Tempus 2000™

User/Operator Manual

Part number CUD-34

Basingstoke, Hampshire, UK

Contents

1 Introduction

1.1 Manufacturer's Address

The Tempus 2000 is designed and manufactured by:

Remote Diagnostic Technologies Limited
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RG25 2HT
UK

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www.rdtltd.com

1.2 CE Statement

Marking by the CE symbol indicates compliance of this device to the Medical Devices Directive 93/42/EEC and the Radio and Telecom Terminal Equipment Directive 1995/5/EC.

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

1.3 FDA Prescription Statement

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

1.4 FCC/ACTA Compliance Statement

The Tempus 2000 complies with the requirements of US 47 CFR Part 68. A Supplier's Declaration of Conformity is provided later in this document.

1.5 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 2000. Every effort has been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that the document is error free or that it is accurate with regard to any specification. Tempus 2000™ is a registered trademark of RDT Ltd.

1.6 Patent Claims

RDT has applied for patents covering the Tempus 2000 and its communications technology in the following jurisdictions:

Australia (Application No. 63050/98);

Canada (Application No. 2,281,909);

Europe (Application No. 98907073.5, Publication No. 0 969 792 and Application No. 00303932.8);

Hong Kong (Application No. 00103571.1);

Israel (Application No. 131432);

Japan (Application No. 539332/98);

Singapore (Application No. 9904269.9);

UK (Application No. 9704843.3 and Application No. 9910938.1);

USA (Application No. 09/380,724);

UK (Application No. 01271279).

1.7 Limited Warranty

Remote Diagnostic Technologies Limited ('RDT') warrants each new Tempus 2000 to be free from defects in workmanship and materials under normal conditions of use and service for a period of one (1) year from the date of shipment. Consumable items are expressly excluded from this Warranty. RDT's sole obligation under this warranty will be to repair or (at RDT's option) replace products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. Except as set forth herein, RDT makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. The warranty shall be void if the Tempus 2000 is in any way modified or if it is used with non-approved consumables, unless specifically authorised in writing by RDT, and RDT shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

Full terms and conditions of sale are contained later in this document.

1.7.1 Service Support and Preventative Maintenance Check

Repairs to the Tempus 2000 under warranty must be made by the manufacturer. If the Tempus 2000 requires repair, contact your local distributor or Remote Diagnostic Technologies at the address in section 1.1. When calling, please be ready to quote the serial number of the Tempus 2000.

A preventative maintenance check is required every 10-14 months. This is described later in this document. The device must be returned to the manufacturer at this time. Failure to return the device for the preventive maintenance check will void all guarantees on the device. In this instance the device must not be used. Please note that all returns must be performed within the restrictions of RDT's Terms and Conditions of Sale as described later in this document.

2 Warnings and Cautions

2.1 EMC Statement

The Tempus 2000 remote patient monitor has been tested and approved to EN60601-1-2:2001. This means that the device 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 device has been tested according to the requirements of RTCA DO160-D section 21 category M.

It should be noted that the Tempus 2000 may be affected by high levels of stray EM radiation from other electronic devices that are being used in close proximity to it. Details are given in this manual on those devices that are known to cause such levels of interference. Where such details are given, attention to them should be paid during the use of the Tempus 2000.

2.2 Indications for Use

The Tempus 2000 is a patient monitor intended to be used in remote locations where medical staff may not be present.

The device is intended to be applied to the patient by a trained operator who is not a medical expert. The device is not intended to allow the operator to make any clinical decision for treatment or diagnosis. The device permits the operator to take measurements from a patient, store this information for later transmission or transmit medical information to a Response Centre at the time of recording, where trained staff can make clinical assessments based on the information transmitted and advise the operator on the nature of the medical incident. A trained physician may use the Tempus 2000 as a standalone diagnostic device.

The Tempus 2000 is suitable for use on adults or children (over 10 years old and over 20kg in weight).

2.3 Contraindications

The Tempus 2000 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 device is not intended to, and does not, sound alarms for physiological parameters. The device does not replace physician's care. The device is not intended for neonatal use. The device is not an apnoea monitor. The device is not intended to be a long term monitor, it is only intended to be used in short, discrete incidents where the immediate health of the patient is in question.

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

The ECG is not suitable to be used on patients with prosthetic limbs.

2.4 Warnings, Cautions and Notes

2.4.1 Warnings

The following warnings relate to things that could cause serious hurt to the patient or the operator.

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

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

WARNING: Do not autoclave, ethylene oxide sterilise, or immerse in liquid.

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

WARNING: Use only SpO_2 sensors supplied with the Tempus 2000, or specifically intended for use with the Tempus 2000.

WARNING: Do not use this device in the presence of magnetic resonance imaging (MR or MRI) or HF transmitting equipment.

WARNING: Do not use the Tempus 2000 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 harm skin integrity and circulatory status. Change the sensor site every four hours.

