User/Operator Manual

English

Part number:
41-2017EN-06

Document date:
2022-05-23

Tempus IC2

Patient monitor

PHILIPS

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About this manual

This manual is for the Tempus IC2 patient monitor.

Important

If any serious incident has occurred in relation to the device it should be reported to Remote Diagnostic Technologies Limited and the competent authority of the Member State in which the user and/or patient is established.

Document library

Consult the instructions for use. These are provided in electronic format in the Philips Document Library.

Important

Please check the Philips Document Library regularly for new versions of this document.

A paper copy of this document may be requested from the Philips Document Library or by sending a request to RDT_Customerservice@philips.com.

Use of this manual

The instructions and safety precautions provided in this manual must be observed during all phases of the operation, usage, service or repair of the Tempus IC2 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 assumes no liability for customer failure to comply with the information contained in this manual.

Users of Tempus IC2 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.

Safety and note icons

The following icons are used to indicate safety, caution and warning messages (per ISO 3864-2):

DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

The note icon is used for important and helpful information:

Important

Indicates a condition that may lead to equipment damage or malfunction.

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

Proprietary notice

The purpose of this document is to provide the user with adequately detailed information to efficiently install, operate, maintain and order spare parts for the Tempus IC2. Every effort has been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that the document is error free or that it is accurate with regard to any specification. RDT reserves the right to change specifications without notice.

NO IMPLIED LICENSE: Possession of this device does not convey any expressed or implied license to use the device with unauthorized sensors or cables that would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

Tempus IC2®, Tempus IC® and i2i™ 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.

TaiDoc™ and TD-4279™ are trademarks of TaiDoc Technology Corporation.

MyGlucoHealth® and Entra Health Systems™ are protected by registered trademarks and trademark applications of Entra Health Systems Ltd.

Sennheiser™ is a trademark of Sennheiser electronic GmbH & Co. KG.

Fora® is a trademark of Fora Care Inc.

The following trademarks are the property of Medtronic: Microstream™ Advance filter line, Microstream™ technology, Microstream™ capnography and Integrated Pulmonary Index™ algorithm.

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

Masimo® and the Masimo SET® logos are the property of Masimo Inc.

Limited warranty

Remote Diagnostic Technologies Limited ('RDT') warrants each new Tempus IC2 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 IC2 is in any way modified or if it is used with non-approved consumables, unless specifically authorized in writing by RDT, and RDT shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

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

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

Service support and returns

Repairs made under warranty to any Tempus IC2 must be made by the manufacturer. If the Tempus IC2 requires repair or return for any reason, please contact your local distributor or Remote Diagnostic Technologies in order to first obtain a returns reference (RMA) number. RDT reserves the right not to accept returns which have not first been provided with an RMA number. When calling, please be ready to quote the serial number of the Tempus.

The Tempus IC2 is designed to be as maintenance free as possible. The only user replaceable and user serviceable parts in the Tempus IC2 are those listed in the *Tempus IC2 User/Operator 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. If the device malfunctions and may have caused or contributed to a serious injury of a patient or user, RDT must be notified immediately by telephone, fax or written correspondence.

Patent claims

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

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

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

CE statement

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

The Tempus IC2 is a class IIb device under the MDD and is a class I device (harmonized frequencies) under the Radio Equipment Directive (RED) 2014/53/EU.

A Declaration of Conformity in accordance with the above regulations has been made and is on file with RDT at the "Manufacturer's address". The wireless portion of this equipment may be operated in GB, France, Italy, Switzerland, Germany, Holland, Portugal, Spain, Sweden, Norway, Denmark and Finland.

FDA prescription statement

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

1 Introduction to the Tempus IC2

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1.1 Intended purpose

The Tempus IC2 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 center elsewhere. Typical examples are remote land, sea or air locations.

The Tempus IC2 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 Center which would be staffed by physicians who would advise the operator on the nature of the medical incident.

1.2 Indications for use

Tempus IC2 measures non-invasive blood pressure, SpO_2, pulse rate, respiration rate and $ETCO_2$, 12 Lead ECG, tympanic temperature (via a wireless external module) and blood glucose (via a wireless external module, if installed).

The Tempus IC2 does not replace a physician's care. The device is not intended for neonatal use. The device is not an apnoea monitor.

The Tempus IC2 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.

1.2.1 Contraindications

The Tempus IC2 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 IC2 is not intended to allow a lay user to make any clinical decision for treatment or diagnosis.

The Tempus IC2 is not intended to, and does not sound alarms for physiological parameters.

The 12 lead ECG harness 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 12 lead ECG harness is not intended to be used on patients with prosthetic limbs.

1.2.2 Patient target populations

Tempus IC2 is suitable for use on adults or children (over 10 years old and over 20kg in weight).

1.1 Warnings, cautions and notes

1.1.1 Tempus IC2 warnings, cautions and notes

WARNING

It is essential to switch off the Tempus IC2 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 IC2 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 IC2 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 sterilize, 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: "A.4 EMC statement".

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 IC2 with the relevant cables and peripherals provided by RDT. It is not safe to use the Tempus IC2 with other cable and peripherals.

WARNING

Do not interconnect the Tempus IC2 with any equipment that is not described in this manual.

WARNING

Exposure of the wireless communication features of the Tempus IC2 or its accessories may be interfered with by other devices which operate at the same frequencies.

WARNING

The sensors of the Tempus IC2 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 IC2 is not for use on neonates.

WARNING

The device should not be used on patients undergoing defibrillation. The Tempus IC2 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 synchronization 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 (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 rechargeable batteries and battery chargers specified by RDT.

WARNING

Ensure patient cabling or tubing is carefully routed on device to reduce the possibility of patient entanglement or strangulation.

WARNING

Keep the cabling and tubing away from babies and young children, as they may create a strangulation hazard.

WARNING

Do not allow any small parts to be separated from the Tempus IC2 or its bag, as they may create a choking hazard for babies and young children.

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 IC2 (including patient cables) directly into an electrical outlet.

WARNING

Explosion Hazard: DO NOT use the Tempus IC2 in the presence of flammable anaesthetics or other flammable gasses. Use of the Tempus IC2 in such environment may present an explosion hazard.

WARNING

Failure of Operation: If the Tempus IC2 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 USB memory device) or to interface accessories provided by RDT. Any connections made to the USB port must be to medical or IT peripherals or communications systems which comply with the applicable IEC safety standard (i.e. IEC60601-1 or IEC60950). Any connection arrangements must be made in a manner compliant with IEC60601-1-1.

WARNING

The Tempus is designed to enable a non-expert user to collect medical data from a patient and to then transmit that data to a Response Center staffed by physicians, who will use this data to provide medical support and advice. Under no circumstances should non-expert users attempt to use data generated by the Tempus to make diagnostic or treatment decisions. If a physician is present at the incident, they can use the data from the Tempus to make diagnostic or treatment decisions.

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

The Tempus IC2 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 approved accessories supplied by RDT.

CAUTION

DO NOT clean the IC2 or its accessories except as directed in this guide.

CAUTION
DO NOT apply excessive tension to any of the Tempus IC2 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 IC2 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 organizations, mandated by local governments or organized 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 nebulized 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 IEC60601-1-2:2014.

If the intended patient has an implantable device (e.g. implantable pacemaker), do not use any of the Tempus IC2'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 Center 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

The SAR (Specific Absorption Rate) limit as dictated by the FCC (in the USA) is 1.6W/kg averaged over 1 gram of tissue. The Tempus IC2 has been tested against these SAR limits to maintain compliance with FCC RF exposure requirements. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. The antennas used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter except as defined in the FCC filing.

CAUTION

A minimum distance of at least 10 cm (3.94 inches) must be maintained between the Bluetooth devices (headset, thermometer and glucometer) and a cardiac pacemaker or implanted defibrillator (ICDs).

CAUTION

When using the device with portable satellite terminals such as 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 familiarize 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 approx.), care should be taken to ensure that the antenna remains fixed and to maintain the device away from the face (and therefore the beam) of the antenna.

CAUTION

RF energy may affect some electronic systems in motor vehicles, such as car stereo, safety equipment, etc. Check with your vehicle manufacturer's representative to be sure that your product will not affect the electronic system in your vehicle.

CAUTION

Do not use the Tempus IC2's Bluetooth® or WiFi communications on-board any aircraft where its use is prohibited.

CAUTION

Do not use the Tempus IC2 during take-off or landing.

CAUTION

Take care to minimise the risk that trailing cables will be caught by passers by.

CAUTION

Do not attempt to calibrate the Tempus IC2 or its accessories. If there is any indication that calibration is necessary, for example a warning message, contact RDT support.

CAUTION

Tempus IC2 must only be used with the devices listed in this manual. Do not use it with any other devices or general purpose equipment.

The Tempus is intended for use in locations remote from emergency medical care. It should therefore only be used outside the USA (within the USA conventional emergency medical care should be contacted) except where it is used by a physician.

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.

Important

The Tempus IC2 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).

The Tempus IC2 or its accessories contain no user serviceable parts except as detailed by this manual or accompanying documents. Refer service to qualified service personnel.

This product and its accessories are latex free.

After the life cycle of the Tempus IC2 and its accessories have been met, disposal should be accomplished following national and/or local requirements.

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.

All user and patient accessible materials are non-toxic.

Hazards arising from software errors have been minimised. Hazard analysis was performed to meet the requirements of EN ISO 14971 and IEC60601-1-4.

Each external medical connection and part of the device is electrically isolated.

Performance and safety test data are available on request from RDT at the manufacturer's address (see end page).

This equipment is not hearing aid compatible.

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.

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

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.

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.

IP sealing is not guaranteed if the device is subject to rough handling, impact, improper use, rapid decompression.

Device should be returned for service if it is subject to rough handling and IP sealing is needed to be relied upon.

The Tempus IC2's water ingress seals are warranted for 1 year from the date of manufacture.

The device specifications are subject to change without notice.

It is recommended that the device is connected to the Response Center every month for a test patch.

The iAssist help processes on your Tempus IC2 may differ from the example iAssist help process used in this manual; however the process always follows the same key elements.

Always ensure that you read the complete iAssist help process in order and do exactly what it requires.

For optimum performance of the wireless communications, please make sure that there is no metal surrounding the Tempus IC2.

Over-bending the folding foot or RapidPak clip could cause them to be damaged. Do not over-bend these items.

Take care when repacking cables to ensure they cannot be snagged or damaged in the RapidPak clip and the folding foot.

The Tempus IC2 should be repacked following the relevant instructions. Lost or damaged cables and accessories should be replaced with spares ordered from RDT.

The Tempus IC2 takes up to 30 seconds to become ready for operation after switching on. It is recommended that you switch on Tempus IC2 at the same time as you remove it from its storage location rather than when you arrive at the patient.

1.1.2 Capnometer - warnings, cautions, & adverse reactions

WARNING

The device should not be used as an apnoea monitor.

WARNING

To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

WARNING

Carefully route the Filter Line to reduce the possibility of patient entanglement or strangulation.

WARNING

Do not lift the monitor by the Filter Line, as they could disconnect from the monitor, causing the monitor to fall on the patient.

WARNING

To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, such as rain.

WARNING

The use of accessories, transducers, sensors and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system.

WARNING

CO_2 readings and respiratory rate can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.

1.1.3 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

The Tempus IC2 operator should check and communicate to the medical expert that the patient is a nail polish/varnish wearer and ideally communicate the full information on the type and darkness. The Consulting Health Care Professional can advise on further options as fingernail polish or false fingernails may cause inaccurate SpO_2 readings. Nail polish remover wipes have been excluded from the Tempus IC2 bag, please take guidance from the consulting Health Care Professional when following the steps to take and transmit the SpO_2 reading.

WARNING

Significant levels of dysfunctional haemoglobins, such as carboxyhaemoglobin or methhaemoglobin, 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.

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.

DESAT trails were performed in the normal sensitivity mode.

Use proper disposal guidelines when discarding the device.

1.1.4 ECG recorder sensor - warnings, cautions and 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 the Harness is 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 IC2 is rated as being proof against the effects of a defibrillator discharge. Follow these warnings if using an AED or defibrillator with the Tempus IC2:

- Follow the instructions of the defibrillator or AED when using it with the Tempus IC2.
- Remove the ECG harness from the patient so the defibrillator or AED pads can be fitted correctly.
- 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.

1.1.5 The blood pressure monitor - warnings, cautions and 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.

1.1.6 Use in high ambient temperatures

CAUTION

Since the Tempus IC2 is rated for use in high ambient temperatures, users are reminded to give consideration to the potential for outer surfaces of the Tempus IC2 to become hot in such ambient temperatures. Further to Table 23 of IEC60601-1:2005, plastic parts (such as the sides, touchscreen, handle etc.) which may be acceptable for long term physical contact at ambient temperatures up to 48°C need to be touched for shorter durations (e.g. less than 1 minute) when used in higher ambient temperatures. Similarly users should note that while the rear heat sink may be touched permanently in ambient temperatures up to 36°C, in higher ambient temperatures contact with it should be reduced. Users should pay attention to this if instead of using the handle, they grip the device around its sides.

In ambient temperatures above 40°C users should ensure that the device is used in an upright position and that there is air flow around the back of the unit.

Users are reminded that the Tempus IC2 (when using its external power supply) should not be used to recharge batteries above 40°C – see section "A.2 Physical characteristics and environmental specifications".

Users are reminded that the specification of the power supply limits its use to 40°C maximum – see section "A.3 Miscellaneous features and specifications".

1.2 Product description

1.2.1 Vital signs monitor

The Tempus IC2 is a multi-parameter vital signs monitor which connects to a dedicated Response Center. 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 IC2 as a stand-alone diagnostic device (without it being connected to the Response Center).

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

1.2.2 Patient readings from device sensors

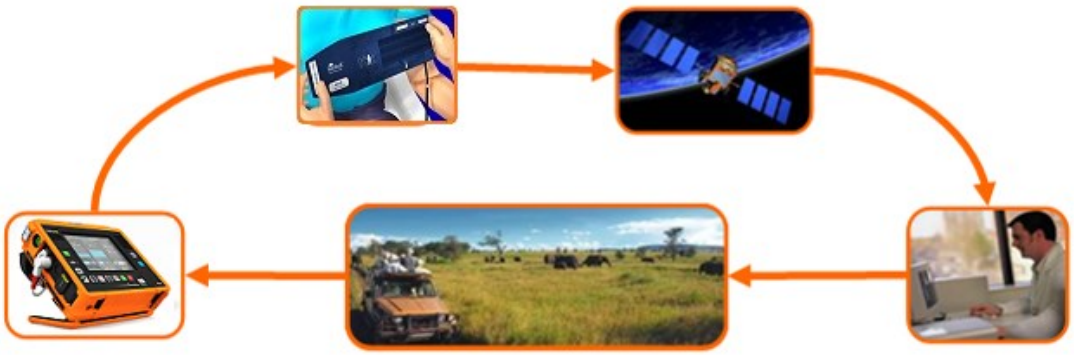
The Tempus IC2 provides the following information about the patient from its sensors:

- Pulse rate
- Oxygen saturation (SpO_2)
- Blood pressure
- 12 lead Electrocardiograph (ECG)
- End tidal CO_2 ($ETCO_2$)
- Respiration rate
- Temperature
- Blood glucose level (if glucometer installed)

These readings are transmitted via a communications link to a computer at a Response Center which enables the physician to see all the vital signs data.

1.2.3 Response center

Everything that is displayed on the Tempus IC2 screen is simultaneously seen at the Response Center, enabling the medical expert to fully interact with the operator. The medical expert can, fully control the Tempus IC2 if required, giving added comfort to the operator and patient at the remote location.



Tempus IC2 in use

The Tempus IC2 sends all of its measurements and displays via the communication connection to the Response Center, where the displays are duplicated. The medical expert at the Response Center is also able to annotate (with words, symbols and markings) and send back the still camera 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 IC2, giving added comfort to both the user and patient.

1.2.4 Digital camera

A digital camera is mounted in the unit. Images from this camera can be sent to the Response Center to provide the physician with a view of what is happening to the patient.

Video from the camera is captured by the Tempus IC2 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.

1.2.5 Voice and data communications

The Tempus IC2 can connect over GSM, wireless (WiFi), or wired Ethernet networks.

RDT recommends that users perform a test connection to the Response Center every month in order to verify that their communications remain open for the Tempus IC2 to use.

The Tempus IC2 operates over third-party communications links, such as, GSM or satellite links and the Internet. RDT does not accept liability for the failure of these links to reliably transmit information from RDT's products. Users are reminded that it is their responsibility to ensure that GSM network and other communications contracts are maintained and suitably setup and configured for the areas in which they need to be used.

1.3 Device sensors

All of the measurements made by the Tempus IC2 are transmitted in real time except the ECG (and digital pictures) which is first recorded and then transmitted to the Response Center.

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

- 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.

1.3.1 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 rubber boot. 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.

1.3.2 Blood pressure

Tempus IC2 uses non-invasive techniques to measure the patient's blood pressure. A pump within Tempus IC2 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 and diastolic pressures 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.

1.3.3 Electrocardiograph (ECG)

Electrical currents influenced by the cardiac impulse flow through the body tissue around the heart. Tempus IC2 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 IC2 uses a specially moulded electrode apron which has seven of the electrodes positioned in the correct places to pick up the signals on the chest. The remaining electrodes are positioned separately on the right wrist, left wrist and patient's left 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.

1.3.4 End Tidal CO_2 ($ETCO_2$) and respiration rate

The capnometer is used to monitor continuous carbon dioxide and report the end tidal carbon dioxide ($ETCO_2$) and respiratory rate values of non-intubated adult patients. The capnometer is used for the continuous measurement of CO_2 (carbon dioxide) and respiratory rate.

The capnometer uses a Microstream sampling system 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 unit 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.

1.3.5 Temperature

The thermometer that is provided is an infra-red tympanic device used for spot-checking a patient's temperature. The thermometer operates by measuring the patient's temperature in the end of the ear canal (across the tympanic membrane). This is detected and measured using an infra-red detector that is built in to the thermometer's head.

The thermometer displays the reading on an LCD screen built into its handle and communicates the reading to the Tempus IC2 using Bluetooth® technology. The thermometer's Bluetooth® radio must be "paired" with the Tempus IC2 before it can be used.

> **CAUTION**
> The thermometer's reading can be presented in °F or °C.

The thermometer is paired with the Tempus IC2 before shipping.

1.3.6 Blood glucose level (if installed)

The glucometer (if installed) that is provided with the Tempus IC2 is for spot-checking a patient's blood glucose level. The glucose enzyme oxidase on the test strip reacts with the glucose in the blood sample and the result is displayed as a blood glucose level on the meter.

The glucometer displays the reading on an LCD screen built into the glucometer and communicates the reading to the Tempus IC2 using Bluetooth® technology. The glucometer's Bluetooth® radio must be "paired" with the Tempus IC2 before it can be used.

Your organization's maintenance user must pair the TD-4279 glucometer with the Tempus IC2 before deployment.

1.4 Disposal at end of life

The expected life of the Tempus IC2 (excluding batteries) is 5 years.

The WEEE logo refers to the EU Directive on Waste Electrical and Electronic Equipment (WEEE). This Directive entered into force as European law on 13th February 2003; it resulted in a major change in the treatment of electrical equipment at end-of-life. The purpose of this Directive is, as a first priority, the prevention of WEEE, and in addition, to promote the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste.

The symbol indicates that this product must not be disposed of or dumped with household waste. The owner of the equipment is liable to dispose of all electronic or electrical waste equipment by delivering to the specified collection point for recycling of such hazardous waste, collection and proper recovery of electronic and electrical waste equipment at the time of disposal will allow the producer to help conserve natural resources. Recycling of the electronic and electrical waste equipment will ensure safety of human health and the environment. For more information about electronic and electrical waste equipment disposal, recovery and collection points, please contact your local, waste disposal service or producer / distributor of this equipment.

WARNING

Batteries should not be crushed or incinerated as they could present a risk of fire or explosion. Batteries should be handed to an appropriate organization that is competent in the disposal of such devices; this must be done in accordance with local regulations.

Disposal of single use devices

Any accessories that are designated as single-use devices 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 could present a bio-hazard and therefore should be disposed of in accordance with local regulations governing such matters.

2 Getting started

The iAssist help processes on your Tempus IC2 may differ from this example iAssist help process in the following sections. However the process always follows the same key elements.

Always ensure that you read the complete iAssist help process in order and do exactly what it requires.

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2.1 Unpacking the Tempus IC2

On receipt of a new Tempus IC2 device, it must be unpacked, inspected and tested by maintenance, engineering or other technical support personnel. For instructions, see the *Tempus IC2 Maintenance Manual*.

