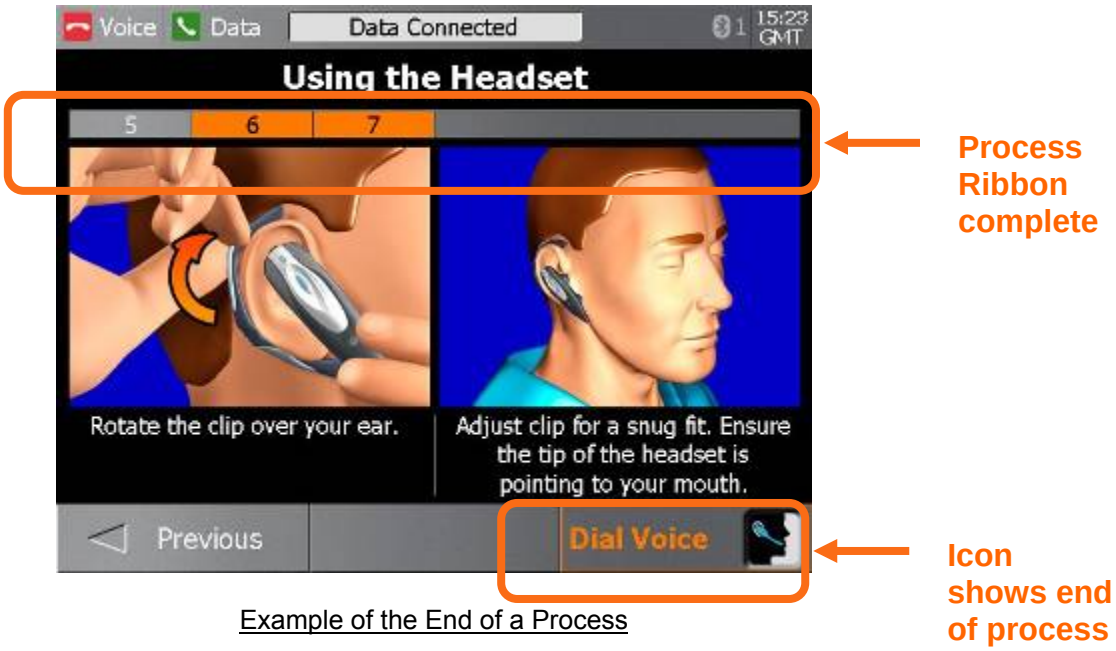
In the example shown above, the screen shows that the process has 6 steps and that the device is showing steps 1-2.

The user follows the instructions given on the screen, ensuring that they review both the image and the text. Once they have completed both steps they proceed onto the next steps by pressing the **Next** touchscreen button.

Pressing this will bring up the instructions for the next 1 or 2 steps in the process. Similarly they can go back to earlier steps by pressing the **Previous** touchscreen button.

Example of the Middle Steps of a Process

At the end of a process, the **Next** touchscreen button changes to show an icon that relates to starting the action that the process has prepared for. So at the end of the process that has been shown in this example, the user would start the voice link connection.



Example of the End of a Process

5.1.1.3 Getting Help

As mentioned earlier, the user can get help at any time by pressing the ? button at any time. This will bring up the Help Menu. There are multiple sequential menus covering different aspects of using **Tempus IC**. For example, when the first Help Menu is on the screen, the next menu (Cleaning and Repacking Menu) can be accessed by pressing the **Next** touchscreen button.

Example of the Help Menu

Example of the Cleaning and Repacking Menu

The user can move backwards and forwards through the Menus by pressing the **Next** and **Previous** touchscreen buttons.

5.2 Explanation of the Tempus IC Screen

Tempus IC screen normally divides into two sections:

- Connection status and time of day at the top
- Instrument readings in the middle

Example of the Tempus IC Screen Display

5.2.1 Status Bar – Clock (Time Stamp)

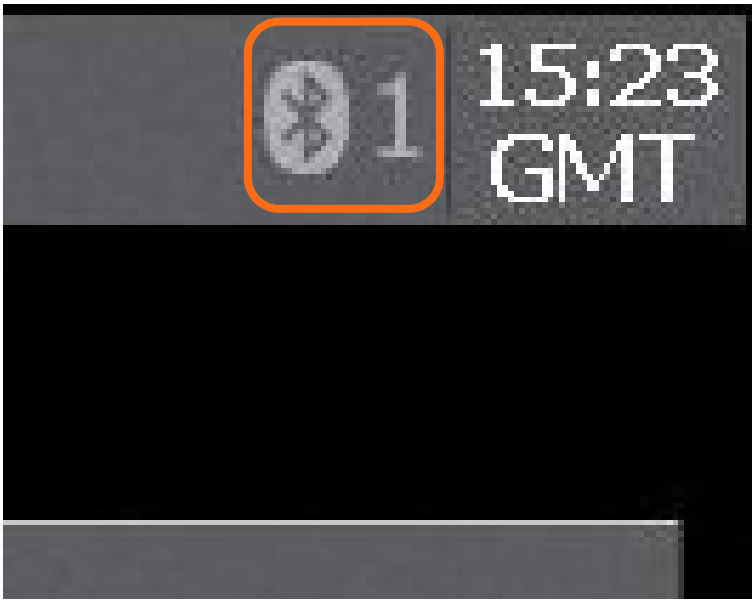
The time of day is shown in Greenwich Mean Time (GMT), which is also known as Universal Time Co-ordinate (UTC). **Tempus IC** has an internal clock which is automatically synchronised to an accurate time reference at the Response Centre as soon as a call is made.

5.2.2 Status Bar - Bluetooth Indicator

The Bluetooth indicator identifies the number of Bluetooth sensor connected to the device, i.e. 1 sensor at this time.

NOTE: It does not identify the specific sensor connected to **Tempus IC**.

Time of day is shown in Greenwich Mean Time (GMT), which is also known as Universal Time Co-ordinate (UTC). **Tempus IC** has an internal clock which is automatically synchronised to an accurate time reference at the Response Centre as soon as a call is made.



5.2.3 Status Bar - Wifi Indicator

This indicator is displayed when **Tempus IC** is connected to the Response Centre using WiFi communications technology.

5.2.4 Status Bar - GSM Indicator

5.2.5 Status Bar - Video Indicator

This indicator is displayed when **Tempus IC** is connected to the Response Centre using GSM communications technology.

5.2.6 Instrument Readings

This section of the screen shows the results (if any) from the five different medical devices (ECGs are displayed separately). Each of the five areas shows more than one piece of information i.e. data taken, time taken and type of units are displayed. Descriptions of the instrument readings are contained in the sections of this manual which describe each instrument.

When iAssist help processes are displayed, they take up the space normally occupied by the instrument readings and the status indicators.

All of the measurements except blood pressure, temperature and ECG are continuous, that is they are taken automatically without operator intervention. Data from these measurements is sent automatically to the Response Centre in real-time (if the data line is active), otherwise the measurements are memorised and sent when the data line is next active.

- Temperature measurements require the operator to physically take a reading.
- ECG measurements produce a lot of data which takes a few minutes to transmit to the Response Centre. ECG measurements can be initiated manually by the operator or remotely by the Response Centre.

All data which is generated by **Tempus IC** is automatically time-stamped.

5.2.7 Instrument Status Indicators

The Instrument Status indicators show what each instrument is doing. The status can be one of the following:

Measuring	The instrument is currently taking a reading
Idle	The instrument is currently idle
On timer	The instrument is making timed measurements (e.g. blood pressure) and will make another measurement in due course.
Disabled	The instrument is disabled, possibly due to a fault (see Troubleshooting in section 10.4)

Additionally, further informative Status messages may appear during readings (e.g. press 'STOP' on the touch screen o stop reading during a capnometer measurement).

When iAssist help processes are displayed, they take up the space normally occupied by the instrument readings and the status indicators.

5.3 Device Sensors

Many of the measurements made by **Tempus IC** are continuous, but the ECG is only measured when specifically initiated by the operator or Response Centre medical expert. All the measurements except ECG are continuously transmitted to the Response Centre.

ECG data and video images take an appreciable amount of time to send to the Response Centre, approximate times are as follows:

- 12 lead ECG – 2-3 minutes
- Low resolution video image - about half a minute
- High resolution video images – 2-3 minutes.

These times are for guidance only and are based on the worst case communications system (off-aircraft satellite link running at 2.4Kbaud V22BIS) and may vary depending on the quality of the connection.

5.3.1 Pulse Rate and Oxygen Saturation (SpO_2)

Pulse rate and oxygen saturation are detected by the clip-on reusable finger probe. This probe contains a visible (red) and invisible (infrared) light source and matching sensors. The sources and sensors are arranged so that the lights shine through the patient's finger when it is inserted into the clip. An amount of light also reaches the sensor via scattering within the skin.

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. In order to obtain accurate results it is necessary to ensure that the patient's finger (and fingernail) is clean. Readings will not be obtainable from patient's with nail varnish or polish, consequently the **Tempus IC** is stocked with nail varnish removing wipes in the foam block. In the event that these are needed, the operator should follow the instructions on the wipe.

5.3.2 Blood Pressure

Tempus IC uses non-invasive techniques to measure the patient's blood pressure. A pump within **Tempus IC** 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 and the specified operating precautions are observed.

Changing ambient pressures e.g. if **Tempus IC** is being used on an aircraft that is rapidly descending or ascending, will not have an effect on the results provided by the blood pressure monitor.

5.3.3 Electrocardiograph (ECG)

Electrical currents influenced by the cardiac impulse flow through the body tissue around the heart. **Tempus IC** uses 10 electrodes (in a pre-set reusable apron configuration) placed mainly on opposite sides of the heart to detect these currents.

The position of the electrodes is critical and so **Tempus IC** uses a specially moulded electrode apron which has nine of the electrodes positioned in the correct places to pick up the signals. The tenth electrode is positioned separately on the patient's leg. The electrode apron is made of elastic material so that as it stretches to accommodate different sizes of patient, the positions of the electrodes vary to maintain correct placement.

5.3.4 End Tidal CO_2 ($ETCO_2$) and Respiration Rate

The Capnometer CO_2 Module is used to monitor continuous carbon dioxide and report the End Tidal carbon dioxide ($ETCO_2$), inspired CO_2 and respiratory rate values of the intubated and non-intubated adult, paediatric, infant and neonatal patient. The Capnometer CO_2 Module is used for the continuous measurement of CO_2 (carbon dioxide) and respiratory rate.

Capnometer is a sidestream sampling system with a 50 ml/minute low sampling rate that is used to measure the CO_2. A tube inserted into the patient's nostrils detects samples of their exhaled breath. The tube is connected to a pump within the **Tempus IC**, which draws the sample through a measuring chamber.

In capnometer, infrared light is generated by the sensor and beamed through the sample cell to a detector on the opposite side. CO_2 from the patient that is aspirated into the sample cell absorbs some of this infrared energy. The monitor determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases. $ETCO_2$ is displayed as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). Respiration rate is calculated by measuring the time interval between detected breaths.

5.4 Video Camera

A miniature colour video camera is mounted in the unit. Still images from this camera can be sent to the Response Centre to provide the physician with a view of what is happening to the patient.

Moving pictures from the camera are captured by the **Tempus IC** and displayed on the screen. Individual pictures for transmission to the Response Centre are converted into digital information and sent via the data communications channel.

Images can be sent in low-resolution or high-resolution mode. Low resolution images require less time to transmit (typically more than 2 per minute), but high resolution images provide the Response Centre with much more detailed pictures (normally requiring 2-3 minutes to transmit). The selection of high- or low-resolution pictures is done by the Response Centre operator, who will advise the expected time it will take to transmit the picture.

5.5 Voice and Data Communications

The Tempus IC uses a number of different communications technologies to connect to the Response Centre. These can vary depending on the configuration of the Tempus IC, some examples include:

- Using two telephone lines over low-speed satellite channels to connect voice and data to the Response Centre. In low speed applications, two lines are needed, one for voice and one for data.
- Using a single medium-high speed satellite channel to connect voice and data simultaneously over a single line.
- Using a built-in Cell Phone to connect a simultaneous voice and data link over the wireless network.
- Using a single analog land-line to connect a simultaneous voice and data call.

In all examples, the voice line uses an earpiece and microphone to enable normal telephone type conversations with the physician at the Response Centre.

NOTE: User needs to connect the Tempus IC to the response centre every month for a test patch

6 Setting Up

NOTE: The iAssist help processes on your **Tempus IC** may differ from this example iAssist help process in the following sections. 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.

6.1 Setting up

6.1.1 Unpacking the Tempus IC

The Tempus IC is supplied from the factory in protective outer packaging. No special precautions are required when unpacking the Tempus IC, other than to ensure that the outer packaging material is retained in good order. The packaging material will be required when the Tempus IC is returned for periodic preventative maintenance (described in section **Error! Reference source not found.**).

6.2 Tempus IC Bag

Tempus IC bag is a custom design part made from moulded rubber. It is provided with a shoulder strap and carry handle, the hard plastic parts of which are branded.

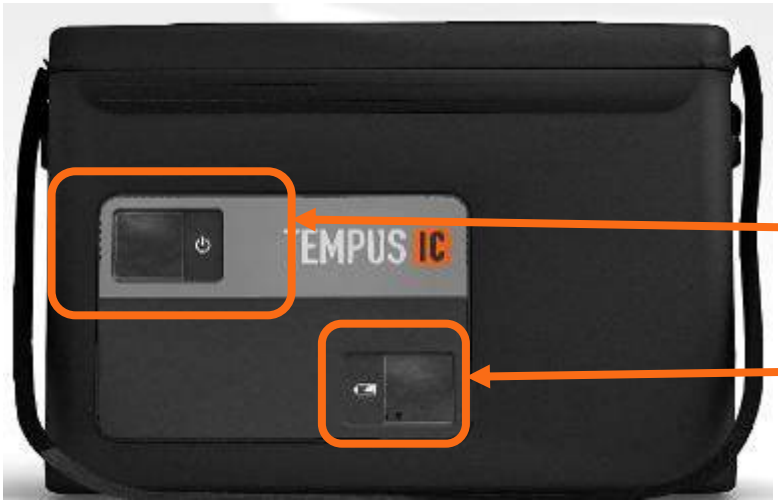
The bag provides a main storage area for **Tempus IC** (including windows to check the battery status and turn the device on externally to avoid the user opening the bag to do this), a storage area for the ECG harness, a range of pockets for consumables in the lid and a range of pockets for accessories and consumables on the rear. The sides are fitted with studs to allow the potential future attachment of small additional bags to houses power supplies and spare batteries.

The lid of **Tempus IC** bag contains

- 1 vial of 10 glucometer strips
- 1 bottle of ECG electrode spray
- 5 disinfectant wipes
- 5 nail varnish removal wipes
- 10 thermometer covers and one application tool
- 3 disposable single-use lancets

The rear pocket of the Tempus IC bag contains:

- The thermometer
- The glucometer
- Spare communications cables
- The wired headset
- An communications extension reel
- A repack kit of consumables
- The capnometer
- 2 disposable adult size nasal cannula



Tempus IC Bag

Tempus IC Bag open with the Tempus IC removed

6.2.1 Ensure that Tempus IC is Packed Properly with Sufficient Consumable Items

Tempus IC is provided with, and should be stored with, the following consumable items:

- 5 cleaning wipes
- 5 nail varnish removal wipes
- Three blood pressure cuffs: child, adult and large adult
- Two cannula and filter packs,
- One full spray of ECG contact spray
- One bag of 10 thermometer covers and ring tool
- One Consumables Replenishment Kit
- One Glucometer Replenishment Kit

Refer to section 11.1 for details of how to obtain further supplies of these disposable items.

6.3 Switching On

6.3.1 Immediately after Switching On

Note

Tempus IC takes up to one minute to become ready for operation after switching on. It is recommended that you switch on **Tempus IC** at the same time as you remove it from its storage location rather than when you arrive at the patient.

To switch on **Tempus IC**, press and hold the  button on the front panel for 3 seconds. Release the button when the lamp at the top left corner of the button starts flashing green. **Tempus IC** is ready for use when the LED shines green constantly. This takes about one minute. If no buttons are pressed within 8 minutes, the unit will switch off automatically to save battery power.

Note that if the lamp on the  button flashes red and green then there is not sufficient power in the battery to start the device properly. In this case the battery must be replaced or recharged before Tempus IC can be used.

Note: Do not press any of Tempus IC control buttons until the first iAssist help process artwork is displayed on the screen.

After switching on, the **Tempus IC** goes through a pre-defined set of iAssist help processes. These are:

- Making the data and voice connection
- Using the headset
- Taking a photo
- Blood Pressure and Pulse Oximeter

You can press  to jump straight to the results screen, or any other button to get help for that instrument e.g. pressing  will bring up the first Help Menu or pressing  will bring up the help menu for the capnometer.

7 Establishing Communication with the Response Centre

7.1.1 Process for Connecting the Tempus IC

The first step for using the Tempus IC is to establish communication with the Response Centre. To do this you will need to:

- Ensure the Tempus is set to use an appropriate communications Mode.
- Connect the Tempus IC to the Response Centre.
- Fit the Headset comfortably in your ear.

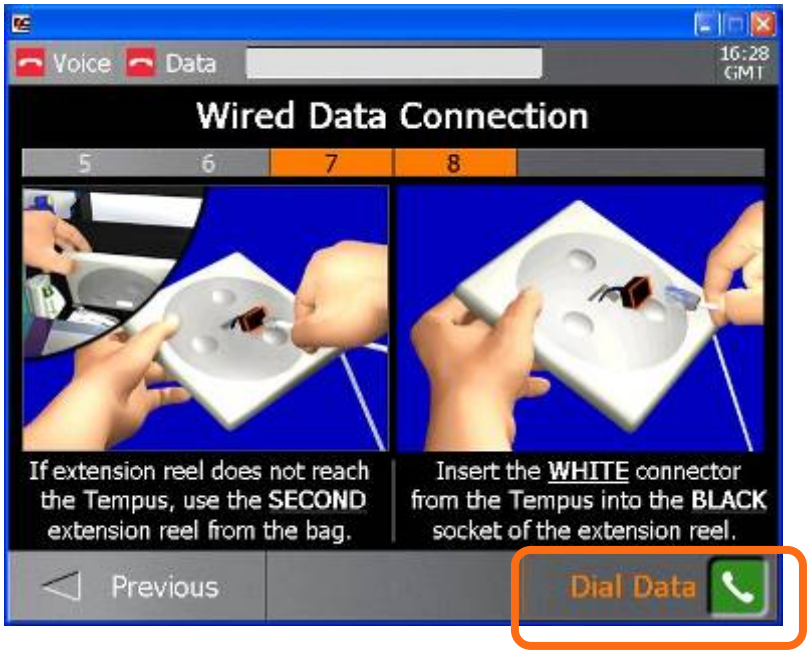
It is possible for a physician to use **Tempus IC** as a standalone diagnostic tool without connecting to the Response Centre. Under these circumstances, just press the appropriate measurement function button to access that function. It is still possible to be connected to the Response Centre at any time by pressing the Connect button.

