Tempus IC

User/Operator Manual

Part number 41-1001

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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 with RDT 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

Information contained in this document is copyright © 2009 by Remote Diagnostic Technologies Limited ('RDT') and may not be reproduced in full or in part by any means or in any form by any person without prior written permission from RDT.

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. RDT reserves the right to change specifications without notice.

Tempus IC™, i2i™ and TempusNET™ are all trademarks of RDT.

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

BodyTel® and GlucoTel® are protected by registered trademarks and trademark applications of BodyTel Europe Gmbh.

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

The **Tempus IC** remote patient monitor has been tested and approved to IEC/EN60601-1-2:2007. This means that the **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, the **Tempus IC** has been tested according to the requirements of RTCA DO160-E section 21 category M.

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

2.2 Indications for Use

The **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.

The **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.

The **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.

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

2.3 Contraindications

The **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.

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

The **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.

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

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

The **Tempus IC** is not intended to be a long-term monitor; it is only intended to be used in short, discrete incidents where the immediate health of the patient is in question.

The **Tempus IC** is not intended to, and does not sound alarms for physiological parameters.

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: The use of the  symbol indicates that the user must read the user manual before using the product.

WARNING: Only connect Tempus IC to IT and communications systems which are compliant with the relevant IEC standard e.g. IEC60950. Signal input and output connectors are only for connection to equipment complying with relevant IEC safety standards and must be configured to comply with IEC60601-1-1.

WARNING: The user should not touch the patient at the same time as touching accessible conductive parts of the Tempus e.g. connectors.

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

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

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

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

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

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

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

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 use different types of batteries which includes rechargeable and non-rechargeable types. If any battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly. 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 m 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:

Example of a PC display with no interference

Example of a PC display with interference

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter except as defined in the FCC filing

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 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: 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 with 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

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. Only use hoses provided by RDT.

CAUTION: Incorrectly sized cuffs may cause measurement inaccuracy or errors.

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

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

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

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

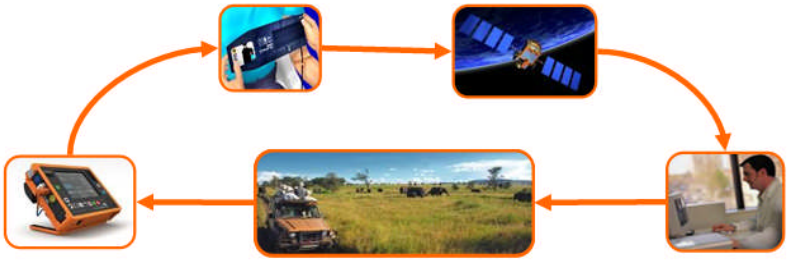
CAUTION: Petechia (a minute reddish or purplish spot containing blood that appears in the skin) formation or Rumple-Leede phenomenon (multiple Petechia) on the forearm following the application of the cuff, which may lead to Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of 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 the **Tempus IC** screen is simultaneously seen at 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

The **Tempus IC** sends all of its measurements and displays via the telephone connection to the response centre, where the displays are duplicated. The medical expert at the Response Centre 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 the **Tempus IC**, giving added comfort to both the user and patient.

4 Introduction to the Tempus IC

4.1 Tempus IC Device

The **Tempus IC** is a multi-parameter 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 the **Tempus IC** as a stand-alone diagnostic device (without it being connected to the Response Centre).

The **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 a communications link to a computer at a response centre which enables the physician to see all the vital signs data.

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

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

The **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 the **Tempus IC** has a large screen which is fitted with a touch-screen.

The front panel houses two keypads which are graphically labelled with their function. Also present is a jog wheel which can be used to scroll through instructions.

4.1.2 Tempus IC Base

The base of the **Tempus IC** houses the battery.

4.1.3 Tempus IC Rear

The rear of the **Tempus IC** houses the RapidPak™ 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 device contains four connectors for:

- ECG - blue,
- NIBP – white latching connector;
- SpO_2 – orange;
- $ETCO_2$. – yellow.

Normally the NIBP and SpO_2 connectors will have their mating half attached at all times.

Left Side of the Tempus

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

- USB – this is reserved **ONLY** for non-mains powered USB peripherals (such as mouse and keyboards) approved for use with the Tempus IC by RDT. It is also for use with the USB - Serial Cable (part number 01-1022) for customers using Iridium or other serial satcoms systems.

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

- RJ-45 Ethernet – use only the Ethernet Cable pn 01-1021 or Dual Modem Cable pn 01-1014 supplied by RDT
- Power – use only the Cincon TR60M12 power supply pn 01-1017 provided by RDT
- Audio – this is only for use with the Wired Headset pn 01-1019 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

The **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.

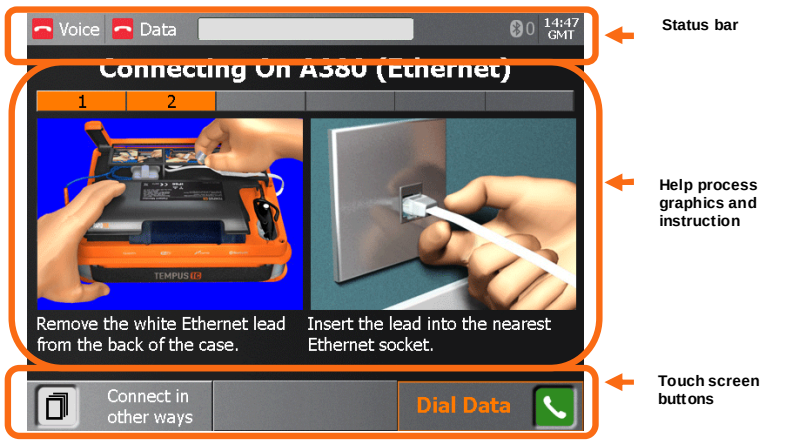
5.1.1.1 Layout of Instructions on the Tempus IC

The **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 the **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.

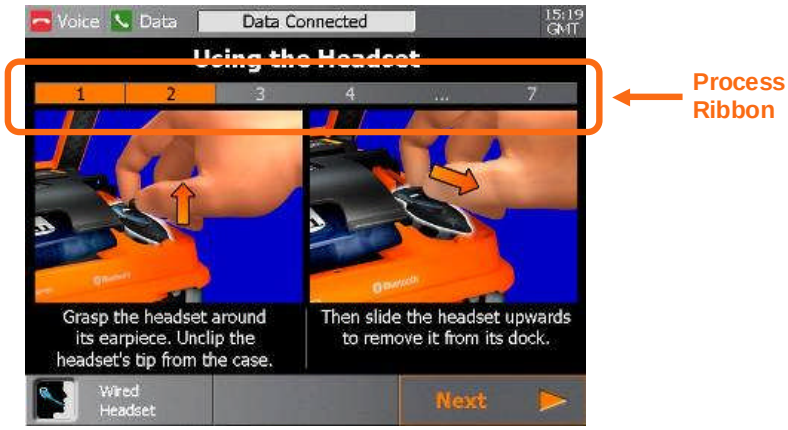


Example of the **Tempus IC** Screen Layout

5.1.1.2 Progressing through Help Processes

As mentioned above, the **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

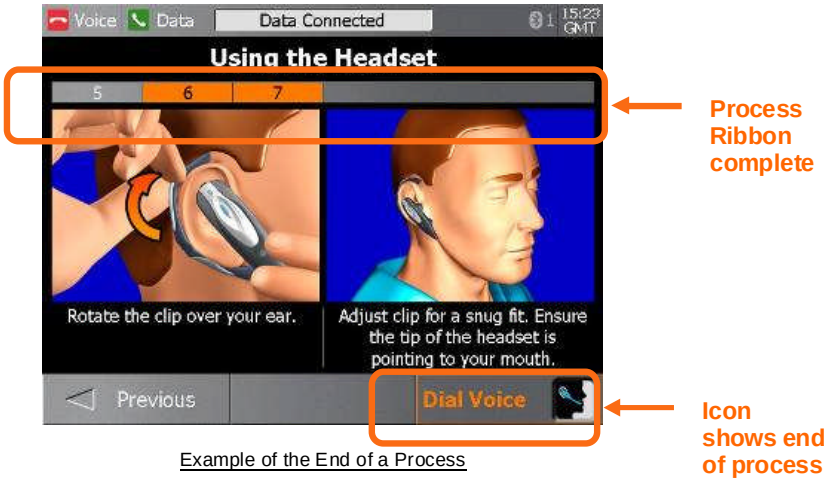
In the example shown above, the screen shows that the process has 6 steps and that the device is showing steps 1-2.

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 the **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

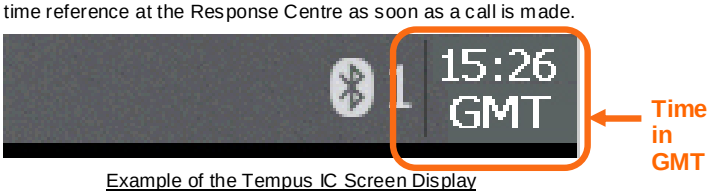
Tempus IC screen normally divides into two sections:

- 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.



Example of the Tempus IC Screen Display

5.2.2 Status Bar – Bluetooth® Indicator

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

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

Bluetooth® Peripheral Indicator

5.2.3 Status Bar - WiFi Indicator

WiFi Status Indicator

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

5.2.4 Status Bar – GSM/GPRS Indicator

GSM Status Indicator

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

- Note that the display shows 5 coloured bars under the GSM symbol.
- A single red bar means that a GSM or GPRS network is present but the signal strength is not sufficient to support a data connection
- Two orange bars means that a data connection can be made but that the performance may be impaired.
- Three to five green bars means that the signal strength is sufficient for a data connection.

NOTE: The **Tempus IC** uses GSM and GPRS networks to make a data connection. This requires the network signal strength to be better than is required for a conventional GSM handset (which makes a voice only connection). Users should note that the signal strength readouts from the Tempus are not comparable to those of third-party handsets as the scale, setting, sensitivity and networks between the two devices may be different.

5.2.5 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 three 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 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.

- 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 the **Tempus IC** is automatically time-stamped.

5.2.6 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 10.3)

Additionally, further informative Status messages may appear during readings (e.g. press 'STOP' on the touch screen to 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

All of the measurements made by the **Tempus IC** are transmitted in real time except the ECG (and digital pictures) which is first recorded and then transmitted to the Response Centre.

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

- 12 lead ECG – 2-3 minutes*
- Digital picture – up to 1 minute

* 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. Higher bandwidth connections (e.g. using Inmarsat Swift 64, Fleet 77, B-GAN or Swift Broadband) will provide lower transmission times.

5.3.1 Pulse Rate and Oxygen Saturation (SpO_2)

Pulse rate and oxygen saturation are detected by a 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. 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 bag. 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.

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 non-intubated adult patients. The Capnometer CO_2 module is used for the continuous measurement of CO_2 (carbon dioxide) and respiratory rate.

The capnometer uses a Sidestream sampling system with a 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 module which draws the sample through a measuring chamber.

In the 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 partial pressure in millimetres of mercury (mmHg). Respiration rate is calculated by measuring the time interval between detected breaths.

5.4 Digital Camera

A miniature digital camera is mounted in the unit. 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.

Still images require as much as 1 minute to transmit on a low-speed (2k5baud) link. Links with greater bandwidth will transmit the picture in less time.

5.5 Voice and Data Communications

The Tempus IC can connect over either modem connections, over serial channels and over wired or wireless (WiFi) Ethernet networks. The Tempus IC will be pre-configured by RDT to operate over the user's network.