2.2 Tempus IC2 bag

The Tempus IC2 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 IC2 (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.

WARNING

Color-blind users may be unable to distinguish all of the colors used for bag pockets and consumable packages.

Each bag contains the following items:

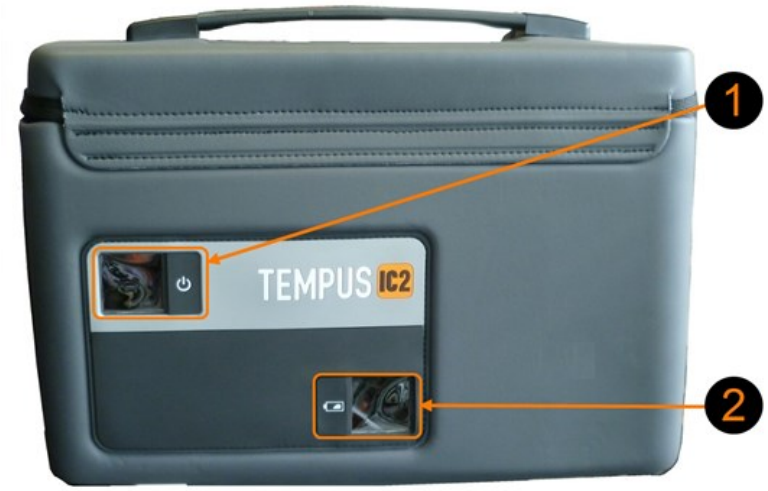
- 1 Tempus IC2 fully packed including battery, adult BP cuff and hose, SpO_2 probe, Ethernet cable and Bluetooth® headset
- 1 vial of glucometer strips (*1)
- 1 ECG spray
- 1 pack of 5 AlcoWipes
- 1 pack of 3 glucometer lancets (*1)
- 1 pack of 10 thermometer probe covers
- 1 ECG harness
- 1 blood pressure cuff – large adult
- 1 blood pressure cuff – child
- 1 Bluetooth thermometer
- 1 Bluetooth glucometer (*1)
- 1 pack of vinyl gloves (pair)
- 1 wired headset
- 1 extension reel
- 1 consumables replenishment kit
- 1 glucometer replenishment kit (*1)
- 2 capnometer cannulas - adult nasal

(*1) These items should only be present if a glucometer is installed.

Refer to "Accessories list" for details of how to obtain further supplies of these disposable items.

In addition, the Tempus IC2 is supplied with the following components which are not packaged in the bag:

- 1 mains power supply
- 1 mains cable pack
- 1 battery charger
- 1 spare battery
- 1 accessory pouch (for storing the spare battery or PSU)
- 1 user manual and maintenance manual CD-ROM



(1) Window to access the ON/OFF button

(2) Window to access the battery charge indicator

The Tempus IC2 bag

(1) ECG harness

(2) Consumables in color-coded pockets

(3) Tempus IC2 location

(4) Accessories in color-coded pockets

The bag open with the Tempus IC2 removed

2.3 Tempus IC2 device

The Tempus IC2 consists of an 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.

(1) Touchscreen.

(2) Membrane buttons.

(3) Battery.

(4) Deployable feet.

The Tempus IC2

2.3.1 Tempus IC2 front

The front of the Tempus IC2 has a large screen which is fitted with a touch-screen.

The front panel houses two keypads which are graphically labelled with their function.

2.3.2 Tempus IC2 base

The base of the Tempus IC2 houses the battery.

2.3.3 Tempus IC2 rear

The rear of the Tempus IC2 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. The clip carries a general product label for regulatory purposes and also two labels which help guide the user to repack the SpO_2 sensor and the communications cable. The top of the clip carries a product-specific brand also.

2.3.4 Tempus IC2 sides

The left side of the device contains four connectors for:

- ECG - green,
- NIBP – white latching connector;
- SpO_2 – grey;
- $ETCO_2$ – yellow.

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

Left side of the Tempus IC2

The right side of the Tempus IC2 houses the non-medical connections. These comprise:

- USB – this is reserved ONLY for non-mains powered USB peripherals approved for use with the Tempus IC2 by RDT.

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

- RJ-45 Ethernet – use only the Ethernet Cable supplied by RDT.
- Power – use only the power supply provided by RDT.
- Audio – this is only for use with the Wired Headset supplied by RDT.

See section "Annex D : Accessories of the Tempus IC2" for part numbers of the above accessories.

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

Communications connection panel

2.4 Controlling the Tempus IC2

The Tempus IC2 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.

2.4.1 Layout of instructions on the Tempus IC2

The Tempus IC2 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 Response Center,
- through applying all the medical devices;
- and then cleaning, repacking and replenishing the device.

The help screen shows a typical screen from the Tempus IC2. It shows that there are three distinct areas on the screen that give different types of information:

- **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. It also shows signal strength of the wireless connection and battery charge level.
- **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 in one or two steps at a time.
- **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.

(1) Status bar

(2) Help process graphics and instructions

(3) Touch screen buttons

Example of the Tempus IC2 screen layout:

2.4.2 Progressing through help processes

As mentioned above, the Tempus IC2 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.

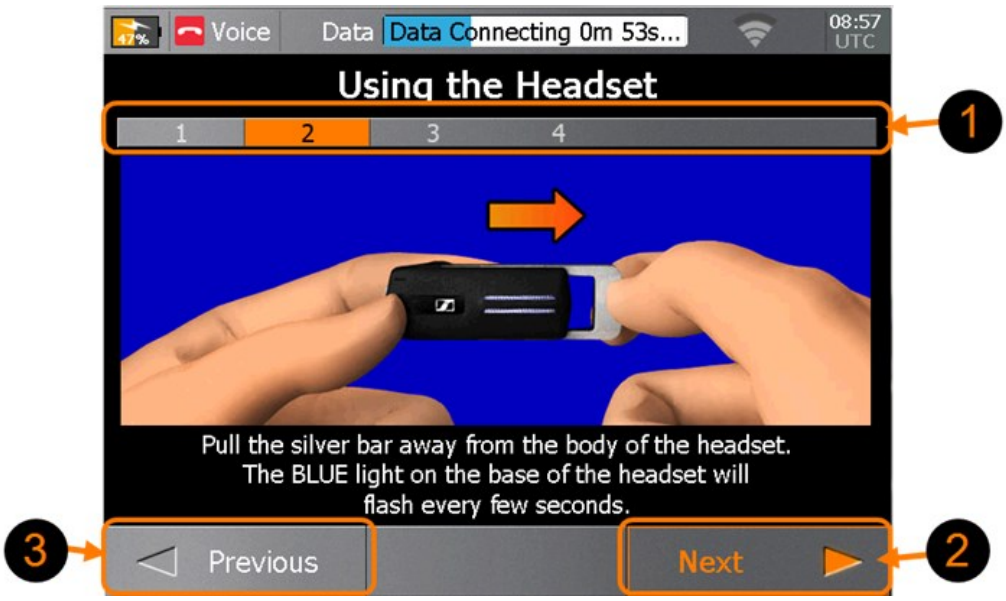
(1) Process ribbon

Example of the process ribbon

In the example shown above, the screen shows that the process has 4 steps and that the device is showing step 1.

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.



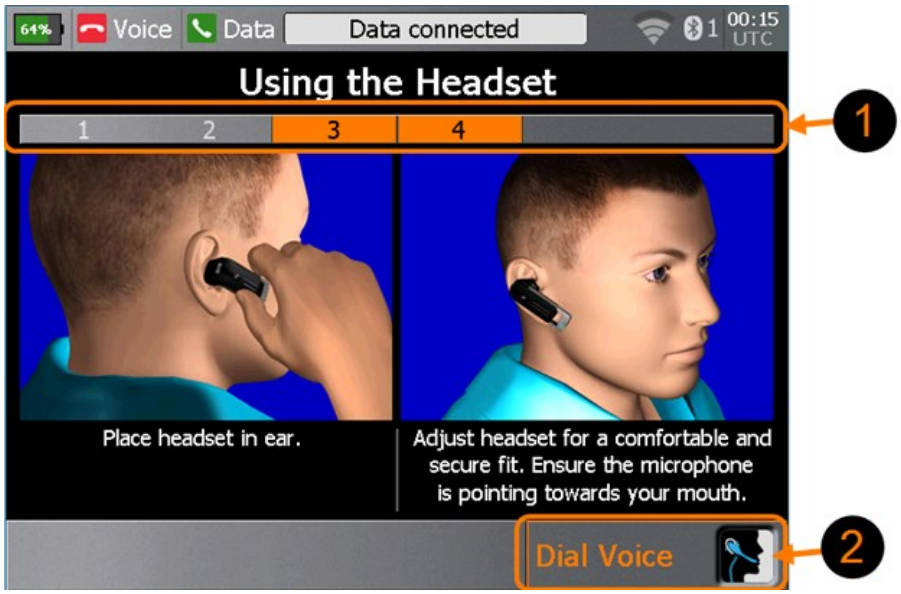
(1) Process Ribbon updated

(2) **Next** button to progress to next step

(3) **Previous** button to return to last step

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.



(1) Process ribbon complete

(2) Icon shows end of process

Example of the end of a process

2.4.3 Getting help

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 IC2. 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.

From the Help Menu, press the **Cleaning & Repacking** button to bring up the Cleaning and Repacking Menu

Example of the Help Menu

Example of the Cleaning and Repacking Menu

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

2.5 Switching on

CAUTION
Do not press any of the control buttons until the first iAssist help process artwork is displayed on the screen.

The Tempus IC2 takes approximately 30 seconds to become ready for operation after switching on. It is recommended that you switch on Tempus IC2 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 IC2, 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 15 minutes, the unit will switch off automatically to save battery power.

After switching on, the Tempus IC2 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
- Pulse Oximeter and Blood Pressure

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 NIBP and pulse oximeter process.

2.6 Explanation of the Tempus IC2 home screen

Tempus IC2 home screen normally divides into two sections:

- Status bar at the top
- Instrument readings in the middle

Example of the Tempus IC2 screen display

2.6.1 Status bar – clock (time stamp)

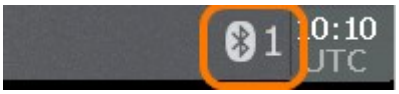
The time of day is shown in Coordinated Universal (UTC) time. Tempus IC2 has an internal clock for accurate time reference.

Tempus IC2 time display

2.6.2 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.

It does not identify the specific peripheral connected to the Tempus IC2.



Bluetooth® peripheral indicator

2.6.3 Status bar - WiFi indicator

This indicator is displayed when the Tempus IC2 is connected to the Response Center using WiFi communications technology.

WiFi status indicator

2.6.4 Status bar – GSM/GPRS/UMTS indicator

This indicator is displayed when the Tempus IC2 is connected to the Response Center using GSM, GPRS or UMTS communications technology.

GSM status indicator

The Tempus IC2 uses GSM, GPRS and UMTS networks to make a data connection. This requires the network signal strength to be better than is required for a conventional mobile handset making a voice only connection. Users should note that the signal strength readouts from the Tempus IC2 are not comparable to those of third-party handsets as the scale, setting, sensitivity and networks between the two devices may be different.

2.6.5 Instrument readings

This section of the screen shows the results (if any) from five of the six different medical devices (ECGs are displayed separately). Each of the 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.

The iAssist help processes on your Tempus IC2 may differ from the example iAssist help process in the following sections. However the process always follows the same key elements.

Always ensure that you read the complete iAssist help process in order and do exactly what it requires.

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 Center in real-time (if the connection is active), otherwise the measurements are memorized 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 Center. ECG measurements can be initiated manually by the operator or remotely by the Response Center.

All data which is generated by the Tempus IC2 is automatically time-stamped.

2.6.6 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 section "6.3 Troubleshooting").

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.

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3 Establishing communication with the Response Center

3.1 Preparing to connect 52
3.2 Making the phone connection 52
3.3 Fitting the headset and making the voice connection 53
3.4 Connection status indicators 60
3.5 Communications modes 62

3.1 Preparing to connect

The first step for using the Tempus IC2 is to establish communication with the Response Center. To do this you will need to:

- Ensure the device is set to use an appropriate communications Mode.
- Connect the Tempus IC2 to the Response Center.
- Fit the Headset comfortably in your ear.

It is possible for a physician to use Tempus IC2 as a standalone diagnostic tool without connecting to the Response Center. Under these circumstances, just press the appropriate measurement function button to access that function. It is still possible to be connected to the Response Center at any time by pressing the Connect button.

The Tempus IC2 can also be left running with the data link connected but the voice link disconnected i.e. if the Response Center physician wishes to continue monitoring the patient for a long duration but without keeping the voice link open with Tempus IC2 User. In this case the voice link can be reconnected at any time by pressing the Connect button.

3.2 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 on the screen, the Wireless Headset screen will appear.

Dialling the data connection

If the Response Center cannot be contacted, this could be due to errors in the way that the connection has been attempted (see section "6.3 Troubleshooting" 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.

The Tempus has been configured to automatically redial the Response Center 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.

3.3 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 Center can be made quickly.

You can remove the headset from its dock and turn it on before dialling the data link. If you do this, the headset automatically connects to the Tempus IC2 and the bluetooth icon appears on the right of the top status bar:

If you do this, the Tempus IC2 skips steps 1 to 4 of the voice connection instructions.

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.

3.3.1 Using the Sennheiser Presence wireless headset

The Tempus IC2 uses the Presence wireless headset manufactured by Sennheiser®. The headset is 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.

The Presence is supplied paired with the Tempus IC2. You cannot use different wireless headsets with the Tempus IC2 and RDT recommends that you do not attempt to use the Presence headset supplied with the Tempus IC2 with any other wireless devices (including other Tempus IC2 or other communications devices such as mobile phones).

Each Presence headset is paired to only the Tempus IC2 to which it is attached on delivery. While attaching the Presence headset to other Tempus IC2 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 Presence headset is lost or is damaged, contact RDT for a replacement.

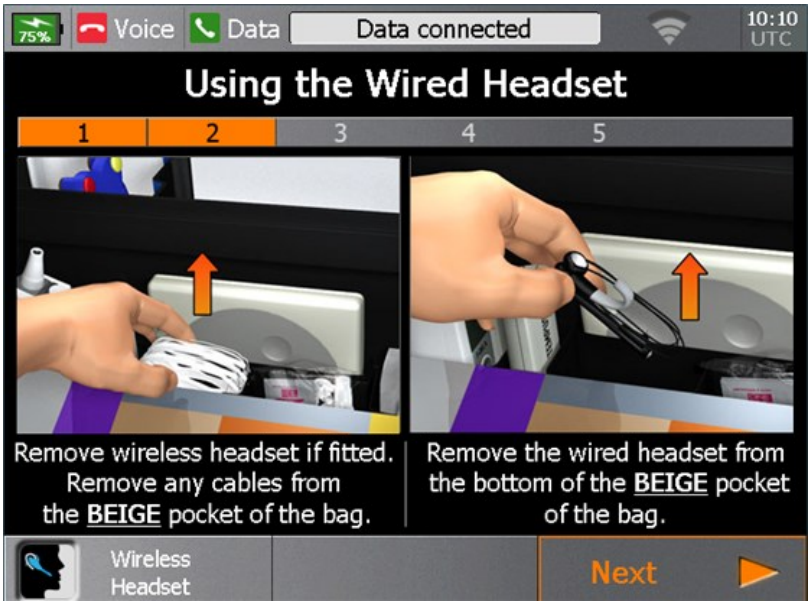
RDT recommends that the Sennheiser instructions (provided with the Tempus IC2) are read in addition to the instructions below.

(1) Instructions on using the wired headset can be found here

(2) Press here for the next instructions in the process

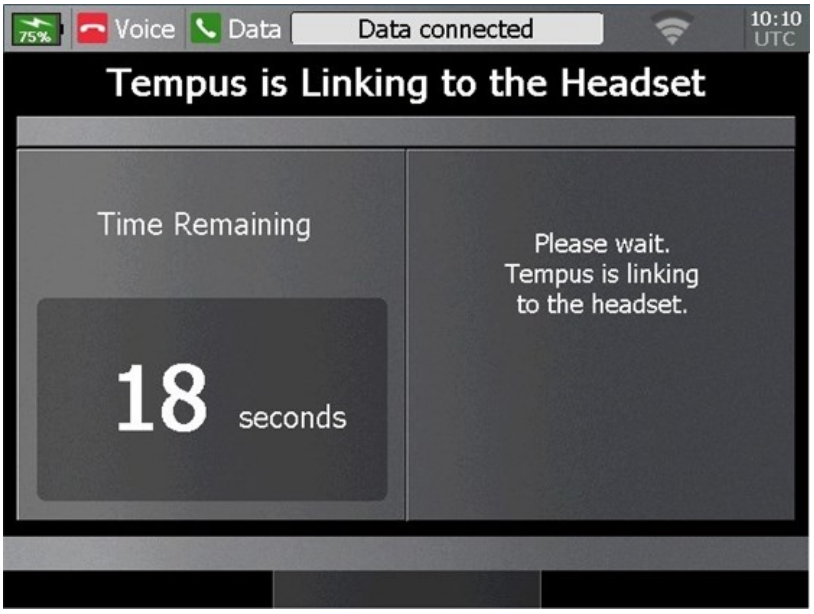
Example of the Sennheiser Presence wireless headset IAssist help process

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

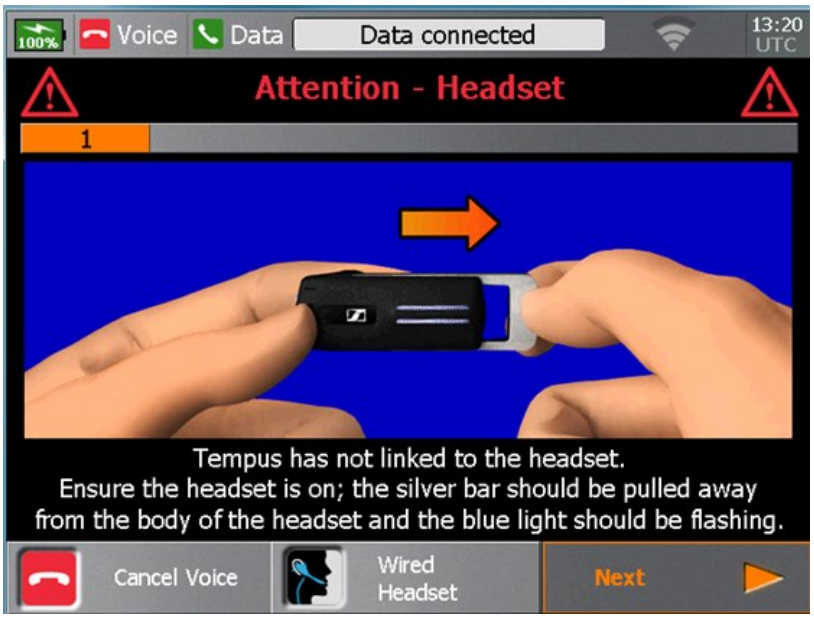
To switch to the Wireless Headset press the  button on the touch screen as identified in the above screen.



Setting up the Sennheiser Presence wireless Bluetooth® headset

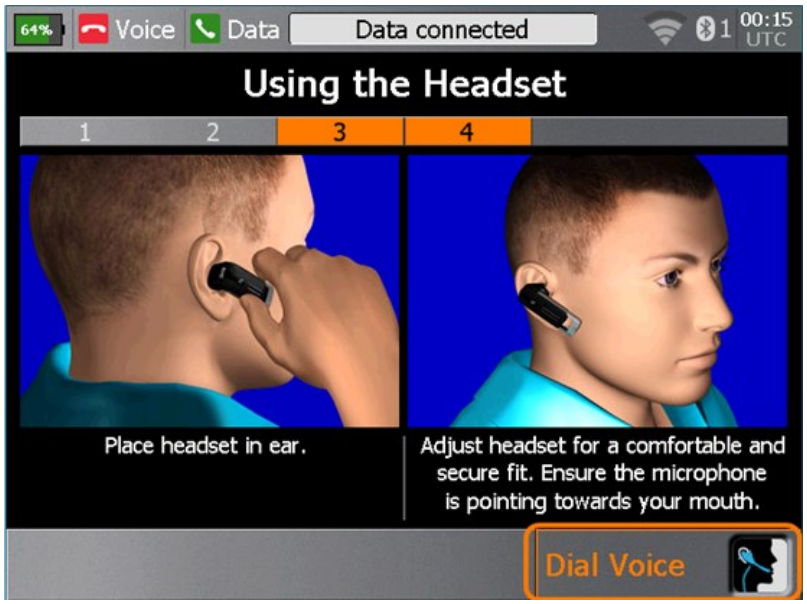
To use the Bluetooth® headset, follow the on-screen instructions. When the headset is turned on, the Tempus IC2 will attempt to find it. During this time (20 seconds) a countdown will be displayed. Once the Tempus IC2 has located the headset it will confirm this on screen before resuming with the voice connection instructions.