Tempus IC can also be left running with the data link connected but the voice link disconnected i.e. if the Response Centre physician wishes to continue monitoring the patient for a long duration but without keeping the Voicelink open with **Tempus IC** User. In this case the Voicelink can be reconnected at any time by pressing the Connect button.

7.1.1.1 Making the Phone Connection

Press the  button on the touch screen to make the **Tempus IC** dial and establish the voice and data connections to the Response Centre.

As soon you press the  button, the *Wireless Headset* screen will appear.



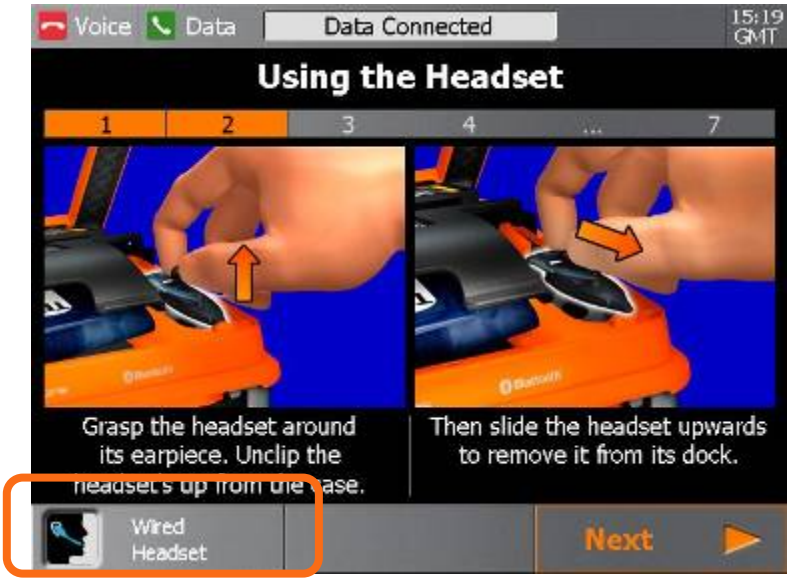
If the Response Centre cannot be contacted, this could be due to errors in the way that the connection has been attempted (see section 10.4 of this manual for Troubleshooting information). Help will be given in the form of iAssist help process, follow the instructions given and wait for a few minutes before trying again.

If your Tempus has been configured for automatic redialling, then it will attempt to connect to the Response Centre if the first call fails. The system will indicate the redial process by displaying a number over the Data Link status indicator. The system will attempt a number of redials (typically 4), and will display the corresponding number over the Data Link status indicator bar.

7.1.1.2 Fitting the Headset and Making the Voice Connection

7.1.1.2.1 Wireless Headset

1. Remove the Headset from its storage position at the back of the device.
2. Fit the Headset into your ear.
3. The Headset will work equally well in either ear.
4. The Headset is a microphone as well as a speaker.
5. Speak clearly and the operator at the Response Centre will be able to hear you.
6. Note that the volume of the earpiece can be adjusted using the '-' and '+' buttons on the side of the Headset.



Example of the Wireless Headset IAssist help process

NOTE: To switch to the Wired Headset press the  button on the touch screen as identified in the above screen.

7.1.1.2.2 Wired Headset

1. Remove the Headset from its storage position at the bag.
2. Fit the Headset into your ear.
3. The Headset will work equally well in either ear.
4. The Headset is a microphone as well as a speaker.
5. Speak clearly and the operator at the Response Centre will be able to hear you.
6. Note that the volume of the earpiece can be adjusted using the '-' and '+' buttons on the side of the Headset.

Example of the Wired Headset IAssist help process

NOTE: To switch to the Wireless Headset press the  button on the touch screen as identified in the above screen.

7.2 Connection Status Indicators

NOTE: The iAssist help processes on your **Tempus IC** may differ from this example iAssist help process in the following sections. 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.

The connection status indicators show whether **Tempus IC** is connected to the Response Centre. There are separate indicators for the voice link and the data link.

The following symbols indicate the state of the links:

Call in progress ('connected')

No call in progress ('disconnected').

Note that the words 'connected' and 'disconnected' refer to whether there is a call in progress, NOT whether the Tempus IC phone wires are plugged in.

7.2.1.1 Dialling Order and Indicators When Dialling

Once a voice or data link has been initiated, the “No call in progress” indicator will change to a “Call in progress” indicator which will start to flash. The voice and data link indicators will flash independently until each link has been connected.

While waiting for the voice link to connect, **Tempus IC** can be used to take measurements of the patient e.g. blood pressure, pulse oximetry and a video picture, which will then be available to the response centre as soon as the connections have been completed.

7.2.1.1.1 Data Dialling

Once dialling has been initiated, text will appear giving a countdown to when the data link is expected to connect. This is accompanied by a blue progress bar which grows as the time to connection gets closer.

Once the data link has been established the text indicator will display “Data Connected” and the “Call in progress” indicator which will stop flashing.

7.2.1.1.2 Voice Dialling

The voice link will start to dial as soon as the data link is connected. If the data link is taking longer to connect than usual (as a result of difficulties with the communications channel) then the voice link will dial within a preset time (typically 3 minutes 40 seconds).

In addition, a countdown will flash behind the “Voice Link?” status indicator to show how long it can be before the voice line will start to dial, the voice link will typically dial before the countdown is completed.

Once the voice link has been established the text indicator will display “Data Connected” and the “Call in progress” indicator which will stop flashing.

NOTE: If your Tempus has a built in Cell Phone (GSM) phone built into it, then it will need to log onto the network at the beginning of each call. This is shown by similar text and a separate progress bar for logging on.

7.2.1.2 Automatic Redialling

If **Tempus IC** is configured to redial the voice or data links automatically then it will indicate that a redial is taking place by displaying a number behind the “Call in progress” indicator.

7.2.1.3 Indicators Once Connections Have Been Established

Once the voice and data links have been connected, their status indicators will stop flashing. In addition, once the data link has been established the progress bar will disappear and the following text will be displayed.

7.2.1.4 File Transfer Status Indicator

When data files (either an ECG or a still video image) are being transmitted, the progress bar shows how far the transmission has progressed. In the above screen, a data transfer is 6% complete.

7.2.1.5 Advanced Data Robustness (ADR)

Tempus IC software includes the unique, patented feature called ADR. ADR was developed to reduce the problems encountered when transmitting data across satellite links. Satellite links are noisy when compared to land line connections and this can cause data connections to fail.

An analogy of this is that when speaking over mobile phones, noise or pauses in the line will be recognised by the callers. They wait for the pause or noise to pass and then continue their conversation. With data connections this does not happen as the modems do not understand or recognise the noise or delays and so drop the connection as soon as noise is present.

This causes poor reliability on data connections over satellite links. Consequently, ADR manages the existing connection when the line is noisy so that the connection is not dropped.

When ADR becomes active, it presents as:

- the data link status indicator tick changing from a green tick to a flashing yellow tick to indicate that ADR is in operation
- a delay in the data line activity – the Tempus will still record data but none of the new information will be transmitted to the Response Centre until ADR has ceased operation
- the data connection tick changing from flashing yellow to solid yellow to indicate the device is reconnected but is uploading data recorded in the interval (this will last for a few seconds only)
- the voice line will operate normally except for simultaneous voice and data calls where the voice call will be interrupted until ADR has ceased operation
- any file uploads will be suspended while ADR is active but will resume once ADR activity ceases

If there is so much noise on the telephone line that it is not practical for ADR to manage it then the system will disconnect the connection. In this event, **Tempus IC** can be re-connected to the Response Centre normally.

7.3 Communications Modes

Tempus IC can connect to the Response Centre using different communications technologies. Examples of these include conventional 2k4baud satellite communications systems and analog landlines. Both of these examples require connecting the Tempus using the white cable. In addition, **Tempus IC** may be fitted with built-in communications devices which will enable it to connect using the GSM Cell Phone network or via an Ethernet (LAN) connection.

In order to take advantage of these different technologies, **Tempus IC** is pre-set to connect using different communication "Modes". Each Mode is supported by a full set of graphical connection iAssist help process that provide the User with instructions specific to connecting using that technology.

Tempus IC shows what Mode it is in with a banner at the top of the Connection IAssist help process.

Tempus IC will stay in this Mode until it has been set to another Mode (even if it has been turned off and on again).

7.3.1.1 Changing Modes

You can change the Mode that **Tempus IC** is set to by pressing  from the Help Menu IAssist help process. This will bring up the Communications Modes Menu.

NOTE: Follow the instructions provided on the Menu shows what Modes are available to use (See Section 7.10.2.1).

7.3.1.2 Using Available Modes

The Modes that are available on each **Tempus IC** are dependent on the requirements of each User. Refer to the Modes Menu on your Tempus for specific details of each Mode that is available.

Remember that each Mode may have a different set of instructions for connecting, fault finding and repacking. Consequently it is vital that you remember to read and follow what each iAssist help process says at all times.

It is also important to remember that if one Mode cannot be used then another may be usable in its place e.g. if GSM coverage is not available then a landline connection may be useable instead.

7.3.1.3 Changing the Connection Mode

1 **Tempus IC** is capable of connecting in a number of different modes e.g. for different locations, satcoms or communications configurations. Each Tempus will be supplied programmed with the modes that the customer needs based on their requirements.

2 The User should follow the process detailed below to access the menu of available modes from which to make a selection.

3 Switch **Tempus IC** on by pressing the green ON/OFF button on the front panel.

4 When the unit has switched on (after about a minute), press the "?"button on the right hand side of the front panel.

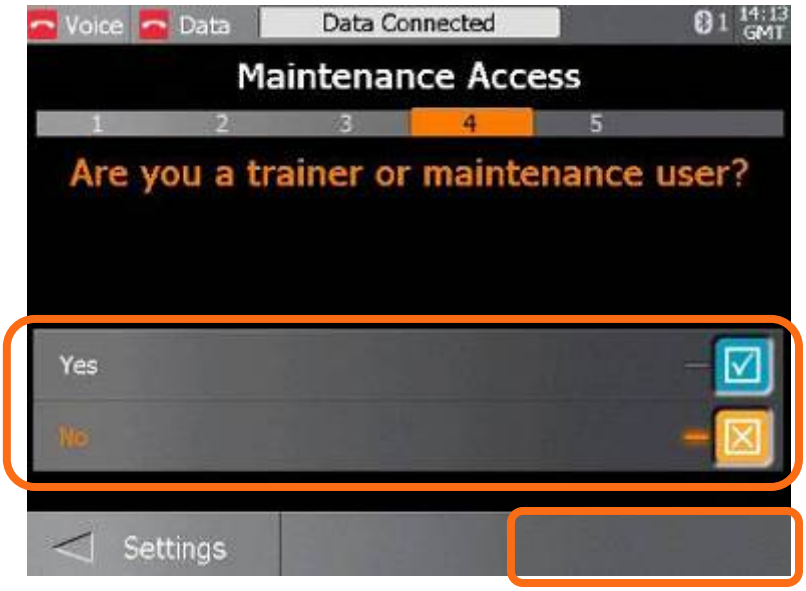
5 Press the "Yes" button on the touchscreen.

6 You will then see the Help Menu

1. Press the touchscreen here

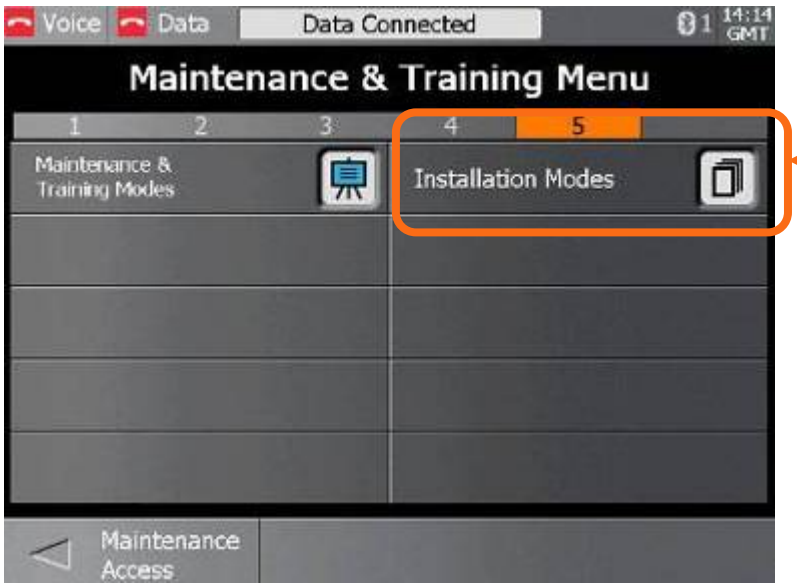
2. Then press the touchscreen here

3. Then press the touchscreen here

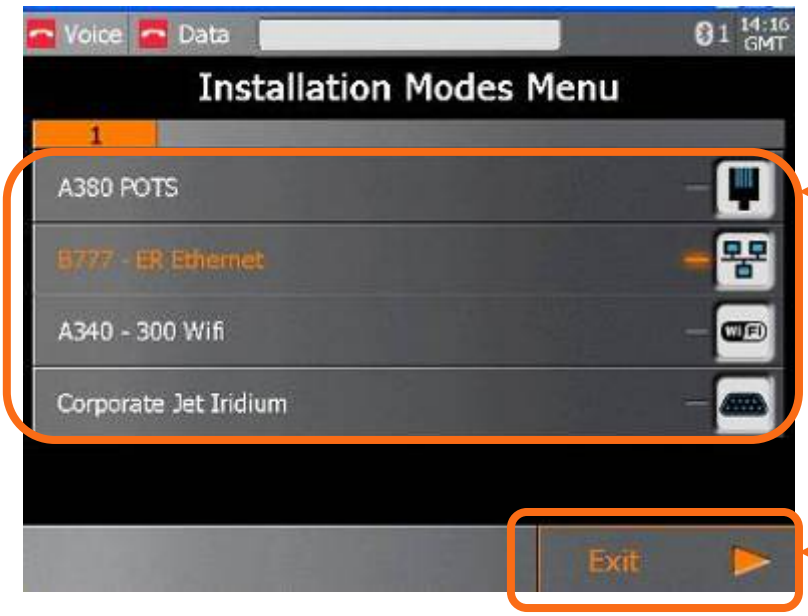


4. Then confirm that you are maintenance personnel

5. Then press the touchscreen here



6. Then press the touchscreen here to access the list of available communications modes



7. Then make the relevant selection by pressing on one of the buttons shown here – CHECK the title of the mode is what you want.

8. Then confirm the selection by pressing here.

9. You can confirm that the correct selection has been made by checking the title.

10. You can now power the unit down by pressing the green ON/OFF button on the front panel.

8 Taking Medical Readings

NOTE: The iAssist help processes on your **Tempus IC** may differ from this example iAssist help process in the following sections. 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.

Tempus IC is intended for use on one patient per incident. It must not be used on more than one patient because **Tempus IC** has no way of associating a measurement with a particular patient.

WARNING
It is essential to switch off the Tempus IC in between different patients to avoid confusion between different patient records.

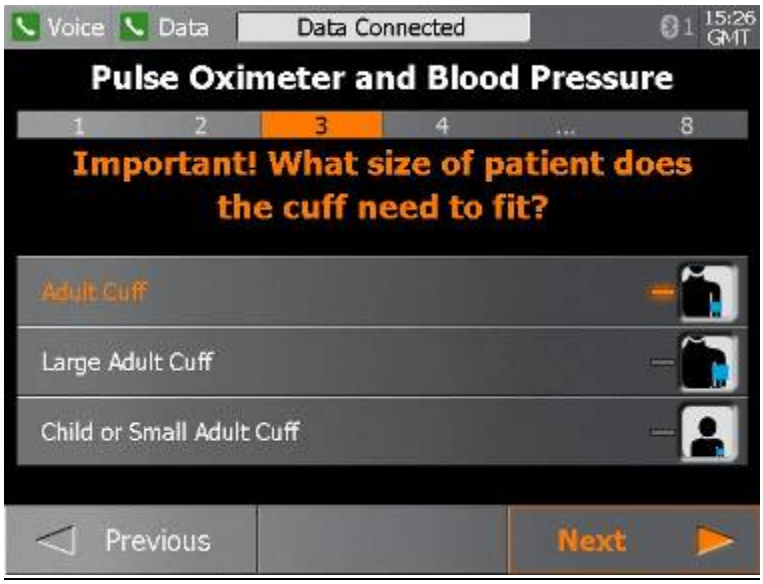
8.1 Blood Pressure and Pulse Oximeter

To activate the Blood Pressure & Pulse Oximeter function, press the  button on the device. The first Blood Pressure & Pulse Oximeter help screen will appear.

Follow the instructions provided on the iAssist help process to activate Blood Pressure & Pulse Oximeter.

Select the correct size blood pressure cuff from the storage compartment (the normal size adult cuff is highlighted on the Blood Pressure And Pulse Oximeter Help Screen shown on the device).

The cuff must fit comfortably on the upper arm. To connect and connect the tube to a cuff, insert using a twisting motion



Example of the Blood Pressure And Pulse Oximeter Help Screen

WARNINGS

The Tempus IC is not for use on neonates (young babies).

The Tempus IC is not intended for long term patient monitoring. There are no audible or visible alarms.

Reposition the oximeter probe at least once every 1hour to allow the patient's skin to respire.

SpO2 sensor should snugly fit the finger without straining it and if not alternative fingers should be tried.

The Tempus IC will not operate effectively on patients who are experiencing convulsions or tremors.

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

Notes

Dyes introduced into the bloodstream, including methylene blue, indocyanine green, indigo carmine and fluorescein may cause an inability to determine accurate SpO_2 readings.

Any condition that restricts blood flow, such as use of a blood pressure cuff (other than the Tempus IC cuff used in accordance with the instructions herein) may cause an inability to determine accurate pulse and SpO_2 readings.

Compression or restriction of the blood pressure hose or cuff, or induced movement or vibration may prevent the monitor from taking a reading.

SpO_2 measurements may be adversely affected in the presence of high ambient light levels. If necessary, shield the sensor area (e.g. with a towel).

Remove fingernail polish or false fingernails using the wipe provided before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

Performance and safety test data are available on request from the address in section 1.1.