NOTE: RDT recommends that users perform a test connection to the response centre every month in order to verify that their communications remain open for the Tempus to use.

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.

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

6.2 Tempus IC Bag

The **Tempus IC** bag is a custom design part made from moulded rubber. It is provided with a shoulder strap and carry handle.

The bag provides a main storage area for the **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.

Each bag contains the following items:

- 1 **Tempus IC** fully packed including battery, Adult BP cuff and hose, SpO2 probe and Ethernet cable
- 1 Vial of Glucometer Strips*
- 1 ECG spray
- 5 AlcoWipes
- 5 Nail varnish wipes
- 1 pack of 10 thermometer covers with application tool*
- 1 pack of 3 glucometer lancets*
- 1 Bluetrek® Thermometer*
- 1 Bluetrek® Glucometer*
- 1 pack of Vinyl Gloves (pair)
- 2 Extension Reels**
- 1 Wired Headset
- 1 Consumables Replenishment kit
- 1 Glucometer Replenishment kit
- 1 Lo-Flo® Capnometer
- 2 Capnometer Cannula - Adult Nasal
- 1 Blood Pressure Cuff – Large Adult
- 1 Blood Pressure Cuff – Child
- 1 Dual Modem Cable
- 1 Ethernet Cable to Modem Adaptor ***
- 1 USB - Serial Cable***

* Note: that Tempus IC will initially be shipped with Glucometer and Thermometers that are ready for use but disabled in software. They will be enabled for use by a future software upgrade. The thermometer and glucometer will not be operable until the software upgrade has been performed.

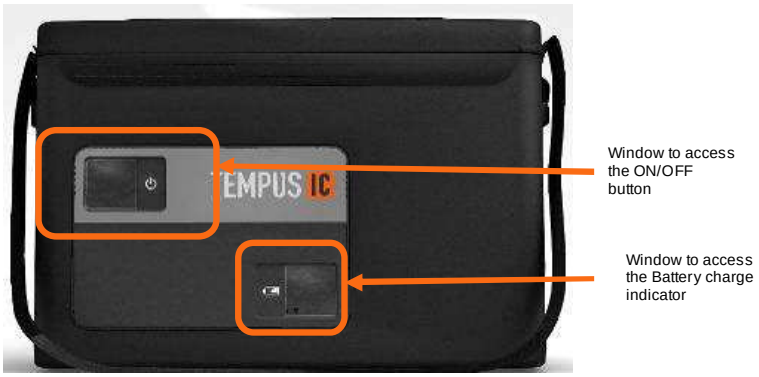
** Note: non-commercial aviation users who do not use Iridium satcoms systems are provided with a single extension reel.

*** Note: not supplied to commercial aviation customers

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

In addition, the **Tempus IC** is supplied with the following accessories which are not packaged in the Bag:

- 1 Mains Power Supply
- 1 Mains Cable Pack
- 1 Battery Charger
- 1 spare battery
- 1 Accessory Pouch (note this is only supplied to commercial aviation customers)
- 1 User manual (CD-ROM)



The **Tempus IC** Bag

The Bag open with the Tempus IC removed

6.3 Switching On

6.3.1 Immediately after Switching On

Note

The **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 the **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. The device is ready for use when the LED shines green constantly. If no buttons are pressed within 8 minutes, the unit will switch off automatically to save battery power.

CAUTION: Do not press any of the 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 connection
- Using the headset and making a voice connection
- Transmitting a digital picture
- 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

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 device 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.

The **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 Making the Phone Connection

Press the  button on the touch screen to get instructions on how to setup and connect the data connection. Note that these instructions will appear by default every time you turn the unit on.

When you have followed the instructions and have pressed the  button, the *Wireless Headset* screen will appear.

Dialling the Data Connection

If the Response Centre cannot be contacted, this could be due to errors in the way that the connection has been attempted (see section 10.3 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.

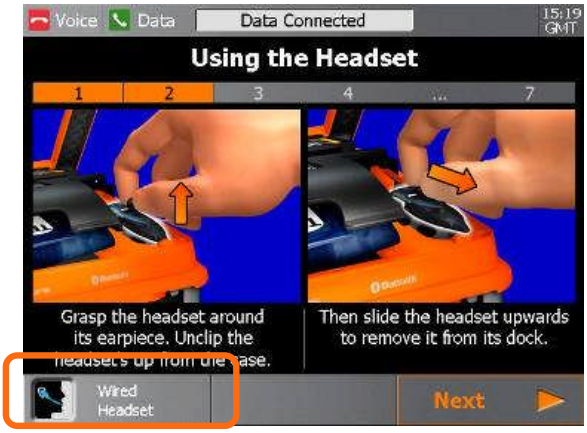
If your Tempus has been configured for automatic redialling, then it will attempt to connect to the Response Centre if the first call fails. The system will indicate the redial process by displaying a number over the Data Link status indicator. The system will attempt a number of redials (typically 3), and will display the corresponding number over the Data Link status indicator bar.

7.2 Fitting the Headset and Making the Voice Connection

After dialling the data link the device will by default bring up instructions to fit the wireless headset. Follow the onscreen instructions and at the end of the process press the  button on screen to dial the voice link.

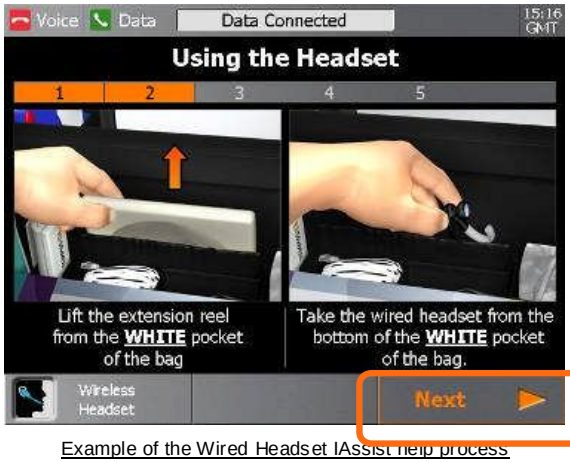
It is important to have attached the headset before dialling as the voice connection to the response centre can be made quickly.

Remember that often the voice connection will be made over a satellite link so you may experience background noise or drop-outs. RDT recommends that you adopt a process of only one person speaking on the line at a time and then handing over to the other speaker by saying "over" or similar.



Example of the Wireless Headset IAssist help process

NOTE: If you do not wish to use the wireless headset, a wired headset is provided in the bag as an alternative. To switch to the wired headset press the  button on the touch screen as identified in the above screen and follow the on-screen instructions showing you how to use it.



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.

7.2.1 Using the Wireless Headset

The Tempus IC uses the G3 headset provided by Bluetrek®. Note that the headset will be supplied in a charged state and its charge level is automatically maintained so long as it is regularly docked on the charging pin on the back of the device.

It should also be noted that the G3 is a Bluetrek® wireless device. It is supplied "paired" with the Tempus IC. You cannot use different wireless headsets with the Tempus IC and RDT recommends that you do not attempt to use the G3 supplied with the Tempus IC with any other wireless devices (including other Tempus ICs or other communications devices such as mobile phones).

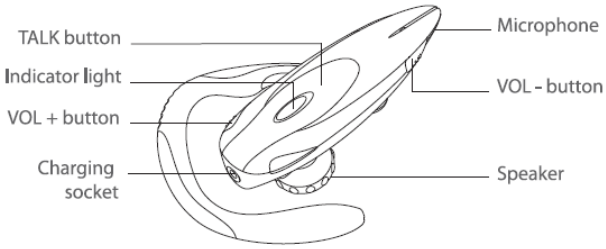
Each G3 is "paired" to only the Tempus IC to which it is attached on delivery. While attaching the G3 to other Tempus IC units will not cause any damage, users should avoid this practise as it may cause confusion and ultimately prevent voice calls from being made when needed.

If the G3 is lost or is damaged, contact RDT for a replacement.

7.2.1.1 Introduction

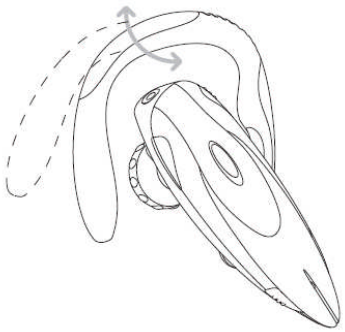
The headset has 3 buttons:

- TALK
- VOL +
- VOL –



7.2.1.1.1 Wearing the Headset

To put the headset on, follow the instructions given on screen. Note that the ear clamp is made from soft material. It can be flexed and shaped to fit your ear. You should ensure the speaker is properly inserted into your ear.



7.2.1.1.2 Controlling the Wireless Headset

To turn the headset on, remove it from its dock and press and hold the talk button for 2-3 seconds until the blue indicator light is on. A beep (2 tones) can be heard in the speaker. Release the talk button as soon as the headset is on.

NOTE: If you keep the talk button held down after the headset is on, you can put the headset into pairing mode. This is not desirable as it could potentially cause the headset to cease being paired with the Tempus IC and thus prevent it from operating with the device. Airing mode can be recognised by the indicator light slowly flashing red and then blue. If the headset is inadvertently put into pairing mode it should be placed back onto the docking pin on the Tempus to turn the headset off; the voice call should be disconnected and re-initiated.

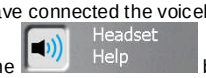
You can check if your headset is on by pressing the talk button once. If the indicator light flashes blue then this means the unit is on.

You do not need to switch the headset off, this is achieved by docking the headset back onto the Tempus IC. If you do wish to turn the headset off, press and hold the talk button for 5 seconds until the indicator light first flashes blue and then goes red.

NOTE: If you turn the headset off during a call, you will not be able to receive the call again with the headset i.e. if you turn the headset back on you will not hear the call again. If the headset is turned off during a call, disconnect the call using the Tempus IC and then re-initiate the connection again following the on-screen instructions.

To adjust the volume during a call, press the “vol+” button or “vol-“ button on the headset.

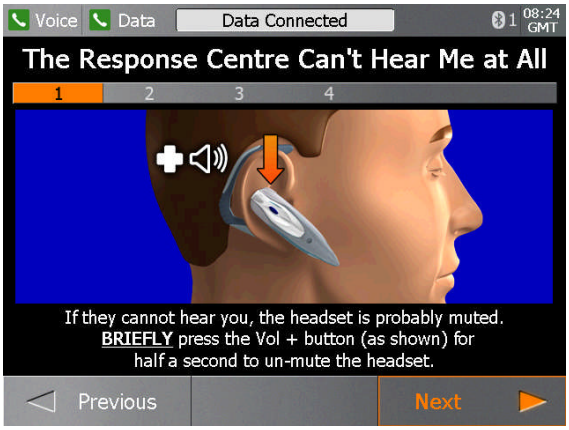
NOTE: If you press and hold the “vol+” button for 2 seconds you will mute the headset. A periodic tone can be heard in the speaker when the microphone is muted. To release muting, quickly press the “vol+” button on the headset. RDT does not recommend that you use the muting function as this could cause confusion during a call.

If you need to adjust the volume of the headset of the wireless headset (the wired headset has no volume controls) after you have connected the voicelink, you can get instructions on how to adjust the volume by pressing the 

button. This is shown the first time you go into the camera iAssist process and the first time you go into the blood pressure and pulse oximetry process after switching on. You can also access the same instructions by pressing the Headset button on the main help menu after you have connected the voicelink.