If the Headset is not turned on then communications between it and the Tempus IC2 will not start. In this event the Tempus IC2 will display a screen with headset instructions:



Sennheiser Bluetooth® linking error

Once the Tempus IC2 has linked to the headset, press the **Dial Voice** button to start the voice connection process:



Voice connection process instructions – last step

When using VoIP, the voice connection may take 10-15 seconds to setup after the **Dial Voice** button has been pressed.

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 IC2 and then re-initiate the connection again following the on-screen instructions.

3.3.2 Introduction to the Sennheiser Presence wireless headset

The headset has the following controls:

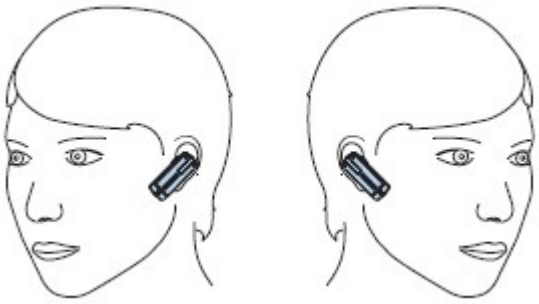
(1) Volume + button
(2) Volume - button
(3) Multi-function button
(4) Microphones
(5) On/Off power slide
(6) Speaker
(7) LED
(8) USB socket

Headset controls

Users should avoid using the headset speaker volume controls. The speaker volume can be controlled through the Tempus IC2 and is pre-set to maximum.

Wearing the Sennheiser Presence wireless headset

To put the headset on, follow the instructions given on screen. Simply put the headset into your ear (either ear), as described in the Sennheiser instruction manual provided with the Tempus IC2. You should ensure the speaker is well seated in your ear so that it feels stable.



Wearing the headset

Controlling the Sennheiser Presence wireless headset

To use the headset:

1. Press the green dial button.
2. Following the on-screen instructions, remove the headset from its dock.

3. Following the on-screen instructions, pull the silver bar away from the body of the headset. The blue light on the base of the headset will flash every few seconds.
4. The Tempus IC2 will go through a process to link to the headset via Bluetooth®.
5. Following the on-screen instructions, put the headset into your ear.
6. Following the on-screen instructions, press the Dial Voice button on the touchscreen.

If you keep the multi-function 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 IC2 and thus prevent it from operating with the device. Pairing mode can be recognized by the LED slowly flashing red and then blue. If the headset is inadvertently put into pairing mode it should be placed back onto the USB docking connector on the Tempus IC2 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 multi-function 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 pushing the silver bar into the headset and docking the headset back onto the Tempus IC2. If you do wish to turn the headset off, press and hold the multi-function button for 3 seconds until the LED flashes blue once and red three times.

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 IC2 and then re-initiate the connection again following the on-screen instructions.

RDT recommends that users do not use the multi-function button for any other purpose than turning the headset on (as described above). If you use the multi-function button then other functions and features (as described in the Sennheiser manual) of the headset can be engaged – these may cause confusion.

If you press and hold the “vol-” button for 1 second you will mute the headset microphone. 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.

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

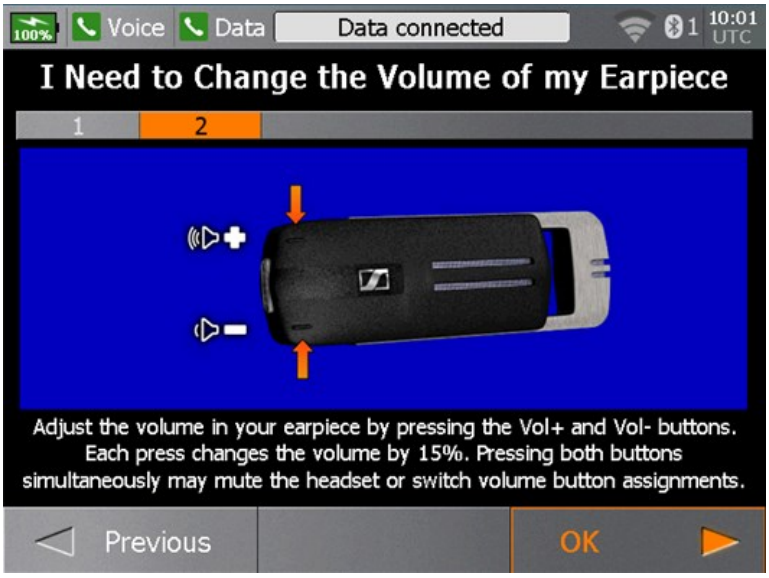
If you need to adjust the volume of the headset of the wireless headset (the wired headset has no volume controls) after you have connected the voice link, you can get instructions on how to adjust the volume by pressing the 

button. This is shown the first time you go into the camera iAssist process and the first time you go into the pulse oximetry and blood pressure 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 voice link.

Headset Help button

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

iAssist process for adjusting the Sennheiser wireless headset's volume (1)



iAssist process for adjusting the Sennheiser wireless headset's volume (2)

3.4 Connection status indicators

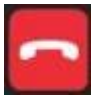
The iAssist help processes on your Tempus IC2 may differ from this example iAssist help process in the following sections. However the process always follows the same key elements.

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 IC2 is connected to the Response Center. 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')

The words 'connected' and 'disconnected' refer to whether there is a call in progress, NOT whether the Tempus IC2 phone wires are plugged in.

3.4.1 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 IC2 can be used to take measurements of the patient e.g. blood pressure, pulse oximetry and a photo, which will then be available to the Response Center as soon as the connections have been completed.

Data dialling

Once dialling has been initiated, text will appear giving a countdown to when the data link is expected to connect, and the Data symbol will flash green. 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.

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 pre-set 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.

If you are using the built in Cell Phone (GSM), 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.

Automatic redialling

The Tempus IC2 is configured to redial the voice or data links automatically it will indicate that a redial is taking place by displaying a number behind the “Call in progress” indicator.

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.

File transfer status indicator

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

3.5 Communications modes

Tempus IC2 can connect to the Response Center using 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 IC2 is pre-set to connect using different communication “Modes”. Each Mode is supported by a full set of graphical connection iAssist help processes that provide the User with instructions specific to connecting using that technology.

The Tempus IC2 shows what Mode it is in with a banner at the top of the Connection IAssist help process.

Current communication mode (example)

The Tempus IC2 will stay in this Mode until it has been set to another Mode (even if it has been turned off and on again).

3.5.1 Changing modes

You can change the Mode that the Tempus IC2 is set to by pressing from the Help Menu IAssist help process. This will bring up the Communications Modes Menu.

3.5.2 Using available modes

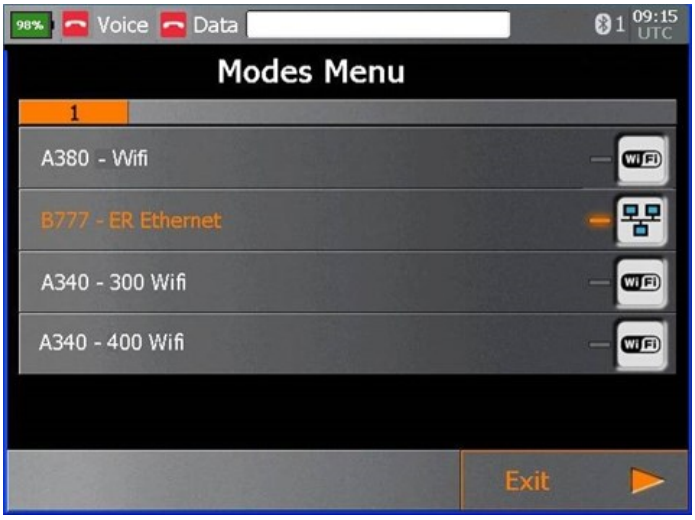
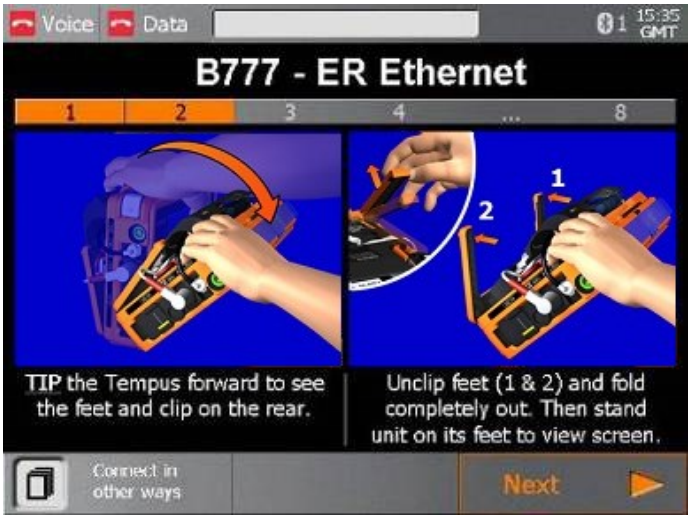
The Modes that are available on each Tempus IC2 are dependent on the requirements of each User. Refer to the Modes Menu on your Tempus IC2 for specific details of each Mode that is available.

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 WIFI connection may be useable instead.

3.5.3 Changing the connection mode

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

Step	Description	Photos and notes
1.	Press **Connection Modes** on the touchscreen.	
2.	Make the relevant selection by pressing on one of the buttons, for example **B777 - ER Ethernet**. Check the title of the mode is what you want. If you wish to exit the Modes Menu, press **Exit**.	
3.	Confirm that the correct selection has been made by checking the title, for example **B777 - ER Ethernet**.	

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4 Taking medical readings

WARNING

It is essential to switch off the Tempus IC2 in between different patients to avoid confusion between different patient records.

The iAssist help processes on your Tempus IC2 may differ from this example iAssist help process in the following sections. However the process always follows the same key elements.

Always ensure that you read the complete iAssist help process and look at the pictures in order and do exactly what it requires.

The Tempus IC2 is intended for use on one patient per incident. It must not be used on more than one patient because the Tempus IC2 has no way of associating a measurement with a particular patient.

4.1 Pulse oximeter and blood pressure 66

4.2 Electrocardiograph (ECG) 70

4.3 Capnometer 74

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4.5 TD-4279 glucometer (if installed) 81

4.6 MyGlucoHealth glucometer (if installed) 85

4.7 Digital camera 88

4.8 Interacting with the Response Center 91

4.9 GPS location 93

4.10 Actions after use 95

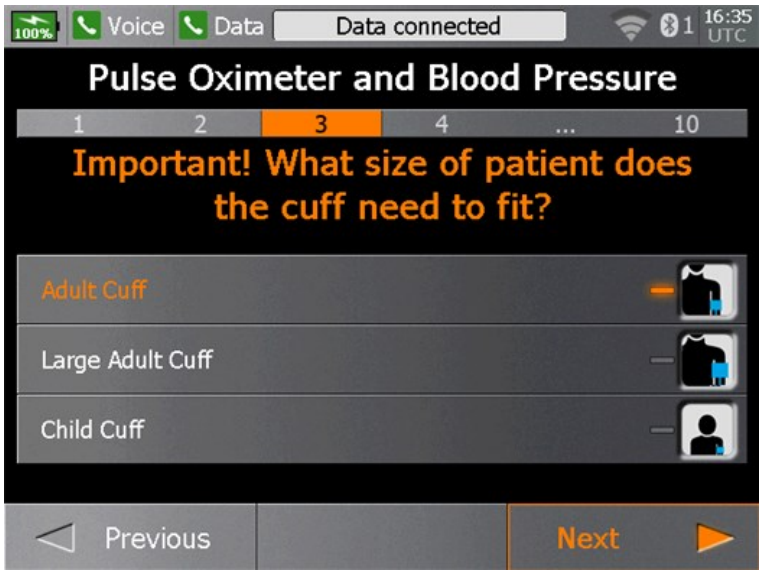
4.1 Pulse oximeter and blood pressure

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

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

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

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



Example of the Pulse Oximeter and Blood Pressure help screen

WARNING

The Tempus IC2 is not for use on neonates (young babies).

WARNING

The Tempus IC2 is not intended for long term patient monitoring. There are no audible or visible alarms.

WARNING

Reposition the oximeter probe at least once every 1 hour to allow the patient's skin to respire. This time should be reduced in ambient temperatures over 41°C. No other special actions are required for use in such ambient temperatures although users are advised to check the sensor site frequently in high temperatures to avoid skin damage.

WARNING

The SpO_2 sensor should snugly fit the finger without straining it and if not alternative fingers should be tried.

WARNING

The Tempus IC2 will not operate effectively on patients who are experiencing convulsions or tremors.

WARNING

Prolonged or repetitive use of the blood pressure cuff may harm skin integrity and circulatory status. Observe the limb concerned to check that circulation is not impaired.

WARNING

The Tempus IC2 operator should check and communicate to the medical expert that the patient is a nail polish/varnish wearer and ideally communicate the full information on the type and darkness. The Consulting Health Care Professional can advise on further options as fingernail polish or false fingernails may cause inaccurate SpO_2 readings. Nail polish remover wipes have been excluded from the Tempus IC2 bag, please take guidance from the consulting Health Care Professional when following the steps to take and transmit the SpO_2 reading.

CAUTION

You must use the right size of blood pressure cuff to suit the patient, and you must tell the Tempus IC2 if you are using the large cuff or child cuff. The cuffs are marked as follows:

- Adult (23 – 33 cm). Cuff is colored BLUE.
- Large adult (31 – 40 cm). Cuff is colored DARK RED.
- Child (12 – 19 cm). Cuff is colored GREEN.

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 IC2 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_2measurements may be adversely affected in the presence of high ambient light levels. If necessary, shield the sensor area (e.g. with a towel).

Performance and safety test data are available on request from RDT at the manufacturer's address (see end page).

Significant levels of dysfunctional haemoglobins, such as carboxyhaemoglobin or methaemoglobin 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.

4.1.1 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 Center 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).

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.

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

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.

4.1.2 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 UTC. 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 Center every time they are made, provided that the data link is active.

4.1.3 Blood pressure monitor error iAssist help process

The Tempus IC2 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 IC2 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 IC2 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.

4.2 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.

The electrodes must be sprayed with the ECG spray (contact solution) before use.

WARNING

The Tempus IC2 should not be used on patients undergoing defibrillation. The Tempus IC2 is protected against defibrillator discharge but rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.

WARNING

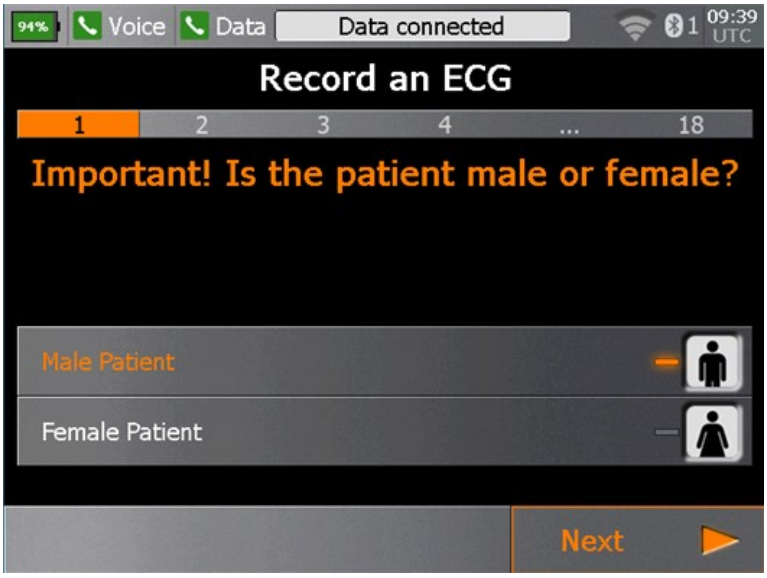
The Tempus IC2 will not operate effectively on patients who are experiencing convulsions or tremors.

WARNING

The electrodes of the ECG harness 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.

WARNING

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



Example of an ECG help screen

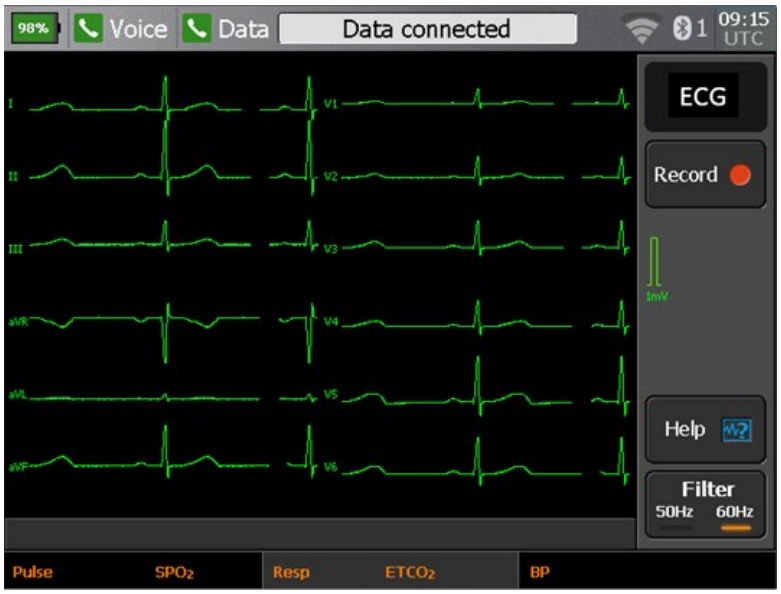
Whilst the ECG harness fits many patients, one size cannot fit all patients. Consequently, the ECG data collected may not be of diagnostic quality for some patients.

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 IC2 will display the ECG.



The ECG monitoring screen

The Tempus IC2 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 right hand side of the screen shows the current status of the ECG settings.

ECG Filter 50Hz 60Hz. This should either be set to 50Hz 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 right corner of the ECG. It will either show 50Hz or 60Hz as lit, pressing on this area of the touchscreen will change the setting.

Hz means Hertz, or cycles per second. In North America, mains electricity supplies operate at 60 Hz; most of the rest of the world uses 50 Hz. In aircraft the filter should normally be set to 50 Hz. In remote land and maritime applications the local voltage could be either 50 Hz or 60 Hz.

4.2.1 Monitoring an ECG

To record an ECG, press **Record** 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.

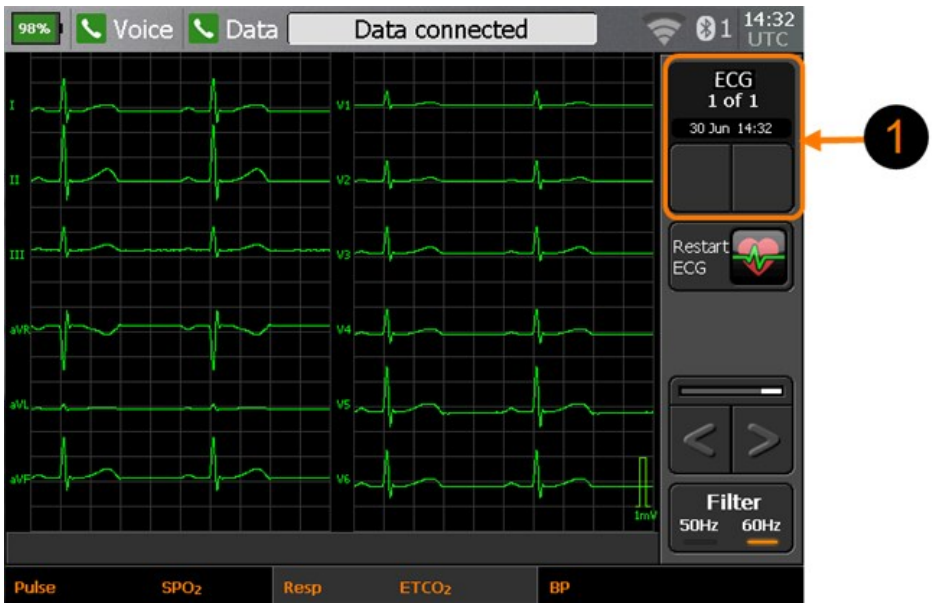
Wait for the ECG trace to stabilize (like the trace shown above), ask the patient to breath in and out and then to hold their breath for 10 seconds before pressing ‘record’ If the trace does not stabilize, check the following:

- 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 ECG 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.