WARNING: Any Tempus 2000 unit or accessory that has been dropped or damaged should be inspected by qualified service personnel prior to use to ensure proper operation.

WARNING: The Tempus 2000 is not for use on neonates.

WARNING: The Tempus 2000 should not be used on patients undergoing defibrillation. The Tempus 2000 is protected against defibrillator discharge but rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.

WARNING: The Tempus 2000 is not intended for long term patient monitoring. There are no audible or visible alarms.

WARNING: Reposition the oximeter probe at least once every 4 hours to allow the patient's skin to respire.

WARNING: The thermometer provides fast, accurate temperature measurements on any patient into which the temperature 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 temperature probe if the probe cannot be inserted into the ear canal.

WARNING: There is no defibrillator synchronisation output on the Tempus 2000. Make no connections between the Tempus 2000 and a defibrillator.

WARNING: The Tempus 2000 will not operate effectively on patients who are experiencing convulsions or tremors.

WARNING: The Tempus 2000 is not for apnoea detection. The Tempus 2000 has not been tested or validated for use in apnoea detection.

WARNING: Misuse or improper handling of the Tempus 2000 or its sensors or cables can cause damage which may lead to equipment failure or inaccurate readings.

WARNING: The Tempus 2000 and its batteries are not to be used in the presence of fuel or other flammable gasses or vapours.

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 recharge batteries using battery chargers specified by RDT.

WARNING

It is essential to switch off the Tempus 2000 in between different patients to avoid confusion between different patient records.

2.4.2 Cautions

The following cautions relate to things that could damage the Tempus 2000 or cause inaccurate readings or that could potentially cause harm to patients or operators.

CAUTION: The Tempus 2000 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 Tempus 2000.

CAUTION: In the event that the Tempus 2000 displays an error that is not described within this manual e.g. Windows applications errors, turn the Tempus 2000 off and then on again. This should clear the error and allow normal operation to resume. Do not continue to use the device if such an error is displayed. If symptoms persist, please contact RDT.

CAUTION: The Tempus 2000 must be switched off between taking readings from different patients.

CAUTION: Should the Tempus 2000 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 Tempus 2000 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 components.

CAUTION: The Tempus 2000 contains a 4 hour lithium-ion battery. If the battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly. Remote Diagnostic Technologies Ltd cannot dispose of used batteries. Dispose of batteries in accordance with applicable regulations which vary from country to country.

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

CAUTION: Pressing front panel or wrist keypad keys with sharp or pointed instruments may permanently damage the keypad. Only fingers should be used to press these keys.

CAUTION: Do not disassemble the Tempus 2000. There are no user-serviceable parts inside. Refer servicing to the manufacturer.

CAUTION: Use of monitoring during continuous nebulised medication delivery will result in damage to the Tempus 2000 which is not covered by the warranty. Disconnect the capnometer sample line from the Tempus 2000, or switch off the Tempus 2000, 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: Use of the Tempus 2000 in Cell Phone Mode will 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. In addition, the use of the Tempus in Cell Phone Mode will 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.

In addition, the use of the Tempus 2000 in Cell Phone Mode may cause interference with some implanted pacemakers and other medically implanted equipment. Avoid placing the Tempus over a pacemaker. If you suspect interference is being caused, disconnect the connection to the Tempus Monitoring Station by pressing  twice.

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

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

2.4.3 Notes

The following notes provide important information on the use of the Tempus 2000.

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

Note: Any condition that restricts blood flow, such as use of a blood pressure cuff (other than the Tempus 2000 cuff used in accordance with the instructions herein) may cause an inability to determine accurate pulse and SpO_2 readings.

Note: Operation of the Tempus 2000 may be adversely affected in the presence of conducted electrical transients or strong electromagnetic or radio frequency sources such as electrosurgery and electrocautery equipment, HF radio transmission antenna, x-ray machines and high intensity infrared radiation.

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

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

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

Note: All user and patient accessible materials are non-toxic.

Note: Hazards arising from software errors have been minimised. Hazard analysis was performed to meet the requirements of EN14971 and IEC60601-1-4.

Note: Each external connection and part of the Tempus 2000 is electrically isolated.

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

Note: Allow the temperature probe and the patient to acclimate to the same ambient temperature before taking temperature readings.

Note: Dirt, greasy films or moisture on the temperature probe lens may affect the accuracy of the instrument.

- **Note:** Do not open the temperature probe case. The temperature probe will require factory recalibration if the case is opened.

Note: This equipment complies with Part 68 of the US FCC Rules and the requirements adopted by ACTA . On the base of this equipment is a label that contains, among other information, a product identifier in the format US:AAAEQ###TXXXX. If requested, this number must be provided to the telephone company.

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

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

Note: If the Tempus 2000 causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice isn't practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it is necessary.

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

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

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

Note: If your home or area of installation has specially wired alarm equipment connected to the telephone line, ensure the installation of the Tempus 2000 does not disable your alarm equipment. If you have questions about what will disable alarm equipment, consult the supplier.