Headset Help Button

Pressing the Headset Help button will bring up an iAssist process. This contains four different steps, each of which gives instructions on addressing a different type of issue e.g. you can't hear the response centre, they can't hear you etc.



iAssist Process for Adjusting the Wireless Headset's Volume

7.2.1.1.3 Charging

RDT do not supply a separate charger for the headset. The charger is built into the Tempus IC.

You must follow the repacking instructions provided by the Tempus IC on screen. These will instruct you to clean the headset after use and to replace it on its docking pin before shutting down.

If you do not replace the headset then the Tempus will show an error advising that the headset should be refitted.

Placing the headset onto the docking pin enables the Tempus IC to recharge it. The Tempus IC recharges the headset for up to 4 hours 30 minutes (apx) every time the headset is replaced. The charging cycle will continue regardless if the Tempus IC is switched on or off. Charging is started as soon as the headset is fitted to the docking pin. The indicator light on the headset will light red for the duration of the charging process although it may switch off intermittently for 8 second periods (this is part of the charging process). The indicator light will go off when charging is complete – which could be less than the 4 hour 30 minute maximum cycle time depending on how depleted the headset battery is.

In addition, the Tempus IC will top up the charge of the headset approximately every 97 days. This occurs when the Tempus is switched off and lasts for up to 4 hours 30 minutes (apx).

The Tempus IC will not recharge the headset battery if the main battery is nearly empty (less than 5% charge).

Caution: Do not attempt to charge the headset using any other charging device. This will automatically suspend the warranty and could be dangerous.

Note: The headset has a life of up to 500 charge cycles.

7.2.1.1.4 General Guidelines for Safe Use

- Do not drop or try to alter the shape of your headset.
- Do not expose the headset to liquid or moisture. Unlike the Tempus, the headset has no protection against ingress of solids or liquids.
- Do not expose your headset to extreme temperatures. The temperature range of the headset is 0-40°C.
- Do not try to disassembly your headset. Service and Maintenance can only be performed by RDT.
- Do not let children play with the headset since it contains small parts that could become detached and create a choking hazard.

CAUTION: Danger of explosion if battery is incorrectly replaced. Do not attempt to repair or replace the battery. If the battery is worn out a new headset is required from RDT. Dispose of the headset in accordance with local regulations. Do not dispose as household waste.

The user manual for the Bluetrek® G3 headset is supplied on the same CD-ROM as this manual. Details from that manual have been reproduced in this section courtesy of Bluetrek®.

7.3 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 the **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.

7.3.1 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, the **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.

7.3.1.1 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.

7.3.1.2 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 IC** 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.

7.3.1.3 Automatic Redialling

If the **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.

7.3.1.4 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.

7.3.1.5 File Transfer Status Indicator

When data files (either an ECG or a still digital picture) are being transmitted, the progress bar shows how far the transmission has progressed.

7.4 Communications Modes

Tempus IC can connect to the Response Centre using different connection a number of wired and wireless communications interfaces e.g. Ethernet or WiFi.

Connecting over wired interfaces such as Ethernet requires connecting the Tempus using a cable; connecting over wireless interfaces such as WiFi require no physical connection to be made.

To switch between these types of connection, the **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.

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

The **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).

7.4.1 Changing Modes

You can change the Mode that the **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 7.4.3).

7.4.2 Using Available Modes

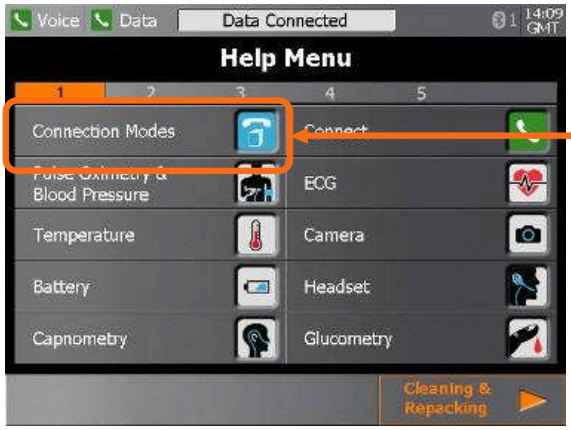
The Modes that are available on each **Tempus IC** are dependent on the requirements of each User. Refer to the Modes Menu on your Tempus IC for specific details of each Mode that is available.

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.

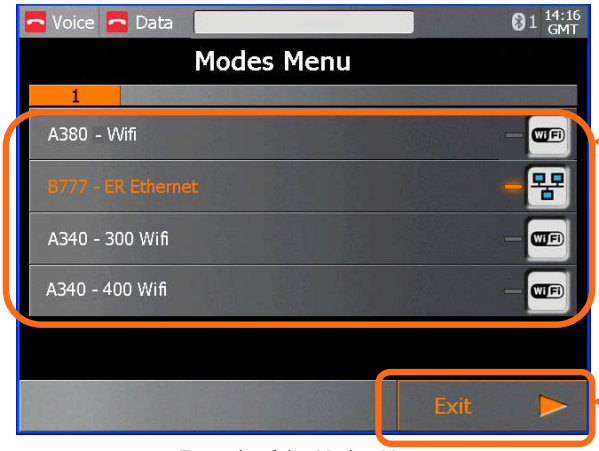
7.4.3 Changing the Connection Mode

To change mode, bring up the help menu and then follow the instructions below:



1. Press the touchscreen here

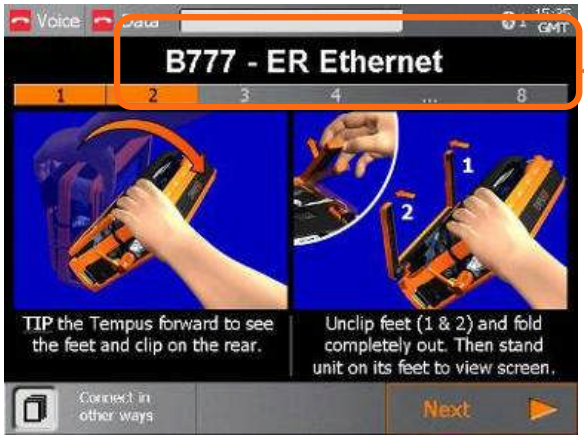
The Modes Menu Button on the Help Menu



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

If you wish to exit the Modes Menu press here.

Example of the Modes Menu



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

Example of the New Mode Title

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.

The **Tempus IC** is intended for use on one patient per incident. It must not be used on more than one patient because the **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.

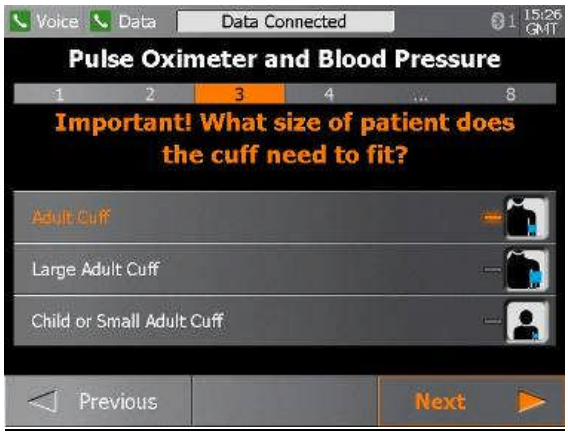
8.1 Blood Pressure and Pulse Oximeter

To activate the Blood Pressure & Pulse Oximeter function, press the  button on the device. The first step in the Blood Pressure & Pulse Oximeter help process 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.

The 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.

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.

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.

The SpO_2 sensor 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). 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.

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 GREEN.

8.1.1 Understanding the Pulse Oximeter Results

The Pulse Oximeter display has four data elements. 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 bar graph and digital display of the patient's pulse rate, in beats per minute (Bpm).

- Note that extreme pulse rates above 175 Bpm or below 25 Bpm are outside the range of the bar graph display but will be shown accurately on the digital display.

The SpO_2 section gives the oxygen saturation of the blood, and displays the result in bar graph and digital form.

- Note that extreme blood oxygen levels below 50% are outside the range of the bar graph display but will be shown on the digital display (readings below 40% are not shown).

The Signal Strength bar graph 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. Similarly the Perfusion Index gives a numerical indication of the level of arterial pulsatile blood at the sensor site.

8.1.2 Understanding the Blood Pressure Results

The Blood Pressure display has three elements plus a status indicator. The results comprise Systolic and Diastolic readings in mmHg and a timestamp in GMT. Once the BP is active (either inflating or deflating or on timer), the 

button will be shown next to the Cuff Status icon. Pressing this button at any time will stop the blood pressure monitor and cause the cuff to deflate immediately.

The measurements are normally made every five minutes via an automatic timer. Note that when the unit is in timer mode, the Cuff Status icon will change state. The possible states of the blood pressure monitor are:

-  Blood pressure monitor is idle;
-  Cuff is inflating;
-  Cuff is deflating;
-  Cuff is on timer;
-  Cuff is on timer;

-  Cuff is on timer.

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

8.1.3 Blood Pressure Monitor Error iAssist Help Process

The Tempus IC will automatically display iAssist help process in the event that it encounters problems in taking a blood pressure 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.

The conditions that could occur are:

- The cuff or hose leaking;
- Overpressure – caused by blockage or compression on the cuff;
- Weak signal – caused by a poor connection to the patient, a blockage or similar;
- Timeout – the Tempus IC could be detecting noise from the cuff which prevents a valid reading from being made, this could be caused by movement on the cuff or hose, vibration, patient activity etc.

If the Tempus IC experiences one of these types of errors, it will provide on-screen instructions on how to check for and clear the problem. It should be understood that it can be normal to experience these types of errors when taking readings if the usage instructions have not been followed carefully.

8.2 Electrocardiograph (ECG)

To activate the ECG function, press  button on the device

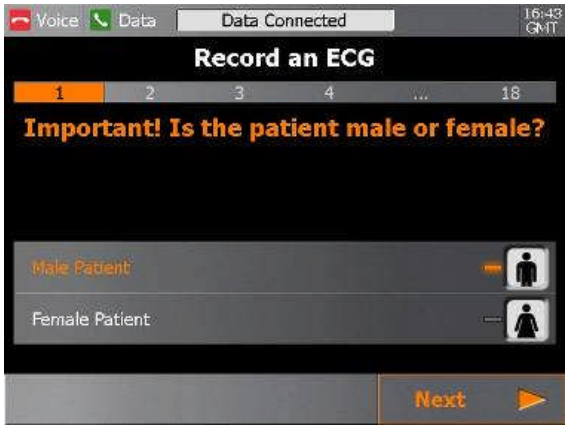
The first step in the ECG help process will appear.

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

WARNINGS

The Tempus IC 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.

The 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

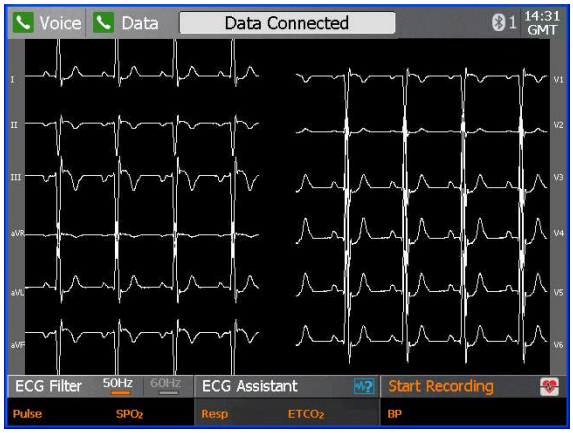
Whilst the ECG harness fits many patients, one size cannot fit all patients. Consequently, the ECG data collected may not be of diagnostic quality for some patients.

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.

Once the iAssist process has been completed the Tempus will display the ECG.