4.2.2 Recording an ECG

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



(1) You can navigate to previous recording carried out during the incident

ECG recorded

If the Tempus IC2 is connected to a Response Center, it will automatically start to transfer the ECG file.

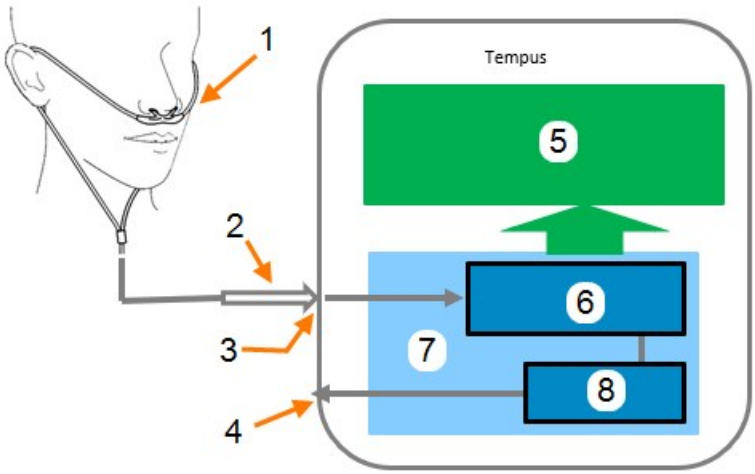
At this point you can press  to close the ECG view to return to the main screen or you can press 'Restart ECG' on the touch screen to return to monitoring mode.

If you turn the ECG off at this point and then restart the ECG function later during the same incident (without switching the Tempus IC2 off), these results will be shown again. The Tempus IC2 allows you view up to the last 20 ECG's recorded from the patient during the incident.

CAUTION

It is essential that the Tempus IC2 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.

4.3 Capnometer



(1) Side-stream sampling line

(2) Water trap

(3) Luer-lock inlet

(4) Exhaust

(5) Micro-processor and display

(6) IRCO2 Optical Micro-sample cell

(7) Capnometer module

(8) Pump

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

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 a capnometer help screen

-

WARNING

The Tempus IC2 is not intended for long term patient monitoring. There are no audible or visible alarm

WARNING

The Tempus IC2 is not for apnoea detection. The Tempus IC2 has not been tested or validated for use in apnoea detection.

WARNING

Loose or damaged connections may compromise ventilation or cause an inaccurate measurement of respiratory gases. Securely connect all components and check connections for leaks according to standard clinical procedures.

WARNING

Do not cut or remove any part of the sample line. Cutting the sample line could lead to erroneous readings.

WARNING

Check capnometer tubing regularly during use to ensure that no kinks are present. Kinked tubing may cause inaccurate CO_2 sampling.

WARNING

At temperatures below 0 °C, water vapor may condense and freeze in the capnometer filter line. This will cause a blockage that will cause capnometry monitoring to stop

CAUTION

Use of monitoring during continuous nebulized medication delivery will result in damage to the Tempus IC2 which is not covered by the warranty. Disconnect the capnometer sample line from the Tempus IC2 or switch off the Tempus IC2 during medication delivery.

CAUTION

Ensure that tubing is not stretched during use.

CAUTION

Do not attempt to clean disinfect, sterilize or flush any part of the sampling line as this can cause damage to the monitor.

CAUTION

Dispose of sampling lines according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

Replace the sampling line according to your organization’s protocol or when a blockage is indicated by the device. Excessive patient secretions or a build-up of liquids in the airway tubing may occlude the sampling line, requiring more frequent replacement.

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

At intervals of a few hours, the capnometer stops patient measurements for 30 seconds. During this 30 second period, it sets its measurements to zero but it does not display a zero reading. After the 30 second period, it continues to display correct patient measurements.

This automatic function prevents "measurement drift", that is, errors caused by differences between components, changes in ambient temperature and pressure conditions.

4.3.1 Understanding the capnometer results

The Capnometer display has two elements. Measurements are made continuously and are updated in real time. Measurements are sent in real time to the Response Center 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.

If the 

button is not visible, press  to restart the capnometer. The device does not display “pump off” or “standby” status messages.

If the $ETCO_2$ and Respiration Rate readings are blank when the Capnometer is active, please wait for the device to resolve the problem. The most likely cause is a blockage which the device will clear by pumping air into the cannula. If the blockage cannot be cleared, the device will report an error.

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

Extreme rates above 50 Rpm 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.

4.4 Thermometer

To activate the thermometer, press  button on the device

The first instructions will be displayed.

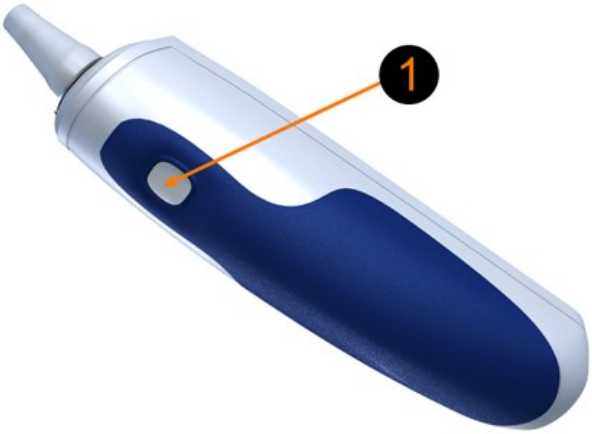
Follow the instructions provided on the iAssist help process to use the thermometer.

The thermometer is the large white and blue device in the front pocket of the Tempus IC2 bag. It connects to the Tempus IC2 via Bluetooth®.

(1) The display shows on/off status, temperature reading and error messages

(2) The ON/MEM button: press once to turn on, double-press to turn off

(3) The battery cover: slide it away to replace the battery



(1) The measurement button: press and hold for 3 seconds to take a reading

Thermometer controls

Example of a temperature help screen

WARNING

This thermometer is only for use with the Tempus IC2. It is not to be used with a Tempus IC device.

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.

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.

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 IC2 over the Bluetooth® link. Press the ON/MEM button twice in quick succession to turn it off. Note that to extend the battery life the thermometer will automatically shut off if left idle for more than 3 minutes.

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 IC2) if the ON/MEM button is pressed and held for 3 seconds after the device has been turned on. The most recent reading ("1") will be shown first, then if ON/MEM is pressed again the reading taken before that ("2") will be shown, 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.

Only use non-rechargeable batteries with the thermometer.

Do not attempt to use, swap or pair the thermometer with other Tempus IC2 units or other devices. Consult RDT if you need replacement thermometers. Users must ensure the thermometer that is paired with the Tempus remains with it. Unpaired thermometers will not work when required unless they are first paired with the device.

Users are reminded to ONLY use the thermometer within the range specified in section "A.1.5 Thermometer".

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 IC2.

4.4.1 Using the thermometer

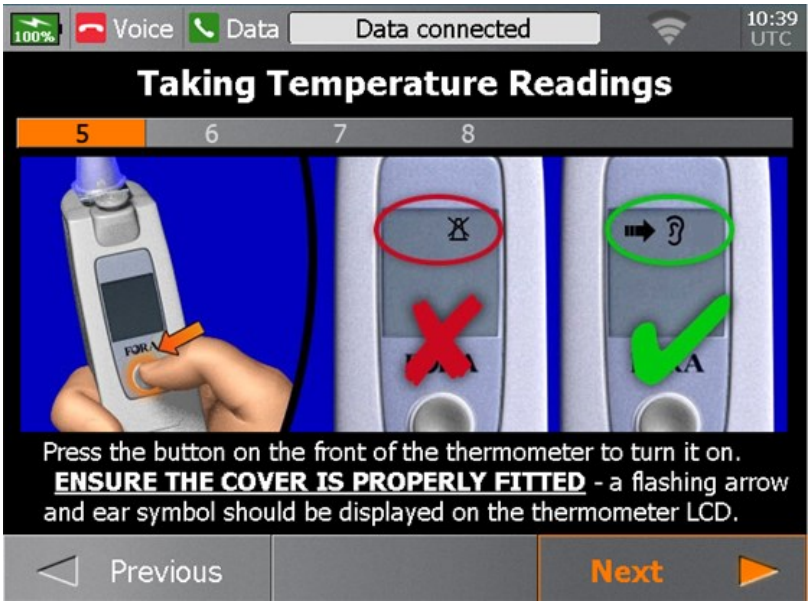
When following the on-screen instructions, attention should be paid to the signals given out by the thermometer. Errors are discussed in section "6.3 Troubleshooting".

It should be noted that once the thermometer is turned on it will power itself off after 3 minutes 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.

CAUTION

As stated in steps 3 to 5 of the thermometer help process, ensure the thermometer cover is fully fitted, otherwise temperature readings will not be taken. If the cover is not correctly fitted, the "cover off" symbol is displayed on the thermometer LCD:



Step 5 of the thermometer help process

4.4.2 Understanding the thermometer results

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

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

4.5 TD-4279 glucometer (if installed)

The TD-4279 glucometer must be configured and its Bluetooth radio must be “paired” with the Tempus IC2 before it can be used. For instructions see the *Tempus IC2 Maintenance Manual* (41-2018EN).

To activate the glucometer function (if installed), press  button on the device

The first glucometer help screen will appear. Follow the instructions provided on the iAssist help process to activate the glucometer.

Example of a TD-4279 glucometer help screen

At altitude, the blood sugar level reading will be slightly lower than that at ground level but within the stated accuracy of the glucometer.

WARNING

The glucometer’s readings are shown in mg/dl on the glucometer display.

WARNING

The results shown on the Tempus IC2 will be in mg/dl format for users based in the USA and in mg/dl or mmol/l format in all other areas.

WARNING

Inaccurate results may occur in severely hypotensive individuals or patients in shock.

Inaccurate low results may occur for individuals experiencing a hyperglycemic-hypersmolar state, with or without ketosis.

WARNING

Critically ill patients should not be tested with blood glucose meters.

WARNING

The *TaiDoc TD-4279 User Manual* is provided with the glucometer. While applicable extracts are reproduced in the *Tempus IC2 User/Operator Manual*, users should also read the *TaiDoc TD-4279 User Manual* to ensure they have familiarized themselves with the device.

WARNING

Ensure that the instructions for use attached to the strips are heeded. Use only TD-4279 test strips with the TD-4279 glucometer.

CAUTION

Do not store the glucometer strips outside of the stated environmental limits and ensure their shelf life information is heeded.

CAUTION

Use fresh capillary whole blood only when taking measurements.

CAUTION

Dehydration may lower test results.

CAUTION

When the strip is inserted do not to press the main switch as this toggles measurement mode from GEN. For all measurements please use the meter default “GEN”.

CAUTION

Do not use glucometer test strips after their date of expiry (printed on vial labels in format YYYY-MM-DD or YYYY-MM).

CAUTION

If the clock is incorrect by more than 1 hour, the meter reading is ignored by the Tempus IC2, the time is corrected by a Bluetooth message to the meter and the user is requested to take a new reading.

The glucometer measures the patient’s blood glucose levels and transmits them wirelessly (over Bluetooth®) to the Tempus IC2.

Do not attempt to use, swap or pair the glucometer with other Tempus IC2 units or other devices. Consult RDT if you need replacement glucometers.

Users are reminded to ONLY use the glucometer within the Bluetooth range specified in section "A.1.6 Glucometer (if installed)".

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 IC2.

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 >700 mg/dl or <10 mg/dl respectively.

The glucometer is accurate provided that testing areas are clean and dry and contain no foreign substances such as lotions or creams.

Lancet notes:

For use with either glucometer, RDT supplies the “Press II” 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.

When the batteries are changed the configuration of the device may be lost, always repeat the configuration step.

4.5.1 Understanding the glucometer results (if installed)

When measurements are made, they are time stamped and sent to the Response Center provided that the data link is active. The measurements will be reviewed and interpreted by the Response Center.

4.5.2 Configuring and setting the clock on the TD-4279 (if installed)

Use this procedure to set the date, time and unit of measurement on the TD-4279 glucometer. This procedure should only be necessary when the batteries are changed or when a new TD-4279 glucometer is deployed.

The date and time on the glucometer must be the same as the date and time set on the Tempus IC2 in order for the Tempus IC2 to be sure the correct measurement value has been received from the glucometer. Therefore set the TD-4279 time to be within 2 minutes of Tempus IC2 time.

The Tempus IC2 time is always set to UTC time.

To configure the TD-4279 follow these steps:

1. Start with the meter off (no test strip inserted).

   Press the **SET** button (inside battery compartment).

2. Setting the date - the sequence of the date setting is: YEAR → MONTH → DAY:

   With the YEAR flashing, press the **M** button (center button on front panel) to select the correct year. Press **SET**.

   With the MONTH flashing, press the **M** button to select the correct month. Press **SET**.

   With the DAY flashing, press the **M** button to select the correct day. Press **SET**.

3. Setting the time format:

   Press **M** to select the desired time format - 12h or 24h. Press **SET**.

4. Setting the time - the sequence of the time setting is: HOUR → MINUTE:

   With HOUR flashing, press **M** until the correct hour appears. Press **SET**.

   With MINUTE flashing, press **M** until the correct minute appears. Press **SET**.

   The time should be set to the same as the time displayed on the Tempus IC2 within +/-2 minutes.

5. Setting the unit of measurement:

   Press **M** to switch between mg/dL and mmol/L.

   Select mg/dL by pressing **SET**.

6. Setting the buzzer:

   Press **SET** to skip this entry.

7. Deleting memory:

   Press **SET** to skip this entry.

8. Setting the reminder alarm:

   Press **SET** four times to skip all four alarms.

9. Setting the backlight:

   The default setting for the meter backlight is “BL”, i.e. set to on.

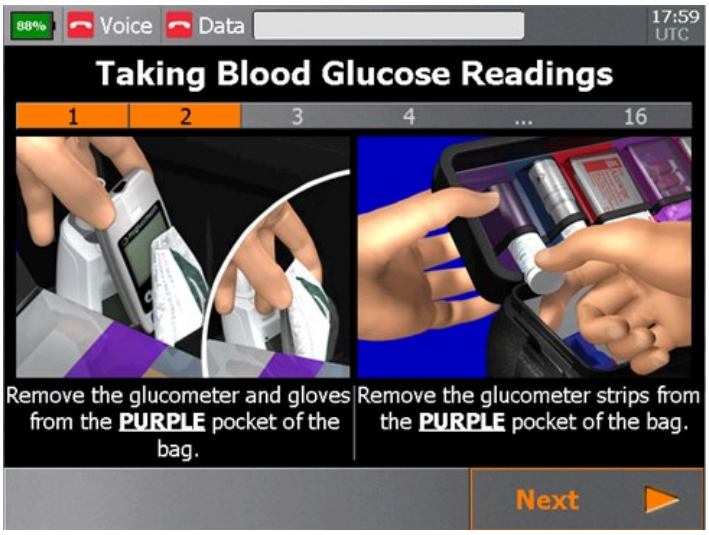
   Press **SET** to skip entry.

   The glucometer will power off automatically.

4.6 MyGlucoHealth glucometer (if installed)

To activate the glucometer function (if installed), press  button on the device

The first glucometer help screen will appear. Follow the instructions provided on the iAssist help process to activate the glucometer.



Example of a MyGlucoHealth glucometer help screen

If the timestamp, received alongside the blood glucose reading, is more than ±1 hour out from the current Tempus time, a warning is displayed to the user. This warning gives the user the option of taking another reading in order to correct the time stamp. See below for details on how to set the clock on the glucometer.

At altitude, the blood sugar level reading will be slightly lower than that at ground level but within the stated accuracy of the glucometer.

WARNING

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

WARNING

The results shown on the Tempus IC2 will be in mg/dl format for users based in the USA and in mg/dl or mmol/l format in all other areas.

WARNING

Inaccurate results may occur in severely hypotensive individuals or patients in shock.

Inaccurate low results may occur for individuals experiencing a hyperglycemic-hypersmolar state, with or without ketosis.

WARNING

Critically ill patients should not be tested with blood glucose meters.

WARNING

The *MyGlucoHealth User Manual* is provided with the glucometer. While applicable extracts are reproduced in the *Tempus IC2 User/Operator Manual*, users should also read the *MyGlucoHealth User Manual* to ensure they have familiarized themselves with the device.

CAUTION

Do not store the glucometer strips outside of the stated environmental limits and ensure their shelf life information is heeded.

CAUTION

Ensure that the instructions for use attached to the strips are heeded. Only MyGlucoHealth test strips are to be used with the MyGlucoHealth glucometer.

CAUTION

Use fresh capillary whole blood only when taking measurements.

CAUTION

Dehydration may lower test results.

The Tempus IC2 uses the MyGlucoHealth® 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 IC2) for re-transmission. The only difference is that the measured result is forwarded to the Response Center that receives the Tempus IC2 call rather than the MyGlucoHealth® web portal.

The MyGlucoHealth® meter measures the patient's blood glucose levels and transmits them wirelessly (over Bluetooth®) to the Tempus IC2.

Do not attempt to use, swap or pair the glucometer with other Tempus IC2 units or other devices. Consult RDT if you need replacement glucometers.

Users are reminded to ONLY use the glucometer within the Bluetooth range specified in section "A.1.6 Glucometer (if installed)"

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 IC2.

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 >599.4 mg/dl or <10.8 mg/dl respectively.

The glucometer is accurate provided that testing areas are clean and dry and contain no foreign substances such as lotions or creams.

The MyGlucoHealth glucometer has a memory of the last 250 readings it has taken. These will be shown on the glucometer's display (but not transmitted to the Tempus IC2) if the CENTER/POWER button is briefly pressed. The newest data appears first and the up and down buttons are used to scroll through the list. For this reason it is recommended to avoid pressing the CENTER/POWER button, unless when instructed to do so during the measurement process.

Lancet notes:

For use with either glucometer, RDT supplies the "Press II" 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.

4.6.1 Understanding the glucometer results (if installed)

When measurements are made, they are time stamped and sent to the Response Center provided that the data link is active. The measurements will be reviewed and interpreted by the Response Center.

4.6.2 Setting the clock on the MyGlucoHealth (if installed)

The date and time on the glucometer must be the same as the date and time set on the Tempus IC2 in order for the Tempus to be sure the correct measurement value has been received from the glucometer. Therefore set the MyGlucoHealth time to be within 2 minutes of Tempus IC2 time.

The Tempus IC2 time is always set to UTC time.

To set the date and time follow these steps:

1. Press and hold the CENTER/POWER button on the Glucometer for at least 3 seconds until the 'year' starts flashing.
2. Press either the UP or DOWN button to set the current year. Press the CENTER/POWER button. The month (MON) will now be flashing.

3. Use either the UP or DOWN button to set the values for the month, day, hours, and minutes using the CENTER/POWER button to move to the next value to be set.
4. Then Press and hold the CENTER/POWER button for at least 3 seconds to exit the process.

4.7 Digital camera

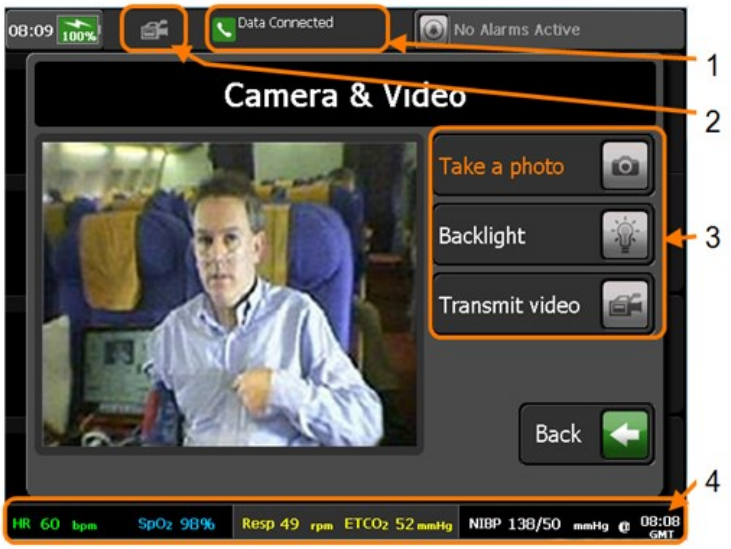
When requested by the Response Center, it is possible to capture and send still digital pictures using the camera built into the device. Digital pictures are shown live on the Tempus IC2 screen so that you can see what the camera is seeing. When you are happy with the displayed image, you capture the picture and can then send it to the Response Center (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 IC2 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 IC2 display showing location of the digital picture

The Tempus IC2 will start the camera process as soon as the voice connection has started dialling.