Note: This equipment is not hearing aid compatible.

2.5 What to do in the Event of Device Failure

You should respond to error messages shown on screen as the message instructs you.

In the event that the Tempus 2000 fails to operate correctly or in a way that is not described in this manual, stop using the device immediately and switch the Tempus 2000 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.

3 Features and Intended Use

3.1 Likely Conditions of Use

The Tempus 2000 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. Typical examples are remote land, sea or air locations.

The Tempus 2000 is intended to be used by medically unqualified people who have received basic training in the use of the device. Medical expertise is provided through communication with the Response Centre, which is staffed by physicians 24 hours a day, 7 days a week.

3.2 Product Description and List of Features

The Tempus 2000 is fully automated and includes a 12 lead ECG, which can easily be operated by a non-expert. The device also has automated blood pressure, pulse oximetry, temperature, respiration rate and breath gas analysis.

There is a removable colour display screen, a hands-free integrated voice link with automatic dialling, and the facility to send and receive still video images. A wrist-mounted keypad provides easy access to the Tempus 2000 functions. The wrist keypad includes a full colour still-video camera

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

Everything that is displayed on the Tempus 2000 screen is simultaneously seen at the Tempus Monitoring Station in the Response Centre, enabling the medical expert to fully interact with the operator. The medical expert can, in fact, fully control the Tempus 2000 if required, giving added comfort to the operator and patient at the remote location.

3.3 Theory of operation

The Tempus 2000 is a self-contained medical data capture system which connects to a dedicated Response Centre. Connection is achieved using different communications technologies, refer to the specific User Supplement attached with this manual for details of connecting the Tempus.

A physician may use the Tempus 2000 as a stand-alone diagnostic device (without it being connected to the Response Centre).

The Tempus 2000 provides the following information about the patient from its sensors:

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

- Respiration rate

These readings are transmitted via a telecommunications link to the Tempus Monitoring Station.

Additionally, the Tempus 2000 includes a colour video camera which is capable of sending colour still images to the Tempus Monitoring Station.

4 Setting Up and Installation

4.1 Setting up

4.1.1 Connecting the Battery

It is necessary to install the supplied battery into the Tempus 2000 before it will operate.

4.1.2 Charging the Battery

It is necessary to ensure that the battery is fully charged before the Tempus 2000 is put into service.

Refer to the Tempus 2000 Battery Charger manual (part number 41-0003) for a detailed description of how to charge the battery.

WARNING

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

4.1.3 Ensure that the Device is Packed Properly with Sufficient Consumable Items

The Tempus 2000 is provided with, and should be stored with, the following consumable items:

- 4 cleaning wipes
- 4 nail varnish removal wipes
- Three blood pressure cuffs: child, adult and large adult
- Two cannula and filter packs, one on the top of the foam block and the other stored beneath the wrist keypad
- Three earpiece covers, stored beneath the wrist keypad plus one cover attached to the earpiece
- One full spray of ECG contact spray
- One full box of thermometer covers

5 Using the Tempus 2000

5.1 Controlling the Tempus 2000

The Tempus 2000 has three sets of controls that enable it to be operated. These are:

- The front panel controls
- The screen controls
- The wrist keypad controls

All of the controls are “membrane” buttons, which are made of plastic and are operated by pressing the centre of the button to activate the function. Undue force is not required to activate the buttons, they only require to be pressed in until it can be felt that the internal contact has been made.

The front panel controls consist of the on/off button and the battery power gauge. Use of these controls is described later in this manual. These are the only buttons where they must be pressed down and held down to activate their function. To make the power switch tamper-proof it is designed so that it must be held down for 3 seconds to activate it.

The screen controls and the wrist keypad controls have the same function. They consist of 8 buttons (each) and these buttons enable all the functions of the Tempus 2000 to be operated. Two sets of controls are provided so that the Tempus 2000 can be controlled and operated in small and restrictive areas. The buttons on both the display and the wrist keypad do not need to be held down to make them operate, they only need to be pressed briefly to make them perform their function.

The buttons on the display and the wrist keypad have symbols on them that relate to their function. It should be noted that these symbols relate to the primary functions of the buttons e.g. activating the medical functions and connecting and disconnecting the telephone links. However, the buttons can have other functions allocated to them at certain points e.g. when changing system configurations the control buttons allow the telephone number of the Response Centre to be changed. The function of the buttons is always indicated on the screen at any given point, even if it has been altered for a particular process. It should also be noted that when that process is finished, the functions of the buttons revert to their normal mode.

5.2 Using the Tempus 2000

The Tempus 2000 is controlled by using 8 buttons on the control pad (either on the screen or the Wrist Keypad) and the button on the thermometer. The buttons are labelled to indicate their general function. These are:

To bring up the helpscreen for this activity.

Press the green button on the temperature probe to bring up the helpscreen for taking temperature readings.

To activate the ECG and to bring up the helpscreens for this activity.