Significant levels of dysfunctional haemoglobins, such as carboxyhaemoglobin or methemoglobin will affect the accuracy of the SpO_2 measurement.

The graphical displays of pulse rate, SpO_2 and pulse strength are not proportional to the pulse volume.

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.

The Pulse Oximeter must 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 laying down) or below the shoulder (if the patient is sitting upright).

IMPORTANT

You must use the right size of blood pressure cuff to suit the patient, and you must tell the Tempus IC if you are using the Large cuff or Child cuff.

The cuffs are marked as follows:

Normal adult (23 – 33 CM). Cuff is coloured BLUE.

Large adult (41 – 40 CM). Cuff is coloured DARK RED.

Child or small adult (12 – 18 CM). Cuff is coloured BLACK.

IMPORTANT

The Pulse Oximeter must be on the opposite arm to the blood pressure cuff.

CAUTION

OneTime® nail polish remover is flammable. Keep away from heat and flame. Use adequate ventilation. Exposed pad should be placed on glass or tile surface only. FOR EXTERNAL USE ONLY. KEEP OUT OF THE REACH OF CHILDREN.

8.1.1 Understanding the Pulse Oximeter Results

The Pulse Oximeter display has four data elements plus a status indicator. Measurements are made continuously and updated in real time. Measurements are sent in real time to the Response Centre provided that the data link is active.

The Pulse section contains a bargraph and digital display of the patient's pulse rate, in beats per minute (Bpm).

- Note that extreme pulse rates above 200 Bpm or below 50 Bpm are outside the range of the bargraph display but will be shown accurately on the digital display.

The signal strength bargraph shows the 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.

The SpO_2 reading indicates the oxygen saturation of the blood, and displays the result in bargraph and digital form.

The status bar shows the status of the Pulse Oximeter, which should normally be 'Measuring'.

8.1.2 Understanding the Blood Pressure Results

The Blood Pressure display has three elements plus a status indicator. Measurements are normally made every five minutes via an automatic timer. Note that when the unit is in timer mode, pressing  will cause a reading to be taken. If the unit is taking a measurement, pressing  will cause the reading to be stopped. If the cycle is stopped, the status indicator below will read “dle” to indicate that the unit is no longer operating.

Measurements are sent to the Response Centre every time they are made, provided that the data link is active.

Blood pressure measurements are time stamped, and the time that the last measurement was made is shown at the top of the Blood Pressure section. The Systolic and Diastolic measurements are shown beneath the time.

The status bar shows the status of the Blood Pressure Monitor, which should normally be 'On Timer' when the system is waiting between measurements, or 'Measuring' when a measurement is actually being made.

8.1.3 Blood Pressure Monitor Error iAssist help process

The Blood Pressure Monitor will automatically display iAssist help process in the event that it encounters problems in taking a measurement. The problems that it can encounter may often have a fairly simple solution, consequently, the iAssist help process attempt to guide the Operator through some basic checks that can be made.

Most of the time, the problems that the monitor experiences are related to being able to build the correct pressure in the cuff and then maintain and release the pressure at the correct rates.

NOTE: All four of the iAssist help process may be produced if the Monitor has been activated but not connected to the patient e.g. if only the Pulse Oximeter is being used.

8.1.3.1 Leaks

If the Blood Pressure Monitor is leaking, then this could be due to a poor connection to the cuff or a leak in the cuff and the Monitor will display instruction. If these are the causes, re-establishing the cuff connection and/or changing the cuff to another (if the new cuff size fits the patient) may resolve the issue.

IMPORTANT: Follow the on screen help steps to rectify the error

8.1.3.2 Overpressure

If the cuff is compressed in some way, the Monitor may read an overpressure error and the Monitor will display instructions. This may be caused by the cuff being fitted improperly, by the cuff being compressed within the patient's elbow or by the cuff being compressed against a surface.

IMPORTANT: Follow the on screen help steps to rectify the error

8.1.3.3 Time-out

If the cuff is subjected to movement, it will attempt to retake the reading. If the Monitor consistently cannot take a reading, the Monitor will display instructions. The potential causes of this include improper cuff placement on the patient, induced movement into the cuff from moving bodies next to the patient or that the patient himself is moving or speaking and thus inducing movement into the cuff.

IMPORTANT: Follow the on screen help steps to rectify the error

8.1.3.4 Weak signal

If the signal from the cuff is too weak, the Monitor will display instructions. Potential causes of the problem include blockages, or knots in the hose and a cuff that has been loosely fitted.

IMPORTANT: Follow the on screen help steps to rectify the error

8.2 Electrocardiograph (ECG)

To activate the ECG function, press  button on the device

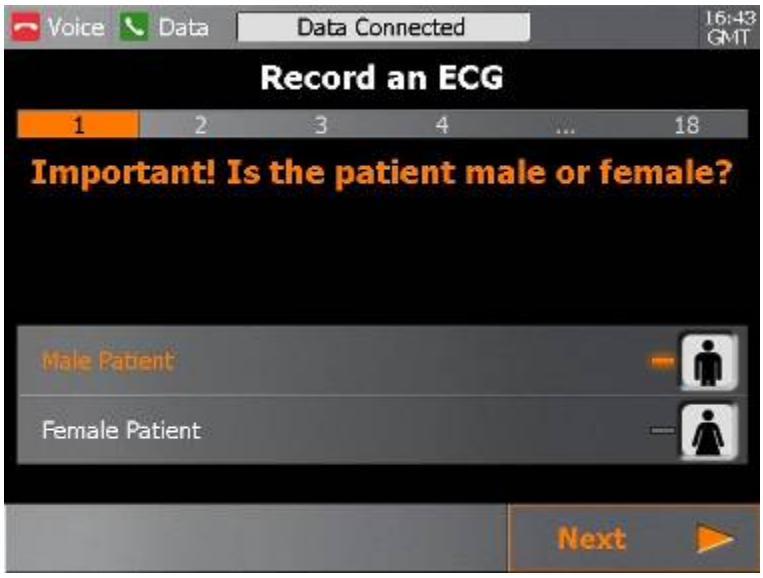
8.3 The first ECG help screen will appear.

8.4 Follow the instructions provided on the iAssist help process to activate ECG.

WARNINGS

Tempus IC should not be used on patients undergoing defibrillation. Tempus IC is protected against defibrillator discharge but rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.

Tempus IC will not operate effectively on patients who are experiencing convulsions or tremors.



Example of the ECG Help Screen

CAUTIONS

The electrodes of the ECG apron must be applied carefully.

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

The ECG spray is not to be used on broken or irritated skin

Note

Whilst the ECG harness fits many patients, one size cannot fit all patients. Consequently, the ECG data collected may not be of diagnostic quality for some patients.

The leads and cables of the ECG should be checked for fraying, tears, knots or other signs of damage before and after use.

The ECG spray is not a disinfectant. If the ECG contact spray goes into a person's eyes, it may be washed out using clean water.

The ECG spray bottle is marked with a label reading “USE BY:” and then giving a date. All bottles of fluid must be discarded once this date has been reached.

The Tempus IC is now monitoring the patient's ECG, but is not recording the information. The traces move across the screen from right to left, erasing and replacing old readings as the monitoring progresses. It takes ten seconds for the trace to cross the screen.

The displayed waveforms may be partially or totally disrupted if,

- The patient is moving or talking
- The harness is not connected properly
- The harness is not positioned correctly.

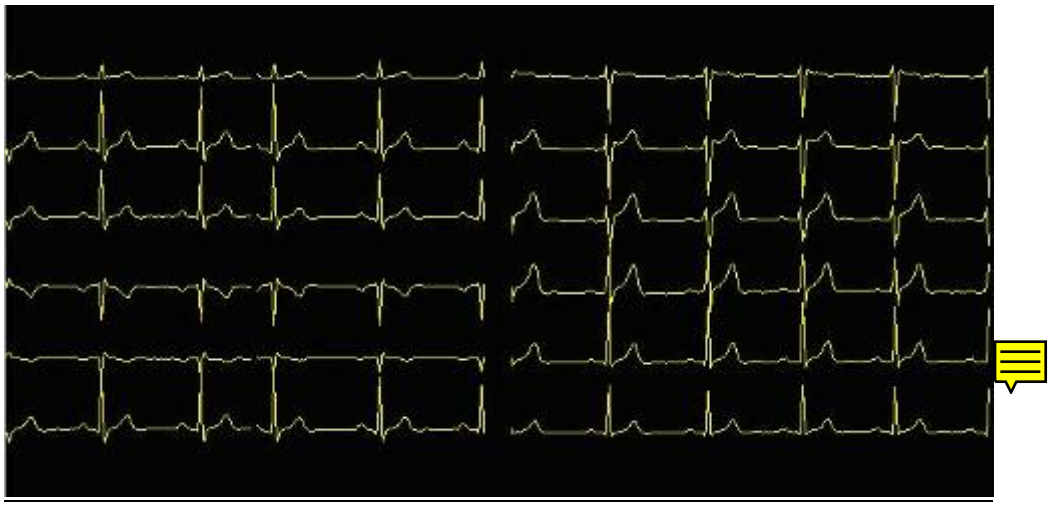
The bottom of the screen shows the current status of the ECG settings. The most important of these are:

Mains filter set to 50Hz. This should either be set to 50Hz[1] or 60Hz. ECG systems can pick up interference from mains electricity supplies. This interference appears on the screen as regular interference patterns. An internal filter is provided to remove this interference. Details of how to change this setting are contained in section **Error! Reference source not found.**.

8.4.1 Monitoring an ECG

To record an ECG, press ‘record’ on the touch screen. The display will change to the Recording screen.

[1] Hz means Hertz, or cycles per second. In North America, mains electricity supplies operate at 60Hz; most of the rest of the world uses 50Hz. In aircraft, although there is no actual mains supply, the filter should normally be set to 50Hz.



Monitoring an ECG

Recording an ECG takes ten seconds. It is essential that the patient is relaxed and does not talk or move while an ECG is recorded. If the patient is moving then the muscle movement can produce small electrical signals (known as “artefact”) into the ECG. An ECG containing artefact may not be clear enough for a medical professional to make a diagnosis so it is important that the patient remains completely still during the recording.

Wait for the ECG trace to stabilise (like the trace shown above), ask the patient to breath in and out and then to hold their breath for 10 seconds before pressing ‘record’ If the trace does not stabilise, check the following:

- Patient should not be moving
- The apron should be aligned correctly
- The wrist electrodes should be on the correct sides
- The hip electrode should be on the left hip
- All the electrodes should be in good contact with the skin (use plenty of the spray if in doubt).

8.4.2 Recording an ECG

When an ECG is being recorded, the word 'Recording' and a progress indicator bar 

appear on the screen. This indicates that the ECG is being recorded, and the progress bar shows how the recording is progressing. When the bar reaches the right hand edge of the box, the recording is complete.

Once the recording is complete, the results will be displayed as shown in the following picture.

ECG Recorded

If the Tempus IC is connected to a Response Centre, it will automatically start to transfer the ECG file.

At this point you can press  to close the ECG view to return to the main screen or you can press 'monitor' on the touch screen to return to monitoring mode. Note that if you turn the ECG off at this point and then restart the ECG function later during the same incident (without switching the Tempus IC off), these results will be shown again. This means that you can view the last ECG that was recorded from the patient.

CAUTION

It is essential that the Tempus IC is switched off before it is connected to another patient, otherwise information from one patient (e.g. an ECG recording) may be confused with that taken from another patient.

8.4.3 ECG Configuration

From this point you can access the configuration screens for the ECG and thermometer (where you can change the filter frequency settings or change from °F to °C) or for the telecoms connections (where the telephone numbers of the Response Centre are stored).

If you press the  button in the System Configuration menu, you will see the following screen:

You can see that the main part of the screen shows three sections. The right hand section contains the thermometer readings setting which can be set to either °C or °F.

The left hand sections contain the settings for the filter frequency and ECG mode. The filter frequency should be set to the mains supply frequency that is local to the Tempus IC or to 50Hz for use on-board aircraft. The ECG mode can be set to one of two types, either standard or training mode.

If the Tempus IC is set into training mode (see section 10.3), then you will be able to set the ECG into training mode. In this mode, the ECG (when activated) will produce artificial ECG traces on the screen (labelled "**DEMO**"). The trainer mode is **only** designed for use when training operators of the Tempus IC. It provides no purpose for real incidents and should not be used. If the trainer mode is selected, the Tempus IC will revert to standard mode once it has been turned off.

In the example shown, the data phone number is being edited, however the screen is the same for all of the character based selections.

ECG lead-off LA	Process to step user through checking ECG harness.	Button: RESTART ECG at end of process. Keypad keys (eg HOME) to cancel this error and goto the process associated with the button.
ECG lead-off V1, V2	Process to step user through checking ECG harness.	Button: RESTART ECG at end of process. Keypad keys (eg HOME) to cancel this error and goto the process associated with the button.
ECG lead-off V3, V4, V5, V6	Process to step user through checking ECG harness.	Button: RESTART ECG at end of process. Keypad keys (eg HOME) to cancel this error and goto the process associated with the button.

8.5 Capnometer

To activate the Capnometer function, press  button on the device

The first Capnometer help screen will appear.

Follow the instructions provided on the iAssist help process to activate Capnometer.

Example of the Capnometer Help Screen

WARNINGS

The Tempus IC is not intended for long term patient monitoring. There are no audible or visible alarms.

The Tempus IC is not for apnoea detection. The Tempus IC has not been tested or validated for use in apnoea detection.

CAUTION

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

Notes

The capnometer requires regular calibration. A source of calibration gas is fitted within the **Tempus IC** to enable the device to remain accurate and ready for use during its period of intended use. The calibration gas can only be replaced by the manufacturer. If the **Tempus IC** is not returned to RDT Ltd. for its regular preventative maintenance check, the capnometer will eventually cease to operate.

The capnometer will perform self-calibrations as required when the **Tempus IC** is switched on and the capnometer is operating. These operations may cause short delays (approximately 5-10 seconds) in the display of measured results.

The capnometer is not for use in conjunction with breathing or anaesthetic systems.

8.5.1 Understanding the Capnometer Results

The Capnometer display has four data elements plus a status indicator. Measurements are made continuously and updated in real time. Measurements are sent in real time to the Response Centre provided that the data link is active.

Owing to the nature of the instrument, readings take a little time to first appear (up to 30 seconds), and a little longer to stabilise. This is perfectly normal.

The Respiration Rate section contains a bargraph and digital display of the patient's respiration rate, in respirations per minute (Rpm).

- Note extreme respiration rates above 150 Rpm are outside the range of the bargraph display but will be shown accurately on the digital display.

The $ETCO_2$ reading indicates the end tidal mmHg reading of the breath, and displays the result in bargraph and digital form.

The capnometer will take readings for 15 minutes and then stop. The capnometer can then be re-activated by pressing the  button.

The status bar beneath the results area will read “Press  to stop” while the capnometer is running. The capnometer will cease taking readings if the  button is pressed while it is running. To re-start the capnometer, simply press the  button to bring the help screen up and begin the process again.

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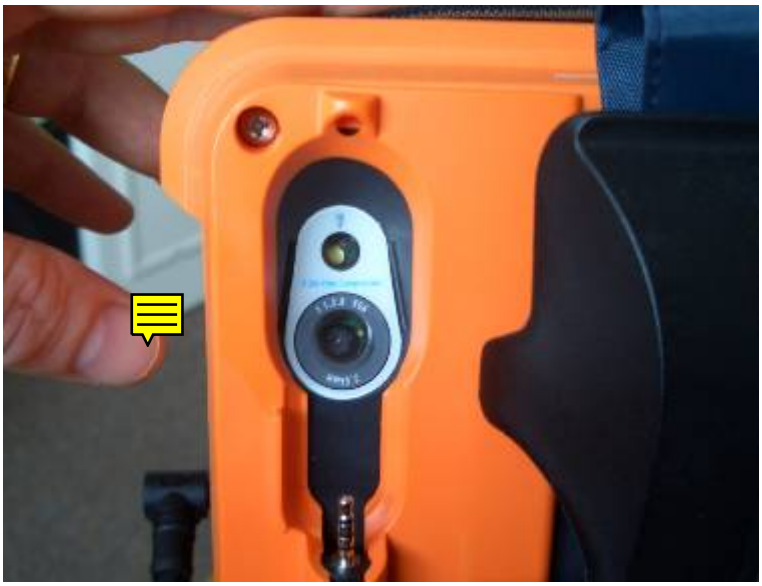
8.6 Video Camera

When requested by the Response Centre, it is possible to capture and send still video images using the camera built into the device. Video images are shown live on the Tempus IC screen so that you can see what the camera is seeing. When you are happy with the displayed image, you capture the picture and can then send it to the Response Centre (if you are not connected the image will be stored for transmission later). Moving pictures cannot be sent to the Response Centre.



To activate the Camera, press  button on the device

The first Camera help screen will appear.

A video image from the camera will appear on the Tempus IC display in the position shown in the following picture.

Follow the instructions provided on the iAssist help process to take a photo.

Example of the **Tempus IC** Display Showing Location of Video Image

Example of the **Tempus IC** Display Showing Photo Image

Aim the video camera so that you get the picture you need on the screen (e.g. a close-up of the patient).

When you are happy that the displayed image shows what you want, press  on the touch screen to freeze the image.

A countdown will appear on the screen before the picture is sent. To discard the image during the countdown and take another picture, press  , otherwise the picture will be sent when the countdown reaches zero.

8.6.1 Annotation of Video Images

Images transmitted from the Tempus IC can be altered using the software at the Response Centre. The altered image can then be sent back to the Tempus IC to act as a support in the remote diagnostic procedure i.e. the physician can send pictures back that can be used to confirm exactly the issue being examined or discussed, thus avoiding the danger of misunderstanding verbal descriptions.

Images can be amended using the following tools:

- Zooming in and out
- Addition of text
- Addition of circles
- Addition of lines and arrows
- Addition of free-form lines
- Selection of colours for added graphics

An example of an amended video image is shown above.

8.7 Interacting with the Response Centre

Although the Tempus IC may be used without connection to a Response Centre (i.e. if there is a physician locally or if the unit is being used to collect data for later transmission), in most incidents it is likely that a Response Centre will be contacted as the first priority after having activated the device. Each Tempus IC device is pre-configured to dial automatically to a specific Response Centre. This centre is staffed 24 hours a day, 365 days a year and staff will always be waiting to receive your connection. If a connection cannot be established, you should wait a short time and attempt to connect again.