The ECG Monitoring Screen

The Tempus IC is now monitoring the patient's ECG, but is not recording the information. The traces move across the screen from left to right, erasing and replacing old readings as the monitoring progresses. It takes 3-4 seconds for the trace to cross the screen. You should wait at least 30 seconds before recording the ECG. While the ECG is on the patient should sit still, relax and not talk as any of these activities can disrupt the ECG.

The displayed waveforms may be partially or totally disrupted if,

- The patient is moving or talking;
- The harness is not connected properly;
- The electrodes have not been sprayed with the contact solution or the solution has dried off;
- The harness is not positioned correctly.

The bottom of the screen shows the current status of the ECG settings.

ECG Filter 50Hz 60Hz. 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. The filter setting is shown in the bottom left corner of the ECG. It will either show 50Hz or 60Hz as lit, pressing on this area of the touchscreen will change the setting.

8.2.1 Monitoring an ECG

To record an ECG, press 'Start Recording' on the touch screen.

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 (additional signals appearing on the ECG which are generated by muscle movement and not by the heart) 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.

[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 the filter should normally be set to 50Hz. In remote land and maritime applications the local voltage could be either 50Hz or 60Hz.

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).

If you are not satisfied with the EGC trace e.g. it is unstable on some or all of the traces, you can press the ECG Assistant button on the touchscreen. This will ask you to confirm which part of the ECG you are dissatisfied with and will then offer more detailed instructions on the application of the ECG harness based on which traces you have indicated are suspect.

8.2.2 Recording an ECG

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.

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8.3 Capnometer

To activate the Capnometer function, press  button on the device

The first step in the Capnometer help process 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 is not for use in conjunction with breathing or anaesthetic systems.

8.3.1 Understanding the Capnometer Results

The Capnometer display has two elements. Measurements are made continuously (for 15 minutes after the capnometer has been activated) and are updated in real time. Measurements are sent in real time to the Response Centre provided that the data link is active.

Once the Capnometer is active, the 

button will be shown next to the $ETCO_2$ results. Pressing this button at any time will stop the Capnometer immediately.

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

- Note that extreme rates above 50Rpm are outside the range of the bar graph display but will be shown accurately on the digital display.

The $ETCO_2$ section gives the partial pressure of the exhaled CO_2 at the end of the breath. This is displayed in bar graph and digital form.

8.4 Thermometer[2]

To activate the thermometer, press  button on the device

The first instructions will be displayed.

Follow the instructions provided on the iAssist help process to use the thermometer.

The thermometer is the large white and green device. It connects to the **Tempus IC** via Bluetooth®.

Example of the Temperature Help Screen

CAUTION

The thermometer provides fast, accurate temperature measurements on any patient into which its probe can be inserted into the ear canal to view the tympanic membrane. It can be considered for use on any patient above three (3) years of age. Do not use the thermometer if the probe cannot be inserted into the ear canal.

The thermometer should always be used with a probe cover attached. Probe covers should be replaced between each measurement.

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[2] Note that the thermometer functionality is currently not enabled for US customers pending regulatory clearance.

Notes

Allow the thermometer and the patient to acclimatise to the same ambient temperature before taking temperature readings.

Dirt, greasy films or moisture on the thermometer lens may affect the accuracy of the instrument.

Deposits of cerumen (ear wax) can affect the measurement.

Do not open the thermometer case. The thermometer will require factory recalibration if the case is opened.

Place the smooth side (not the adhesive side) of the probe cover to the connection ring.

The device should be checked for damage if it has been dropped.

Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.

Do not press the thermometer button until instructed by the steps shown on the screen as the device will not operate.

The thermometer's sensor requires a few seconds to stabilise at the measurement site before a reading can be taken. If the measurement button is pressed too quickly after the thermometer is inserted into the ear, the device may not be able to take a reading. In this event it will emit a "double-beep" and flash a symbol on its display (see section 10.3.2). In this event, place the thermometer back into the patient's ear (as per instructions), wait 6 seconds and then take the reading.

The device should be checked for damage if it has been dropped.

Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.

The thermometer is switched on and off using the "ON/MEM" button. Press the button briefly once (when instructed by the on-screen instructions) to turn the thermometer on. It will automatically try to communicate with the Tempus IC over the Bluetooth® link. Press and hold the ON/MEM button for 3 seconds to turn it off. Note that to extend the battery life the thermometer will automatically shut off if left idle for more than 1 minute.

Note that the thermometer has a memory of the last 10 readings it has taken. These will be shown on the thermometer's display (but not transmitted to the Tempus IC) if the ON/MEM button is pressed after the device has been turned on e.g. if the button is pressed once it will show the most recent reading (preceded by a "1"), if pressed twice it will show the reading taken before that (preceded by a "2") and so on. For this reason it is recommended that the ON/MEM button is not pressed and also that the thermometer display is not reviewed while obtaining temperature readings.

The thermometer is normally supplied set to read in Centigrade (ºC). If required, it can be changed over to read in Fahrenheit (ºF). See section 12 for information on how to change the thermometer reading. If the user wishes to switch the units that the thermometer itself displays, this can be achieved by pressing and holding the measurement button at the when turning the thermometer on.

Note that holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.

Only use non-rechargeable batteries with the thermometer.

Do not attempt to use, swap or pair the thermometer with other Tempus IC units or other devices. Consult RDT if you need replacement thermometers.

Users are reminded to ONLY use the thermometer within the range specified in section 13.1.5.

Due to its nature Bluetooth technology is wireless and therefore results may not be received 100% of the time. Risk factors for example would include the user moving out of range during the measurement or environmental factors e.g. building materials and construction design reducing operational effectiveness. Users should note that if a reading is not received they should repeat the process, if possible this should be done closer to the Tempus IC.

Users should note that while the Bluetooth technology will operate in environments where other Bluetooth devices are in use, operation can be affected if the number of other devices becomes very high (e.g. there can be high densities of devices at trade shows). If issues with a Bluetooth connection are experienced then the measurement should be attempted again either in a different environment (with less Bluetooth devices turned on locally) or closer to the product.

Note that the thermometer is only provided to customers outside of North America. This functionality will be provided to customers based in North America once the relevant regulatory approvals have been granted.

8.4.1 Using the Thermometer

When following the on-screen instructions, attention should be paid to the signals given out by the thermometer. If measurements are taken incorrectly (too quickly, at the wrong measurement site etc.) then the thermometer's display will show an error. Errors are discussed in section 10.3.

It should be noted that once the thermometer is turned on it will power itself off after 1 minute if no buttons are pressed, therefore the onscreen instructions should be followed promptly after the thermometer has been turned on.

It is recommended that 3 measurements are taken from the same ear and the highest of the three used.

8.4.2 Understanding the Thermometer Results

When measurements are made, they are time stamped and sent to the Response Centre provided that the data link is active.

The clinical repeatability of the thermometer is 0.23°C (<1 year old), 0.22°C (1~5 years old), 0.21°C (>5 years old).

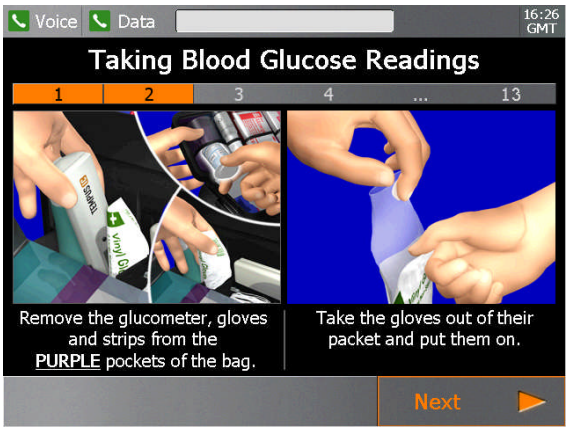
It should be noted that normal temperature variation in healthy patients can be between 0.2-1°C across different parts of the body.

8.5 Glucometer[3]

To activate the Glucometer function, press  button on the device

The first Glucometer help screen will appear.

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



Example of the Glucometer Help Screen

WARNING

The GlucoTel meter is provided pre-set to provide results in mg/dl format ONLY.

The results shown on the Tempus IC will be in mg/dl format for users based in North America and in mmol/l format in all other areas.

CAUTIONS

Do not store the glucometer strips outside of the stated environmental limits. Ensure that shelf life information is heeded.

Ensure that the instructions for use attached to the strips are heeded.

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[3] Note that the glucometer functionality is currently not enabled for US customers pending regulatory clearance.

Glucometer Notes

The glucometer used with the Tempus IC is the GlucoTel® meter made by BodyTel® of Germany. The Tempus IC uses the GlucoTel® meter as it is intended i.e. to measure a patient's blood glucose and to transmit this over Bluetooth® to a second device (the Tempus IC) for re-transmission. The only difference is that the measured result is forwarded to the response centre that receives the Tempus IC call rather than the BodyTel® Centre.

The GlucoTel® meter measures the patient's blood glucose levels and transmits them wirelessly (over Bluetooth®) to the Tempus IC.

The GlucoTel® meter has been labelled with a Tempus IC badge on the top in order that it can be visually associated with the Tempus in case the two products are separated. However the meter remains a product of BodyTel® and retains their labelling and contact details on the labelling on the underside.

The user manual for the GlucoTel® meter is provided on the same CD-ROM as this manual. While applicable extracts of the GlucoTel® manual are reproduced in this manual, Users should also read the manual of the GlucoTel® meter to ensure they have familiarised themselves with the device.

Do not insert objects (e.g. pins, paper clips etc.) through the hole on the RDT label on the top face of the glucometer. This can cause the glucometer to lose its pairing with the Tempus (which will stop it from working). Pairing is described in the Maintenance Manual.

Do not attempt to use, swap or pair the glucometer with other Tempus IC units or other devices. Consult RDT if you need replacement glucometers.

Users are reminded to ONLY use the glucometer within the range specified in section 13.1.6.

Due to its nature Bluetooth technology is wireless and therefore results may not be received 100% of the time. Risk factors for example would include the user moving out of range during the measurement or environmental factors e.g. building materials and construction design reducing operational effectiveness. Users should note that if a reading is not received they should repeat the process, if possible this should be done closer to the Tempus IC.

Users should note that while the Bluetooth technology will operate in environments where other Bluetooth devices are in use, operation can be affected if the number of other devices becomes very high (e.g. there can be high densities of devices at trade shows). If issues with a Bluetooth connection are experienced then the measurement should be attempted again either in a different environment (with less Bluetooth devices turned on locally) or closer to the product.

If the Tempus displays a reading of HIGH or LOW from the glucometer then this corresponds to a value of >525mg/dl or <20mg/dl respectively.

Note that the glucometer is only provided to customers outside of North America. This functionality will be provided to customers based in North America once the relevant regulatory approvals have been granted.

Lancet Notes

For use with the glucometer, RDT supplies the "SAFE Press" sterile safety lancets manufactured by Vitrex Medical A/S of Denmark.

These are single use devices which are supplied sterile and are labelled accordingly.

Users should follow the on-screen instructions for using, discarding and repacking the glucometer as these include the relevant information on the use of the lancets.

Users should not use lancets if the protective cap has been removed.

8.5.1 Testing the Glucometer

The GlucoTel® meter can be tested by pressing the  button, following the onscreen instructions and then applying the control solution (either HIGH or LOW) as described in section 4.7 of the GlucoTel® manual.

8.5.2 Understanding the Glucometer Results

When measurements are made, they are time stamped and sent to the Response Centre provided that the data link is active.

8.6 Digital Camera

When requested by the Response Centre, it is possible to capture and send still digital pictures using the camera built into the device. Digital pictures 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).