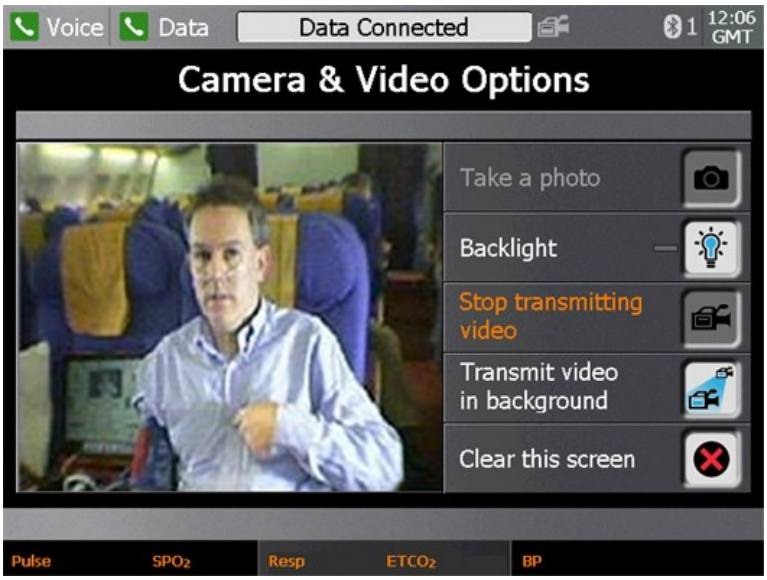
Example of the Tempus IC2 display showing photo image

The steps are:

1. Aim the camera so that you get the picture you need on the screen (e.g. a close-up of the patient).
2. When you are happy that the displayed image shows what you want, press  on the touch screen to freeze the image.
3. 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.

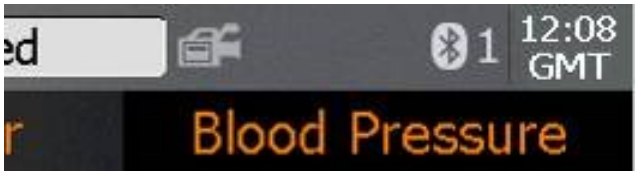
If you are connected over either an Ethernet or WiFi link, it will be possible to send moving video to the Response Center. This can be done in two ways:

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



Example of the Tempus IC2 when transmitting a 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 IC2 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

If the user opens the 12-lead ECG while transmitting video in background, the video transmission is terminated.

Moving video is intended to give the Response Center 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 IC2 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.

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

4.7.1 Annotation of digital pictures

Images transmitted from the Tempus IC2 can be altered using the software at the Response Center. The altered image can then be sent back to the Tempus IC2 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 colors for added graphics

4.8 Interacting with the Response Center

4.8.1 The Response Center

Although the Tempus IC2 may be used without connection to a Response Center (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 Center will be contacted as the first priority after having activated the device. Each Tempus IC2 device is pre-configured to dial automatically to a specific Response Center. The center 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 IC2 is designed to allow maximum ease of use for the operator (even extending to partial remote control by the Response Center if necessary) and also to transmit the medical data to the Response Center. It is the function of the Response Center 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 Center 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 Center 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 IC2 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 Center 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 IC2 and the Tempus Monitoring Station (the Response Center hardware) are pre-set to operate on UTC time.

If informed by the Response Center staff that the results or video have stopped appearing on the Response Center, stop the connection and reconnect the Tempus IC2.

4.8.2 Remote viewing and control

The Response Center operators will have exactly the same information on their screens as those displayed on the Tempus IC2. Should the Tempus IC2 display change e.g. if a new help screen is brought up, new data is displayed or an error message appears, the Response Center system will display exactly the same information a few seconds later. The only exceptions to this are when you are taking a digital picture, in this situations the Response Center only sees that you are in the process of taking the photo but they don't see the photo until it has been downloaded.

Since the Response Center can see what you see on the device, and since they can control it remotely, if you are experiencing problems using the Tempus IC2, they can guide and support you in its use.

If the Response Center need to operate the Tempus IC2 remotely, they should make you aware that they are activating a function of the device before they do so. Ideally the Response Center will only take control of the Tempus IC2 if the operator is having difficulty with an operation.

4.8.3 Recording data off-line and transmitting on-line

The iAssist help processes on your Tempus IC2 may differ from this example iAssist help process in the following sections. However the process always follows the same key elements.

Always ensure that you read the complete iAssist help process in order and do exactly what it requires.

Although the Tempus IC2 is generally intended to be used whilst connected from the remote location to a Response Center, the Tempus IC2 can also be used without the telecoms connection having been made. All the functions of the Tempus IC2 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 IC2 provides.

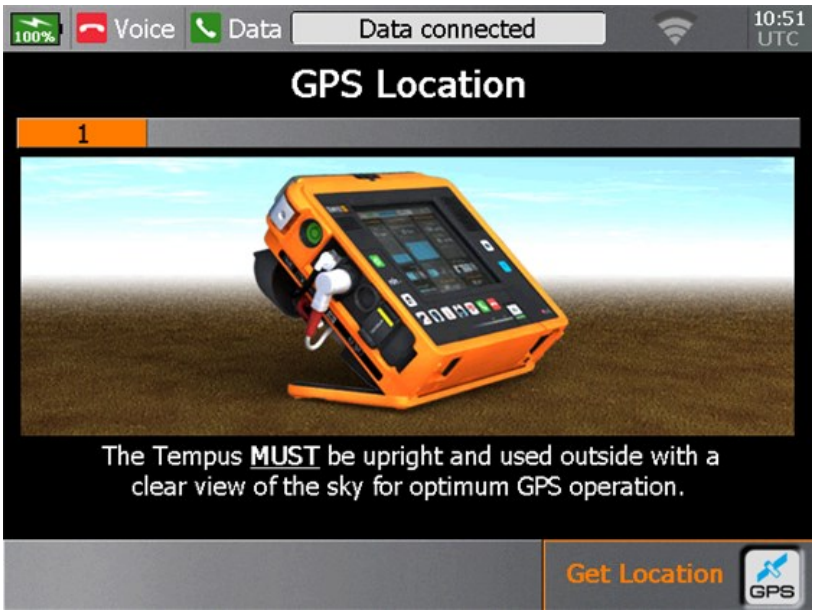
Naturally, if a connection has not been established, no data or photographs can be transmitted and there will be no voice connection to the Response Center operator. However, if the Tempus IC2 is used on a patient without a connection being made, the data is stored and automatically transmitted once the device is connected. If the device is turned off before it is connected the data will not be saved.

4.9 GPS location

The Tempus IC2 has a built-in GPS receiver. You can access this feature from the Help menu.

The GPS Location 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

The GPS operation will be limited if the Tempus IC2 is not used outside with a clear view of the sky.

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

The Tempus IC2 will be supplied with the GPS not enabled in aviation modes and enabled in all other modes. To turn the GPS receiver on or off, refer to "6.5 Configuring the Tempus IC2".

GPS fix obtained

The GPS may take between 2-4 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 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 +/-2.5 km.

4.10 Actions after use

4.10.1 Turning the Tempus IC2 off

Before switching the Tempus IC2 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 the On/Off switch . The system will then bring up the dialog shown below and give a 10 second countdown.

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

When shutting down, the Tempus IC2 will show dialog containing a countdown timer from ten seconds. The dialog reminds you to clean and repack Tempus IC2 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. If the device has been used and the cleaning & repack menu is not entered the user will be reminded they need to clean and repack the device before putting it away

Option C: let the unit shutdown.

Example of the Shutdown screen

4.10.2 Logging maintenance requirements

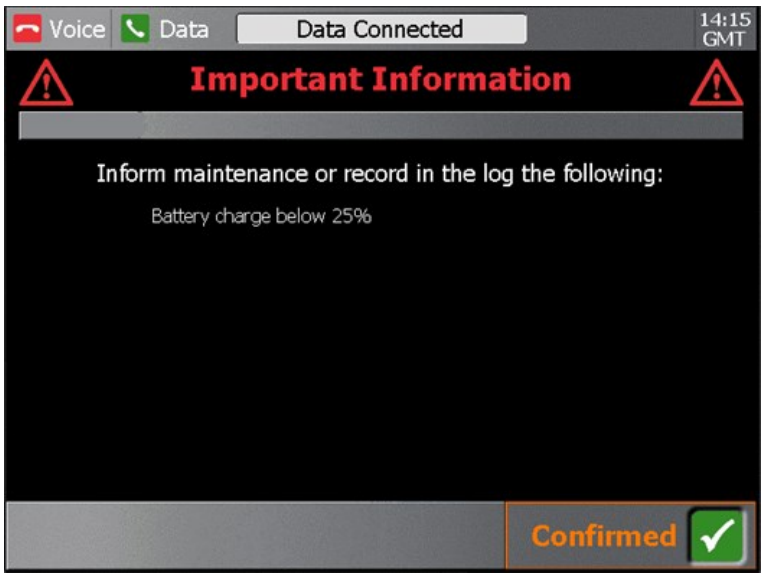
If consumable items such as the repack kit or a cannula have been used, the Tempus IC2 will alert you to report the need for these items to be replaced. This alert will be provided after the shutdown has been initiated.

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;
- if a software update is required.

You should use the information displayed to log or report that the Tempus IC2 requires your maintenance staff to provide indicated items.

> This feature DOES NOT indicate that the Tempus IC2 has developed a fault. This feature is to remind users to report that consumable items or maintenance activities are required. Users should not report the information displayed by this feature as a fault to RDT.



Example of an information screen displayed at shutdown

In the example above, the Tempus IC2 is indicating that the battery is now below 25% charge. RDT recommends that users respond to the information posted to ensure that the Tempus IC2 is maintained in good working order and fully operational for the next time it is used.

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 calibration due	If capnometer is due for calibration
Capnometer cannula required	If capnometer was started during the incident
Glucometer repack kit required (*1)	If the glucometer repack process was followed

Text	Condition
Glucometer battery required (*2)	If the MyGlucoHealth glucometer battery low was reported during incident
Software update required	If software update was notified during incident (*3)
Device fault reported	If any device was disabled due to a fault
Glucometer clock needs to be checked (*2)	if the most recent glucometer reading time from the MyGlucoHealth glucometer was more than 1 hour different from theTempus IC2 time setting

(*1) Only report this condition if a TD-4279 or MyGlucoHealth glucometer is installed.

(*2) Only report this condition if a MyGlucoHealth glucometer is installed

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

If one of these messages occurs during shutdown, the shutdown process will be paused until the message is confirmed. If the confirm button is not pressed and the message left on the screen, the shutdown will continue after 15 minutes.

Blank page

5 After using the Tempus IC2

The iAssist help processes on your Tempus IC2 may differ from the examples in the following sections. However the processes always contain the same key elements.

Always ensure that you read the complete iAssist help process in order and do exactly what it requires.

5.1 Inspecting the Tempus IC2 ..... **100**

5.2 Cleaning the Tempus IC2 ..... **101**

5.3 Cleaning and re-packing help screen **102**

5.4 Single-use devices **104**

5.1 Inspecting the Tempus IC2

WARNING

Do not open the battery case or in any way disassemble, modify or repair the battery.

CAUTION

All leads, cables and accessories should be checked before and after use to ensure that they are not subject to wear, fraying, tears, knots or other signs of damage. Damaged or worn parts should be replaced.

After using the Tempus IC2, always inspect the device, its accessories (including power supplies, mains cable, batteries and charger) for signs of damage or wear. Make the following checks:

- Check the strain reliefs of cables and connectors to ensure they remain fit for use.
- Check that all connectors engage properly and that cable securements work acceptably.
- Check connector covers, particularly the capnometer door cover, to ensure they close and latch acceptably.

Inform your service department about any signs of wear, damage or malfunction.

At least once a year inspect the whole unit, in particular the mains power supply and battery charger, for signs of extreme damage. This inspection should be performed by appropriately trained and equipped personnel who are able to perform locally prescribed safety tests. In addition, RDT recommends the device is tested by an appropriately trained and equipped Electro-Biomedical Engineer to confirm the medical and other functions of the Tempus IC2 are within specification, and locally prescribed safety limits.

5.1.1 Daily checks

RDT recommends that Tempus IC2 users perform the following daily checks and replace any damaged parts or missing equipment:

- Cleanliness:
  - Tempus IC2, cables and accessories are clean with no fluid spills.
- Damage and wear:
  - Tempus IC2, cables and accessories have no damage or excessive wear, e.g. cuts in insulation, fraying or broken wires, bent or damaged connector pins.
- Consumables:
  - Appropriate quantities of all disposable supplies available.
  - Any accessories or consumables are within the shelf life printed on their packages.
- Battery:

- Properly inserted into the Tempus IC2 and fully charged.
- Fully charged spare is available.

- Power and controls:
  - Tempus IC2 powers on.
  - All buttons and touchscreen areas operate as described.

5.1.2 Weekly checks

RDT recommends that Tempus IC2 users perform the following weekly checks:

Battery

> **CAUTION**
> To prevent battery failure, perform this check every week when the Tempus IC2 is in use.

Remove the battery from the Tempus IC2 and inspect its contacts.

- If contacts are damaged, replace the battery.
- If contacts are dirty, clean them.

5.2 Cleaning the Tempus IC2

It is necessary to clean the Tempus IC2 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 IC2 instruments must be cleaned during the re-packing process.

If the Tempus IC2 is dirty it should be cleaned to remove any cosmetic contamination. Wipe it 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 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 IC2 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.

5.2.1 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.

WARNING

The Thermometer probe must be cleaned prior to repacking.

Clean the probe as follows:

- Use a cotton swab or soft cloth dosed with the alcohol (70% concentration) or use the alcohol wipes provided with the Tempus IC2 to clean the lens on the end of the thermometer.
- Allow the probe to fully dry for at least 1 minute before using it.

5.2.2 Cleaning the glucometer (if installed)

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

Clean the meter as follows:

- Use a soft cloth dosed with alcohol (70% concentration) or use the alcohol wipes provided with the Tempus IC2.
- Before use, squeeze out any excess liquid in order to prevent damage to the meter.
- Wipe all the meters external surface, display and buttons, cleaning the entire instrument but ensuring no excess liquid enters the strip test slot.
- Allow the meter to fully dry before re-packing.

5.3 Cleaning and re-packing help screen

The user can get help at any time by pressing the  button. 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 AlcoWipes (supplied in the Tempus IC2 bag) 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.

Keep wipes away from open flame.

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

Wipes are not to be used as baby wipes.

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 RDT contacted for advice on how to clean.

From the Help Menu, press the **Cleaning & Repacking** button to bring up the Cleaning and Repacking Menu

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 IC2. 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.

5.4 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:

- AlcoWipes
- Capnometer cannulas
- Glucometer strips (if installed)
- Lancets (if installed)
- Gloves

6 Maintenance, servicing and troubleshooting

The Tempus IC2 is designed to be as maintenance-free as possible. The only user-replaceable and user-serviceable parts in the Tempus IC2 are those listed in this section of the manual.

More details on maintenance are given in the *Tempus IC2 Maintenance Manual* which is supplied on the same CD-ROM as this manual.

If the Tempus IC2 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.

6.1 The Tempus IC2 battery **106**

6.2 Other Tempus IC2 batteries **111**

6.3 Troubleshooting **116**

6.4 Fitting the accessory pouch to the bag **123**

6.5 Configuring the Tempus IC2 ..... **125**

6.1 The Tempus IC2 battery

The Tempus IC2 contains a removable, rechargeable battery fitted in the base of the device.

The Tempus IC2 battery

The Tempus IC2 battery (example rear view)

In normal usage, this battery provides power for at least 11 hours' continuous use (*) when fully charged.

A spare battery pn 01-2029 is commonly shipped with each device (the spare battery will be found with the Mains Power Supply pn 01-2049, Battery Charger pn 01-1012 and Mains Cable Pack pn 01-2164 in the accessories box with the Tempus IC2).

Every battery is provided with an integral battery life indicator which is also visible through the front panel of the bag. The battery life should be monitored periodically over time when the device is in storage and also before and after use.

CAUTION
A legacy Tempus IC battery (part number 01-1001) will not fit or work in a Tempus IC2.

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

The Tempus IC2 battery will be shipped with half charge or less. RDT recommends that users fully charge batteries before placing them into service.

It is the user's responsibility to recharge batteries. Batteries should not be returned to RDT for recharging. If the battery indicates it has a low charge state, this should not be treated as a fault – batteries can have a low or empty charge state as a result of normal use.

RDT recommends that the battery charge status should be checked twice a year and recharged if necessary. RDT also recommends that the battery be completely discharged and recharged once a year. The RDT warranty period on a battery pack is 1 year.

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 IC2 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.

6.1.1 Checking the charge state of the battery

The battery life should be monitored periodically when the device is in storage and also before and after use. The Tempus IC2 does not need to be removed from its bag or turned on to check the battery:

Example of the battery life indicator showing full charge

To check the charge state of the battery, press the button on the front.

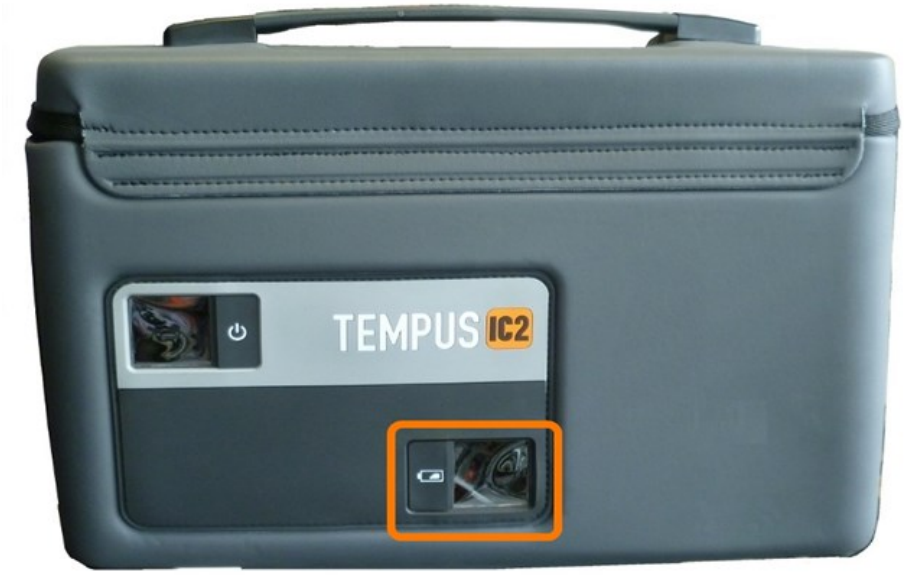
Pressing the button will light one or more LEDs. Each LED corresponds to 25% of the charge state of the battery in the order (from highest to lowest):

- Four green LEDs – 76-100%
- Three green LEDs – 51-75%
- Two green LEDs – 26-50%
- One green LED – 1-25%
- No green LEDs – deep discharge

If one LED is flashing, the battery has 10% or less charge remaining.

Checking the charge state in the bag

-



To check the charge state of the battery when the Tempus IC2 is in its bag, press the battery button by the window. This will light the battery charge LEDs, which will be visible through the window

Window to check the battery

6.1.2 Replacing the Tempus IC2 battery

WARNING

Ensure the latches on both sides of the battery are fully engaged prior to using the Tempus IC2. An incorrectly fitted battery could result in the Tempus IC2 loosing power during use.

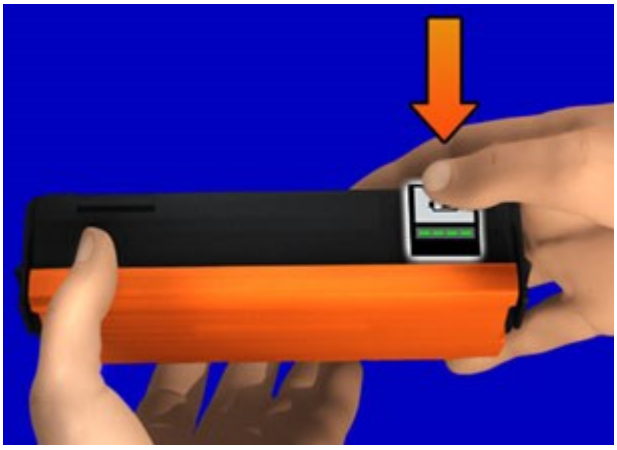
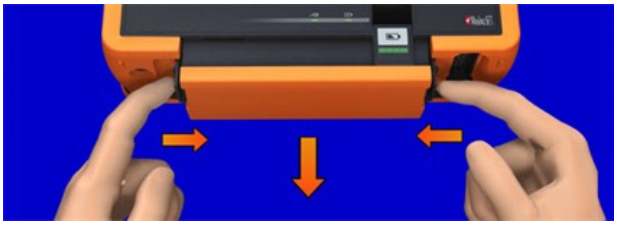
WARNING

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.