The Tempus IC is designed to allow maximum ease of use for the operator (even extending to partial remote control by the Response Centre if necessary) and also to transmit the medical data to the Response Centre. It is the function of the Response Centre staff to help control the situation, make an assessment based on the data received and to offer advice on the appropriate steps to take.

When interacting with the Response Centre staff, please carry out all of their instructions to the best of your ability. If anything is not obvious, do not hesitate to ask for clarification or further guidance. Most incidents will begin with the Response Centre staff asking questions relating to the nature of the incident. These questions may include such areas as:

- Nature of the patient e.g. name, sex, age, doctor's details
- Nature of the problem e.g. perceived symptoms, known history (has the patient been monitored using the Tempus IC before)
- Nature of the incident e.g. where the incident is taking place, who is responsible for the remote location

Do not be concerned if any questions are asked that you do not have the answer to. The questions are asked for the purpose of adding patient details in the Response Centre database and to help aid diagnosis. If answers cannot be given at the time of asking, there will always be opportunities to answer the questions once the incident is under control. In the event that the incident is a serious one, the Response Centre will help to arrange for medical support to be available either to the remote location or, if the incident occurs during a journey, at the point where the journey will end.

When interacting with the Response centre staff, you should also realise that they will almost always be operating in a different time zone to the one where the incident is taking place. However, the time of the both the Tempus IC and the Tempus Monitoring Station (the Response Centre hardware) are pre-set to operate on GMT (Greenwich Mean Time).

It is also likely that the Response Centre will ask for a video image to be transmitted as soon as connection has been established. Videos transmitted to the Response Centre may be sent back to the Tempus IC with markings or "annotations" placed onto the original image.

The Response Centre is continuously staffed by medical experts who will guide you in the use of the Tempus IC. Once connection with the Response Centre is established, the operators there will have exactly the same information on their screens as those displayed on the Tempus IC. Should the Tempus IC display change e.g. if a new help screen is brought up, new data is displayed or an error message appears, the Response Centre system will display exactly the same information a few seconds later.

To give the Response Centre staff the best possible understanding of the nature of the situation, verbal communication will also be needed. This is achieved using the Voicelink earpiece speaker/microphone. In addition, the Response Centre staff can receive video images from the Tempus IC via the data link. The Response Centre staff can receive still video pictures from you so that they can further assess the condition of the patient. They can also annotate the pictures you supply and send them back, for example to provide precise instructions which may not be easy to convey via the spoken word.

If necessary, the Response Centre staff can operate the Tempus IC remotely, obtaining most of the necessary readings and data via remote control. The operator at the Response Centre will make you aware that they are activating a function of the device before or as they do it. It should be noted that the Response Centre can only operate most functions of the device. The thermometer must be operated locally to the Tempus IC and the camera must be positioned by the Tempus IC operator (although the Response Centre can activate the camera remotely). Ideally the Response Centre will only take control of the Tempus IC if the operator is having difficulty with an operation.

8.8 Recording Data Off-line and Transmitting On-line

NOTE: The iAssist help processes on your **Tempus IC** may differ from this example iAssist help process in the following sections. 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.

Although **Tempus IC** is generally intended to be used whilst connected from the remote location to a Response Centre, **Tempus IC** can also be used without the telecoms connection having been made. All the functions of **Tempus IC** operate normally if the telecoms connections are not made, and data can be taken from a patient using all of the medical devices that **Tempus IC** provides.

Naturally, if a connection has not been established, no data or photographs can be transmitted and there will be no voice connection to the Response Centre operator. However, if **Tempus IC** is used on a patient without a connection being made, the data is stored and can be transmitted at a later date. There can be two advantages in this situation:

1. If a physician is present at the remote location, **Tempus IC** can be used and the data may be used by the physician to help in the diagnosis and treatment of the patient.
2. **Tempus IC** can be used by the trained operator to take readings over a period of time which can then be transmitted later to a Response Centre. This could be appropriate for monitoring a patient after an initial incident has finished e.g. the Response Centre may want to confirm that a patient's condition has recovered and so wish readings to be taken every 30 minutes (off line) and the data to be transmitted 4 hours later.

In the event that readings are taken off-line, all the normal requirements for using **Tempus IC** must be followed. Once a connection has been established, **Tempus IC** will automatically inform the Response Centre that there is stored data that can be transmitted. The Response Centre operator will want to know the incident details of the recorded data (patient's name, time of the incident etc.). Since it may not be an appropriate time for you to give this information, and since the download of the recorded incident may take some time (this will of course depend on how long the previous incident was and how many ECGs or photographs were taken), and potentially prevent you downloading data from the current incident, the Response Centre operator will give you the option whether or not you wish to transmit the data immediately. The Response Centre operator will give you the option of when to transmit the information and will activate the download when it is appropriate to do so. There is no control or mechanism that you have to operate to control this activity, it is all controlled for you by the Response Centre.

There are two kinds of situations where data will be recorded off-line:

1. **Tempus IC** has been turned on, data has been recorded and **Tempus IC** then turned off without a connection to the Response Centre being made. **Tempus IC** is then turned on at a later date (probably for a different incident or patient) and the previously recorded data is queued in the memory for transmission (if required).
2. **Tempus IC** is turned on, data has been recorded (e.g. recording taken for one hour) and then the Tempus IC is connected to the Response Centre without being turned off i.e. connection is established during the incident for the incident.

In the first case, the data recorded may be part of the same incident, or part of a different incident but for the same patient, or for a new patient in a new incident. There can also be more than one off-line recorded incident before a connection is established. Consequently the Response Centre operator will need to know the details from the “historic” incidents when they are downloaded.

In the second case, there can only be one set of data, and this can only be for the same patient and incident that **Tempus IC** is attached to when connection to the Response Centre is established.

Tempus IC is able to record as many off-line incidents as is required (until its capacity is full) but it will delete the records of incidents once they are more than 7 days old. This means that an off-line incident can only be transmitted within 7 days.

8.9 Actions After Use – Turning the Tempus IC Off

Make sure that **Tempus IC** is not in use. Make sure that the voice and data links are not in use and that the device is not being used to monitor a patient off-line.

Press-release the On/Off switch . The system will then bring up the dialog shown below and give a 10 second countdown.

The lamp on the On/Off button will change from solid green to flashing orange.

When shutting down, the **Tempus IC** will show dialog containing a countdown timer from ten seconds. The dialog reminds you to clean and repack **Tempus IC** using the icon provided.

Option A:

Press to stop the countdown and bring up the Instrument readings and results screen.

Option B:

Press to stop the countdown and bring up the Cleaning & Repacking Menu iAssist help process.

Option C:

Let the unit shutdown.

Example of the Shutdown Screen

9 After Using the Tempus IC

NOTE: The iAssist help processes on your **Tempus IC** may differ from this example iAssist help process in the following sections. 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.

9.1 Cleaning the Tempus IC

It is necessary to clean the **Tempus IC** after use.

The screen may be cleaned using a proprietary screen cleaning wipe of the type used for other LCD screens. Under no circumstances should any abrasive substance be applied to the screen.

The **Tempus IC** instruments must be cleaned during the re-packing process.

If the **Tempus IC** is dirty it should be cleaned with to remove any cosmetic contamination. It should be wiped down with a soft cloth, which may optionally be dampened with water and a mild detergent solution.

The screen may be cleaned using a proprietary screen cleaning wipe of the type used for other LCD screens. Under no circumstances should any abrasive substance be applied to the screen.

The outer case of the **Tempus IC** should be cleaned to remove any cosmetic contamination. It should be wiped down with a soft cloth, which may optionally be dampened with water and a mild detergent solution.

9.2 Cleaning and Re-packing Help Screen

The user can get help at any time by pressing the  button at any time. This will bring up the Help Menu. There are multiple sequential menus covering different aspects of using the device

When the first Help Menu is on the screen, the next menu (Cleaning and Repacking Menu) can be accessed by pressing the **Next** touchscreen button.

WARNING: The fluid contained within the wipes will cause temporary damage to the eye. In the event of contact to the eye, wash thoroughly with water for 15 minutes. Wash hands with soap and water after use

WARNING: Keep wipes away from open flame

NOTE: Wiped surfaces must be left wet for at least 1 minute.

NOTE: Wipes are not to be used as baby wipes.

NOTE: The wipes are not to be used to disinfect surfaces that have been soiled with internal bodily fluids (other than sweat). If such soiling has occurred, the item should not be used and should be returned to RDT.

Example of the Help Menu

The user can press any one of the following icons on the touch screen to get help cleaning and repacking the device.

Example of the Cleaning and Repacking Menu

The user can move backwards and forwards through the iAssist help processes by pressing the **Next** and **Previous** touchscreen buttons.

It is important that you follow all the applicable repacking steps starting with ECG Harness and finishing with Final Check. It is important that you always perform the Final Check process.

Suitable cleaning wipes labelled "Alcowipe" are provided within the **Tempus IC**. The help screen shows the location of the wipes and the user must follow the instructions provided on the iAssist help process to clean and repack the device.

9.2.1 Cleaning the Tempus and its Accessories:

Use a cloth dampened with isopropyl alcohol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), a 2% gluteraldehyde solution, ammonia, mild soap or disinfectant spray cleaner such as Steris Coverage® Spray HB.

Wipe down with a clean water-dampened cloth to rinse and dry before use. Make certain that the sensor windows are clean and dry before reuse.

9.3 Single-use Devices

The following accessories are single-use devices and must be discarded after use. No particular precautions are required when disposing of these items provided that they are not contaminated with bodily fluids. In case of such contamination, the items should be disposed of in accordance with local regulations.

Part Description:

- AlcoWipes
- Nail Varnish Wipes
- Vinyl Gloves
- Thermometer Covers
- Glucometer Lancets
- Glucometer Strips

10 Maintenance, Servicing and Troubleshooting

NOTE: The iAssist help processes on your **Tempus IC** may differ from this example iAssist help process in the following sections. 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.

10.1 General

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

NOTE: If the Tempus IC is no longer serviceable and is beyond repair, it may be scrapped. Scrapping the device and its accessories must be performed in compliance with applicable local regulations. It should be noted that special conditions may apply to the rechargeable battery if it is required to be scrapped. The battery should be discharged before scrapping and should not be crushed or incinerated.

10.2 Battery Management

10.2.1 The Battery

The Tempus IC is provided with a rechargeable battery. In normal usage, the rechargeable battery provides power for at least 4 hours' continuous* use when fully charged.

Every battery is provided with an integral battery life indicator which is also visible through the front panel of the case.

The battery life should be monitored periodically over time when the device is in storage and also before and after use.

NOTE: RDT recommends that the battery charge status should be checked once a year and recharged if necessary. RDT also recommends that the battery be completely discharged and recharged once a year.

NOTE: The User should remember that battery life of older batteries will not be the same as new batteries.

By monitoring the remaining battery life, situations where the battery is too weak to power the Tempus IC for the duration of an incident can be avoided. If the battery strength indicator shows less than 20% power remaining, you should change the battery if possible to ensure that there is adequate power for the patient incident.

However, using the battery down to the point where it is completely empty will not cause any hazards or damage to the system.

Example of the Battery Front

Example of the Battery Rear

*Assessment of use is based on projections of reasonable device usage within a patient incident made by RDT.

10.2.2 Connecting the Battery

It is necessary to install the supplied battery into the Tempus IC before it will operate. Section **Error! Reference source not found.** describes this procedure in detail.

10.2.3 Charging the Battery

It is necessary to ensure that the battery is fully charged before the Tempus IC is put into service.

NOTE: Batteries self discharge over time and lose charge capacity over time (see Battery Specification) Refer to the Tempus IC Battery Charger manual (part number 41-10XX) for a detailed description of how to charge the battery.

WARNING

BATTERY CHARGING MUST ONLY BE CARRIED OUT USING THE BATTERY CHARGER SUPPLIED FOR THAT PURPOSE BY RDT.

10.2.4 Understanding the Battery Life Indicator

Tempus IC battery is provided with a battery life indicator which gives an indication of the amount of charge left in the battery in three grades relative to full charge. The battery life indicator is also accessible from the front panel of **Tempus IC**. This battery life indicator is located to the left of the power switch.

Example of the Battery Life Indicator

The following description applies both to the battery life indicator on the battery and the front panel indicator.

To activate the battery life indicator, press the  button. One of the different coloured lights will illuminate:

- Green light is on (with or without any other light) = 100%-71% of full charge (the battery is fresh and will give at least 4 hours of run time)
- Yellow light is on (but green is not) = 70%-21% of full charge
- Red = 20%-6% of full charge (the battery is nearly exhausted)
- Red flashing = less than 5% of battery charge remaining
- No lights = battery completely exhausted.

The battery life indicator should only be regarded as a guide to the battery condition.

10.2.5 The Tempus IC Battery

The **Tempus IC** contains a removable, rechargeable battery.

Example of the **Tempus IC** Battery

The battery is fitted in the base of the **Tempus IC**. The charge state of the battery can be obtained by pressing the button on the front.

The battery is provided with 4 charge state LEDs. Pressing the button will light one or more lights. Each light corresponds to 25% of the charge state of the battery in the order (from highest to lowest):

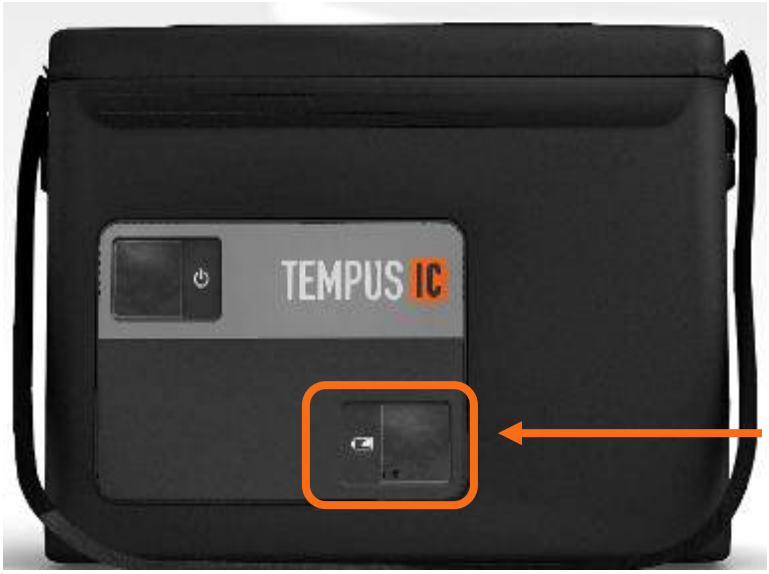
- Green – 76-100%
- Green – 51-75%
- Amber – 26-50%
- Red – 1-25%

NOTE: If the red light is flashing the battery has 10% or less charge remaining.

These will light cumulatively when the battery button is pressed i.e. only the red light will light if the charge state is 1-25% after which the amber light will light as well.

10.2.6 Checking the Charge State of the Battery

The charge state of the battery can be checked while the **Tempus IC** is in its storage Bag.



Example of the **Tempus IC** Bag

Pressing the battery button behind the window will light one to four coloured lights.

The **Tempus IC** does not need to be removed or turned on to check the battery.

10.2.7 Removing the Battery from the Tempus IC

To replace the battery:

1 First check the replacement battery has sufficient charge by checking its indicator.

Example of the Battery Indicator

2 Next, ensure the Tempus is switched off. Then remove the battery by squeezing the two latches inwards, then pull the battery away.

WARNING: Do not short-circuit the terminals of any battery. A short circuit can occur if the battery terminals come into contact with any metal or other electrically conductive object. The battery may be irreversibly damaged if it is short-circuited.

NOTE: Before removing the battery you must switch off the Tempus IC by pressing and holding the power button for two seconds.

NOTE: Remember that the battery cannot be removed until the red lamp on the front panel has gone out.

3 Slide the new battery all the way into the Tempus until it clicks into place on both sides.

10.2.8 Charging the Battery

The battery can be charged either when it is fitted to the **Tempus IC** or when it is removed from the separate battery charger.

10.2.8.1 Charging the battery from the Tempus IC

1. When fitted to the **Tempus IC**, the battery can be charged by connecting the power supply (part number 01-1017) to the 3 pin connector on the right hand side of the Tempus.
2. When the power supply is attached to the **Tempus IC**, the green power light on the **Tempus IC** front panel will turn on.
3. If a battery is attached the green charge light will flash. The lights on the battery will light solidly up to the charge state of the battery at the time.

NOTE: Batteries cannot be charged on board aircraft but may be charged in land or sea based locations (where no other restrictions apply e.g. in hazardous locations).

The Power Connector

The PSU Plug Attached to the **Tempus IC** Connector

The Power Light and the Charge Light

NOTE: Power supply is rated 110-240V 50-60Hz 1.5A.

NOTE: Charge times of the battery will vary depending on the how the **Tempus IC** is being used. If the Tempus is switched off charging will be faster than if the Tempus is on and all features are being used.

NOTE: Charging a completely empty battery will take 6 hours when the **Tempus IC** is switched off.

10.2.8.2 Charging the battery directly from the Battery Charger IC

When the battery is separate from the **Tempus IC**, the battery may be charged by connecting it to the battery charger (part number 01-1012). To attach the charger to the battery, the clip must be firmly pressed onto the connections of the battery. Note that the clip of the charger can only be connected to the battery in one way.

The Battery Connector Attached to the Battery

1. Clip the charger to the battery (the clip only attaches in one way).
2. Attach the charger to the main supply.
3. The charger's LED will light orange (for approximately 0-85% charge), change to yellow during charging (at approximately 86-100% charge) and will turn green when finished. If the battery is only partially discharged then the LED may start on yellow.

NOTE: Battery charger is rated at 100-240V 50-60Hz 0.9A.

NOTE: Recharging the battery takes up to 6 hours for a fully discharged battery.

10.2.9 Tempus IC Battery Shelf Life

10.2.9.1 Shelf Life of Batteries Stored as Spares

A new and fully charged battery retains approximately 70% of its charge after 12 months in storage detached from the **Tempus IC**. This equates to approximately 4 hours of use.

NOTE: RDT recommends that the battery is topped up annually.

NOTE: Specifications for the battery are based on a new, fully charged battery. Shelf life ratings are based on new, fully charged packs which are stored separately from the device at 20°C. Shelf life performance will decrease over time and will be lower if the battery is stored in higher or lower ambient temperatures.

10.2.9.2 Shelf Life of Batteries Stored in the Tempus IC

A new and fully charged battery retains approximately 70% of its charge after 12 months in storage attached to the **Tempus IC**. This equates to approximately 4 hours of use.

NOTE: RDT recommends that the battery is topped up annually.