To activate the Camera, press  button on the device

The first Camera help screen will appear.

A digital picture 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 Digital picture

NOTE: The **Tempus IC** will go into the camera process as soon as the voice connection has started dialling.

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

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

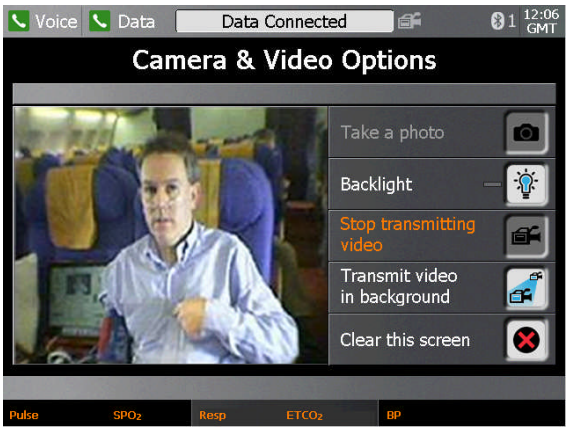
When you are happy that the displayed image shows what you want, press  on the touch screen to freeze the image.

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.

If you are connected over either an Ethernet or WiFi link, it will be possible to send moving video to the Response Centre.

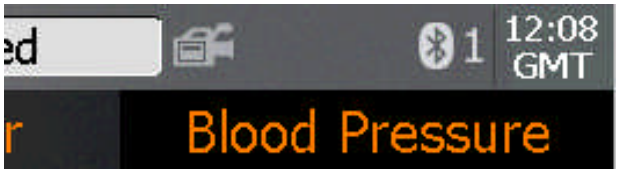
This can be done in two ways:

- Press the “Transmit Video” button. The “Camera and Video Options” dialog will stay on the screen and the Response Centre will see what you see in the viewfinder window on the left hand side of the dialog.



Example of the **Tempus IC** Transmitting Video

- Press the “Transmit Video in Background” button. The “Camera and Video Options” dialog will disappear from the screen; you will be able to see that video is being transmitted because a video icon will appear at the top of the screen. This feature is intended to allow users to transmit video while using other features of the device. Users should note that when the Tempus IC has its foot deployed, the angle of the camera should enable them to frame a patient without the need to hold the Tempus in position.



Video Icon

NOTE: Moving video is intended to give the Response Centre the ability to see the patient moving or to see around the patient’s environment. Users should remember that the resolution and quality of the received video stream will not be the same as they see on the screen of the Tempus IC due to the effects of the video being compressed during transmission. This effect is lessened when the image being filmed is more stable or has less activity in it. Therefore in order to ensure the received video is good quality, Users should try to move the camera slowly. If rapid movement of the camera is necessary then the received image is likely to be have a temporarily lower level of resolution (will appear “blocky”) while the camera is being moved around, this effect will reduce once the camera movement is reduced.

NOTE: The overall image quality and resolution of the camera is greater for still pictures than moving video. If the Response Centre require an image with a reasonable level of detail (such as a close-up image) then a still photo would probably be more suitable.

8.6.1 Annotation of Digital pictures

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

8.7 Interacting with the Response Centre

8.7.1 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. The centre should be staffed 24 hours a day, 365 days a year and be always able 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

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).

8.7.2 Remote Viewing and Control

The Response Centre operators 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. The only exceptions to this are when you are taking a digital picture or when you are monitoring or recording an ECG, in these situations the Response Centre only see that you are in the process of recording the ECG or taking the photo but they don't see the ECG or photo until its has been downloaded.

Since the Response Centre can see what you see on the device, and since they can control it remotely, if you are experiencing problems using the Tempus IC, they can guide and support you in its use.

If the Response Centre need to operate the Tempus IC remotely, they should make you aware that they are activating a function of the device before they do so. 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 the **Tempus IC** is generally intended to be used whilst connected from the remote location to a Response Centre, the **Tempus IC** can also be used without the telecoms connection having been made. All the functions of the **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 the **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 the **Tempus IC** is used on a patient without a connection being made, the data is stored and automatically transmitted once the device is connected. If the device is turned off before it is connected the data will not be saved.

8.9 GPS Location

The Tempus IC has a built-in GPS receiver. You can access this feature from the Help menu.

The GPS Button

Having pressed the GPS button, you will be shown a graphic instructing you to use the feature when outside with a clear view of the sky.

GPS Help Instruction

NOTE: The GPS operation will be limited if the Tempus IC is not used outside with a clear view of the sky.

NOTE: The GPS is intended to provide the User and Response Centre with the patient's location. It should not be used as a guidance or navigation device.

NOTE: The **Tempus** IC will be supplied with the GPS enabled in non-aviation modes and enabled in all other modes. To turn the GPS receiver on or off, refer to section 12.

GPS Fix Obtained

The GPS may take up to 2 minutes to display a fix. If it unable to obtain a fix (if the view of the sky is obstructed or if the unit is used indoors) then it will display an error.

The most recent fix (with the time and date of the fix) is always displayed.

If the signal from only a limited number of GPS positioning satellites can be received by the Tempus (e.g. because of partial blocking of the sky by objects, buildings etc.) then the fix may be less accurate. In this case the fix will be labelled "Approximate fix" and the reading may be +/-2.5km.

8.10 Actions after Use – Turning the Tempus IC Off

Before switching the Tempus IC off, you should make sure that it 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 and hold the On/Off switch for 3 seconds. 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

8.10.1 Logging Maintenance Requirements

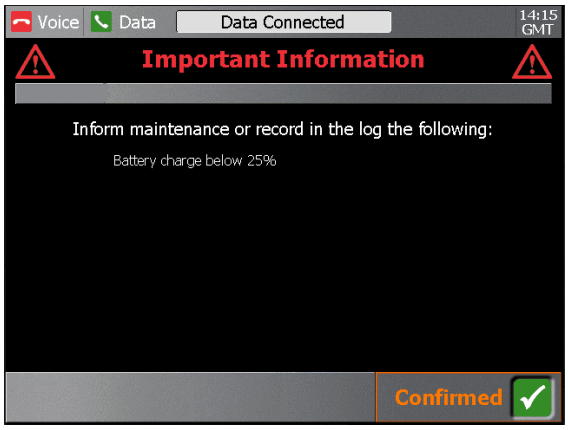
If consumable items such as the repack kit or a cannula have been used, the Tempus IC will alert you to the need to report the need for these items to be replaced. This alert will be provided after the shut down has been initiated.

In addition to flagging the need for certain consumable items to be replaced, the alert will also inform you if:

- batteries are depleted;
- if specific errors have occurred;
- or if a software update is required.

You should use the information displayed to log or report that the Tempus IC requires your maintenance staff to provide indicated items.

NOTE: This feature DOES NOT indicate that the Tempus has developed a fault. This feature is to help remind users to report that basic consumable items or maintenance activities are required. Users should not report the information displayed by this feature as a fault to RDT.



Example of the Shutdown Screen

In the example above, the Tempus IC is indicating that the battery is now below 25% charge. RDT recommends that users respond to the information posted to ensure that the Tempus IC is maintained in good working order.

The potential conditions that can be logged are:

Text	Condition
Battery charge below 70%	The battery charge is below 70% of its potential full capacity
Battery charge below 50%	The battery charge is below 50% of its potential full capacity
Battery charge below 25%	Or < 25%
Repack kit required	If “Final Check” process was completed using the “Yes” daughter process
Capnometer cannula required	If Capnometer was started during the incident
Glucometer repack kit required	If the glucometer repack process was followed
Thermometer battery required	If the thermometer battery low error was reported during incident
Glucometer battery required	If the glucometer battery low was reported during incident
Software update required	If software update was notified during incident*
Device fault reported	If any device was disabled due to a fault

*If a software update is required you should refer to your maintenance manual for instructions on how to perform this process.

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.

9.1.1 Cleaning the Thermometer

The probe is the most delicate part of the thermometer. It should be used with care when cleaning the lens to avoid damage.

Keep the unit dry and away from any liquids and direct sunlight.

The thermometer should not be submerged into liquids.

If the thermometer is accidentally used without a probe cover, clean the probe as follows:

1. Use a cotton swab dosed with the Alcohol (70% concentration) to clean the lens on the end of the thermometer.
2. Allow the probe to fully dry for at least 1 minute before using it.

9.1.2 Cleaning the Glucometer

If the GlucoTel is used according to its instructions, only minor cleaning is necessary.

For best results perform the following:

1. Use a damp cloth for cleaning the entire surface of the instrument.

2. After maintenance check the meter with control solution to ensure that it is functioning properly.

3. The GlucoTel or labeling will not be damaged or permanently discolored by cleaning with alcohol (70%), bleach (1:10) or ammonia (1:10)

4. Checking the operation of the meter is recommended after each cleaning.

This can be done using the control 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

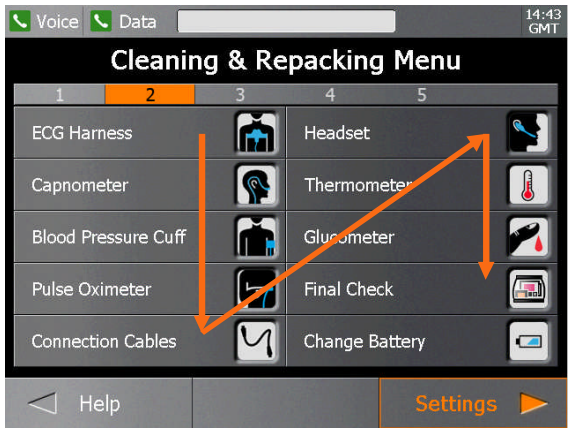
NOTE: Wiped surfaces must be left wet for at least 1 minute.

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, through to the Pulse Oximeter repack process, then following with the Connection Cables 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.

9.3 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
- Capnometer cannulae
- Glucometer strips
- Lancets
- Gloves

10 Maintenance, Servicing and Troubleshooting

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.

More details on maintenance are given in the Tempus IC Maintenance Manual pn. 41-1002 which is supplied on the same CD-ROM as this 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** contains a removable, rechargeable battery.

Example of the Battery Front

Example of the Battery Rear

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 25% power remaining, you should change the battery if possible to ensure that there is adequate power for the next time it is needed.

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

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

10.2.1.1 Checking the Charge of the Battery

Example of the Battery Life Indicator Showing Full Charge

The charge state of the battery can be obtained by pressing the button on the front.

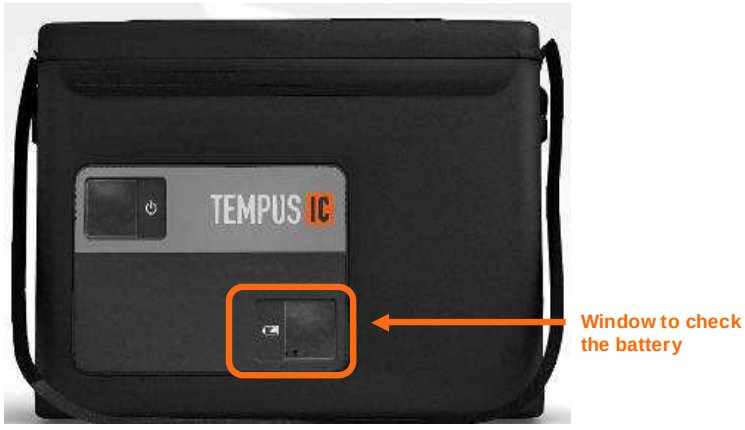
The battery is provided with 4 charge state LEDs. Pressing the button will light one or more lights. Each light corresponds to 25% of the charge state of the battery in the order (from highest to lowest):

- 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.