Before removing the battery you must switch off the Tempus IC2 by pressing the power button.

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

To replace the battery:

Step	Description	Photos and notes
1.	Ensure the replacement battery has sufficient charge by checking its indicator.	
2.	Ensure the Tempus IC2 is switched off. Remove the battery by squeezing the two latches inwards, then pull the battery away.	
3.	Slide the new battery all the way into the Tempus IC2 until it clicks into place on both sides. **WARNING** Ensure battery is fully engaged. Incorrect fitting could result in the Tempus IC2 losing power during use!	

6.1.3 Charging the battery

The battery can be charged either when it is fitted to the Tempus IC2 or when it is removed.

WARNING

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

Charge times of the battery will vary depending on the how the Tempus IC2 is being used. If the Tempus IC2 is switched off charging will be faster than if the Tempus IC2 is on and all features are being used.

Charging a fully discharged battery will take approximately 6 hours (assuming the battery is new) when the Tempus IC2 is switched off or when charging the battery separately.

Charging in the Tempus IC2

The Tempus IC2 power supply is rated 100-240 V, 50-60 Hz, 5 A.

To charge the battery when fitted to the Tempus IC2, proceed as follows:

Step	Description	Photos and notes
1	Connect the power supply (part number 01-2049) to the connector on the right hand side of the Tempus IC2.	
2	When the power supply is attached to the Tempus IC2, the green power light on the Tempus IC2 front panel will turn on. 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.	

Charging separately from the Tempus IC2

The battery charger is rated 100-240 V, 50-60 Hz, 0.9 A.

To charge the battery when removed from the Tempus IC2, proceed as follows:

Step	Description	Photos and notes
1	Connect 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. The clip of the charger can only be connected to the battery 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.	

6.1.4 Tempus IC2 battery shelf life

RDT recommends that if devices are not used frequently (e.g. not used once every 8 weeks) users should check the battery(s) every 8-12 weeks. RDT recommends that spare batteries (and power supplies) are carried with the Tempus IC2.

6.2 Other Tempus IC2 batteries

6.2.1 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.

WARNING

Danger of explosion if battery is incorrectly replaced. Do not attempt to repair or replace the battery.

WARNING

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

CAUTION

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.

CAUTION

Always maintain a level of at least 10% in the Tempus IC2 battery. Leaving the Tempus IC2 battery in a low charge state can risk it being depleted by the headset charging process.

You must follow the repacking instructions provided by the Tempus IC2 on screen. These instruct you to clean the headset after use and to replace it on its USB docking connector before shutting down. If you do not replace the headset, the Tempus IC2 will show an error advising that it should be refitted.

RDT do not supply a separate charger for the headset. The Tempus IC2 automatically recharges the headset in the following situations:

- Every time the headset is replaced onto its USB docking connector after use:

  The indicator light on the headset flashes and then goes off. Press the multi-function button to check the battery charge level. When the battery is fully charged, the LED lights up blue constantly. Charging continues regardless of whether the Tempus IC2 is switched on or off.

- Once every 97 days when the Tempus IC2 is switch off.

Charging time from empty is approximately 1 hour 20 minutes.

General Guidelines for Safe Use of the Sennheiser Presence Wireless Headset:

- Do not drop or try to alter the shape of your headset.
- Do not expose the headset to liquid or moisture. Unlike the Tempus IC2, 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 10°C to 40 °C.
- Do not try to disassemble 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.

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

6.2.2 Glucometer batteries (if installed)

The glucometer (if installed) is powered by two AAA type non-rechargeable batteries. 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.

RDT recommends that glucometer batteries are replaced annually or sooner if the low battery symbol  appears on the glucometer display. Higher levels of usage (e.g. in a training department) may require the batteries to be changed more often.

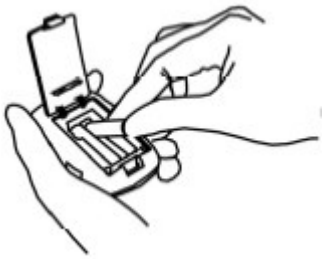
CAUTION

After changing the glucometer batteries:

- If the glucometer is TD-4279: reset the date, time and unit of measurement by following the procedure "4.5.2 Configuring and setting the clock on the TD-4279 (if installed)".
- If the glucometer is MyGlucoHealth: reset the date and time by following the procedure "4.6.2 Setting the clock on the MyGlucoHealth (if installed)".

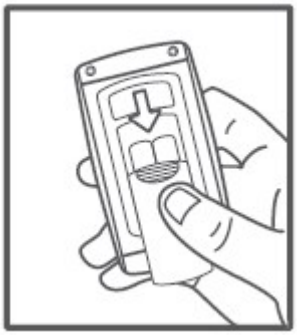
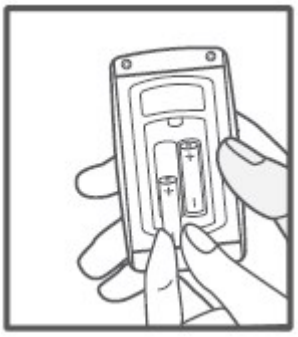
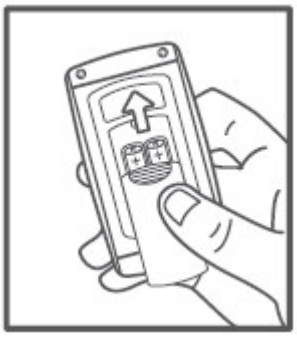
TD-4279 (if installed)

To change the TD-4279 glucometer battery:

Step	Description	Photos and notes
1	Press the edge of the battery cover and lift it up to remove.	
2	Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.	
3	Close the battery cover. If the batteries are inserted correctly, you will hear a “beep” afterwards.	

MyGlucoHealth (if installed)

To change the MyGlucoHealth battery:

Step	Description	Photos and notes
1	Slide open the battery cover.	
2	Remove the old batteries and replace with two 1.5V AAA size alkaline batteries. Press them in until firmly secured. The batteries must be inserted in the orientation shown on the inside of the plastic case of the device.	
3	Slide the battery cover back into place.	

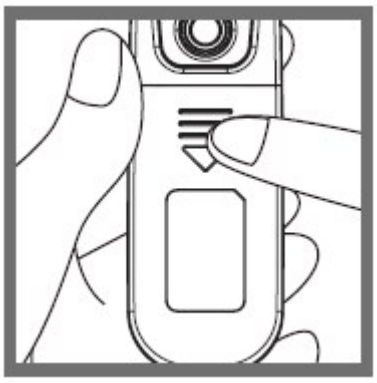
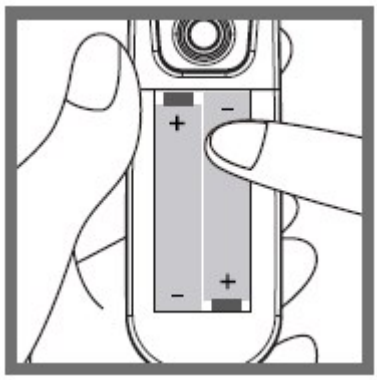
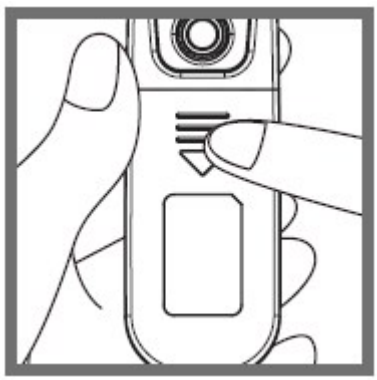
6.2.3 Thermometer batteries

The thermometer is powered by two 1.5V AAA non-rechargeable alkaline batteries. 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.

RDT recommends that thermometer batteries are replaced annually or sooner if the low battery symbol  appears on the thermometer display. Higher levels of usage (e.g. in a training department) may require the batteries to be changed more often.

Remove the batteries if the thermometer (or Tempus IC2 kit) is stored for a long period.

To change the thermometer batteries:

Step	Description	Photos and notes
1	Remove the battery cover.	
2	Place the new batteries in the compartment and press them in until firmly secured.	
3	Reattach the battery cover	

6.2.4 Disposal of batteries

Dispose of batteries in accordance with the applicable local regulations (these can 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 organizations, mandated by local governments or organized on a voluntary basis by professionals.

For more information, see "1.4 Disposal at end of life".

6.3 Troubleshooting

Occasionally, problems may occur with the Tempus IC2. Operator error, sensor problems or a failure within the Tempus IC2 could cause these problems. In most instances, the Tempus IC2 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 IC2 displays an error that is not described within this manual e.g. Windows applications errors, turn the Tempus IC2 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.

6.3.1 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 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	Pulse Oximeter has been disabled. Please restart the Tempus IC2 at an appropriate time.
Attention - Blood Pressure	Blood Pressure has been disabled. Please restart the Tempus IC2 at an appropriate time.
Attention - Capnometer	The Capnometer is blocked. Disconnect and reconnect the cannula. Check the cannula for blockages or kinks. Use another cannula if the problem persists.
Attention - Capnometer	Capnometer has been disabled. Please restart the Tempus IC2 at an appropriate time.
Attention - ECG	ECG has been disabled. Please restart the Tempus IC2 at an appropriate time.
Attention - Battery	The battery requires recharging. Complete ops log or recharge battery.
Attention - Connection	Tempus IC2 is already trying to make a connection.

Audio message	Text message
Attention - Connection	Tempus IC2 is already connected.
Attention - Connection	The Tempus IC2 is connected so the mode cannot be changed.
Attention - Headset	Tempus IC2 has not linked to the headset.
Attention - Headset	Headset should be replaced before shutdown.
Attention - Training Mode	This unit is in a training mode.
Attention - Capnometer	The capnometer is not currently enabled on this unit. It will be enabled by a future software upgrade.
Attention - Pulse Oximeter	Please connect the pulse oximeter sensor before shutdown.
Attention - Socket	The connection could not be established.
Attention - Voice Connection	Headset voice connection will be started after connecting data.
Bluetooth Pairing Error	The required Bluetooth device not found.
Bluetooth Pairing Error	Entered PIN is incorrect.
Attention - Datalink	Cell Phone SIM card error or registration denied.
Attention - Connection	Before pairing please switch the device off and on again.
Attention - GPS	GPS is not enabled in this communication mode, please ask the captain for your location.
Attention - GPS	The Tempus IC2 may not have a clear view of the sky. The Tempus IC2 will continue searching for a GPS location, please check for location again in a few minutes.
Network Settings Error	There are no network settings in this mode.
Attention - Connection	The Response Center is either busy or unavailable, call your Physician and read the patient's medical readings over the phone.
Attention - Communications	Communications are not enabled on this product. For support on enabling product options contact RDT.
Attention Datalink Encryption	Initialising data encryption engine; please wait 5 seconds.
Attention - ECG	Errors in the ECG data were detected during recording. Start the recording again.
Bluetooth Warning	No connection to Bluetooth device, please try again.
Glucometer Reading Error (*)	The Glucometer is unable to connect at this time. Press the center button on the glucometer to turn it off and press it again to display the reading in mg/dl. Read it to the Response Center with the month, day and time. Then get them to read it back to you and CONFIRM it is in mg/dl.
Clock Synchronization Warning	Time synchronization cannot be done, please disconnect and reconnect again.

Audio message	Text message
Glucometer Reading Error (*)	The Glucometer reading has been received successfully, however the Glucometer clock appears to be incorrect. At a convenient time refer to the User Manual to check the Glucometer clock.
Attention - Restart Required	Tempus IC2 has detected an error. Please shutdown and restart.
Attention - Restart Required	Tempus IC2 has detected an error. Please shutdown and restart. If the problem persists please contact your service representative.
Attention - Low Battery	There are less than 60 minutes of battery remaining.
Attention - Low Battery	There are less than 30 minutes of battery remaining. Tempus IC2 will perform a managed switch-off within 30 minutes. Change the battery or connect to a charger.
Attention - Temperature Warning	The device temperature is low. Tempus IC2 may shutdown.
Attention - Temperature	Temperature sensor fault.
Attention - File Error	The software has encountered a CRC error with one or more configuration files. The Tempus IC2 cannot be used in this condition.
Error - CRC	The software has encountered a CRC error with one or more configuration files. The Tempus IC2 will use a Backup.
Warning - Exception Logs	There are exception logs on this SD card.
Warning - Dump Files	There are dump files on this SD card.
Warning - NIBP Calibration	NIBP calibration failed.
Warning - Wifi	Wifi is not currently ready on this device.
Attention - SMBus Error	A problem with the SMBus has been detected. The Tempus IC2 cannot be used in this condition. Please restart the Tempus IC2.
System Memory	System memory is low. Tempus IC2 will automatically restart in 60 seconds.
Internal Storage	Internal storage is low. Tempus IC2 will automatically restart in 60 seconds.
Attention - Battery	Battery not detected. It is recommended that a battery is attached at all times while monitoring. If a battery is currently attached, check that it is inserted correctly.
Attention - Thermometer	The thermometer may not have been turned off. If it is still on, turn the thermometer off by pressing the button on the front once.
Attention - Headset	Tempus IC2 has not linked to the headset, it may be off.
Attention - Pulse Oximeter	There is a problem with the pulse oximeter sensor. Try disconnecting and reconnecting the sensor. If the problem persists contact the service representative.
Attention - Pulse Oximeter	The Pulse Oximeter board has not been activated.

Audio message	Text message
Attention - Pulse Oximeter	There is a problem with the pulse oximeter cable. Try disconnecting and reconnecting the cable. If the problem persists contact the service representative.
Attention - ECG	Unrecognized ECG cable. Please connect the cable that was supplied with the Tempus IC2.
Attention - ECG	The connected ECG cable cannot be used. Please connect the ECG cable supplied with the Tempus IC2.
Attention - Shutdown Required	The Tempus IC2 must now be shut down in order for the changes in hardware configuration to take effect.
Attention - Temperature Warning	The device temperature is high. Tempus IC2 may shutdown.
Attention - Temperature Warning	Due to very high ambient temperature the accuracy of some of the medical modules will be affected if the Tempus IC2 continues operating in this condition. Ensure that: The foot is deployed and the rear of the Tempus IC2 is not covered and screen brightness is reduced if possible.
Attention - Temperature Warning	Due to high ambient temperature being detected battery charging is disabled. The Tempus IC2 can continue to be used on battery. Ensure that: The foot is deployed and the rear of the Tempus IC2 is not covered and screen brightness is reduced if possible.
Attention - ECG	Unable to complete ECG recording. Try repeating the recording.
Attention - Thermometer	Before using the thermometer switch the Tempus IC2 off and on again.
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 - Trainer Mode	This unit is set to restart in training mode and so will not connect to a response center.
Attention - ECG	ECG not plugged in or lead is not in good skin contact.
Glucometer Reading Error (*)	A valid reading has not been received from the Glucometer. Switch the Glucometer off using the center button and then retry.
Glucometer Reading Error (*)	The Glucometer reading appears to have been taken at a different time. You need to take another reading.
Error - Time Remaining (seconds)	A fault has occurred. To clear the problem Tempus IC2 will switch off. Please switch back on once the shutdown is complete. If the problem persists please contact your supplier.
Attention - Temperature - Time Remaining (seconds)	Due to low ambient temperature Tempus IC2 cannot be used and will shut down. Please allow to warm and restart later.
Attention - Temperature - Time Remaining (seconds)	Due to high ambient temperature Tempus IC2 cannot be used and will shut down. Please allow to cool and restart later.

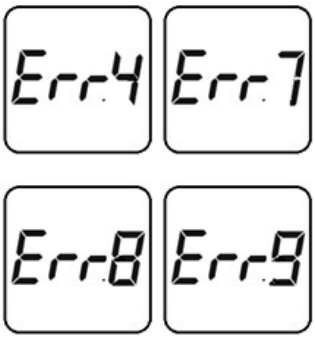
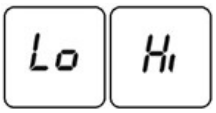
Audio message	Text message
Battery Empty Time Remaining	The battery is empty. Tempus IC2 will perform a managed switch-off. The battery should be changed.
Tempus is Linking to the Thermometer - Time Remaining (seconds)	Please wait, setting up connection to the thermometer.
Tempus is Linking to the Glucometer - Time Remaining (seconds) (*)	Please wait, linking to the glucometer.
Tempus is Linking to the Headset - Time Remaining (seconds)	Please wait. Tempus IC2 is linking to the headset
Attention - Temperature Limit - Time Remaining (seconds)	The device temperature is too low, the device will shut down.
Attention - Temperature Limit - Time Remaining (seconds)	The device temperature is too high, the device will shut down.

(*) Message only relevant if glucometer is installed.

6.3.2 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
	Room temperature is below 10ºC.	Put the thermometer under operating temperature range of 10ºC to 40ºC (50ºF to 104ºF).
	Room temperature is above 40ºC.	Put the thermometer under operating temperature range of 10ºC to 40ºC (50ºF to 104ºF).
	You are not using a probe cover while measuring ear temperature.	Fit a cover to the probe then measure ear temperature again.

Error message	Problem	Solution
	There is a problem with the thermometer.	Review the instructions and re-start the measurement procedure. If the thermometer still does not work, please contact the dealer.
	The low battery symbol  appears on LCD.	Replace batteries as soon as possible.
	The batteries cannot provide enough power for a test.	Replace batteries as soon as possible.
	Temperature measurement falls outside the displayed temperature range: ear temperature range 32ºC to 43ºC.	Please follow this manual to take another reading.

6.3.3 Glucometer errors (if installed)

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.

TD-4279 error messages (if installed)

Error message	Problem	Solution
Lo	Reading is below 10 mg/dl (0.56 mmol/l).	Repeat test with a new strip. If the problem persists, please contact the local customer service for help.
Hi	Reading is above 700 mg/dl (38.89 mmol/l).	Repeat test with a new strip. If the problem persists, please contact the local customer service for help.
	Batteries are low.	Replace the batteries as soon as possible.

Error message	Problem	Solution
E-b 	Batteries are too low for a measurement	Replace the batteries immediately.
E-U	A used test strip is inserted.	Repeat with a new test strip.
E-t	Ambient temperature is above or below system operation range.	Repeat the test after the meter and test strip are within the operation temperature range.
E-F	Test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact the local customer service for help.
E-0 E-A E-E E-C	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact the local customer service for assistance.

Myglucohealth error messages (if installed)

Error message	Problem	Solution
Lo	Reading is below 10.8 mg/dl (0.6 mmol/l).	Check calibration and retry reading.
HI	Reading is above 599.4 mg/dl (33.3 mmol/l).	Check calibration and retry reading.
Lo°C	Ambient temperature too low.	Allow the meter to warm up
HI°C	Ambient temperature too high.	Allow meter to cool down
Er 1	Problem with the meter	Reinstall the battery – if Er 1 persists please email Myglucohealth on support@myglucohealth.com.au
Er 2	The test strip is used or polluted	Repeat the test with a new test strip

Error message	Problem	Solution
Er 3	Problem with the test strip	Repeat the test with a new test strip – If Er 3 persists please email Myglucohealth on support@myglucohealth.com.au If display blinks with “sun”, avoid direct sunlight and retest
Er 4	Problem with the test strip	Repeat the test with a new test strip
Er 5	The blood sample was applied before the device was ready	Repeat the test and ensure the blood is only applied after the test symbol appears on the glucometer

6.4 Fitting the accessory pouch to the bag

The accessory pouch can be fitted to either side of the bag:

Tempus IC2 bag with accessory pouch

To fit the accessory pouch to the Tempus IC2 bag, proceed as follows:

Step	Description	Photos and notes
1	Open the pouch and put its contents (e.g. battery) to one side.	
2	Open the lid of the bag. Slide one hand down inside the bag so you can apply pressure to the inside (note). You will need to be able to reach to the bottom of the bag. Remove the contents of the bag (ECG Harness or Tempus IC2) if necessary. With the pouch open, align the fixing studs of the pouch to the bag. Press each of the 6 studs together in turn.	 Ensure all the studs are fastened together.
3	Once the pouch is attached, put its contents back in.	