NOTE: Specifications for the battery are based on a new, fully charged battery. Shelf life ratings are based on new, fully charged packs which are stored separately from the device at 20°C. Shelf life performance will decrease over time and will be lower if the battery is stored in higher or lower ambient temperatures.

10.3 Other Tempus IC Batteries

10.3.1 Wireless Headset Battery

The headset contains a rechargeable battery. The battery of the headset is not user-replaceable and does not require user intervention. In the unlikely event that the headset's battery becomes completely exhausted and can no longer hold charge, a replacement headset can be purchased.

10.3.2 Disposal of Batteries

Dispose of batteries in accordance with the applicable local regulations (these can vary from country to country).

NOTE: In most countries, the trashing of used batteries is forbidden and the end-users are invited to dispose them properly, eventually through not-for-profit profit organisations, mandated by local governments or organised on a voluntary basis by professionals.

10.4 Troubleshooting

Occasionally, problems may occur with the **Tempus IC**. Operator error, sensor problems or a failure within the **Tempus IC** could cause these problems. In most instances, the **Tempus IC** will display an error message on the screen. This section describes the possible error messages and what they mean.

All of the error messages take the form of a window which appears in the middle of the screen.

The window contains the following text:

- a title which identifies the sensor or system which is having trouble
- a description of the problem
- the effect that the error will have on the performance of the Tempus
- which button to press to clear the error message off the screen.

CAUTION: In the event that the **Tempus IC** displays an error that is not described within this manual e.g. Windows applications errors, turn the **Tempus IC** 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

The following tables list all the error messages which the **Tempus IC** may generate under abnormal conditions.

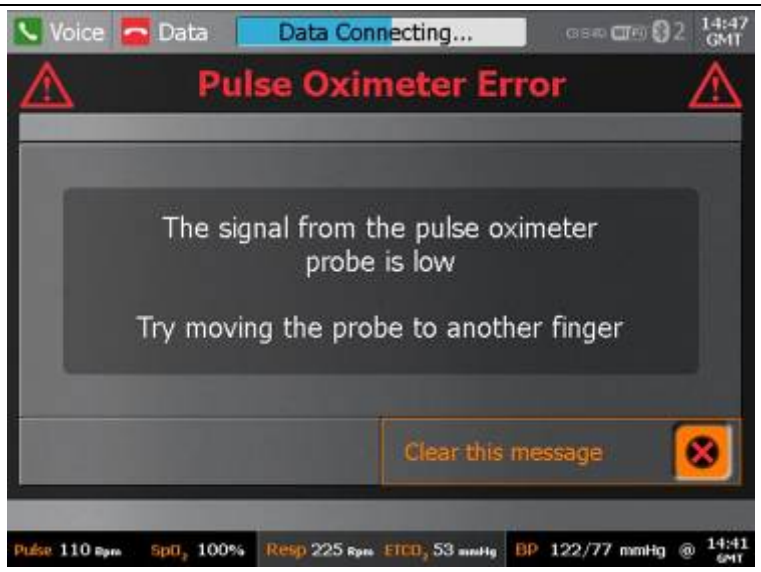
10.5 Audio & Dialog Errors

The audible alerts are on are played every 5 seconds while an error is being displayed, until the error is cleared

The different error dialog types are shown below.

10.5.1 Error Dialog - Type 1

Error Dialog - Type 1

	• Example of Error Message

10.5.1.1 Attention – Pulse Oximeter

Audio Message	Text Message	Button(s)
Pulse Oximeter Error	The signal from the pulse oximeter probe is low Try moving the probe to another finger	Clear this message
Pulse Oximeter Error	There is a fault with the Pulse Oximeter It has been disabled	Clear this message
Blood Pressure Error	There is a fault with the Blood Pressure It has been disabled	Clear this message
Pulse Oximeter Cable Error	Please connect the pulse Oximeter before shutdown	Clear this message

10.5.1.2 Attention - Capnometer

Audio Message	Text Message	Button(s)
Capnometer Error	Capnometer is blocked. Disconnect and reconnect the cannula. Check the cannula for blockages, or kinks.	Clear this message
Capnometer Error	The cannula is not plugged into the capnometer. Repeat step 7 of the instructions.	Return to instruction
Capnometer Error	There is a fault with the Capnometer It has been disabled	Clear this message
Capnometer Error	Capnometer is not plugged in. Repeat step 2 of the instructions.	Return to instruction
Capnometer Error	Capnometer sensor error or range error.	Clear this message
Capnometer Error	Capnometer zero required. Sop and restart Capnometer.	Clear this message
Capnometer Error	No Capnometer is available on this unit.	Clear this message

10.5.1.3 Attention - ECG

Audio Message	Text Message	Button(s)

ECG Error	An error occurred with the ECG Please restart the ECG and try again	Clear this message
ECG Error	There is a fault with the ECG It has been disabled	Clear this message
ECG Leads Error	ECG leads off or cable not plugged in.	Clear this message

10.5.1.4 Attention – Low Battery

Audio Message	Text Message	Button(s)
Battery Warning	There is approximately 60 minutes of battery remaining	Clear this message
Battery Warning	There is less than 30 minutes of battery remaining. Tempus will perform a managed switch-off within 30 minutes. The battery should be changed.	Clear this message

10.5.1.5 Attention – Battery

Audio Message	Text Message	Button(s)
Battery Recharge Error	The battery requires recharging. Complete ops log or recharge battery.	Clear this message

10.5.1.6 Attention – Connection

Audio Message	Text Message	Button(s)
Connection In Progress Error	Tempus is already trying to make a connection	Clear this message
Connection Is Active Error	Tempus is already connected.	Clear this message
Connection Error	The Tempus is connected so the mode cannot be changed.	Clear this message
Connection Error	You have not completed the data connection process. Are you sure this is what you want to do?	Clear this message

10.5.1.7 Attention – Data Centre

Audio Message	Text Message	Button(s)
Error	Response centre is not responding	Clear this message

10.5.1.8 Attention – Headset

Audio Message	Text Message	Button(s)
Headset Not On	The headset has not connected to the Tempus. Repeat step 3 of the instructions.	Return to instruction
Headset Not Replaced	Headset should be replaced before shutdown	Clear this message

10.5.1.9 Attention – Installation Modes Warning

Audio Message	Text Message	Button(s)
Installation Modes Warning	Engineering dept personnel only for installation on a different aircraft.	Clear this message

10.5.1.10 Attention – Video Bandwith

Audio Message	Text Message	Button(s)
Video Bandwidth Error	No datalink connected or bandwidth insufficient for video.	Clear this message

10.5.1.11 Attention – Socket

Audio Message	Text Message	Button(s)
Socket Error	The connection could not be established.	Clear this message

10.5.2 Error Dialog - Type 2

Error Dialog - Type 2	
	• Example of Error Message • Left button: 'Yes - skip this process', allows user to exit the connection process; and go to the state requested by the key that was pressed. • Right button: 'No - return to instructions' – returns to connection process exactly where it was before the key press that triggered the error.

10.5.2.1 Attention – Connection

Audio Message	Text Message	Button(s)
Connection Error	You have not completed the data connection process. Are you sure this is what you want to do?	No - return to instructions Yes - skip this process

10.5.2.2 Attention – Voice Connection

Audio Message	Text Message	Button(s)
Voice Connection Error	You have not completed the voice connection process. Are you sure this is what you want to do?	No - return to instructions Yes - skip this process

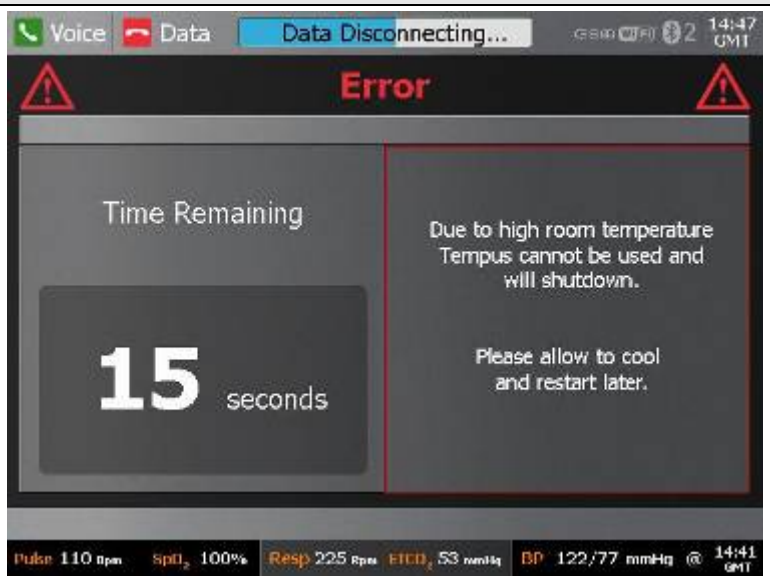
10.5.2.3 Attention – Trainer Mode

Audio Message	Text Message	Button(s)
Trainer Mode Warning	This unit is set to restart in training mode and so will not connect to a response centre.	No - return to instructions Yes - skip this process

10.5.2.4 Attention – ECG

Audio Message	Text Message	Button(s)
EGC Lead-off	ECG not plugged in or lead is not in good skin contact.	No - return to instructions Yes - skip this process

10.5.3 Error Dialog - Type 3a

Error Dialog - Type 3a (shutdown and wireless communication warnings)	
	• Left dialog shows the 'Time Remaining' which is counting down in 'seconds' • Right dialog shows the connection error dialog

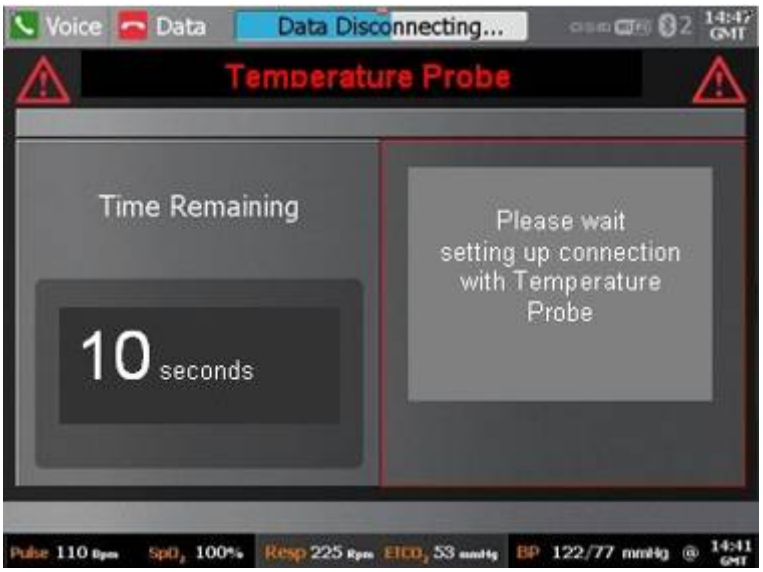
10.5.3.1 Error

Audio Message	Text Message	Button(s)
Shutdown Warning	A fault has occurred. To clear the problem Tempus will switch off. Please switch back on once the shutdown is complete. If the problem persists please contact your supplier.	None
Shutdown Warning	Due to low room temperature Tempus cannot be used and will shutdown. Please allow to warm and restart later.	None
Shutdown Warning	Due to high room temperature Tempus cannot be used and will shutdown. Please allow to cool and restart later.	None

10.5.3.2 Battery Empty

Audio Message	Text Message	Button(s)
Shutdown Warning	The battery is empty. Tempus will perform a managed switch-off. The battery should be changed.	None

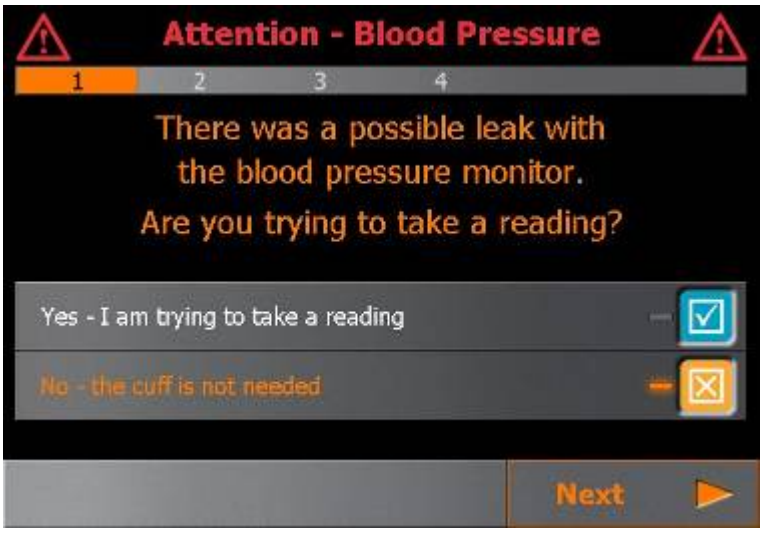
10.5.4 Error Dialog - Type 3b

Error Dialog - Type 3b (shutdown and wireless communication warnings)	
	• Left dialog shows the 'Time Remaining' which is counting down in 'seconds' • Right dialog shows the connection error dialog

10.5.4.1 Tempus is Linking to the Headset

Audio Message	Text Message	Button(s)
Headset Connected	Please wait, setting up connection to the headset.	None

10.5.5 Process Errors

	• If 'No - the cuff is not needed' is selected when 'Next' is pressed the error is cleared: no further steps. • If 'Yes - I am trying to take a reading' is selected when 'Next' is pressed proceed through help steps. • 'Next' step to help user to check the cuff. • Final step button: "Restart", this button starts BP.

10.5.5.1 BP Cuff Leak Error

Audio Message	Text Message	Button(s)
Attention - Blood Pressure	There was a possible leak with the blood pressure monitor. Are you trying to take a reading?	Yes - I am trying to take a reading + Next No - the cuff is not needed + Next
Attention - Blood Pressure	Check that the cuff is properly attached	Next
Attention - Blood Pressure	Check that the cuff is firmly wound around the patient's arm. Tell patient to sit still, relax and not speak during the reading.	Next

10.5.5.2 BP Artefact Error

Audio Message	Text Message	Button(s)
Attention - Blood Pressure	The blood pressure monitor has detected movement. Are you trying to take a reading?	Yes - I am trying to take a reading + Next No - the cuff is not needed + Next
Attention - Blood Pressure	Attention - Blood Pressure Tell patient to sit still, relax and not speak during the reading.	Next

10.5.5.3 BP Weak Signal Error

Audio Message	Text Message	Button(s)
Attention - Blood Pressure	There was a weak signal from the blood pressure monitor. Are you trying to take a reading?	Yes - I am trying to take a reading + Next No - the cuff is not needed + Next
Attention - Blood	Check the hose connector is pushed firmly	Next

Pressure	in.	
Attention - Blood Pressure	Check the hose for kinks and knots. Check the cuff has been correctly placed in the centre of the arm and the hose is not twisted.	Next
Attention - Blood Pressure	Check that the cuff is firmly wound around the patient's arm. Tell patient to sit still, relax and not speak during the reading.	Next

10.5.5.4 BP Over Pressure Error

Audio Message	Text Message	Button(s)
Attention - Blood Pressure	There was an over-pressure signal from the blood pressure monitor. Are you trying to take a reading?	Yes - I am trying to take a reading No - the cuff is not needed + Next
Attention - Blood Pressure	There was an over-pressure signal from the blood pressure monitor. Are you trying to take a reading?	Yes - the cuff is in use + Next No (returns to the previous help step)
Attention - Blood Pressure	Check the hose connector is pushed firmly in.	Next
Attention - Blood Pressure	Check the cuff has been correctly placed in the centre of the arm above the elbow. Make sure that the patient’s arm is not bent and is kept still.	Next
Attention - Blood Pressure	Check the cuff or the hose are not against a vibrating surface and the hose is not being moved. Tell patient to sit still, relax and not speak during the reading.	Next

10.5.5.5 Pulse Oximeter - Finger Not Sensor Error

Audio Message	Text Message	Button(s)
Attention - Pulse Oximeter	There is no signal from the pulse oximeter sensor. Are you trying to take a reading?	Yes - I am trying to take a reading + Next No + Next
Attention - Pulse Oximeter	Check the patient's RIGHT hand finger is fully inserted into the sensor. If necessary move the sensor to another finger.	Next

10.5.5.6 Pulse Oximeter - Unplugged Error

Audio Message	Text Message	Button(s)
Attention - Pulse Oximeter	Attention - Pulse Oximeter Sensor The pulse oximeter sensor is not plugged in. Plug the sensor back in.	OK (process is to plug sensor back in)

10.5.5.7 ECG lead-off (All Off)

Text Message	Text Message	Button(s)
Poor Contact-All or Some Electrodes	Make sure the BLUE plug is firmly pushed all the way in to the BLUE socket.	Next + Restart ECG
Poor Contact-All or Some Electrodes	Remove the bent electrode and generously spray it (GREY side).	Next + Restart ECG
Poor Contact-All or Some Electrodes	Replace bent electrode under LEFT hip waistline between skin and clothes. Electrode (GREY side) MUST touch skin.	Next + Restart ECG
Poor Contact-All or Some Electrodes	Check that the RED lead is pressed onto the strap on the patient's RIGHT wrist. Make sure the strap is tight on the patient's RIGHT wrist. Re-spray the wrist under the strap.	Next + Restart ECG
Poor Contact-All or Some Electrodes	Pull the harness forward, generously spray the GREY electrode at the bottom.	Next + Restart ECG
Poor Contact-All or Some Electrodes	Tell the patient they must be completely relaxed for the recording. Ask the patient to sit still and not to move while you are recording the ECG. REMEMBER to wait for the trace to stabilise before starting the recording.	Next + Restart ECG

10.5.5.8 ECG lead-off (Left Wrist Off)

Text Message	Text Message	Button(s)
Poor Contact - Left Wrist Electrode	Check that the YELLOW lead is pressed onto the strap on the patient's LEFT wrist. Make sure the strap is tight on the patient's LEFT wrist. Respray the wrist under the strap.	Next + Restart ECG
Poor Contact- Left Wrist Electrode	Tell the patient they must be completely relaxed for the recording. Ask the patient to sit still and not to move while you are recording the ECG. REMEMBER to wait for the trace to stabilise before starting the recording.	Next + Restart ECG

10.5.5.9 ECG lead-off (V1-V2)

Text Message	Text Message	Button(s)
Poor Contact - Red or Yellow Electrode	Check the harness is on the centre of the patient's chest and the strap is positioned as shown.	Next + Restart ECG
Poor Contact - Red or Yellow Electrode	Check the strap is tight, the harness must NOT be loose. To tighten the strap, hold the buckle and pull the strap through.	Next + Restart ECG
Poor Contact - Red or	Ensure the RED and YELLOW electrodes	Next + Restart ECG

Yellow Electrode	are touching the skin. If necessary, gently bend them in or out to ensure contact with the patient's skin.	
Poor Contact - Red or Yellow Electrode	Generously spray the RED and YELLOW electrodes. If the patient is hairy, spray the chest directly where the electrodes contact the skin.	Next + Restart ECG
Poor Contact - Red or Yellow Electrode	Tell the patient they must be completely relaxed for the recording. Ask the patient to sit still and not to move while you are recording the ECG. REMEMBER to wait for the trace to stabilise before starting the recording.	Next + Restart ECG

10.5.5.10 ECG lead-off (V3, V4, V5, V6)

Text Message	Text Message	Button(s)
Poor Contact - Green, Brown, Black or Purple Electrode	Check the strap is tight, the harness must NOT be loose. To tighten the strap, hold the buckle and pull the strap through.	Next + Restart ECG
Poor Contact - Green, Brown, Black or Purple Electrode	Check the GREEN, BROWN, BLACK and PURPLE electrodes are touching the skin and that the strap is not twisted.	Next + Restart ECG
Poor Contact - Green, Brown, Black or Purple Electrode	Generously spray the GREEN, BROWN, BLACK and PURPLE electrodes. If the patient is hairy, spray the chest directly where the electrodes contact the skin.	Next + Restart ECG
Poor Contact - Green, Brown, Black or Purple Electrode	Tell the patient they must be completely relaxed for the recording. Ask the patient to sit still and not to move while you are recording the ECG. REMEMBER to wait for the trace to stabilise before starting the recording.	Next + Restart ECG

10.5.5.11 Voice Link Error

Text Message	Text Message	Button(s)
Attention - Voice Connection Error	The Tempus is connected correctly but a communications link is not available at this time.	Next
Attention - Voice Connection Error	IMPORTANT - Select one of the following options • Wait 10 minutes and then redial the voice link • Redial the voice link immediately	Next
Attention - Voice Connection Error	Continue managing the patient and taking readings. Remember to restart the connection process in 10 minutes. If this error is displayed persistently, ask the	OK

	Captain to log onto another GES.	