To activate the capnometer and bring up the helpscreen for this activity.

To activate the video camera.

Press this button to disconnect the telecoms links to the Response centre.

Press this button to exit the screen that you are viewing and return to the main (results) screen or to the next screen in the process

Press this button to get help at any time.

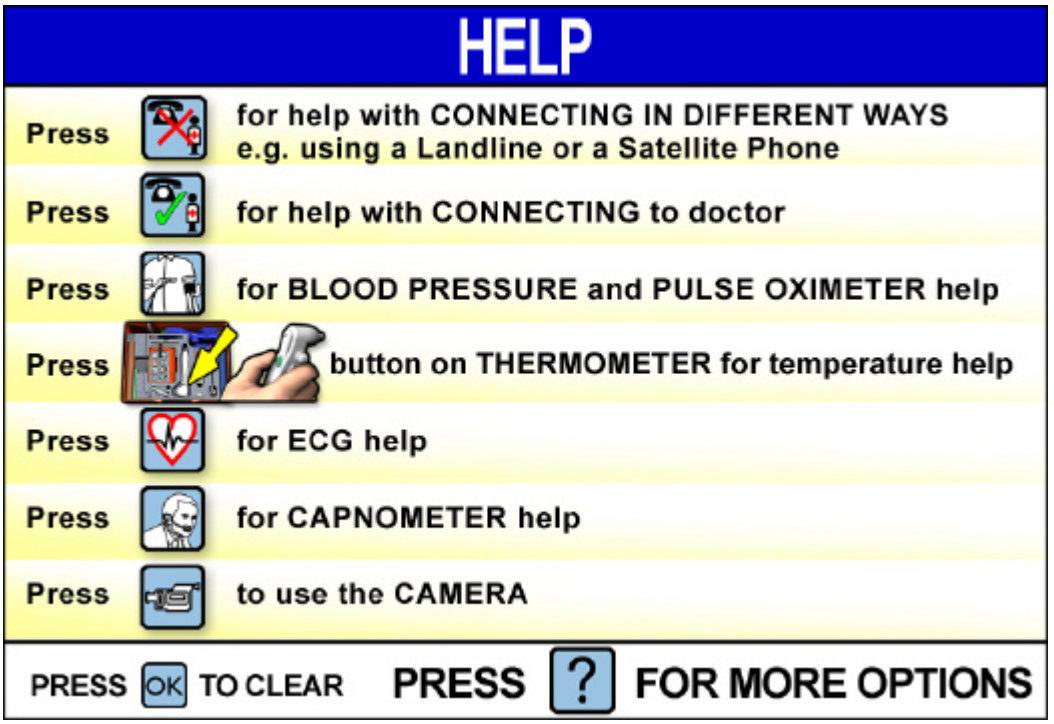
5.2.1 Help in Using the Tempus 2000

The Tempus 2000 includes a comprehensive set of help screens which explain the various procedures in words and pictures. You can get help on any individual instrument by pressing the button with that instrument's icon. Alternatively, you can get high level help at any time by pressing the ? key.

Some parts of the help system use more than one screen. These screens tell you which key to press to get to the next screen.

You can press OK at any time to close the help screen and return to the main screen.

To activate the Help system, press the ? key. The Help index screen will appear.



Help Index Screen

Press one of the following buttons:

To get help on connecting the Tempus 2000 using different ways e.g. help on connecting using a Landline as opposed to a Satellite connection.

To get help on connecting the Tempus 2000 to the phone lines so that you can communicate with the doctor at the Response Centre.

To get help on using the blood pressure and oximeter sensors.

Press the green button on the temperature probe to get help on using the temperature probe.

To get help on using the ECG electrode apron.

To get help on using the capnometer.