Step	Description	Photos and notes
4	Close the pouch.	 Ensure both of the pouch fasteners are secure.

6.5 Configuring the Tempus IC2

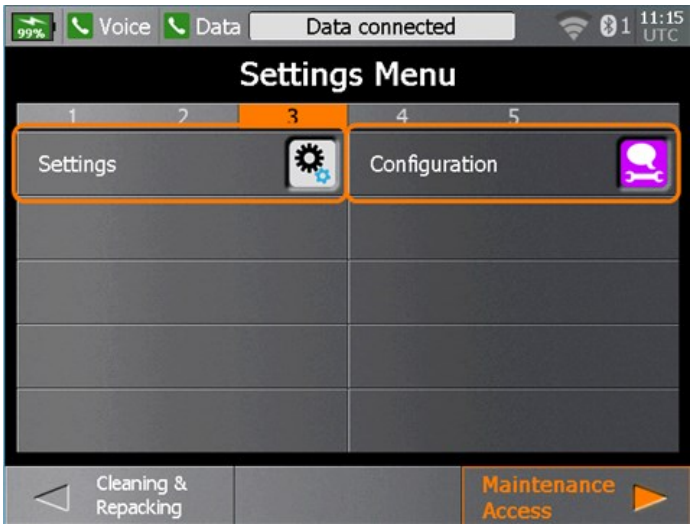
The iAssist help processes on your Tempus IC2 may differ from this example iAssist help process in the following sections. However the process always follows the same key elements.

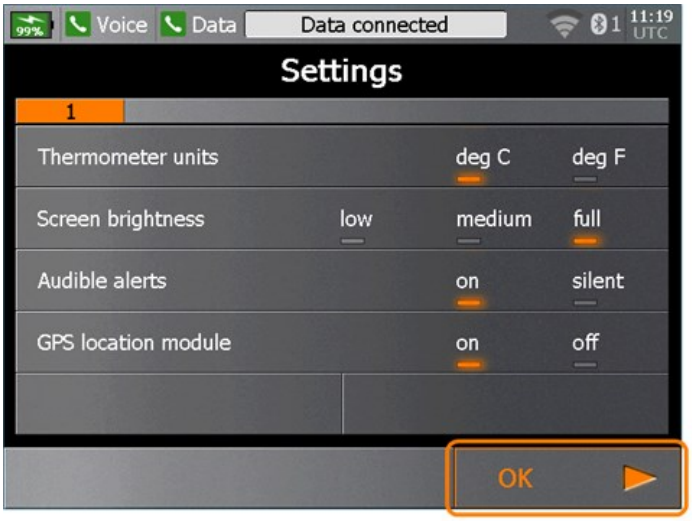
Always ensure that you read the complete iAssist help process in order and do exactly what it requires.

A number of the parameters used by Tempus IC2 are configurable to suit certain requirements.

To configure the device, proceed as follows:

Step	Description	Photos and notes
1.	Press the button to bring up the Help Menu.	

Step	Description	Photos and notes
2.	Press **Cleaning and Repacking**.	
3.	Press **Settings** .	
4.	Press **Settings** to configure the main device settings. Press **Configuration** to configure the device.	

Step	Description	Photos and notes
5.	Press the touchscreen to select the configurable parameters. Press **OK** touchscreen button to confirm the changes you have made.	
6.	The configuration of the device can be seen in the Configuration screen.	

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Annex A : Specifications and standards

A.1 Specifications


All figures quoted are based on room temperature, pressure and humidity unless otherwise stated.

A.1.1 Non-invasive blood pressure

Adult cuff and large adult cuff ratings:

Systolic:	40 - 260 mmHg
Diastolic:	20 - 200 mmHg
Range:	0 - 330 mmHg
Accuracy:	± 3 mmHg or ± 2% (whichever is greater)
Resolution:	1 mmHg
Maximum inflation:	330 mmHg

Child cuff ratings:

Systolic:	40 - 230 mmHg
Diastolic:	20 - 160 mmHg
Range:	0 - 330 mmHg
Accuracy:	± 3 mmHg or ± 2% (whichever is greater)
Resolution:	1 mmHg
Maximum inflation:	330 mmHg

A.1.2 ECG recorder

Regulatory standard	Meets ANSI/AAMI EC11:1991 inc R:2001 & IEC60601-2-27:2011
Cable	For use with RDT's proprietary 12 lead ECG harness
Gain/sensitivity	5, 10 (default), 20, mm/mV
Dynamic range	±5 mV ac
Input impedance	>100 MΩ
DC offset	±300 mV dc
Heart rate detection range	30 to 300 bpm
Accuracy	±3%
Acquisition sample rate	500 Hz
Frequency response	0.05 to 175 Hz ±3dB Note that during monitoring prior and post recording ECG frequency response filters will be 0.5 Hz – 175 Hz.
Defibrillator protection	Patient leads are isolated from system and operator, with 5kV protection
Electrosurgery protection	Protected
Common mode rejection	95 dB minimum, additional filters include mains, muscle, low and high pass and adaptive baseline zeroing
Leads off indicators	Connection status for each lead is shown on acquisition screen
Permanent filters during recordings	High Pass: 0.05 Hz 1st order Low Pass: 175 Hz 1st order Note that during monitoring prior and post recording ECG frequency response filters will be 0.5 Hz – 175 Hz. Baseline Wander: Baseline reset by adaptive zeroing algorithm
Notch filter (mains noise rejection)	50 Hz 4th order Butterworth, 49.1 Hz - 50.9 Hz, 60 Hz 4th order Butterworth, 59.1 Hz - 60.9 Hz
Low pass (muscle artefact filter)	35 Hz 4th order

A.1.3 ETC0$_2$ sensor

The capnometer is automatically compensated for local atmospheric pressure.

CO_2 units	mmHg

$EtCO_2$ range	0-150 mmHg
CO_2 waveform resolution	0.1 mmHg
$EtCO_2$, resolution	1 mmHg
CO_2 accuracy	0-38 mmHg: ± 2 mmHg 39-150 mmHg: ± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) For operation above 35°C, add an additional ± 1 mmHg or ± 2% (whichever is greater).
Respiration rate range	0-149 bpm
Respiration rate accuracy	0-70 bpm: ±1 bpm 71-121 bpm: ±2 bpm 122-149 bpm: ±3 bpm
Flow rate	50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume
Waveform sampling	20 samples/s
Response time (warmed up)	7 s (typical) for $ETCO_2$, <13 seconds for respiration (assuming a breath rate of 15 rpm)
Calibration interval	Calibration required after 4000 hours usage of the Capnometer.
Ventilation system pressure	The module will operate within specifications with over and under pressure from a ventilation system as follows: • Over-pressure +60 cm H_2O • Under-pressure -20 cm H_2O The module will withstand and operate within specifications after being exposed to an over and under pressure from a ventilation system as follows: • Over-pressure +100 cm H_2O • Under-pressure -20 cm H_2O With high over-pressures close to the upper limit above, the module may enter in to a blockage mode in order to prevent damage.

A.1.4 Masimo pulse oximetry

Technology:	Masimo® SET® for use in motion and low-perfusion applications
Pulse range:	25-239 bpm
Pulse accuracy:	Accuracy (all ages): no motion ≤3 digits, motion ≤5 digits

Pulse resolution:	1 bpm
Pulse averaging:	8 seconds (configurable)
SpO_2 range:	1-100%
SpO_2 accuracy:	Accuracy (adults/child): no motion or low perfusion ±2 digits 70-100%, motion ±3 digits 70-100%
SpO_2 resolution:	1%
Data update rate	3 seconds
Type:	Functional saturation (test methods available upon request)
Wavelength range:	Red 660 nm, infra-red 905 nm
Perfusion Index range:	0.02-20%
Signal strength range:	0-7 bars
Plethysmogram:	1 – 100, auto-gain
Patient population:	Reusable soft walled probe – for use in clinical and pre-hospital applications, on fingers and toes for children/adults over 8 years old.

SpO_2 was determined by testing on healthy adult volunteers in the range 60%-100% SpO_2 against a laboratory CO-Oximeter. SpO_2 accuracy was determined on 16 neonatal NICU patients ranging in age from 7 to 135 days old and weighting between 0.5 and 4.25 kgs. Seventy-nine (79) data samples were collected over a range of 70 - 100% SaO_2 with a resultant accuracy of 2.9% SpO_2.

The arterial oxygen saturation accuracy during no motion only applies to LNOP® Blue SpO_2 adhesive sensors.

Masimo SET technology with LNOP Adt sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 4Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The saturation accuracy of the neonatal sensors were validated on adult male and female volunteers with light to dark skin pigmentation and 1% was added to account for the properties of foetal haemoglobin.

The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

A.1.5 Thermometer

Dimensions:	162.2 mm (6.38”) x 38 mm (1.48”) x 32.4 mm (1.27”)
Weight:	102.5 g (3.6 oz) including batteries
Batteries:	2 x 1.5V AAA alkaline
External output:	Bluetooth
Ear temperature displayed range:	32-43°C (89.6-109.4°F)
Display resolution:	0.1°C
Accuracy:	±0.2 °C (0.4 °F) between 36~39°C (96.8~102.2°F) and ±0.3 °C (0.5 °F) outside this range
Temperature unit:	°C or °F
Operating temperature range:	10-40°C (50-104°F)
Operating humidity:	95% RH or less
Storage temperature Range:	-20-60°C (-4-140°F)
Storage humidity:	95% RH or less
Memory capacity:	10 measurements
Compliance with:	ASTM E1965-98 EN ISO 80601-2-56 EN 60601-1-2:2014/AC:2010 EN 60601-1-6:2010

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

Bluetooth® specification:

Operating frequency range	(2402 ... 2480) MHz (ISM Band)
Communication range	0 – 10 m (0 – 32' 9") in an open field Class 2
Compliance	Bluetooth® specification, version 3.0 + EDR
FCC ID	A8TBM57SPPSYC2A
Bluetooth SIG	QDID B017511

A.1.6 Glucometer (if installed)

TD-4279 specifications (if installed)

Model	URIGHT TD-4279
Dimensions and weight	96 (L) x 61 (W) x 26 (H) mm, 67.2 g
Power source	Two 1.5V AAA alkaline batteries
Display	LCD with backlight
Memory	1000 measurement results with respective date and time
External output	Bluetooth
Features	Auto electrode insertion detection Auto reaction time count-down Auto switch-off after 3 minutes without action Temperature Warning
Operating conditions	10°C to 40°C (50°F to 104°F), between 10% and 85% R.H. (noncondensing)
Meter storage/transportation conditions	-20°C to 60°C (-4°F to 140°F), between 10% and 93% R.H. (for EU) or below 93% R.H. (for USA) (non-condensing)
Strip storage/transportation conditions	2°C to 30°C (35.6°F to 86°F), between 10% and 85% R.H. (noncondensing)
Measurement units	mmol/L or mg/dL
Measurement range	0.56 to 38.89 mmol/L (10 to 700 mg/dL)
Accuracy (for EU)	For glucose concentrations <5.55 mmol/L (100 mg/dL) accuracy is within +/-0.83 mmol/L (+/- 15 mg/dL) For glucose concentrations >=5.55 mmol/L (100 mg/dL) accuracy is within +/-15%
Accuracy (for USA)	For glucose concentrations <4.2 mmol/L (75 mg/dL) accuracy is within 0.83 mmol/L (15 mg/dL) For glucose concentrations >=4.2 mmol/L (75 mg/dL) accuracy is within 15%
Reading time	5 seconds
Expected service life	5 years
Operating altitude	Altitudes above 3275 metres (10,742 feet) may cause inaccurate results
Degree of pollution	Pollution degree 2

TD-4279 Bluetooth® specification (if installed)

Bluetooth® type	Version 2.1, class 2
Operating frequency range	(2402 ... 2480) MHz (ISM Band)
Communication range	0 – 5 m (0 – 16' 5") in an open field

TD-4279 regulatory compliance (if installed)

EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment.
EN ISO 15197:2015	In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitis.
RoHS Compliance 2011/65/EU	RoHS Certificate

MyGlucoHealth specifications (if installed)

Sample type	Capillary Whole Blood
Sample volume	0.3 µL
Units used	mg/dL (default) or mmol/L
Test range	10-600 mg/dL (0.6-33.3 mmol/L)
Reading time	3 seconds
Accuracy	±5.6%
Calibration	Auto Coding, Plasma Calibrated
Altitude	Sea Level up to 3048 m (10,000 ft.)
Operating temperature	10 - 40°C (50°- 104°F)
Operating humidity	10 - 90%
Strip storage temperature	2°- 30°C (36°- 86°F)
Display type	LCD
Dimensions	52.2 X 98.5 X 23.4 mm (2.1” X 3.9” X 0.9”)
Weight	74.5 g (2.6 oz.) (including batteries)
Power source	3 V (Alkaline Battery, 1.5V AAA Size X 2)
Battery life	2,000 Tests

MyGlucoHealth Bluetooth® specification (if installed)

Bluetooth module	Movon MD-4DR This is unmodified by RDT and is provided under FCC ID VUG-EHS-MGEU00001 (FCC part 15C)
Maximum power	0.00256 W
Operating frequency range	2402 ... 2480 MHz (ISM band)
Range	Class 2, range up to 3 meters (9' 10") in an open field
Output power	2-4 dBm
Power density	20 dBm
20dB bandwidth	850-1000 KHz
Modulation characteristics	F1 avg 140-175 KHz F2 max 115 KHz
Carrier frequency drift	±25 KHz one slot packet, ±40 KHz 3-5 slot packets
Receiver sensitivity	-80 dBm single slot packets -70 dBm multi slot packets
Maximum input level	-5 dBm
Compliance	Bluetooth® specification, version 2.0 + EDR

MyGlucoHealth MGH-BT1 regulatory compliance (if installed)

EN ISO 13485: 2016	Quality management system-Medical devices-Particular requirements for the application of ISO 9001
EN ISO 15197: 2015	In vitro diagnostic test systems -- Requirements for blood- glucose monitoring systems for self-testing in managing diabetes mellitus
EN ISO 14971: 2012	Medical devices – Application of risk management to medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
EN IS0 17511:2003	Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
EN ISO 15223-1: 2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
ISO 15223-2: 2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
EN ISO 18113-1: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-4: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)

EN ISO 18113-5: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)
EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
BS EN 1658:1997	Requirements for marking of in vitro diagnostic instruments
IEC 61010-1: 2010, 3rd edition	Safety requirements for electrical equipment for measurement, control and laboratory use; General Requirements
IEC 61010-2-101: 2015	Safety requirements for electrical equipment for measurement, control and laboratory use; Particular requirements
IEC 60068-2-64: 2008	Environmental Testing-Part 2-64: Tests– Test Fh: Vibration, broadband random and guidance
EN 60950-1:2006+ A11:2009+A1:2010+ A12:2011+A2:2013	Information technology equipment – Safety – Part 1: General requirements
EN 62304: 2006	Medical device software - Software life cycle processes
EN 62366: 2008	Medical devices - Application of usability engineering to medical devices
IVDD 98/79/EC	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical device
Directive 2014/30/EU	Electromagnetic Compatibility (EMC) Directive
Directive 2014/53/EU	Radio Equipment Directive (RED)
EN 300 328 V2.1.1:2016	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 61326-1:2013	ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE - EMC REQUIREMENTS - PART 1: GENERAL REQUIREMENTS
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

A.2 Physical characteristics and environmental specifications

Standalone size	263 mm (10.4”) wide x 216 mm (8.5”) high x 98 mm (3.9”) deep
Standalone weight	3 kg (6.6 lb) including battery, RapidPak™ clip, BP cuff, pulse ox cable, capnometer hose, communications cable and headset
Bag size	401 mm (15.8”) wide x 276 mm (10.9”) high x 154 mm (6.1”) deep
Weight when packed in bag	5.9 kg (13 lb) including Tempus IC2 and accessories, but excluding mains power supply, mains lead and mains battery charger

The IP sealing has a warranty of 1 year.

IP66 (dust and water ingress under pressure) – whole device. According to IEC60529, “IP” means ingress protection. The following two numerals refer to grades of ingress protection for solid foreign objects (the first numeral) and liquids (the second numeral). The first numeral “6” means the device is “dust-proof” against the ingress of dust to a size <75 µm. The second numeral “6” means the device is protected against the ingress of 100 l/m of water “jetting” at the device from 2.5 to 3 m.

A.2.1 Environmental performance and certification

Drop & impact

Drop	1 m drop per IEC60601-1
Transit drop	1.22 m (4 ft) MIL-STD 810G, 26 drops all corners, faces and edges with and without accessories connected
Operational drop	0.75 m (2.5 ft) IEC60068-2-32 Procedure 1, 6 drops to all faces with the device fully operational and all accessories connected
Impact	500 g (1.1 lb) steel ball from 1.3 m (4.3 ft) as per IEC60601 including the display

Temperature & altitude

Category	A1
Test standard, temperature	RTCA/DO-160G Section 4, Para 4.5.1 to 4.5.4
Test standard, altitude	MIL-STD-810 RTCA/DO-160G Section 4, Para 4.6.1 and 4.6.2
Temperature range:	Operating: 0°C to +50°C Charging: 0°C to +40°C Transport/storage: -37°C to +73.3°C Short Term High: +60°C
Altitude:	Operating: -200 to 5486 m (-656 to 18000 ft) The Tempus IC2 can be used at higher physical altitudes provided the local atmosphere is no higher than 5486 m (18000 ft), e.g. in a pressurized aircraft cabin. The power supply’s altitude rating must be adhered to. Do not use the power supply outside of its specifications.
Transport/storage:	-200 to 5486 m (-656 to 18000 ft) 104 kPa to 53 kPa
Rapid decompression:	2438 m to 15545 m (8,000 ft to 51,000 ft) in 1 second

Temperature variation

Test standard:	RTCA/DO160G Section 5 Cat C
Rate of variation:	2°C per minute.

Humidity

Test standard:	MIL STD 810G Method 501.5 Procedure 1 RTCA/DO-160G Section 6 Cat A
Transport/storage:	15 to 95% RH Non-condensing (tested for 168 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-160G Section 7 Cat B
Operational shock	Para 7.2 (6g for 11ms saw-tooth wave, repeated 3 times in all axis). 40 g per MIL-STD 810G
Crash safety	20g in all directions (sustained)
Bump	15 g per EN1789

Vibration

Test standard	MIL-STD 810G rotary wing (UH-60 and CH-47), fixed wing (jet profile), fixed wing (turboprop profile), composite wheeled vehicle Ground Vehicle per EN1789

Explosion proofing

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

Water proofing

Not tested to RTCA/DO160G

Fluids susceptibility

Not applicable.

Sand & dust

Commercial qualification	IP66 (dust ingress under pressure) – whole device

Fungus resistance

Not applicable.

Salt spray

Not applicable.

Magnetic effect

Not applicable.

Power input

Not tested to RTCA/DO160G Section 16.

Commercial qualification	EN61000-3-2:2006 Mains harmonics EN61000-3-3:2013 inc A1:2001 & A2:2005 Mains flicker EN61000-4-11:2004 Voltage dips and interruptions

Voltage spike

Not tested to RTCA/DO160G Section 17.

Commercial qualification	EN61000-4-4:2012 Fast transient bursts

Audio frequency conducted susceptibility – power inputs

Not tested to RTCA/DO160G Section 18.

Commercial qualification	EN61000-4-5:2006 Surges

Induced signal susceptibility

Not tested to RTCA/DO160G Section 19.

Commercial qualification	EN61000-4-6:2013 inc A1:2001 Conducted RF field

Radio frequency susceptibility (radiated & conducted)

Not tested to RTCA/DO160G Section 20.

Commercial qualification	EN61000-4-3:2006 Radiated RF Interference

Emission of radio frequency energy

Test standard	RTCA/DO160E Section 21 Cat Q

Lightning induced transient susceptibility

Not applicable.

Lightning direct effects

Not applicable.

Icing

Not applicable.

ESD

Not tested to RTCA/DO160G Section 25.

Commercial qualification	EN61000-4-2:2009 inc A1:1999 & A2:2001 ESD

Fire and smoke hazards

Main case material	PC-ABS
Flame	UL94V-0
Overmould material	TPU
Flame	N/A

A.3 Miscellaneous features and specifications

A.3.1 Rechargeable battery

Battery life	At least 11 hours with default display brightness, SpO_2, $ETCO_2$ (used for 25% of the time), and NIBP every 15 minutes.
Nominal voltage	7.4 V
Charging voltage	8.4 V ±1%
Nominal capacity	10.2 Ah, 75.5 Wh
Weight	0.42 kg nominal

Dimensions	152 mm (6”) x 42 mm (1.6”) x 62 mm (2.4”) max
Shelf life	Approximately 7h remaining after 1 year storage


Battery shelf life and run times are based on a new, fully charged battery stored and used at 20 °C. Run time is based on RDT’s model of typical device usage in an incident.