10.5.5.12 Shutdown Error

Audio Message	Text Message	Button(s)
None	Important Information Inform maintenance or record in the log the following: Battery charge below 75%, 50% or 25% Repack kit required Capnometer cannula required Device fault reported	Confirmed
Attention - Headset	Headset should be replaced before shutdown	Clear this message
None	Countdown starts at 10s, counts down in seconds Powers off when countdown reaches 0s. If user requests Cleaning and Repacking Instructions the power-down is cancelled and help screen for cleaning and repacking displayed.	Cleaning and repacking Instructions (this cancels the shut down and returns to repacking menu). or Abort shutdown this cancels the shutdown).

<u>Not able to connect to a network</u>

Not plugged in

Cant see wifi access point

Can’t see GSM

Try new mode

Reboot unit

<u>Can make a connection but not able to connect</u>

Try again

New mode

Can’t get through your network, can

(network error)

10.5.6 Mode Specific Error Processes

The error processes below are mode specific and the principle for each error is the same, there are steps to correct the fault.

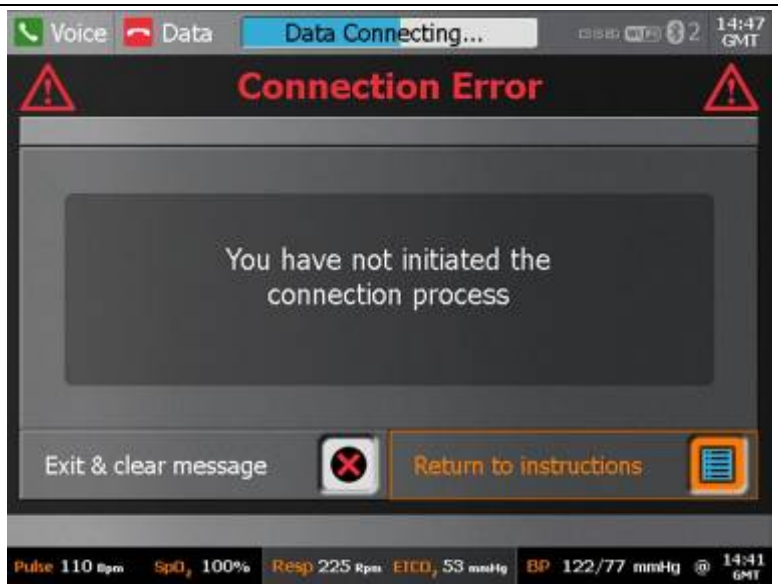
At the end of the error process in some cases the function required is different. For example on data errors the process may end with the user clearing the error without a re-try; in other modes the process may end with a re-try/re-dial of the connection.

Title	Process Notes (for XML configuration)	Button(s)
Datalink Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The final screen in the process will have a default key. This key may have 1 of 3 functions: • Dial data • Clear this message • Backup mode Variations depend on the mode, examples are: • Landline datalink error 4 steps Dual POTS datalink error 10 steps	As standard help process with PREVIOUS, NEXT and Final key defined in XML files. The XML file needs to allow for 2 different keys at the end of this process. In some cases we tell the user to Dial Data and in some cases want to just clear the screen.
Datalink Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The final screen in the process will have a default key. This key may have 1 of 3 functions: • Dial data • Clear this message • Backup mode Variations depend on the mode, examples are: • Landline datalink error 4 steps Dual POTS datalink error 10 steps	As standard help process with PREVIOUS, NEXT and Final key defined in XML files. The XML file needs to allow for 2 different keys at the end of this process. In some cases we tell the user to Dial Data and in some cases want to just clear the screen.
Voicelink Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The last screen in the process will have a default key. This key may have 1 of 2	As standard help process with PREVIOUS, NEXT and Final key defined in XML files.

	functions: • Dial voice • Clear this message	The XML file needs to allow for 2 different keys at the end of this process. In some cases we tell the user to Dial Voice and in some cases want to just clear the screen.
Datalink Error or Data-cable Error Or IFE Seatbox Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The last screen in the process will have a default key. This key will always be to: • Dial data	As standard help process with PREVIOUS, NEXT.
Voicelink Error Or Voice-cable Error Or IFE Seatbox Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The last screen in the process will have a default key. This key will always be to: • Dial voice	As standard help process with PREVIOUS, NEXT
Cellphone Error	• GSM Datalink Error 3 steps	Last step in process will be button: Dial Data
Wifi Error	• Wifi datalink error eg 4 steps	Last step in process will be a button for either attempting a new connection or switching mode. Dial Data Backup mode
Satellite Terminal Error	Satellite terminal error eg 4 steps	Last step in process will be button: Dial Data

10.5.7 Error Dialog - Type 2

Error Dialog - Type 2

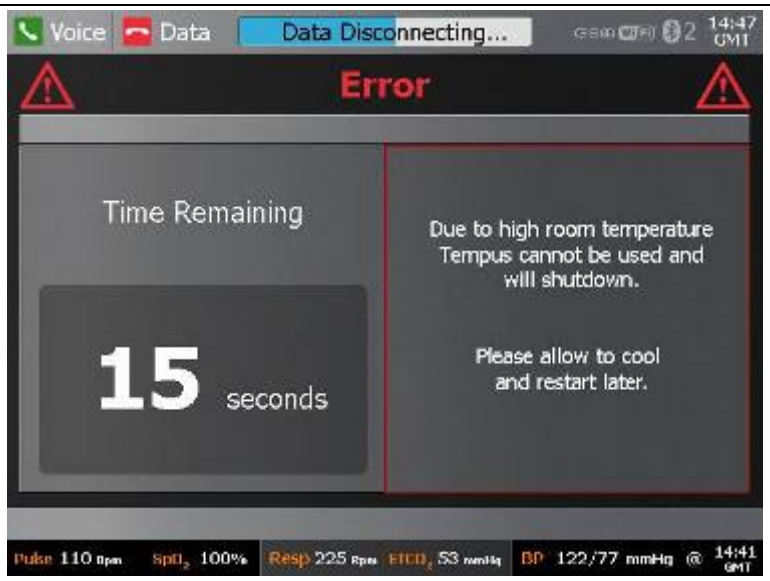


Connetcion Error Dialog shown.

Title	Text	Button(s)
Connection Error	You have not initiated the connection process	Left button: Exit & clear this message allows user to exit the connection process; and go to the state requested by the key that was pressed. Right button (default): Return to Instructions – returns to connection process exactly where it was before the key press that triggered the error.
Voice Connection Error	You have not initiated the voice connection process	Left button: Exit & clear this message (see above) Right button (default): Return to Instructions (see above)
-	-	- (not used)
ECG Lead-off	ECG not plugged in or lead is not in good skin contact	Left button: Exit & clear this message Right button: Return to ECG instructions

10.5.8 Error Dialog - Type 3a

Error Dialog - Type 3a (shutdown and wireless communication warnings)

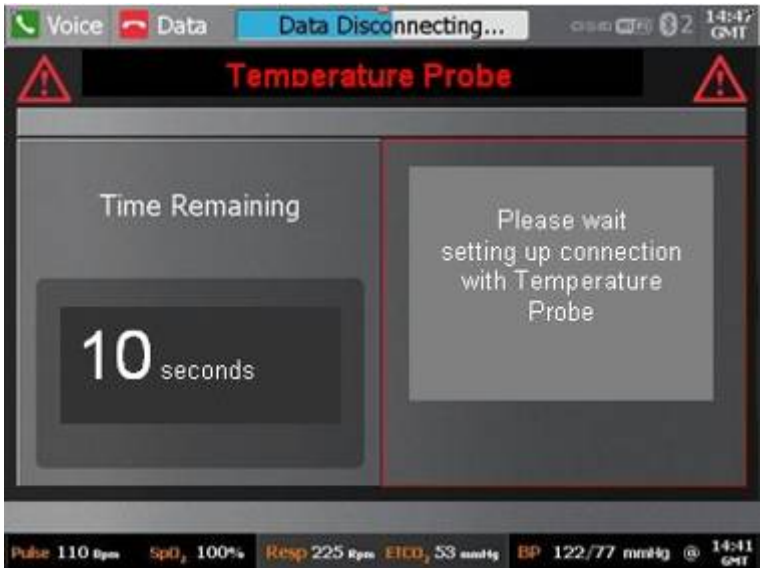


Connetcion Error Dialog shown.

Title	Text	Button(s)
Error	A fault has occurred To clear the problem Tempus will switch off Please switch back on once the shut-down is complete. If the problem persists please contact your supplier	*None*
Error	Due to low room temperature Tempus cannot be used and will shutdown. Please allow to warm and restart later.	*None*
Error	Due to high room temperature Tempus cannot be used and will shutdown. Please allow to cool and restart later.	*None*
Battery Empty	The battery is empty. Tempus will perform a managed switch-off. The battery should be changed.	*None*

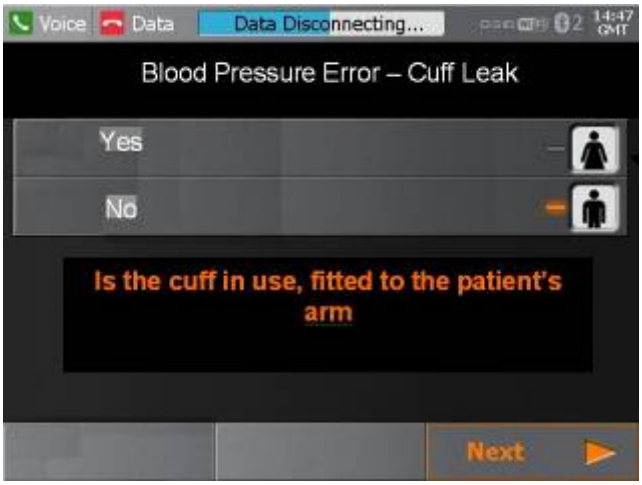
10.5.9 Error Dialog - Type 3b

Error Dialog - Type 3b (shutdown and wireless communication warnings)

	Connection Error Dialog shown.

Title	Text	Button(s)
Headset	Please wait setting up connection to Headset	*None*

10.5.10 Error Processes (Graphical Errors)

Error Process		
Title	**Process Notes (for XML configuration)**	**Button(s)**
Pulse Ox Unplugged	Process to plug sensor back in (never needs to be unplugged)	
Pulse Ox Finger	Title: Pulse oximeter Error Text: Is the pulse oximeter in use?: Yes / No	If user selects No then the error is cleared. If user selects Yes then help to put sensor correctly on finger.
Blood Pressure Error		Step 1: highlight in process ribbon **Yes** icon for cuff in use **No** icon not in use (default button is the not in use) If "No" is selected when Next is pressed the error is cleared: no further steps. If "yes" is selected when Next is pressed proceed through other steps. Steps 2 to 5 help user to check the cuff. Final step button: "Restart Readings", this button starts BP.
Blood Pressure Error	BP timeout/ artefact As above with different title.	

Blood Pressure Error	BP weak signal/tube blocked As above with different title.	
Blood Pressure Error	BP Over-pressure As above with different title.	
ECG lead-off All leads	Process to step user through checking ECG harness.	Button: RESTART ECG at end of process. Keypad keys (eg HOME) to cancel this error and goto the process associated with the button.
ECG lead-off LA	Process to step user through checking ECG harness.	Button: RESTART ECG at end of process. Keypad keys (eg HOME) to cancel this error and goto the process associated with the button.
ECG lead-off V1, V2	Process to step user through checking ECG harness.	Button: RESTART ECG at end of process. Keypad keys (eg HOME) to cancel this error and goto the process associated with the button.
ECG lead-off V3, V4, V5, V6	Process to step user through checking ECG harness.	Button: RESTART ECG at end of process. Keypad keys (eg HOME) to cancel this error and goto the process associated with the button.

10.5.11 Mode Specific Error Processes

The error processes below are mode specific, the XML configuration files will be stored on the disk in mode specific directories so that the GUI uses steps appropriate to the mode in use. The principle for each error is the same, there are steps to correct the fault.

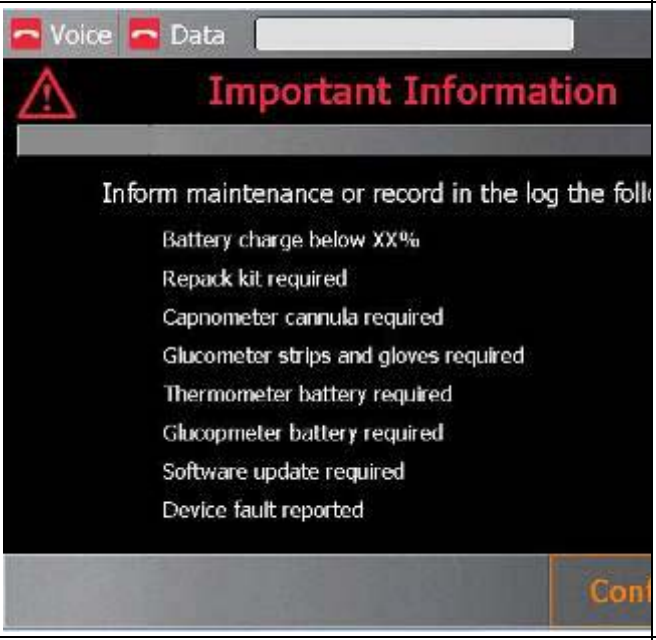
At the end of the error process in some cases the function required is different. For example on data errors the process may end with the user clearing the error without a re-try; in other modes the process may end with a re-try/re-dial of the connection. The configuration file will need to handle these different final step unctions.

Title	Process Notes (for XML configuration)	Button(s)
Datalink Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The final screen in the process will have a default key. This key may have 1 of 3 functions: • Dial data • Clear this message • Backup mode Variations depend on the mode, examples are: • Landline datalink error 4 steps	As standard help process with PREVIOUS, NEXT and Final key defined in XML files. The XML file needs to allow for 2 different keys at the end of this process. In some cases we tell the user to Dial Data and in some cases want to just clear the screen.

	Dual POTS datalink error 10 steps	
Datalink Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The final screen in the process will have a default key. This key may have 1 of 3 functions: • Dial data • Clear this message • Backup mode Variations depend on the mode, examples are: • Landline datalink error 4 steps Dual POTS datalink error 10 steps	As standard help process with PREVIOUS, NEXT and Final key defined in XML files. The XML file needs to allow for 2 different keys at the end of this process. In some cases we tell the user to Dial Data and in some cases want to just clear the screen.
Voicelink Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The last screen in the process will have a default key. This key may have 1 of 2 functions: • Dial voice • Clear this message	As standard help process with PREVIOUS, NEXT and Final key defined in XML files. The XML file needs to allow for 2 different keys at the end of this process. In some cases we tell the user to Dial Voice and in some cases want to just clear the screen.
Datalink Error or Data-cable Error Or IFE Seatbox Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The last screen in the process will have a default key. This key will always be to: • Dial data	As standard help process with PREVIOUS, NEXT.
Voicelink Error Or Voice-cable Error Or IFE Seatbox Error	These processes may have 2, 3, 4, 5, or 6 steps defined in the XML configuration file. The last screen in the process will have a default key. This key will always be to: • Dial voice	As standard help process with PREVIOUS, NEXT
Cellphone Error	• GSM Datalink Error 3 steps	Last step in process will be button: Dial Data
Wifi Error	• Wifi datalink error eg 4 steps	Last step in process will be a button for either attempting a new connection or switching mode. Dial Data Backup mode
Satellite Terminal Error	Satellite terminal error eg 4 steps	Last step in process will be

		button: Dial Data

10.5.12 Shutdown Error Processes

State	Description	Comments / Related Variables
Headset Replaced	Check headset is docked onto the charger before powering down. Triggers single Headset Not Replaced error.	User can acknowledge error and leave the headset if they need to shutdown anyway so the error must not be repeated.
Important Information Screen	Displays list of important reminders for the user relating typically to logging for repack/replenishment etc.	Button for user to confirm they have read the items on the list.
Shutdown (countdown)	Countdown starts at 10s, counts down in seconds Powers off when countdown reaches 0s. If user requests Clearning and Repacking Instructions the power-down is cancelled and help screen for cleaning and repacking displayed.	
	Headset not replaced: standard error dialog.	Button: Clear this message.
		Button: confirmed
		Buttons: Cleaning & repacking: cancels the shut down and returns to repacking menu. Abort shutdown: cancels the shutdown.

11 Spares List

11.1 Spares List of the Tempus IC

The following user-replaceable accessories and consumables are available from the RDT.