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.

10.2.2 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.

Fitting the Battery

10.2.3 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.

WARNING: Do not attempt to charge the battery using any charger other than those supplied by RDT.

10.2.3.1 Charging the Battery when Attached to 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.

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

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.

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.

10.2.3.2 Using the Battery Charger

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.

10.2.4 Tempus IC Battery Shelf Life

10.2.4.1 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.

10.2.4.2 Shelf Life of Batteries Stored in the Tempus IC

A new and fully charged battery retains approximately 60% of its charge after 12 months in storage attached to the **Tempus IC**. This equates to approximately 3.5 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.

10.2.5 Other Tempus IC Batteries

10.2.5.1 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.

10.2.5.1.1 Charging the Headset

RDT do not supply a separate charger for the headset. The charger is built into the Tempus IC.

You must follow the repacking instructions provided by the Tempus IC on screen. These will instruct you to clean the headset after use and to replace it on its docking pin before shutting down.

If you do not replace the headset then the Tempus will show an error advising that the headset should be refitted.

Placing the headset onto the docking pin enables the Tempus IC to recharge it. The Tempus IC recharges the headset for up to 4 hours 30 minutes (apx) every time the headset is replaced. The charging cycle will continue regardless if the Tempus IC is switched on or off. Charging is started as soon as the headset is fitted to the docking pin. The indicator light on the headset will light red for the duration of the charging process although it may switch off intermittently for 8 second periods (this is part of the charging process). The indicator light will go off when charging is complete – which could be less than the 4 hour 30 minute maximum cycle time depending on how depleted the headset battery is.

In addition, the Tempus IC will top up the charge of the headset approximately every 97 days. This occurs when the Tempus is switched off and lasts for up to 4 hours 30 minutes (apx).

The Tempus IC will not recharge the headset battery if the main battery is nearly empty (less than 5% charge).

Caution: Do not attempt to charge the headset using any other charging device. This will automatically suspend the warranty and could be dangerous.

Note: The headset has a life of up to 500 charge cycles.

10.2.5.1.2 General Guidelines for Safe Use

- Do not drop or try to alter the shape of your headset.

- Do not expose the headset to liquid or moisture. Unlike the Tempus, the headset has no protection against ingress of solids or liquids.
- Do not expose your headset to extreme temperatures. The temperature range of the headset is 0-40°C.
- Do not try to disassembly your headset. Service and Maintenance can only be performed by RDT.
- Do not let children play with the headset since it contains small parts that could become detached and create a choking hazard.

CAUTION: Danger of explosion if battery is incorrectly replaced. Do not attempt to repair or replace the battery. If the battery is worn out a new headset is required from RDT. Dispose of the headset in accordance with local regulations. Do not dispose as household waste.

The user manual for the Bluetrek® G3 headset is supplied on the same CD-ROM as this manual. Details from that manual have been reproduced in this section courtesy of Bluetrek®.

10.2.5.2 The Glucometer Batteries

The glucometer is powered by user replaceable non-rechargeable batteries. The batteries are conventional types that are available from common retail and industry sources.

The glucometer is powered by 2 AAA type batteries.

These batteries are rated with a shelf life of 7 years at 20°C.

RDT recommends that these are replaced annually when used in a commercial airline application (once a week). Higher levels of usage (e.g. in a training department) may require the batteries to be changed more often.

RDT recommends that Varta PowerOne alkaline batteries are used, although many other types are commonly available. Replacement batteries do not need to be sourced from RDT.

10.2.5.2.1 Changing the Glucometer Battery

To change the glucometer battery:

- First push back the battery cover

Removing the Glucometer Battery Cover

- Then remove the batteries and dispose of them.
- Then replace the batteries with new units of the same type and ratings. Note that the batteries must be inserted in the orientation shown on the inside of the plastic case of the device.

10.2.5.3 The Thermometer Battery

The thermometer is powered by a user replaceable non-rechargeable battery. The battery is a conventional type that is available from common retail and industry sources.

The thermometer is powered by a single lithium CR2 “Photo” type battery.

The battery is rated for >90% capacity after 12 months storage at 23°C.

RDT recommends that this is replaced annually when used in a commercial airline application (once a week). Higher levels of usage (e.g. in a training department) may require the batteries to be changed more often.

RDT recommends that Varta batteries are used, although many other types are commonly available. Replacement batteries do not need to be sourced from RDT.

10.2.5.3.1 Changing the Thermometer Battery

To change the thermometer battery:

- First push back the battery cover

Removing the Thermometer Battery Cover

- Then remove the battery and dispose of it.
- Then replace the battery with a new unit of the same type and ratings. Note that the battery must be inserted in the orientation shown on the inside of the plastic case of the device.

10.2.6 Disposal of Batteries

Dispose of batteries in accordance with the applicable local regulations (these can vary from country to country).[4]

[4] 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.

10.3 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

10.3.1 Errors

When the device encounters a problem it will display a dialog on the screen. The speaker will announce the message “Attention” followed by the name of the part of the product that the message is concerned with e.g. “Attention – Pulse Oximeter”.

The audible alerts are on are played every 5 seconds while an error is being displayed, until the error is cleared. The alert will be played back both through the speaker and the headset.

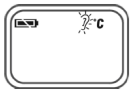
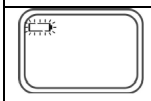
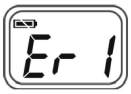
The different error dialogs are shown below.

Audio Message	Text Message
Attention Pulse Oximeter	There is a fault with the Pulse Oximeter It has been disabled
Attention Capnometer	Capnometer is blocked. Disconnect and reconnect the cannula. Check the cannula for blockages, or kinks.
Attention Capnometer	The cannula is not plugged into the capnometer. Repeat step 7 of the instructions.
Attention Capnometer	There is a fault with the Capnometer It has been disabled
Attention Capnometer	Capnometer is not plugged in. Repeat step 2 of the instructions.
Attention Capnometer	Capnometer sensor error or range error.
Attention Capnometer	Capnometer zero required. Sop and restart Capnometer.
Attention Capnometer	No Capnometer is available on this unit.
Attention Blood Pressure Meter	There is a fault with the BP meter. It has been disabled
Attention ECG	An error occurred with the ECG Please restart the ECG and try again
Attention ECG	There is a fault with the ECG It has been disabled
Attention Battery	There is approximately 60 minutes of battery remaining

Audio Message	Text Message
Attention Battery	There is less than 30 minutes of battery remaining. Tempus will perform a managed switch-off within 30 minutes. The battery should be changed.
Attention Battery	The battery is flat, the device will shut down
Attention Connection	Tempus is already trying to make a connection
Attention Connection	Tempus is already connected.
Attention Connection	The Tempus is connected so the mode cannot be changed.
Attention Connection	You have not completed the data connection process. Are you sure this is what you want to do?
Attention Connection	Response centre is not responding
Attention Headset	The headset has not connected to the Tempus. Repeat step 3 of the instructions.
Attention Connection	Headset should be replaced before shutdown
Attention Connection	You have not completed the data connection process. Are you sure this is what you want to do?
Attention Connection	You have not completed the voice connection process. Are you sure this is what you want to do?
Attention Shutdown	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.
Attention Shutdown	Due to low room temperature Tempus cannot be used and will shutdown. Please allow to warm and restart later.
Attention Shutdown	Due to high room temperature Tempus cannot be used and will shutdown. Please allow to cool and restart later.
Attention Shutdown	The battery is empty. Tempus will perform a managed switch-off. The battery should be changed.
Attention Headset	Please wait, setting up connection to the headset.
Attention – Headset	Headset should be replaced before shutdown
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
Attention Battery	The battery is empty. Tempus will perform a managed switch-off. The battery should be changed.
Attention Headset	Please wait setting up connection to Headset

10.3.2 Thermometer Errors

The thermometer display can show a range of error conditions and feedback messages. The thermometer display should be referred to during its use to ensure that this information is seen and responded to.

Error Message	Problem	Solution
	Device stabilization in process.	Repeat the reading (after flashing has stopped) but wait a few seconds after the thermometer has been inserted into the ear before you press the measurement button
	Battery is low and no more measurements are possible.	Replace the battery.
	Measurement before device stabilization.	Repeat the reading (after flashing has stopped) but wait a few seconds after the thermometer has been inserted into the ear before you press the measurement button
	The device showing a rapid ambient temperature change.	Allow the thermometer to rest in a room for at least 30 minutes at room temperature: 10°C and 40°C.
	The ambient temperature is not within the range between 10°C and 40°C.	Allow the thermometer to rest in a room at least 30 minutes at room temperature: 10°C and 40°C
	Error 5~9, the system is not functioning properly.	Unload the battery, wait for 1 minute and repower it. If the message reappears, contact the retailer for service.
	Temperature taken is higher than 42.2°C.	Check the integrity of the probe cover and take a new temperature measurement.
	Temperature taken is lower than 34°C.	Make sure the probe cover is clean and take a new temperature measurement.
	Device can not be powered on to the ready stage.	Change with a new battery.

10.3.3 Glucometer Errors

The glucometer display can show a range of error conditions and feedback messages. The glucometer display should be referred to during its use to ensure that this information is seen and responded to.

Error Message	Problem	Solution
Lo	Reading is below 20 mg/dl (1.1 mmol/l).	Check calibration and retry reading.
Hi	Reading is above 525 mg/dl (29.2 mmol/l).	Check calibration and retry reading.
E50	Internal meter temperature too low.	Allow the meter to warm up to room temperature.
E51	Internal meter temperature too high.	Allow meter to cool to room temperature.
E63	Strip removed during countdown.	Test again and leave strip in the meter until a result is displayed.
E70	Cell phone pairing failed.	Repeat pairing process.

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	Bluetrek® Headset
01-1019	Wired Headset
01-1020	Consumables Replenishment Kit
01-1021	Ethernet Cable
01-1022	USB Serial Cable
01-1023	Ethernet – POTS adaptor
01-1024	Glucometer replenishment kit
01-1025	ECG wrist straps
01-1027	Glucometer Control Solution Set
02-1001	Accessory Pouch (note – only supplied to commercial airlines)

12 Configuring 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.

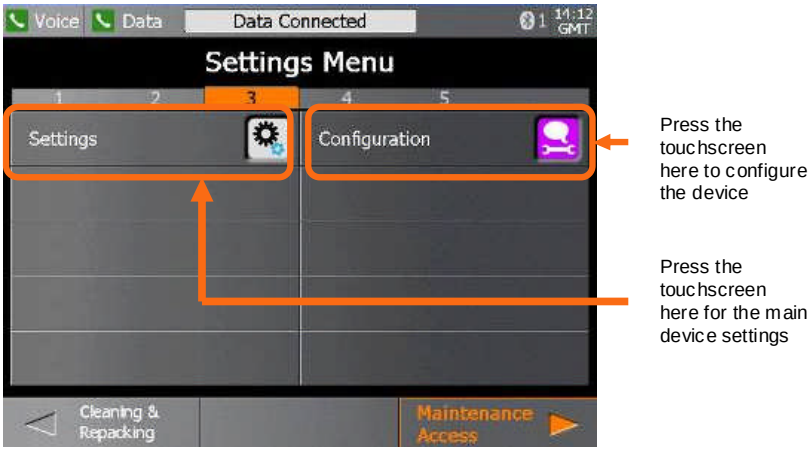
A number of the parameters used by **Tempus IC** are configurable to suit certain requirements.

To configure the device, 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.