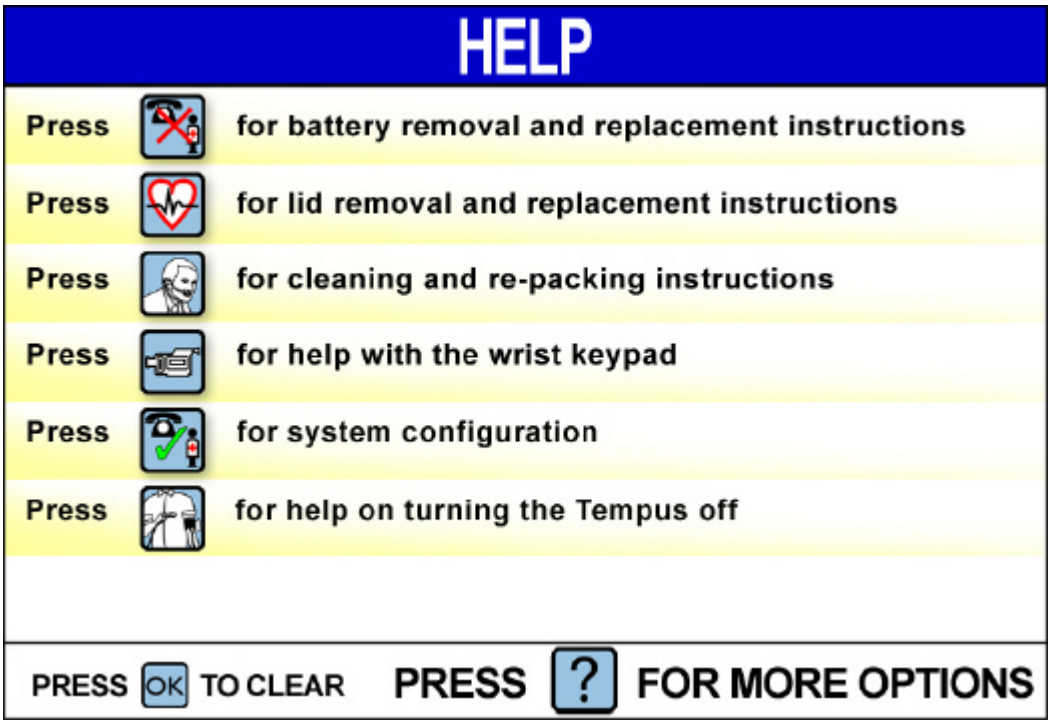
To get help on using the video camera and sending pictures to the Response Centre.

Press this button to exit the Help system and return to the main screen.

Press this button to get to the Advanced Help screen.

5.2.2 Advanced Help Screen

The Advanced Help Menu is available by pressing ? in the first Help Menu.



Advanced help Index Screen

Press one of the following buttons to get additional help:

To get help on removing and replacing the battery.

To get help on removing and replacing the Tempus 2000 lid.

To get help on cleaning and re-packing the Tempus 2000 after use.

To get help on using the wrist keypad.

To get help on setting the system configuration parameters (you are unlikely ever to need to do this during an incident).

For help on turning the Tempus off.

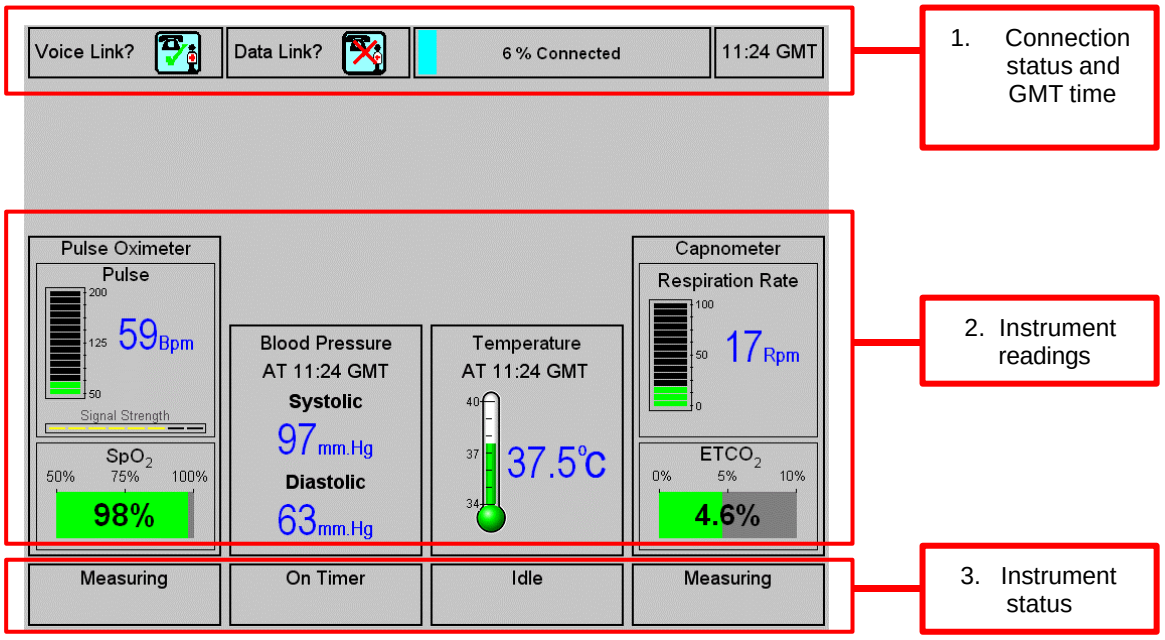
Press this button to exit the Help system and return to the main screen.

Press this button to get more help options. Pressing this button again will bring up the previous (first) help menu.

5.3 Explanation of the Tempus 2000 Screen

The Tempus 2000 screen normally divides into three sections:

- Connection status and time of day at the top
- Instrument readings in the middle
- Instrument status indicators at the bottom of the screen.



Tempus 2000 Screen Display

5.3.1 Connection Status Indicators and GMT

The connection status indicators show whether the Tempus 2000 is connected to the Response Centre. There are separate indicators for the voice link and the data link.