01-1001	Battery Pack
01-1002	Blood Pressure Cuff – Adult
01-1003	Blood Pressure Cuff – Large Adult
01-1004	Blood Pressure Cuff – Child
01-1005	Lo-Flo® Capnometer
01-1006	Blood Pressure Hose
01-1007	Capnometer Cannula - Adult Nasal
01-1008	Pulse Oximeter Sensor
01-1009	Extension Reel
01-1010	12 Lead ECG Harness
01-1011	Bluetooth™ Thermometer
01-1012	Battery Charger
01-1013	Bluetooth™ Glucometer
01-1014	Dual Modem Cable
01-1015	Mains Cable Pack
01-1016	Bag (empty)
01-1017	Mains Power Supply
01-1018	Bluetooth™ Headset
01-1019	Wired Headset
01-1020	Consumables Replenishment Kit
01-1021	Ethernet Cable
01-1022	USB - Serial Cable
01-1023	Ethernet Cable to Modem Adaptor
01-1024	Glucometer Replenishment Kit
01-1025	ECG wrist straps

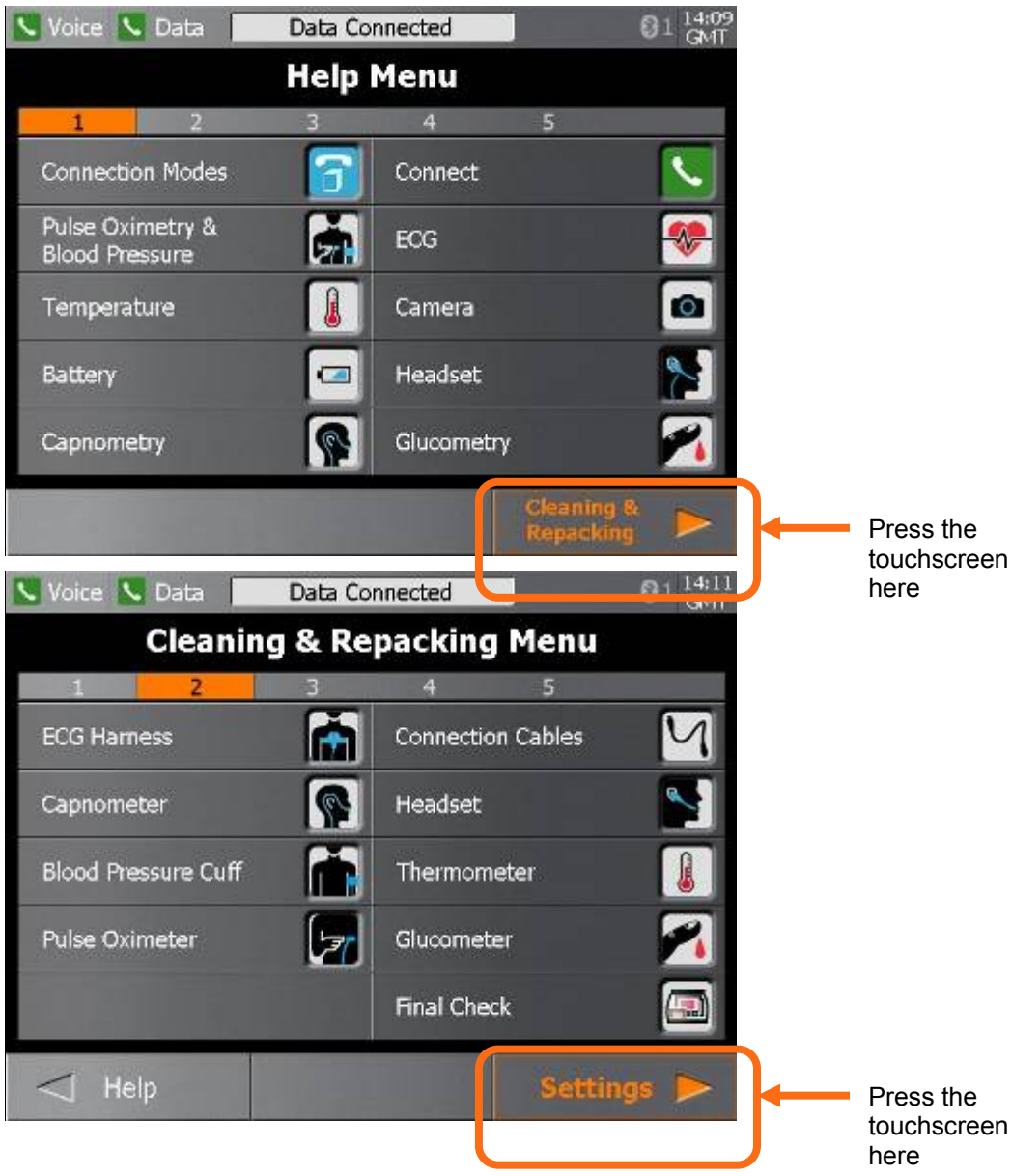
12 Thermometer Units, Screen Brightness & Audible Alerts Configurations

NOTE: The iAssist help processes on your **Tempus IC** may differ from this example iAssist help process in the following sections. 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.

A number of the parameters used by **Tempus IC** are configurable to suit certain requirements, i.e. Thermometer Units, Screen Brightness & Audible Alerts.

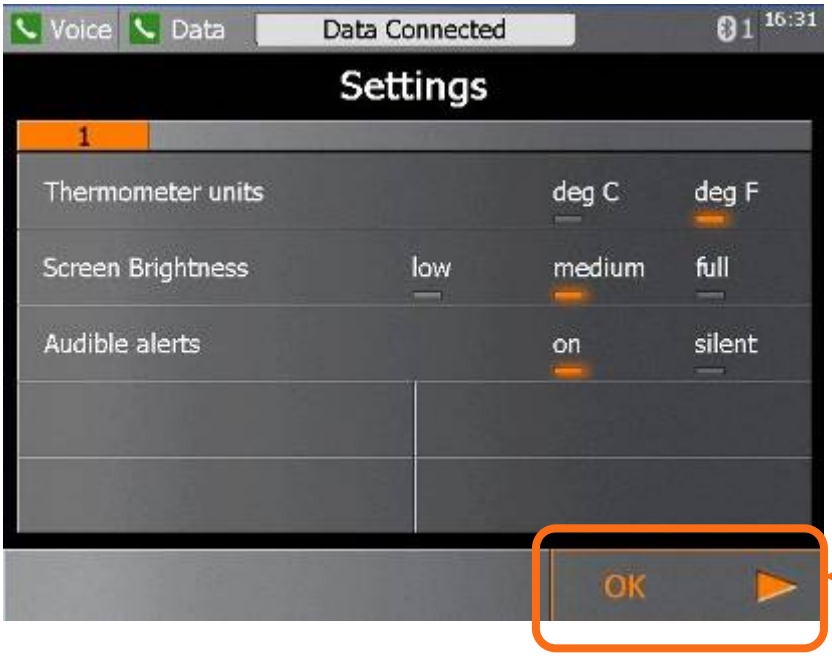
First press the button to bring up the Help Menu. Then to access the Settings menu press **Cleaning and Repacking** touchscreen button followed by pressing the **Settings** touchscreen button.



Press the **Settings** button in the **Cleaning & Repacking Menu** on the touchscreen to bring up the **Settings Menu**.

Press the touchscreen here

Press the **Settings** button in the **Settings Menu** on the touchscreen to bring up the configurable options.



Press the touchscreen here

Press the touchscreen to select the configurable parameters and press **OK** touchscreen button to confirm the changes you have made.

13 Specifications and Standards

13.1 Specifications

Note that all figures quoted are based on room temperature, pressure and humidity unless otherwise stated.

13.1.1 Non-invasive Blood Pressure

13.1.1.1 Adult cuff and Large Adult cuff ratings

Systolic	60 - 250 mmHg
Diastolic	40 - 220 mmHg
Range	0 - 330 mmHg
Accuracy	± 3mmHg or ± 2% (whichever is greater)
Resolution	1 mmHg
Maximum inflation	330mmHg

13.1.1.2 Child cuff ratings

Systolic	60 - 250 mmHg
Diastolic	40 - 220 mmHg
Range	0 - 330 mmHg
Accuracy	± 3mmHg or ± 2% (whichever is greater)
Resolution	1 mmHg
Maximum inflation	330mmHg

13.1.2 ECG Recorder

ECG Specifications	
Gain/Sensitivity	5, 10, 20 mm/mV
Input Range	±6mV
Acquisition sample rate	1000 samples per second (compressed to 500Hz with peak picking and averaging algorithm)
Frequency response	0.05 to 175Hz ±3dB
Defibrillator protection	Patient leads are isolated from system and operator, with 4kV protection
Common Mode Rejection	-60dB (minimum)
Safety Standards	Complies with AAMI EC11, EN60601-1, EN601-1-2, and EN601-2-25
Leads Off Indicators	Connection status for each lead is shown on Acquisition screen
Permanent Filters	High Pass: 0.05Hz 1st order Low Pass: 170Hz 1st order Baseline Wander: Baseline reset by adaptive zeroing algorithm
Notch filter (Mains Noise Rejection)	50Hz 4th order Butterworth, 49.1Hz - 50.9Hz, 60Hz 4th order Butterworth, 59.1Hz - 60.9Hz
Low pass (Muscle Artifact Filter)	35Hz 4th order

13.1.3 ETC0$_2$ Sensor

Unless otherwise stated, all CO_2 measurements are made following an airway adapter zero, with 5% CO_2 gas, balance N_2 at 25 degrees C, and Pb = 760 mmHg with 2 liters per minute flow. The stabilization time for full specification testing of the LoFlo Module over the entire temperature range is 20 minutes.

Range	0-100 BPM
Accuracy	± 2 BPM
Range	0-10% CO2 displayed value
Accuracy	± 4%
Rise time	<2 seconds
Delay time	5 seconds
Operating altitude range	0-15000 feet

LoFlo sidestream Capnometer - SPECIFICATIONS	
Carbon Dioxide Monitoring:	
Mode of Sampling	Sidestream
Principle of Operation	Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts.
Initialization Time	Capnogram displayed in less than 20 seconds, At an ambient temperature of 25° C, full specifications within 2 minutes.
CO_2 Measurement Range	0 to 150 mmHg 0 to 19.7% 0 to 20 kPa (Barometric Pressure supplied by RDT Ltd)
CO_2 Calculation Method	BTPS (Body Temperature Pressure Saturated)
CO_2 Response Time	<3 seconds - includes transport time and rise time
CO_2 Resolution	0.1 mmHg 0 to 69 mmHg 0.25 mmHg 70 to 150 mmHg
CO_2 Accuracy *	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading Above 80 breath per minute ± 12% of reading * NOTE: Gas temperature at 25° C.
CO_2 Stability	Short Term Drift: Drift over four hours shall not exceed 0.8 mmHg maximum. Long Term Drift: Accuracy specification will be maintained over a 120 hour period.
CO_2 Noise	RMS noise of the sensor shall be less than or equal to 0.25 mmHg at 5% CO_2
Sampling Rate	100 Hz
Respiration Rate	Range 2 to 150 breaths per minute (BPM)

LoFlo sidestream Capnometer - SPECIFICATIONS	
Carbon Dioxide Monitoring:	
Respiration Rate Accuracy	± 1 breath
Calibration	No routine user calibration required. Safety lock-outs: • System does not allow sample cell zero for 20 seconds after the last breath is detected. • System does not allow sample cell zero if temperature is not stable. • An adapter zero cannot be performed if a sample cell is not connected to the module
$ETCO_2$ Calculation	Method: Peak of the expired CO_2 waveform Selections: 1 breath, 10 second, 20 second
Inspired CO_2 Measurement	Range: 3 to 50 mmHg Method: lowest reading of the CO_2 waveform in the previous 20 seconds Selection: 20 seconds (not user-selectable)
Compensations (RDT Ltd Controlled)	Compensations for: Expired O_2, Balance gas (N_2, N_2O, He) and Anesthetic Agents[B] Uses gas compensation information and barometric pressure to correct the raw carbon dioxide value
O_2 Compensation	Range: 0 to 100% Resolution: 1% Default: 16%
N_2O Compensation	Range: 0 (off) or 1 (on) Default: Off Note: If ON, the monitor assumes the balance of the mixture is O_2
He Compensation	Range: 0 (off) or 1 (on) Default: Off Note: If ON, the monitor assumes the balance of the mixture is O_2
Airway Pressure	Range: + 120 cmH_2O (88.27 mmhg) - 45 cmH_2O (33.1 mmHg).

LoFlo sidestream Capnometer - SPECIFICATIONS		
Carbon Dioxide Monitoring:		
Anesthetic Agent Effects (MAC levels)	Anesthetic Agent Sensitivity[A] (uncompensated)	Accuracy specification will be maintained for halogenated anesthetic agents present at accepted MAC (Minimum Alveolar Concentration) clinical levels.
	Anesthetic Agent Sensitivity (compensated)	Testing at Agent levels defined by accepted regulatory standards (i.e. ISO 21647, ASTM F1456, IEC/CDV 60601-2-55) currently in process.
Cross-sensitivity Compensation Error*	0-40 mmHg: ± 1 mmHg additional error 41-70 mmHg: ± 2.5% additional error 71-100 mmHg: ± 4% additional error 101-150 mmHg: ± 5% additional error * Additional worst case error when compensation for Pb, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.	

Gas or Vapor	Halothane	Enflurane	Isoflurane	Desflurane
MAC Level % (v/v)	0.74	1.68	2.00	6.30

(From Olivier C. Wenker: *Review of Currently Used Inhalation Anesthetics: Part I*. The Internet Journal of Anesthesiology, 1999, Volume 3 Number.)

Gas or Vapor	Gas Level	Quantitative Effects
Nitrous oxide	60%	No Additional Effect
Halothane	4%	No Additional Effect
Enflurane	5%	No Additional Effect
Isoflurane	5%	No Additional Effect
Sevoflurane	5%	No Additional Effect
Xenon	80%	Negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg
Helium	50%	No Additional Effect
Metered dose inhaler propellants	Unspecified	Unspecified

Desflurane	15%	Concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.
Ethanol	0. 1%	No Additional Effect
Isopropanol	0.1%	No Additional Effect
Acetone	0.1%	No Additional Effect
Methane	1%	No Additional Effect

(From ISO 21647, Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors, Table 105.)

LoFlo sidestream Capnometer - SPECIFICATIONS	
Physical Characteristics and Host Interface:	
Physical characteristics	Module weight is less than 9.6 oz (272.16 g) Module Size: < 2.6" wide x 1.5" high x 3.5" deep [< 66.0 x 38.1 x 88.9 mm] Cable length – 22 inches (55.88 cm)

LoFlo Sidestream Capnometer - SPECIFICATIONS	
Environmental:	
Temperature and Humidity Operating	0 to 40°C, 10 to 90% RH, non-condensing
Storage	-40 to 70°C, 10 to 90% RH, non-condensing
Atmospheric Pressure Storage	400-800 mmHg
Water Resistance	IPX4 - Splash-proof - Module only (When Sample Cell is inserted into Sample Cell Receptacle)
Shock Impact	IEC TR 60721-4-7 Class 7M3 (designed to withstand environments subject to significant vibrations or high shock levels) EN60068-2-27 Shock EN60068-2-64 Random Vibration
Mechanical:	
Mechanical strength	Cable Strain Relief, resistance to pull-out: Cable strain (bend) relief system for the sensor enclosure shall withstand a pull of 30 pounds without failure to either the cable or the enclosure. Cable Strain Relief, flexibility: The connector strain relief system shallwithstand 10,000 bend cycles.

LoFlo Sidestream Capnometer - SPECIFICATIONS	
	Connector Retention Force: The average retention force of the standardconnector when pulling on the cable shall be 90 Newtons (20 pounds).

13.1.4 $Sp0_2$ Sensor

Range	30-240 bpm
Graphic display range	50-200 bpm
Accuracy	± 3bpm or ±2% whichever is greater
Resolution	1%
Range	50% to 100%
Graphic display range	50-100%
Accuracy	±2% at 70%-100%, ±3% at 50%-69%
Type	Functional saturation (test methods available upon request)
Wavelength range	Red 660nm, infra-red 905nm

13.1.4.1 SpO2 Monitor

%SpO2	Range:	0 – 100% with Extended Micro Power Mode 0 – 100% with Digital Micro Power Mode
	Resolution	1%
	Accuracy:	Adult: ±2 @ 70-100% less than 70% is undefined Neonate: ±3 @ 70-100% SpO2 less than 70% is undefined Arms = 1
	Averaging:	2 (Sleep mode), 4, 8, or 16 pulses (default = 8) The lower the number the more responsive the display.
Pulse Rate	Range:	30 - 254 BPM with Extended Micro Power Mode 25 - 300 BPM with Digital Micro Power Mode
	Resolution	1 BPM
	Accuracy:	greater of ±2 BPM or ±2% Arms = 1
	Averaging:	8 seconds

13.1.5 Environmental Specifications

Altitude	0-4500m (0-15000ft) (can be used at higher physical altitudes provided the local atmosphere is no higher than 4500m, e.g. in a pressurised aircraft cabin)
Relative humidity	15%-95% (non-condensing)
Operating temperature range	0ºC to 40ºC
Storage temperature range	-20ºC to +60ºC
Environmental protection	IPX5), 20G shock

NOTE: Note that the IP sealing has a warranty of 1 year.

NOTE: IP66 and MIL810F tests are lab tests and not normal condition. Unit remains intact and functional after tests but rough handling may degrade performance specification i.e. if you hit it with steel ball then IP sealing around the case may degrade, if you drop it from 1.2m then IP sealing may degrade and a drop tests may damage

peripherals. Drop test performance specifications relate to a standalone device with no cables connected.

13.1.6 Miscellaneous Features and Specifications

Dimensions	H 256mm, W 294mm, D 273mm

13.1.6.1 Mass 7.2kg (without batteries)Rechargeable battery

Battery life	At least 6 hours running in normal use.
Nominal voltage	7.4V
Charging voltage	8.4V ±1%
Nominal capacity	7.8Ah
Weight	0.25kg
Shelf life	Approximately 70% remaining after 1 year (before the charge indicator light turns to Amber)

Battery shelf life and run times are based on a new, fully charged battery stored in normal room ambient conditions. Run time is based on RDT's model of typical device usage in an incident.

13.1.6.2 Battery Charger

Mains input voltage	100-240V
Frequency	50-60Hz
Input current	0.9A
Output voltage	8.4V dc
Output current	<2.7A3A
Charge time (from empty)	6 hours

NOTE: Only the RDT Battery Charger pn 01-1012 can be used with the Tempus IC.