The Help Menu

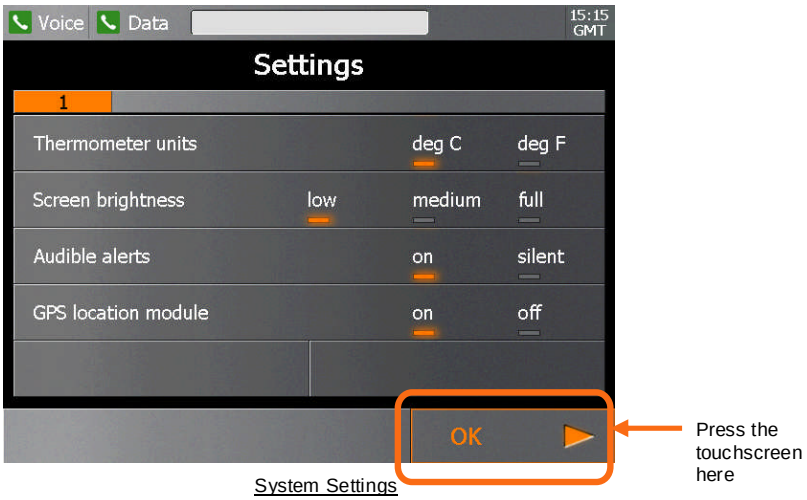
The Cleaning and Repacking Menu

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



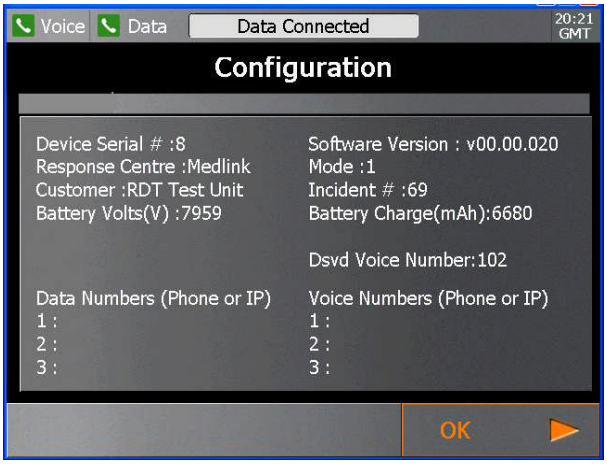
Settings Menu

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



System Settings

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



Configuration Information

The configuration of the device can be seen in the configuration screen. .

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

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)
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 $ETCO_2$ 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 litres 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

The capnometer is automatically compensated for local atmospheric pressure.

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 – 19 inches (46 cm)

Carbon Dioxide Monitoring	
Mode of Sampling	Sidestream
Principle of Operation	Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts.
Initialization Time	Measurement 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)
Respiration Rate Accuracy	± 1 breath
Calibration	No routine user calibration required.

Carbon Dioxide Monitoring		
$ETCO_2$ 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 Anaesthetic 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%	
Airway Pressure	Range: + 120 cmH_2O (88.27 mmhg) - 45 cmH_2O (33.1 mmHg).	
Anaesthetic Agent Effects (MAC levels)	Anaesthetic Agent Sensitivity[A] (uncompensated)	Accuracy specification will be maintained for halogenated anaesthetic agents present at accepted MAC (Minimum Alveolar Concentration) clinical levels.
	Anaesthetic 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, anaesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.	

Gas or Vapour	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 Vapour	**Gas Level**	**Quantitative Effects**
Nitrous oxide	60%	No Additional Effect

Gas or Vapour	Gas Level	Quantitative Effects
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

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
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

13.1.4 $Sp0_2$ Sensor

Pulse Range:	25-300 bpm
Graphic display range:	25-175 bpm
Accuracy:	± 2bpm or ±2% whichever is greater
Resolution:	1bpm
Averaging:	8 seconds

SpO2 Range:	0-100%
Graphic display range:	50-100%
Accuracy:	±2% at 70%-100%
Resolution:	1%
Type:	Functional saturation (test methods available upon request)
Wavelength range:	Red 660nm, infra-red 905nm
Perfusion Index range:	1-20%
Signal strength range:	1-7 bars

13.1.5 Thermometer

Temperature measurement range:	34-42.2°C (93.2-108°F)
Operating temperature range:	10-40°C (50-104°F)
Storage temperature Range:	-20-50°C (-4-122°F), RH85% (non-condensing)
Transportation temperature:	<70°C, RH95% (non-condensing)
Compliance with:	ASTM E1965-98, EN12470-5:2003 Clinical thermometers-Part 5:Performance of infra-red ear thermometers(with maximum device),IEC/EN60601-1-2(EMC),IEC/EN60601-1(Safety) standards.
Accuracy:	+/-0.2 °C (0.4 °F) between 35.5~42°C (95.9~107.6°F) and +/-0.3 °C (0.5 °F) outside this range.
Display type:	oral equivalent
Range:	10m (free field)
Weight:	100g (including battery)
Battery:	3V CR2
Size:	167mm x 39mm x 45mm (max).
Environmental range:	The thermometer has the same environmental range as the Tempus IC, see section 13.1.7
Drop/Shock:	The thermometer has been tested to the same range of environmental standards as the Tempus IC (see section 13.1.7.1

RDT recommends that the batteries are replaced annually when used in a commercial airline application (once a week). Higher levels of usage (e.g. in a training department) may require the batteries to be changed more often.

The Thermometer uses the Bluegiga WT12A Bluetooth® module. This is unmodified by RDT and is provided under FCC ID QOQWT12 under FCC part 15C and Industry Canada REL: 5123A-BGTWT12A under RSS210.

It operates in the frequency bands 2402MHz – 2480MHz and has a maximum power of 0.00222W.

Bluetooth® Specification		
Description	Specification	Note
Operating frequency range	(2400 ... 2483,5) MHz	ISM Band

Bluetooth® Specification			
Description	Specification		Note
Range	Class 2, range up to 10 meters in an open field		
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 frequency
Transmission power	Min	-11 ... -9 dBm	
	Max	+14 ... +18 dBm	
	RSS210	22mW emission designation 1M21G2D	
Compliance	Bluetooth® specification, version 2.0 + EDR		
Certification/ Compliance	FCC: Part 15, FCC ID QOQWT12 Industry Canada license 5123A-BGTWT12E		

13.1.6 Glucometer

Batteries:	The GlucoTel meter requires 2 * AAA Batteries (rechargeable batteries should not be used in the GlucoTel meter).
Operating Temperature Range:	0 to +40 °C. (32°F to 104°F)
Storage Temperature Range:	-20 to +55 °C. (-4°F to 131°F)
Accuracy:	±5.6%
Operating Humidity Range:	20% - 80% RH (relative humidity),
Storage Humidity Range:	10% - 90% RH (relative humidity).
Measuring Range:	20 to 525 mg/dl or 1.1 to 29.2 mmol/l
Transmission range:	3m in an open field when held by the user

Automatic Switch On:	Upon insertion of test strip
Automatic Switch Off:	The GlucoTel meter turns off automatically after 60 seconds and when the test strip is removed.
Size:	140 x 30 x 18 mm
Weight:	65g (including batteries).

The glucometer is provided by BodyTel Inc. of Germany. Its specifications are detailed in its user manual which is provided on the CD-ROM with this manual.

RDT recommends that the batteries are replaced annually when used in a commercial airline application (once a week). Higher levels of usage (e.g. in a training department) may require the batteries to be changed more often.

The glucometer uses the same Bluegiga WT12A Bluetooth® module that is detailed in section 13.1.5.

13.1.7 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

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

NOTE: IPX6 and MIL810F tests are lab tests and not normal condition. The 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.

13.1.7.1 Environmental Performance and Certification

Temperature & Altitude:

Category:	A1
Test Standard,	Temperature, RTCA/DO-160E Section 4, Para 4.5.1, 4.5.2 and 4.5.3
Test Standard, Altitude, Temperature:	RTCA/DO-160E Section 4, Para 4.6.1 and 4.6.2 Operating: 0°C to +40°C Storage: -20°C to +60°C Short Term High: +40°C
Altitude:	Operating: Sea Level to 15,000 ft
Storage:	Sea Level to 15,000 ft
Rapid Decompression:	10,000 ft to 55,000 ft in 10 seconds

Temperature Variation:

Test Standard:	RTCA/DO160E Section 5 Cat C
Rate of Variation:	2°C per minute.

Humidity:

Test Standard:	RTCA/DO-160E Section 6 Cat A
Storage:	15 to 95% RH Non-condensing (tested for 48 hours at 38-50°C)

Operating:	15 to 95% RH Non-condensing (tested at the end of the storage cycle)

Operational Shocks & Crash Safety:

Test Standard:	RTCA/DO-160E Section 7 Cat B
Operational Shock:	Para 7.2 (6g for 11ms saw-tooth wave, repeated 3 times in all axis).
Crash Safety:	20g in all directions (sustained and impulse).

Vibration:

Test Standard:	RTCA/DO-160E Section 8 Para 8.5.2
Jet aircraft test	Procedure: Curve B3, 3hrs per axis (repeated for all axis) – 10 Hz to 31 Hz at 0.02 g2/Hz Falling to 0.002 g2/Hz at 100 Hz 100 Hz to 500 Hz at 0.002 g2/Hz Falling to 0.00013 g2/Hz at 2000 Hz
Helicopter test	Procedure: Curve F, 0.5hrs per axis (repeated for all axis) – 5 Hz to 40 Hz at a ramp rate of +3 dB/Oct to a level of 0.05 g2/Hz at 40 Hz 40 Hz to 200 Hz at 0.05 g2/Hz Ramping from 200 Hz to 300 Hz at a ramp rate of -12 dB/Oct Procedure: Curve F1, 3.5hrs per axis (repeated for all axis) – 5 Hz to 40 Hz at a ramp rate of +3 dB/Oct to a level of 0.10 g2/Hz at 40 Hz 40 Hz to 200 Hz at 0.10 g2/Hz Ramping from 200 Hz to 300 Hz at a ramp rate of -12 dB/Oct

Explosion Proofness:

Not tested. Not to be used in the presence or explosive gasses or vapours.

Water Proofness:

Not tested to RTCA/DO160E Section 10.

Commercial qualification:	IPX6 (high pressure hose) – whole device IPX4 (hoop) – capnometer IPXX (no classification) – glucometer, thermometer, power supply, battery charger, headset

Fluids Susceptibility:

Not applicable. The product is for use in the cabin only.

Sand & Dust:

Not applicable. The product is for use in the cabin only.

Fungus Resistance:

Not applicable. The product is for use in the cabin only.

Salt Spray:

Not applicable. The product is for use in the cabin only.

Magnetic Effect:

Not applicable. The product is for use in the cabin only.

Power Input:

Not tested to RTCA/DO160E Section 16.

Commercial qualification:	EN61000-3-2:2006 Mains harmonics
	EN61000-3-3:1995 inc A1:2001 & A2:2005 Mains flicker
	EN61000-4-11:2004 voltage dips and interruptions

Voltage Spike:

Not tested to RTCA/DO160E Section 17.

Commercial qualification:	EN61000-4-4:2004 Fast transient bursts

Audio Frequency Conducted Susceptibility – Power inputs:

Not tested to RTCA/DO160E Section 18.

Commercial qualification:	EN61000-4-5:2006 Surges

Induced Signal Susceptibility:

Not tested to RTCA/DO160E Section 19.

Commercial qualification:	EN61000-4-6:1996 inc A1:2001 Conducted RF field

Radio Frequency Susceptibility (Radiated & Conducted):

Not tested to RTCA/DO160E Section 20.