The following symbols indicate the state of the links:

Call in progress ('connected')

No call in progress ('disconnected').

Note that the words 'connected' and 'disconnected' refer to whether there is a call in progress, NOT whether the Tempus 2000 phone wires are plugged in.

5.3.2 Instrument Readings

This section of the screen shows the results (if any) from the four different medical devices (ECGs are displayed separately). Each of the four 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 help screens are displayed, they take up the space normally occupied by the instrument readings and the status indicators.

5.3.3 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
Not present	The instrument is not present (e.g. the connection to the instrument has been physically damaged and the Tempus 2000 cannot detect it).

Additionally, further informative Status messages may appear during readings (e.g. "press  to stop reading" during a capnometer measurement).

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

5.4 Use on Several Patients

The Tempus 2000 is intended for use on one patient per incident. It must not be used on more than one patient because the Tempus 2000 has no way of associating a measurement with a particular patient.

WARNING
It is essential to switch off the Tempus 2000 in between different patients to avoid confusion between different patient records.

5.5 Switching On

Note

The Tempus 2000 takes up to one minute to become ready for operation after switching on. It is recommended that you switch on the Tempus 2000 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 2000, 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 Tempus 2000 is ready for use when the LED shines green constantly. This takes about one minute. If no buttons are pressed within 8 minutes, the unit will switch off automatically to save battery power.

Note that if the lamp on the button flashes red and green then there is not sufficient power in the battery to start the device properly. In this case the battery must be replaced or recharged before the Tempus 2000 can be used.

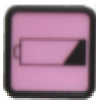
Note: do not press any of the Tempus 2000 control buttons until the first helpscreen artwork is displayed on the screen.

5.5.1 Understanding the Battery Life Indicator

The Tempus 2000 battery is provided with a battery life indicator which gives an indication of the amount of charge left in the battery in three grades relative to full charge. The battery life indicator is also accessible from the front panel of the Tempus 2000. This battery life indicator is located to the left of the power switch.

Battery Life Indicator (left)

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



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

- Green light is on (with or without any other light) = 100%-75% of full charge (the battery is fresh)
- Yellow light is on (but green is not) = 75%-25% of full charge
- Red = 25%-10% of full charge (the battery is nearly exhausted)
- Red flashing = less than 10% of battery charge remaining
- No lights = battery completely exhausted.

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

5.6 Opening the Lid

Insert your fingers at the bottom of the Tempus 2000 lid catch and pull towards you. The catch will partly disengage. Pull the bottom of the catch towards you and upwards to completely disengage the catch from the lid.

Hold both sides of the Tempus 2000 lid at the front and open it to a comfortable angle for viewing the screen and so that you can get at the contents of the device.

5.6.1 Removing the Display for Remote Use

For more comfortable or convenient viewing, the display can be removed from the Tempus 2000 box and placed in a convenient position. The display is connected to the Tempus 2000 box by a flexible cable approximately 2m (6½ ft) long.

To remove the display for more comfortable viewing, bring up the helpscreen for this activity by pressing the  button in the Advanced Help Menu and then follow the instructions given there.

5.7 Immediately after Switching On

After switching on, the Tempus 2000 goes through a pre-defined set of help screens. These are:

- Making the phone connection
- Using the Wrist Keypad
- Blood Pressure and Pulse Oximeter

You can press 

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

5.8 Establishing Communication with the Response Centre

5.8.1 Process for Connecting the Tempus

The first step for using the Tempus 2000 is to establish communication with the Response Centre. To do this you will need to:

- Ensure the Tempus is set to use an appropriate communications Mode e.g. using the built in Cell Phone as opposed to using a Landline.
- Connect the Tempus 2000 to the Response Centre.
- Fit the Wrist Keypad to your arm (note that this is optional – the Tempus can be used without the Keypad if necessary).
- Fit the Voicelink comfortably in your ear.

It is possible for a physician to use the Tempus 2000 as a standalone diagnostic tool without connecting to the Response Centre. Under these circumstances, just press the appropriate measurement function button to access that function. It is still possible to be connected to the Response Centre at any time by pressing the Connect button.

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

5.8.2 Making the Phone Connection

As soon as the Tempus 2000 is operational, the *Making the Phone Connection* screen appears.

This is different for each Communications Mode. Remember to follow the instructions given in the helpscreen to complete the actitivity.

5.8.3 Fitting the Wrist Keypad and Voicelink

Having initiated dialling, the Tempus will display the Wrist Keypad helpscreen. Follow the instructions given in the helpscreen to complete this activity.

5.9 Blood Pressure and Pulse Oximeter

Having left the Wrist Keypad Helpscreen, the Tempus will display the Blood Pressure and Pulse Oximeter helpscreen. Follow the instructions given in the helpscreen to complete this activity.

WARNINGS

The Tempus 2000 is not for use on neonates (young babies).

The Tempus 2000 is not intended for long term patient monitoring. There are no audible or visible alarms.