13.1.6.3 Mains Power Supply

Mains input voltage	100-240V
Frequency	50-60Hz
Input current	0.55A
Output voltage	12V dc
Output current	5A

NOTE: Only the Cincon Electronics TR60M12 as supplied by RDT can be used with the Tempus IC.

13.1.7 Communications

13.1.7.1 Transmission rates

ECG data and video images take an appreciable amount of time to send to the Response Centre, approximate times are as follows:

- 12 lead ECG – 2-3 minutes
- Low resolution video image - about half a minute
- High resolution video images – 2-3 minutes.

These times are for guidance only and are based on the worst case communications system (off-aircraft satellite link running at 2.4Kbaud V22BIS) and may vary depending on the quality of the connection.

13.1.7.2 WiFi Specification

The WiFi technology used by the Tempus operates using IEEE 802.11b and 802.11g standard. It operates in the Industrial, Scientific and Medical (ISM) band between 2.412GHz and 2.484Hz.

The WiFi technology has the following features:

WiFi Specification	
SKU #	North America WL6221-668 International WL6227-674
Transmit Power	CCK: 12 dBm typical OFDM: 9 dBm typical 63mW emission designation 11M5F9W to spec RSS210
Indoor Range	~ 300 feet (typical office environment)
Standards Conformance	Wi-Fi Certified Meets 802.1x requirements WPA2-Enterprise IEEE 802.11b and 802.11g
Certification/ Compliance	FCC: Part 15, Class C FCC ID LUBP300SD-1 Industry Canada license 2529A-WLANSDIO
Data Rate:	**802.11g:** Data rate dynamically shifts between 54, 48, 36, 24, 18, 12, 9 and 6 Mbps based on signal strength, for maximum availability and reliability of connection. OFDM with BPSK, QPSK, 16-QAM and 54-QAM (at 6/9, 12/18, 24/36, and 48/54 Mbps, respectively) **802.11b:** Data rate dynamically shifts between 11, 5, 5M, 2M, and 1 Mbps based on signal strength, for maximum availability and reliability of connection. (802.11g: DSSS with BPSK, QPSK, and CCK (at 1,2, and 5.5/11 Mbps, respectively)
Frequency Range:	**North America:** 2.412-2.462 GHz, channels 1-11 **Europe ETSI:** 2.412-2.472 GHz, channels 1-13 **Japan**: 2.412-2.484 GHz, channels 1-14
Security Encryption/Authentication Hardware Support:	WEP: Open and Shared WPA-PSK, WPA2-PSK (Personal): TKIP and AES-CCMP encryption WPA-E, WPA2-E (Enterprise): TKIP, AES-CCMP, and all EAP authentication processes including LEAP, EAP-TLS, EAP-FAST, PEAP 0 (PEAPMSCHAP), PEAP 1 (PEAP-GTC) and EAP-TTLS − Wi-Fi Multimedia (WMM), a standard for Quality of Service (QoS)

13.1.7.3 Bluetooth Specification

Bluetooth Specification		
Description	Specification	Note
Operating frequency range	(2400 ... 2483,5) MHz	ISM Band
Range	Class 1, range up to 300 meters	

Lower guard band	2 MHz		
Upper guard band	3,5 MHz		
Carrier frequency	2402 MHz ... 2480 MHz		f = 2402 + k, k = 0...78
Modulation method	GFSK (1 Mbps) P/4 DQPSK (2Mbps)		
Hopping	1600 hops/s, 1 MHz channel space		
Maximum data rate	GFSK:	Asynchronous, 723.2 kbps / 57.6 kbps Synchronous: 433.9 kbps / 433.9 kbps	
	P/4 DQPSK:	Asynchronous, 1448.5 kbps / 115.2 kbps Synchronous: 869.7 kbps / 869.7 kbps	
	8DQPSK:	Asynchronous, 2178.1 kbps / 177.2 kbps Synchronous: 1306.9 kbps / 1306.9 kbps	
Receiving signal range	-82 to -20 dBm		Typical condition
Receiver IF frequency	1.5 MHz		Center requency
Transmission power	Min	-11 ... -9 dBm	
	Max	+14 ... +18 dBm	
	RSS210	22mW emission designation 1M21G2D	
RF input impedance	50Ω		
Compliance	Bluetooth specification, version 2.0 + EDR		
Certification/ Compliance	FCC: Part 15, FCC ID QOQWT11 Industry Canada license 5123A-BGTWT11E		

13.1.7.4 Bluetooth Headset Specification

The TempusIC uses the Bluetrek G3 wireless headset. This is unmodified by RDT and is provided under FCC ID QITBTG3 under FCC part 15C and under AusCom approval N1342

It operates in the frequency bands 2402MHz – 2480MHz and has a maximum power of 0.00297W.

Wireless Performance Specifications		
Description	**Transmitter**	**Receiver**
Operating frequency range	2402 - 2480 MHz	2402 - 2480 MHz
Type of modulation	FHSS modulation	FHSS modulation
Number of channels	79	79
Channel separation	1MHz	1MHz
Type of antenna	Ceramic type	
Antenna gain	(dBi) 0	
Power level	Fixed	

Description	**General Specifications**
Bluetooth type	V1.2 class 2
Range	10m max (open field)
Weight	12g
Size	67.5mm x 19.5mm
Talk time	Up to 13 hours*
Stand by time	Up to 400 hours*

*Based on the manufacturer's specification – can be 12.5 hours in HV3, 10 hours in HV2 and 5.3 hours in HV1 modes (HV level set by host device).

13.1.7.5 FCC & Industry Canada Notes on Wireless Communications

FCC ID: ROSTEMPUSIC

CAUTION: Do not disassemble the device. There are no user-serviceable parts inside. Refer servicing to the manufacturer. Changes or modifications not expressly approved by RDT could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules and Industry Canada Radio Standard RSS 210. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause interference and
- This device must accept any interference, including interference that may cause undesired operation of the device.

This equipment is also ETS 300 328, ETS 300 826, ETS 300 328-2, ETS EN301 489-1 and ETS EN301 489-17 compliant. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

The user may find the following booklet helpful: *How to Identify and Resolve Radio-TV Interference Problems.* This booklet is available from U.S. Government Printing Office, Washington, D.C. 20402.

Radio Frequency Interference Requirements – Canada
This Class B digital apparatus meets the requirements of the Canadian Interference-Causing Equipment Regulations.

13.1.7.6 Ethernet Specification

The Ethernet connection has the following specifications:

- IEEE 802.3 compliant

- RJ-45 connection
- DHCP or fixed IP, Mask, Gateway and DNS
- Optional Type of Service setting
- Protocol: TCP Port 2167
- Network diameter: at least 100m

13.1.8 Classification

The system is classified according to the requirements of EN60601-1:1990 inc. A13:1996, the standard for Medical Electrical Equipment, Part 1, General Requirements for Safety, Clause 5 as:

5.1 The Tempus IC is Internally (battery) powered – when powered by an external power supply it is class II as defined by the classification labelled on the power supply specified and supplied by RDT.
5.2 Applied parts type CF defibrillator proof (ECG electrodes), type BF defibrillator proof (capnometer cannula, pulse oximeter probe, non-invasive blood pressure cuff) and type BF (thermometer).
5.3 IPX5, protected against rainfall according to IEC529 (with the display closed)
5.4 No parts supplied sterile or suitable for/requiring sterilising
5.5 Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
5.6 Suitable for continuous use (8 hours maximum before the battery will require replacement).

13.1.9 Standards Compliance

The Tempus IC complies with the applicable parts of the following standards:

- IEC/EN60601-1:1990 inc. amendment A2:1995 and A13:1996, general requirements for the safety of electrical medical products
- IEC/EN60601-1-2:2001, collateral requirements for electromagnetic compatibility, requirements and tests
- IEC 60601-1-4, First edition, 1996 Collateral standard: programmable electrical medical systems (software)
- IEC 60601-2-27, First edition, 1994 Particular requirements for electrocardiographic monitoring equipment
- IEC 60601-2-30, First edition, 1995 Particular requirements for automatic cycling indirect blood pressure monitoring equipment
- ISO 9918, First edition, 1993 Particular requirements for capnometers for use with humans
- ISO 9919, First edition, 1992 Particular requirements for pulse oximeters for medical use
- RTCA/DO-160D/E Environmental conditions and test procedures for airborne equipment
- EN60529:1992 Degrees of protection provided by enclosures (approved to IPX1)
- BS2G 239:1992 Specification for Primary active lithium batteries for use in aircraft
- 3GPP TS 51.010-1 Digital cellular telecommunications system (Phase 2+); Mobile Station (MS) conformance specification; Part 1: Conformance specification
- ETSI EN 301 489-1 V1.4.1 (2002-08) Electromagnetic compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements.
- ETSI EN 301 489-7 V1.2.1 (2002-08) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 7: Specific conditions for mobile and portable radio and ancillary equipment of digital cellular radio telecommunications systems (GSM and DCS).
- ANSI C63.4:2001 Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz - as required by the US CFR 47 Part 15 B & C (FCC requirements for intentional transmitters).

- ETSI EN 300 328 V1.4.1 (2003-04) Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive
- ETSI EN 301 489-17 V1.2.1 (2002-08) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for 2,4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment
- ETSI EN 301 511 V7.0.1 (2000-12) Global System for Mobile communications (GSM); Harmonized standard for mobile stations in the GSM 900 and DCS 1800 bands covering essential requirements under article 3.2 of the R&TTE directive (1999/5/EC)
- ETSI EN 300 328 V1.6.1 – Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive.
- ETSI EN 301 489-17 V 1.5.1 (2004-11) – Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific Conditions for 2.4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment.
- EN 301 489-17 v1.11 (2000-09) Specified Conditions for Wideband Data and HIPERLAN Equipment
- EN61000-4-2 – Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment, Part 2: Electrostatic Discharge Requirements.
- EN61000-4-3 – Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment, Part 3: Radiated Electromagnetic Field Requirements.
- ANSI C95.1 Safety Levels with Respect to Human Exposure to RF Electromagnetic Fields 300 KHz to 300 GHz
- EN 55022:1998+A Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement
- EN 55022:2000+A3 Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement
- EN 55022:2003 Class B Limits and Methods of Measurement of Radio Interference Characteristics Information Technology Equipment.
- EN 61000-3-2:2001 Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)
- EN 61000-3-3:1995 A1:2001 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current up to and including 16 A
- EN 61000-4-3:2002 **Incorporating Amendments Nos. 1 and 2 - Electromagnetic compatibility (EMC) -Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test**
- EN 61000-4-4:1995 A1:2000 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical Fast Transient/Burst Immunity Test
- EN 61000-4-5:1995 A1:2000 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
- EN 61000-4-6:1996 A1:2000 Immunity to Conducted Disturbances, Induced by Radio Frequency Fields
- EN 61000-4-11:1994 A1:2000 Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests

13.1.10 Other Standards Being Used for Reference Purposes

The following standard is used for reference in the design of the Tempus IC:

- IEC/EN60945:1997 Maritime navigational equipment - General requirements - Method of testing and required test results

13.1.11 Cable Length of the Sensors and the Accessories

	RDT Part Number	Cable Length (typ.)	Tested Length
Ethernet cable	01-1021	2.1m	2.1m
SpO2 sensor	01-1008	1.5m	1.5m
ECG harness	01-1010	1.5m	1.5m
Capnometer	01-1005	0.5m	0.5m
Wired headset	01-1019	1.2m	1.2m
Mains Power supply	01-1017	0.45m	0.45m
Mains lead	01-10@@	2m	2m

Warning! The use of longer cable lengths may cause an increased emission or a reduced interference resistance. The use of other sensors or cables except the ones mentioned above is not allowed.

13.1.12 Manufacturer's Declaration - Electromagnetic Emissions (Tab. 201 according to DIN EN 60601-1-2)

The Tempus IC is intended for use in an electromagnetic environment as described below. The customer or user of the device should ensure that the device is used in such an environment.

Emission Measurements	Compliance	Electromagnetic Environment
HF emissions acc. to CISPR11	Group 2	The Tempus IC must emit RF energy in order to perform its function. Nearby electronic devices may be affected. Note that the Tempus IC can be configured for not to emit RF energy in which case it will be group 1 and will not be likely to cause any interference in nearby electronic equipment.
HF emissions acc. to CISPR11	Class B	The Tempus IC is intended for use in all facilities including living quarters and such ones which are connected directly to a public power supply that supplies also buildings used for living purposes.
Emission of overtones acc. to IEC61000-3-2	Class A	
Emission of voltage fluctuation/flicker acc. to IEC61000-3-3	Complies	

13.1.13 Manufacturer's Declaration - Electromagnetic Emissions (Tab. 202 according to DIN EN 60601-1-2)

The Tempus IC is intended for use in an electromagnetic environment as described below. The customer or user of the device should ensure that the device is used in such an environment.

Interference Resistance Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment -

			Guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative air humidity must have 30 % at least.
Fast transient electric disturbances / bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 1 kV for input and output lines	The quality of the supply voltage should conform to a typical business or clinic environment.
Surge voltage acc. to IEC 6100-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV normal mode voltage ± 2 kV common mode voltage	Mains power should be that of a typical hospital or commercial environment.
Voltage drops, short interruptions and variations in supply voltage acc. to IEC 61000-4-11	< 5 % U_T (>95 % break of U_T for 0,5 period 40 % U_T (60% break of U_T) for 5 periods 70 % U_T (30% break of U_T) for 25 periods < 5 % U_T (>95 % break of U_T for 5 seconds	< 5 % U_T (>95 % break of U_T for 0,5 period 40 % U_T (60% break of U_T) for 5 periods 70 % U_T (30% break of U_T) for 25 periods < 5 % U_T (>95 % break of U_T for 5 seconds	Mains power should be that of a typical hospital or commercial environment. If the user of the Tempus IC requires continued operation during power interruptions then the battery may be used for periods up to 6 hours or a UPS may be used.
Magnetic field at the supply frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the supply frequency should conform to the typical values as they occur in the business or clinic environment.
NOTE U_T is the AC mains voltage before the use of testing levels			

13.1.14 Manufacturer's Declaration - Electromagnetic Interference Resistance (Tab. 204 according to DIN EN 60601-1-2)

The Tempus IC is intended for use in an electromagnetic environment as described below. The customer or user of the device should ensure that the device is used in such an environment.

Interference Resistance Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidelines**
Conducted RF disturbances acc. toIEC61000-4-6 Radiated RF disturbances acc. to IEC61000-4-3	3 Vrms 150 KHz to 80 Mhz 3 V/m 80 MHz to 2,5 GHz	3Vrms 3Vrms	Portable and mobile RF communications equipment should be used no closer to the device including the cables than it is recommended by the equation for the frequency. Recommended safety distance: $d = 1.2\sqrt{P}$

			d = 1.2√P for 80MHz to 800 MHz d = 2.3√P for 800 MHz to 2,5 GHz P is the nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer; d is the recommended safety distance in meters (m). The field strength of stationary transmitters should be lower than the Compliance level for all frequencies according to a testing on location. Disturbances are possible near devices with the following symbol: 
NOTE 1: For 80 Hz and 800 MHz the higher frequency range is valid.			
NOTE 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.			
a) The field strength of stationary transmitters such as fixed parts of cellular phones and mobile radio sets, amateur radio stations, AM and FM radio and television cannot be determined exactly in theory. To detect the electromagnetic environment in regard to stationary transmitters a study of the location should be considered. If the measured field strength at the location where the device is being used exceeds the Compliance level above the device should be watched to verify the proper functions. If unusual features are watched additional actions might be necessary such as a modified orientation or another location of the device. b) For the frequency range of 150 kHz to 80 MHz the field strength should be lower than 10 V/m.			

13.1.15 Recommended Safety Distances between portable and mobile RF Telecommunication Devices and the TEMPUS IC (Tab. 206 according to DIN EN 60601-1-2)

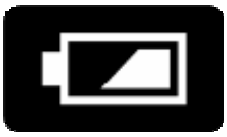
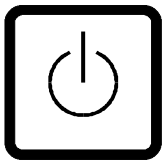
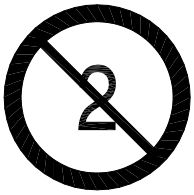
The TEMPUS IC is intended for use in an electromagnetic environment with controlled RF disturbances. The user of the device can help to avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile telecommunication devices (transmitters) and the device - depending on the output power of the telecommunication devices as described below.

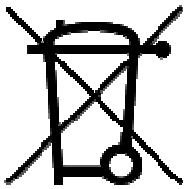
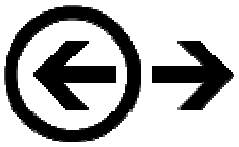
	Safety Distance Depending on the Frequency in m		
Nominal power of the transmitter W	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2,5 GHz d = 2.6√P
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters with a maximum nominal power not mentioned above: To detect the recommended safety distance use the equitation in the corresponding column. P is the maximum nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer.			

NOTE 1: For 80 Hz and 800 MHz the higher frequency range is valid.
NOTE 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.

14 Symbols Used on the Tempus IC

The following symbols are used on the Tempus IC:

Symbol	Description
	Defibrillation proof type CF applied part, The ECG electrodes are floating from earth and meet the patient leakage current requirements of EN60601-1:1990 Inc A13:1996 for type CF applied parts. The ECG electrodes are proof against the effects of a cardiac defibrillator discharge.
	Attention, consult accompanying documents
	Battery Charge indicator – flashes green when the battery is on charge
	Battery power level
	System power on/off (push/push)
 YYYY - MM	Date of manufacture, where the year that the item was manufactured is represented by the year and then the month e.g. 2002 06 is June 2002.
	Single use device only, discard item after use
IPX5	The device is proof against a hose according to IEC529
CE 0473	The device has been declared by the manufacturer to be in accordance with the requirements of the European Union Medical Devices Directive 93/42/EEC as transposed by UK national legislation.

Symbol	Description
	Shelf life, where the time that the unit must be used by is represented by the year and then the month e.g. 2004 06 is June 2004.
LOT **YYYY - MM**	Where the year that the item was manufactured as a part of a larger batch is represented by the year and then the month e.g. 2002 06 is June 2002.
	This product should not be discarded as general waste and must be disposed of as electrical and electronic waste.
	Communications connections
	WiFi connection mode to response centre
	Bluetooth connection to medical modules
	Battery Connection – to indicate positive terminal polarity
	Global Positioning System (GPS) -

Symbol	Description
	Global System for Mobile (GSM) communications
	Headset connector
	Power Status (green indicates mains power is connected)
	Camera Backlight
	Device contains wireless transmitters
	DC connector

15 Software License Agreements

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