Commercial qualification:	EN61000-4-3:2002 Radiated RF Interference

Emission of Radio Frequency Energy:

Test Standard:	RTCA/DO160E Section 21 Cat M.

Lightning Induced Transient Susceptibility:

Not applicable. The product is for use in the cabin only.

Lightning Direct Effects:

Not applicable. The product is for use in the cabin only.

Icing:

Not applicable. The product is for use in the cabin only.

ESD:

Not tested to RTCA/DO160E Section 25.

Commercial qualification:	EN61000-4-2:1995 inc A1:1999 & A2:2001 ESD

Fire and Smoke Hazards:

Main case material:	Glass reinforced nylon PA66+35%GF.
Flame:	UL94V-0

Overmould material:	TPE.
Flame:	N/A

13.1.8 Miscellaneous Features and Specifications

Tempus IC dimensions	289mm wide x 203mm high x 101mm deep.

13.1.8.1 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	0.42kg nominal
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.

13.1.8.2 Battery Charger

Mains input voltage	100-240V
Frequency	50-60Hz
Input current	0.9A max (at 100V apx)
Output voltage	8.4V dc
Output current	<2.73A
Charge time (from empty)	6 hours

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

13.1.8.3 Mains Power Supply

Mains input voltage	100 - 240V
Frequency	50-60Hz
Input current	1.5A - 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.

13.1.8.4 GPS

Antenna	Integral
Channels	20 satellites simultaneously
Sensitivity	Up to -159dBm
Accuracy	±30m (±2.5km with <6 satellites – labelled as "Approximate Fix"

13.1.9 Communications

13.1.9.1 Transmission rates

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

- 12 lead ECG – 2-3 minutes
- Digital photographs – 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.

13.1.9.2 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	
The WiFi module has the following specifications:	
SKU #	North America WL6231-1123 International WL6233-1125
Transmit Power	CCK: 12 dBm typical OFDM: 9 dBm typical 63mW emission designation 11M5F9W to spec RSS210
Indoor Range	~ 300 feet (typical office environment)
Data Rate:	802.11a 54 Mbps OFDM: 9 dBm +1/-1.5 dBm 802.11g 54 Mbps OFDM: 11 dBm +1/-1.5 dBm 802.11 b 11 Mbps CCK: 15 dBm +1/-1.5 dBm
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 64/128, WPA (TKIP/AES), WPA2 (TKIP/AES)

13.1.9.3 Bluetooth® Specification

Bluetooth® Specification		
Description	Specification	Note
Operating frequency range	(2400 ... 2483,5) MHz	ISM Band
Range	Class 1, range up to 100 meters in an open field	
Lower guard band	2 MHz	
Upper guard band	3,5 MHz	

Bluetooth® Specification			
Description	Specification		Note
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 frequency
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		

13.1.9.4 Bluetooth® Headset Specification

The Tempus IC 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 in an 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).

Battery shelf life and run times are based on a new, fully charged battery.

13.1.9.5 FCC & Industry Canada Notes on Wireless Communications

FCC ID: ROSTEMPUSIC-1

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.

13.1.9.6 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

13.1.9.7 Modem Specification

The Tempus IC contains two modems which can be connected to a telephone network via the RJ-45 connector. The modems are used either:

- together over 2k4baud channels (typically Inmarsat classic satcoms for aero or maritime applications where one modem is used to transmit data and the other voice);
- or in landline applications where the a single modem is used to transmit voice and data simultaneously.

The modems support the following data protocols: V.92; V.90, V.34, V.32bis, V.32, V.22bis, V.22, V.23, V.21, Bell 212A & Bell 103. Error correction uses V.42 (LAP-M or MNP 2–4).

13.1.9.8 USB-Serial Adaptor Specification

The Tempus IC's USB connector may be used with the USB-Serial Adaptor cable (pn 01-1022) in order to provide data or voice and data communications over serial (RS-232) channels such as Iridium (data only) or Sat B (voice and data).

Data speeds of from 9600baud.

13.1.9.9 GSM & GPRS Specification

The Cell Phone (GSM) technology used by the Tempus has the following specifications:

GSM/GPRS Specification

Operating frequency range	Parameter		Min	Max	Unit
	Frequency Range Uplink (MS → BTS)	GSM 850	824	849	MHz
		E-GSM 900	880	915	MHz
		GSM 1800	1710	1785	MHz
		GSM 1900	1850	1910	MHz
	Frequency Range Downlink (BTS → MS)	GSM 850	869	894	MHz
		E-GSM 900	925	960	MHz
		GSM 1800	1805	1880	MHz
		GSM 1900	1930	1990	MHz
RF power	Parameter		Min	Max	Unit
	RF power @ARP with 50Ω Load	GSM 850	31	35	dBm
		E-GSM 900	31	35	dBm
		GSM 1800	28	32	dBm
		GSM 1900	28	32	dBm
Number of carriers	Band		Channels		
	GSM 850		124		
	E-GSM 900		174		
	GSM 1800		374		

<table>
<tr><td></td><td>GSM 1900 299</td></tr>
<tr><td>Duplex Spacing</td><td>Band Typical
GSM 850 45 MHz
E-GSM 900 45 MHz
GSM 1800 95 MHz
GSM 1900 80 MHz</td></tr>
<tr><td>Carrier Spacing</td><td>200 KHz</td></tr>
<tr><td>Multiplex, Duplex</td><td>TDMA / FDMA, FDD</td></tr>
<tr><td>Time Slots Per TDMA Fame</td><td>8</td></tr>
<tr><td>Frame duration</td><td>4.615mS</td></tr>
<tr><td>Time Slot duration</td><td>577µS</td></tr>
<tr><td>Modulation</td><td>GMSK</td></tr>
<tr><td>Receiver input sensitivity @ ARP
BER Class II < 2.4% (static input level)</td><td>
<table>
<tr><th>Parameter</th><th>Min</th><th>Typ</th><th>Unit</th></tr>
<tr><td>GSM 850</td><td>-102[3]</td><td>-107[4]</td><td>dBm</td></tr>
<tr><td>E-GSM 900</td><td>-102[3]</td><td>-107[4]</td><td>dBm</td></tr>
<tr><td>GSM 1800</td><td>-102[3]</td><td>-107[4]</td><td>dBm</td></tr>
<tr><td>GSM 1900</td><td>-102[3]</td><td>-107[4]</td><td>dBm</td></tr>
</table>
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Note: Users are reminded that the cell phone is only for use outside north America. Use of the GSM/GPRS radio in north America is subject to a planned regulatory submission

Note: This device contains GSM 900 MHz and GSM 1800MHz functions that are not operational in U.S. Territories.

13.1.10 Tempus IC Device 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. The thermometer is internally (battery) powered.
5.2 Applied parts type CF defibrillator proof, thermometer classified as BF, glucometer is not classified as it is an IVD rather than a medical device.
5.3 The Tempus IC is rated IPX6, protected against rainfall according to IEC529. The capnometer is rated IPX4. All other parts are rated IPXX.
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

Note that the classification of the thermometer is different to those of the Tempus IC.

The thermometer is:

- rated type BF,
- not protected against the effects of a cardiac defibrillator discharge,
- internally powered only (no means of connecting external power),
- not supplied sterile or has any parts which are required to be sterilised,

- not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide,
- is intended for intermittent use (it measures discrete readings rather than being used continuously) – the product will automatically power off after a minute if it is not used.

Similarly it should be noted that the glucometer is not classified under IEC60601-1. This is because the glucometer is classified as an IVD (invitro-diagnostic device) rather than a patient applied medical device.

13.1.11 Standards Compliance

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

Standard	Title
IEC 60601-1 2nd edition: 1988 Amendment A1:1993, A11:1993, A12:1993, A1:1995, A13:1996	Medical electrical equipment: General requirements for safety (as amended)
IEC 60601-1-1:2000 – *reference standard only*	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2:2005	Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-4:1996 Amendment A1:1999	Medical electrical equipment -- Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems (as amended)
IEC 60601-1-6:2004	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Usability
IEC 60601-2-25:1993 Amendment A1:1999	Medical electrical equipment -- Part 2-25: Particular requirements for the safety of electrocardiographs
IEC 60601-2-30:1999	Medical electrical equipment -- Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
IEC 60601-2-49:2006	Medical electrical equipment -- Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
ISO 21647:2004 ISO 21647:2004/AC:2006	Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors (as amended)
ISO 9919:2005	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
ISO 14971:2007	Medical devices - Application of risk management to medical devices
EN 60529:1992	Specification for degrees of protection provided by enclosures (IP code)

Standard	Title
EN 980:2008	Graphical symbols for use in the labelling of medical devices
EN 1041:1998	Information supplied by the manufacturer of medical devices
ISO 10993-1: 2003	Biological evaluation of medical devices - Part 1: Evaluation and testing
RTCA/DO160E	Environmental conditions and test procedures for airborne equipment
UL 1642 Issue 4	Standard for lithium batteries

13.1.11.1 EMC Information

The following tables provide information required to be provided under IEC60601-1-2.

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	01-1015	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.

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 Measurements	Compliance	Electromagnetic Environment
Emission of overtones acc. to IEC61000-3-2	Class A	
Emission of voltage fluctuation/flicker acc. to IEC61000-3-3	Complies	

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			

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√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.			

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

	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,
	Type BF applied part. The thermometer **is not** 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
IPX6	The device is proof against a hose according to IEC529

Symbol	Description
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.
YYYY - MM	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
Wi Fi	WiFi connection mode to response centre
Bluetooth	Bluetooth® connection to medical modules
	Battery Connection – to indicate positive terminal polarity
GPS	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 End User License Agreement

This license covers RDT's Tempus IC software.

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In order to function correctly Tempus IC needs to operate over a communications link such as satellite communications, GSM or a telephone line and other types of links. It is your responsibility to maintain these communications links. Such links may have security or other measures implemented on them such as firewalls. It is your responsibility to ensure that any such firewalls or other elements of the communication link are configured correctly to allow data from Tempus IC to communicate over said link. RDT does not accept any responsibility for failure to transmit data or to transmit data reliably over such links if they have not been configured correctly. Support on configuring such links can be obtained from RDT upon request.

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The software gives users the ability to share and transmit medical data with third parties. Such activities are entirely the responsibility of the user.

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16 Change History

Page/Section	Change	Date/Issue
N/A	First release	00
5.2.4	Added section on GSM/ DPRS display	01
8.4	Section added on using the thermometer	01
8.5	Section added on using the glucometer	01
8.6	Information added on transmitting moving video	01
9.1.1	Section added covering cleaning of the thermometer	01
10.2.5	Added section on batteries (headset, glucometer and thermometer)	01
10.3.1	Section added on thermometer errors	01
10.3.2	Section added on glucometer errors	01
11	Added glucometer calibration kit as an accessory	01
13.1.5	Specification section added for the thermometer.	01
13.1.6	Specification section added for the glucometer.	01
13.1.7.1	Environmental testing section added	01
13.1.9	Expanded details of communications specifications	01
13.1.10	Classification details updated to cover the thermometer and glucometer	01
14	Added BF symbol for the thermometer	01
15	Added EULA to section 15, moved change history to section 16	02
31	Added Accessory Pouch	03
38	Added information to section 7.2.1.1.2 on getting information on how to adjust the volume of the wireless headset.	03
63	Added section 8.9 on GPS	03
83	Added Accessory Pouch	03
96	Added 13.1.8.4 for GPS specification	03
99	Updated WiFi specification	04
101	Updated FCC & IC numbers for Tempus IC	04
102-103	Updated GSM specification	04