A.3.2 Mains power supply


Only the RDT mains power supply pn 01-2049 can be used with the Tempus IC2.

Mains input voltage	100 – 240 V
Frequency	50/60 Hz & 400 Hz
Input current	~2 A (<0.5 A drawn when supplying the Tempus)
Output voltage	12 V dc
Output current	5 A
Relative humidity	15%-95% (non-condensing)
Weight	0.42 kg nominal
Dimensions	151 x 41 x 61 mm max
Operating temperature range	0°C to 50°C
Transport/storage temperature range	-40°C to +85°C

Altitude (*)	0 – 4000 m (0 – 13,123 ft)

* Note that the power supply’s altitude rating of 4000m must be adhered to. Do not use the power supply outside of its specifications.

A.3.3 Battery charger


Only the RDT Battery Charger pn 01-1012 can be used with the Tempus IC2.

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

Weight	0.25 kg nominal
Dimensions	107 x 67 x 36.5 mm

A.3.4 GPS

Antenna	Integral
Accuracy	±10 m (±2.5 km with <6 satellites – labelled as “Approximate Fix”)

A.4 EMC statement

The Tempus IC2 remote patient monitor has been tested and approved to IEC/EN60601-1-2:2014. This means that the Tempus IC2 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 IC2 has been tested according to the requirements of RTCA DO160-G section 21 category Q.

It should be noted that the Tempus IC2 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 IC2 is intended for use in electromagnetic environments of ±6kV static contact (±8kV air discharge) and magnetic fields of 3A/m (50/60Hz). The Tempus IC2 is proof against radiated RF emissions from 80MHz to 2.7GHz to a level of 3V/m. In the event that the Tempus IC2 will be used in environments with RF levels exceeding this, please contact RDT for further information.

A.5 Communications

A.5.1 Transmission rates

ECG data and digital pictures take an appreciable amount of time to send to the Response Center, 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.

A.5.2 Ethernet specification

The Ethernet connection has the following specifications:

- IEEE 802.3 compliant
- RJ-45 connection
- DHCP or fixed IP, Mask, Gateway
- Network cable: CAT5 at least 50 m

A.5.3 FCC & Industry Canada notes on wireless communications

The Tempus IC2 contains the following FCC granted radio - FCC ID: ROSGTM601W and ROSWT2CBW003.

> **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.

A.5.4 Radio frequency interference requirements – Canada

This Class B digital apparatus meets the requirements of the Canadian Interference-Causing Equipment Regulations.

A.5.5 WiFi specification

The WiFi technology used by the Tempus IC2 operates using IEEE 802.11b and 802.11g standard. It operates in the Industrial, Scientific and Medical (ISM) band between 2.412 GHz and 2.484 GHz.

> **WARNING**
>
> Per IEC60601-1-2 cl 5.2.2.5 b), the Tempus IC2 may be interfered with by other systems even if they comply with CISPR emissions.

The WiFi technology has the following features:

Range	Up to 100 m (328') (free field)
Data rate	CCK: 1, 2, 5.5, 11 Mb/s OFDM 6, 9, 12, 18, 24, 36, 48, 54 MB/s
Security	WEP, TKIP, WPA and WPA2 AES/CCMP per IEEE 802.11 i
Baseband modulation	802.11g: OFDM 802.11b: DSSS/CCK
Quality of service	802.11 e EDCF

A.5.6 GSM, GPRS & UMTS specification

The Cell Phone (GSM) technology used by the Tempus IC2 has the following specifications:

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	1920	MHz
	UMTS 850	824	849	MHz
	UMTS 900	880	915	MHz
	UMTS 1900	1850	1910	MHz
	UMTS 2100	1920	1980	MHz

Parameter		Min	Max	Unit
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
	UMTS 850	869	894	MHz
	UMTS 900	925	960	MHz
	UMTS 1900	1930	1990	MHz
	UMTS 2100	2110	2170	MHz

RF power:

Band	Max	Unit
GSM/GPRS 850/900	33	dBm
GSM/GPRS 1800/1900	30	dBm
EDGE 850/900	27	dBm
EDGE 1800/1900	26	dBm
UMTS 850/900/1900/2100	24	dBm

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

A.5.7 Bluetooth® specification

WARNING

Per IEC60601-1-2 cl 5.2.2.5 b), the Tempus may be interfered with by other systems even if they comply with CISPR emissions.

The Bluetooth® module has the following specifications:

Range	10 m (32' 9") (free field), class II
Data rate:	V2.0 up to 1 Mb/s EDR: 2.3 Mb/s
Baseband modulation	V2.0: GFSK EDR: Pi/4 DQPSK, 8DPSK

A.5.8 Bluetooth® Sennheiser headset specification

(FCC ID DMOCBMSKE)

The Tempus IC2 uses the Sennheiser® Presence wireless headset. This is unmodified by RDT.

It operates in the frequency bands 2402 MHz – 2480 MHz.

Users are reminded to refer to the Sennheiser user guide (attached to the CD-ROM provided with the Tempus IC2) that provides instructions for use of the headset. These include environmental performance specifications which may differ from those of the Tempus IC2.

Description	General specifications
Bluetooth® type	Version 4.0, class 1
Range	10m max in an open field
Transmission frequency	2402 MHz to 2480 MHz
Bluetooth® Profiles	HSP, HFP, A2DP
Weight	13 g
Size	51 mm (2”) x 19 mm (0.75”) x 23 mm (0.9”) (WxHxD)
Talk time	Up to 4 hours*
Operating temperature range	+10°C (+50°F) to +40°C (+104°F)
Operating humidity range	20 to 85%, non-condensing
Storage temperature range	-20°C (-4°F) to +60°C (140°F)
Storage humidity range	10 to 95%, non-condensing

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

A.6 Tempus IC2 device classification

The system is classified according to the requirements of EN60601-1:2006, the standard for Medical Electrical Equipment, Part 1, General Requirements for Safety, as:

- The Tempus IC2 is internally (battery) powered. The external power supply is class I (earthed) as defined by the classification of the power supply specified and supplied by RDT. The battery charger is class II (double insulated).
- Applied parts type CF defibrillator proof. All patient coupled connections from the Tempus IC2 are designated as Patient Applied Parts per IEC60601-1.
- The Tempus IC2 is rated IP66, protected against rainfall according to IEC60529. This means that the device is proof against the ingress of talcum powder into the body of the device (into its case) and also proof against the entry of water from a strong hose (akin to a garden hose) into the body of the device (into its case). All other parts are rated IPXX. The device is rated IP66 with all connectors either mated or unmated (except the Capnometer cannula which must be unconnected and its door clicked shut).
- No parts supplied sterile or suitable for/requiring sterilising.

- Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Suitable for continuous use, for use with defibrillators and for use with electrosurgical systems.
- The expected service life of the device (excluding batteries) is 5 years. This can be extended through maintenance of the device.

The thermometer is:

- 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 sterilized,
- 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 (if installed) 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.

A.6.1 Standards compliance

The Tempus IC2 complies with the applicable parts of the following standards:

Standard	Title
AAMI 60601-2-25	Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-1 3rd edition	Medical electrical equipment: General requirements for safety (as amended)
IEC 60601-1-2:2014 4th edition	Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC/EN 62366	Medical devices -- Part 1: Application of usability engineering to medical devices
IEC 60601-2-25:2011	Medical electrical equipment -- Part 2-25: Particular requirements for the safety of electrocardiographs
IEC80601-2-30:2009 + A1:2013	Medical electrical equipment -- Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
IEC 60601-2-49:2001/2011	Medical electrical equipment -- Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
ISO 80601-2-55:2018	Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-61:2011	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
IEC62304:2006 + A1:2015	Medical device software -- Software life cycle processes

Standard	Title
EN ISO 15197:2015	In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
IEC60601-1-11:2010	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-1:2005/2006 – reference standard only	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 60529:1992 + A2:2013	Specification for degrees of protection provided by enclosures (IP code)
EN 1041:2008/2013	Information supplied by the manufacturer of medical devices
ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing
RTCA DO-160G:2010	Environmental conditions and test procedures for airborne equipment
EN1789:2007 + A2:2014	European Standard Ambulances (EN1789)
EN13718-1:2008	Medical vehicles and their equipment. Air ambulances. Requirements for medical devices used in air ambulances.
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
FCC/CFR 47; Part 15B	EMC emissions

A.6.2 EMC information

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

Cable Length of the Sensors and the Accessories

Cable	RDT part number	Cable length (typical)	Tested length
Ethernet cable	01-2109	3.1 m	3.1 m
SpO_2 sensor	01-2089	2.4 m	2.4 m
ECG harness	01-2001	2.4 m	2.4 m
Capnometry cannula	01-2206	0.5 m	0.5 m
Wired headset	01-1019	1.2 m	1.2 m
Mains Power supply	01-2049	0.45 m	0.45 m
Mains lead	01-2164	2 m	2 m

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.

A.6.3 Manufacturers' declarations

Manufacturer's declaration - electromagnetic emissions (Tab. 201 according to DIN EN 60601-1-2)

The Tempus IC2 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 IC2 must emit RF energy in order to perform its function. Nearby electronic devices may be affected. The Tempus IC2 can be configured 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 IC2 is intended for use in all facilities including living quarters and such ones which are connected directly to a public power supply that supplies also buildings used for living purposes.
Emission of overtones acc. to IEC61000-3-2	Class B	
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 IC2 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.

Interference resistance test	IEC 60601 test level	Compliance level	Electromagnetic environment guidelines
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 % UT (>95 % break of U_T) for 0.5 period. 40 % UT (60% break of U_T) for 5 periods. 70 % UT (30% break of U_T) for 25 periods. < 5 % UT (>95 % break of U_T for 5 seconds.	< 5 % UT (>95 % break of U_T) for 0.5 period. 40 % UT (60% break of U_T) for 5 periods. 70 % UT (30% break of U_T) for 25 periods. < 5 % UT (>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 IC2 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 IC2 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	3 Vrms 150 KHz to 80 Mhz	3 Vrms	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.

Interference resistance test	IEC 60601 test level	Compliance level	Electromagnetic environment guidelines
Radiated RF disturbances acc. to IEC61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m and 20 V/m	Recommended safety distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 observed, 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 IC2 (Tab. 206 according to DIN EN 60601-1-2)

The TEMPUS IC2 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.

Nominal power of the transmitter (W)	Safety distance (metres) depending on the frequency		
	150 kHz to 80 MHz **$d = 1.2\sqrt{P}$**	**80 MHz to 800 MHz** **$d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz** **$d = 2.6\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

Nominal power of the transmitter (W)	Safety distance (metres) depending on the frequency		
	150 kHz to 80 MHz **$d = 1.2\sqrt{P}$**	**80 MHz to 800 MHz** **$d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz** **$d = 2.6\sqrt{P}$**
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.			

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Annex B : End user license agreement

B.1 Tempus IC2 end user license agreement

This license covers RDT's Tempus IC2 software.

Warning: The software contained herein is protected by copyright law and international treaties. Unauthorized reproduction, distribution or reverse engineering of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.

You acknowledge that you will read and adhere to the user manual and ensure that users receive proper training from RDT or an appropriately trained individual. You also acknowledge that you will maintain the software by installing new software updates supplied by RDT within 5 working days of receiving or being notified of them.

License:
You may transfer the program and license to another party if the party agrees to accept the terms and conditions of this agreement. You will not share the program with other parties and will keep the program and details of its functions confidential. You will ensure that access to the software and use of it will be restricted to properly trained and authorized personnel only. You will not try to copy or reverse engineer the software.

The Tempus IC2 operates over third-party communications links, such as telephone lines, GSM or satellite links and the Internet. RDT does not accept liability for the failure of these links to reliably transmit information from RDT's products. Users are reminded that it is their responsibility to ensure that GSM network and other communications contracts are maintained and suitably setup and configured for the areas in which they need to be used.

In order to function correctly Tempus IC2 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 IC2 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.

Neither the Tempus IC2 or RDT are a "covered entity" under the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder ("HIPAA"). As a result, HIPAA does not apply to the transmission of health information by RDT or Tempus IC2 to any third party. However, users of the Tempus IC2 may be "covered entities" under the HIPAA act and so are reminded that they are responsible for acting accordingly. All users are reminded that it is their responsibility to maintain all patient records in a manner that is compliant with applicable local regulations.

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

RDT owns all proprietary rights to the Tempus IC2. RDT gives you a personal, revocable, non-assignable, and non-exclusive license to use the Tempus IC2.

Limited Warranty and Remedies:
In no event shall RDT or its distributors or agents, be liable for any damages resulting from loss of data, loss of revenue or for any incidental or consequential damages incurred arising out of or relating to the use of this

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You acknowledge that you have read this agreement, understood it, and agree to be bound by its terms and conditions.

Failure to enforce any provision will not constitute a waiver of that provision. If any provision is found unenforceable, it and any related provisions will be interpreted to best accomplish the unenforceable provision's essential purpose.

This agreement is governed by UK law. The exclusive venue for any dispute relating to this agreement is London UK. You and RDT consent to the personal jurisdiction of these courts. Nothing in this agreement limits either party's ability to seek equitable relief.

B.2 Pocket medic

This license covers QRS Pocket Medic software.

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You acknowledge that you have read this agreement, understood it, and agree to be bound by its terms and conditions; you further agree that it is the complete and exclusive statement of the agreement between us which supersedes any proposal or prior agreement, oral or written, and any other communications between us relating to the subject matter of this agreement.

B.3 MPEG4 end user license agreement

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(i) ENCODE VIDEO IN COMPLIANCE WITH THE STANDARDS LICENSED UNDER SUCH PATENT PORTFOLIO LICENSES AND/OR

(ii) DECODE VIDEO THAT WAS ENCODED BY A CONSUMER ENGAGED IN A PERSONAL AND NON-COMMERCIAL ACTIVITY AND/OR WAS OBTAINED FROM A VIDEO PROVIDER LICENSED TO PROVIDE VIDEO UNDER SUCH PATENT PORTFOLIO LICENSES.

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B.4 Masimo® end user license agreement

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6.Transfer Restrictions. The software/firmware is licensed to the Purchaser, and may not be transferred to anyone, except other end-users, without the prior written consent of RDT. In no event may you transfer, assign, rent, lease, sell, or otherwise dispose of the software/firmware or the products on a temporary basis.

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B.5 Firebird – Interbase public license

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B.7 OpenSSL license

The product includes software developed by the OpenSSL Project for use in the OpenSSL Toolkit (http://www.openssl.org/).

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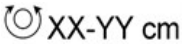
Annex C : Symbols used

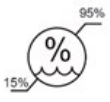
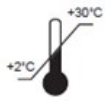
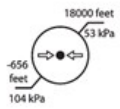
The following symbols are used either on this product or on the accessories and packaging provided with it:

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

	A caution symbol indicating that federal law restricts the device for sale by or on the order of a physician (US market).
	Signifies European technical conformity for a device/accessory, CE marked by notified body number 0413
	Signifies European technical conformity for a device/accessory. For class I devices.
	Consult the instructions for use for important warning information.
	Consult the instructions for use for important cautionary information.
	Name and address of the European Union Authorized Representative.
	Catalogue Number Indicates the manufacturer’s catalogue number
	Serial Number Indicates the manufacturer’s serial number
	Unique Device Identifier Indicates a carrier that contains unique device information
	Indicates the medical device manufacturer.
	Date of manufacture. The year that the item was manufactured is represented by the year and then the month e.g. 2019 06 is June 2019.

LOT **YYYY - MM - DD**	The manufacturer's batch code. The year that the item was manufactured as a part of a larger batch is represented by the year and then the month e.g. 2019 06 is June 2019.
	EU Directive on Waste Electrical and Electronic Equipment (WEEE). This product must not be disposed of or dumped with household waste.
	Type CF defibrillation-proof applied part complying with IEC 60601-1.
ECG	ECG socket.
BP by SunTech.	Blood pressure socket.
SpO_2	Pulse oximeter socket.
Capnometer/$ETCO_2$	Capnometer socket.
	Capnometer Cannula inlet connection.
	Type BF applied part. The thermometer is not proof against the effects of a cardiac defibrillator discharge.
	Battery charge indicator – flashes green when the battery is on charge.
	Battery power level.
	System power on/off (push/push).
	Single use device only, discard item after use.
IP66	The device is dust-tight and protected against powerful water jetting according to IEC 60529.
 YYYY - MM - DD	Shelf life, where the time that the unit must be used by is represented by the year and then the month e.g. 2020 06 is June 2020.
	Communications connections.

	WiFi is connected.
	Bluetooth® connection to Bluetooth peripherals.
	Battery connection – to indicate positive terminal polarity.
	Global Positioning System (GPS).
	Global System for Mobile (GSM) communications.
	Headset connector.
	Ethernet socket (RJ-45).
	USB 2.0 & 1.0 sockets.
	Power status (green indicates mains power is connected).
	Device contains wireless transmitters.
	DC connector.
	Indicates keep dry.
 	The user must check that the blood pressure cuff is the correct size. Once the blood pressure cuff is wrapped round the arm, the INDEX mark should be between the RANGE marks.
	Center point of blood pressure cuff bladder - to be aligned with the patient's artery.
	Diameter size for the blood pressure cuff.

	Item does not contain any latex (blood pressure cuffs).
	Item does not contain any PVC (blood pressure cuffs).
	Store this way up.
	Fragile, handle with care.
	Recyclable packaging.
	Packaging should not be discarded.
	Storage humidity range.
	Storage temperature range.
	Storage pressure/altitude range.
	Medical Device Indicates that the product is a medical device
	Consult the instructions for use.These are provided in paper format with the device.
	Country of Manufacture The country of manufacture is identified by the two-letter ISO 3166-1 country code. The date of manufacture of the device may be placed adjacent to this symbol in YYYY-MM-DD format.

PN	Technical Part Number Indicates the manufacturer’s technical part number

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Annex D : Accessories of the Tempus IC2

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

Accessories list

Product name & description	Part number
Blood Pressure Cuff – Adult	01-1002
Blood Pressure Cuff – Large Adult	01-1003
Blood Pressure Cuff – Child	01-1004
Blood Pressure Hose	01-1006
Pulse Oximetry cable (MasimoSET Rainbow Patient Cable 4ft 25-Pin R/A RC4 RA)	01-2088
Pulse Oximetry Sensor (MasimoSET M-LNCS DBI Adt SpO2 Reusable Sensor [1] – Boot)	01-2089
Tempus 12-Lead Electrocardiogram Harness	01-2001
ECG Elastic Wrist Straps (Pair)	01-1025
MicroStream Advance Adult Nasal CO_2 Filterline (Box of 25)	01-2206
Fora Bluetooth Thermometer	01-2027
Fora IR20 Disposable Cover	01-2307
Tempus IC2 Glucometer Update Kit (TD-4279)	01-2299 (*1)
Tempus IC2 Glucometer kit (TD-4279)	01-2292 (*1)
Glucometer Replenishment Kit (TD-4279)	01-2293 (*1)
Glucometer Test Strips (TD-4279)	01-2294 (*1)
Glucometer Control Solution (TD-4279)	01-2295 (*1)
Bluetooth® Glucometer (MyGlucoHealth™) (if installed)	01-2015 (*2)
Glucometer Replenishment Kit (MyGlucoHealth™)	01-2020 (*3)
MyGlucoHealth Control Solution COMBO Pack (Low-Normal-High)	01-2043 (*3)
Tempus IC2 Consumables Replenishment Kit	01-2303
Sennheiser Presence Bluetooth® Headset	01-2098
Wired Headset	01-1019
Tempus Ethernet Cable 3.1 m (10 ft)	01-2109
Extension Reel	01-1009

Product name & description	Part number
Mains Power Supply	01-2049
Mains Cable Pack TEMPUS IC2	01-2164
Battery Pack	01-2029
Battery Charger	01-1012
TEMPUS IC2 bag assembly	01-2105
Bag Front Pocket Clips	01-1035
Accessory Pouch	02-1001

(*1) These items are only required if a TD-4279 glucometer is installed.

(*2) The MyGlucoHealth glucometer is now obsolescent. Customers who wish to replace this item will be offered the TD-4279 glucometer.

(*3) These items are only required if a MyGlucoHealth glucometer is installed.

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Part number: 41-2017EN-06