Reposition the oximeter probe at least once every 4 hours to allow the patient's skin to respire.

The Tempus 2000 will not operate effectively on patients who are experiencing convulsions or tremors.

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

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Notes

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

Any condition that restricts blood flow, such as use of a blood pressure cuff (other than the Tempus 2000 cuff used in accordance with the instructions herein) may cause an inability to determine accurate pulse and SpO_2 readings.

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

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

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

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

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

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

The arm of the patient must be kept still and either be horizontal to the shoulder (if the patient is laying down) or below the shoulder (if the patient is sitting upright).

IMPORTANT

You must use the right size of blood pressure cuff to suit the patient, and you must tell the Tempus 2000 if you are using the Large cuff or Child cuff.

The cuffs are marked to show the size that they are suited to i.e. Normal Adult, Large Adult, Child or small adult.

IMPORTANT

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

CAUTION

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

5.9.1 Understanding the Pulse Oximeter Results

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

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

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

The signal strength bargraph shows the how well the pulse sensor is detecting the pulse. The amplitude of the indication indicates the quality of detection. If the indication on the Signal Strength meter is low, or becomes low, then the finger sensor should be repositioned.

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

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

5.9.2 Understanding the Blood Pressure Results

The Blood Pressure display has three elements plus a status indicator. Measurements are normally made every five minutes via an automatic timer, but can be triggered at any time by pressing the  button on the wrist keypad or display keypad to re-start the process. Note that when the unit is in timer mode, pressing  will cause a reading to be taken. If the unit is taking a measurement, pressing  will cause the reading to be stopped. If the cycle is stopped, the status indicator below will read “Idle” to indicate that the unit is no longer operating.

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

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

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

5.9.3 Blood Pressure Monitor Error helpscreens

The Blood Pressure Monitor will automatically display helpscreens in the event that it encounters problems in taking a measurement. The problems that it can encounter may often have a fairly simple solution, consequently, the helpscreens attempt to guide the Operator through some basic checks that can be made. Most of the time, the problems that the monitor experiences are related to being able to build the correct pressure in the cuff and then maintain and release the pressure at the correct rates.

Follow the instructions given in each error helpscreen to clear the fault and to restart the blood pressure reading.

5.10 Electrocardiograph (ECG)

To activate the ECG function, press  on the front of the display or on the wrist keypad.

The first ECG help screen will appear.

Follow the instructions given in the helpscreen and then in the ECG recording screen to complete this activity.

WARNINGS

The Tempus 2000 should not be used on patients undergoing defibrillation. The Tempus 2000 is protected against defibrillator discharge but rate meters and displays may be temporarily affected during defibrillator discharge but will rapidly recover.

The Tempus 2000 will not operate effectively on patients who are experiencing convulsions or tremors.

CAUTIONS

The electrodes of the ECG apron must be applied carefully.

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

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

Note

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.

CAUTION

It is essential that the Tempus 2000 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.

5.11 Capnometer

WARNINGS

The Tempus 2000 is not intended for long term patient monitoring. There are no audible or visible alarms.

The Tempus 2000 is not for apnoea detection. The Tempus 2000 has not been tested or validated for use in apnoea detection.

CAUTION

Use of monitoring during continuous nebulised medication delivery will result in damage to the Tempus 2000 which is not covered by the warranty. Disconnect the capnometer sample line from the Tempus 2000 or switch off the Tempus 2000 during medication delivery.

Notes

The capnometer requires regular calibration. A source of calibration gas is fitted within the Tempus 2000 to enable the device to remain accurate and ready for use during its period of intended use. The calibration gas can only be replaced by the manufacturer. If the Tempus 2000 is not returned to RDT Ltd. for its regular preventative maintenance check, the capnometer will eventually cease to operate.

The capnometer will perform self-calibrations as required when the Tempus 2000 is switched on and the capnometer is operating. These operations may cause short delays (approximately 5-10 seconds) in the display of measured results.

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

To activate the Capnometer function, press  on the front of the display or on the wrist keypad. The Capnometer help screen will appear.

Follow the instructions given in the helpscreen to complete this activity.

5.11.1 Understanding the Capnometer Results

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

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

The Capnometer section of the results screen is shown below.

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

- Note extreme respiration rates above 100 Rpm are outside the range of the bargraph display but will be shown accurately on the digital display.

The $ETCO_2$ reading indicates the end tidal CO_2 reading of the breath, and displays the result in bargraph and digital form.

The capnometer will take readings for 5 minutes and then stop.

5.12 Temperature

Press the green button on the temperature probe to bring up the help screen.

Follow the instructions given in the helpscreen to complete this activity.

WARNING

The thermometer provides fast, accurate temperature measurements on any patient into which the temperature 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 temperature probe if the probe cannot be inserted into the ear canal.

Notes

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

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

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

The Temperature Probe is normally supplied set to read in Centigrade (ºC). If required, it can be changed over to read in Fahrenheit (ºF). To make the change, locate the small hole in the label at the bottom of the handle near where the wire is connected. A small pushbutton is located behind the hole. Use a suitably sized, non-pointed object to press the button. While holding this recessed button down, press the green button on the Thermometer. Subsequent readings will be made in Fahrenheit. The Temperature Probe can be reset to Centigrade in the same way.

Note that the thermometer operates on a timer. This means that if the green button is pressed once, the help screen will be brought up on the display, if it is pressed a second time, a measurement will be made. If the button is pressed a again, within 30 seconds of the previous measurement being made, then another measurement will be made. However, if more than 30 seconds have passed, then the Tempus 2000 will assume that help may be required and so the help screen will be brought up on screen again.

5.12.1 Understanding the Temperature Probe Results

The Temperature Probe display has three data elements plus a status indicator. When measurements are made, they are time stamped and sent to the Response Centre provided that the data link is active.

At the top of the Temperature display is a time stamp which shows when the last measurement was made. The temperature reading is shown as a thermometer bargraph, accompanied by a digital display.

- Note that extreme temperatures above 40ºC or below 34ºC are outside the range of the bargraph but will be shown accurately on the digital display.

5.13 Video Camera

When requested by the Response Centre, it is possible to capture and send still video images using the camera built into the Wrist Keypad. Video images are shown live on the Tempus 2000 screen so that you can see what the camera is seeing. When you are happy with the displayed image, you capture the picture and can then send it to the Response Centre (if you are not connected the image will be stored for transmission later). Moving pictures cannot be sent to the Response Centre.

To activate the video function, press  on the front of the display or on the wrist keypad. A video image from the camera will appear on the Tempus 2000 display in the position shown in the following picture.

5.14 Actions After Use – Turning the Tempus 2000 Off

For help on how to turn the Tempus off, bring up the Advanced Help Menu and press the  button. Follow the instructions given in the helpscreen to complete this activity.

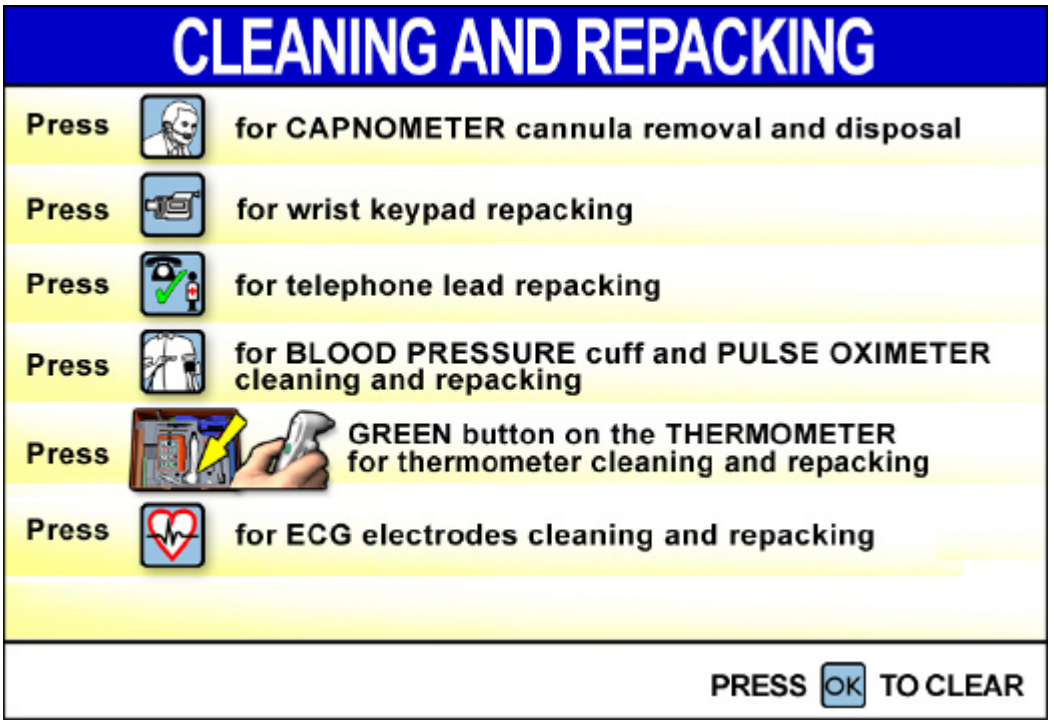
When the countdown is in progress, the power-on lamp will flash red. The lamp will glow solid red for 10 seconds after the screen goes blank. It is important that the battery is not removed until the lamp goes blank also. It is possible to cause damage to the Tempus 2000 if the battery is removed before the LED turns off.

6 After using the Tempus 2000

6.1 Cleaning and Re-packing Help Screen

The cleaning and re-packing help screen is shown below. To get to this help screen, and the screens shown in the rest of this section,

- press [?] to get the main help index screen, then
- press [?] again to get the advanced help screen, then
- press [face] to get the cleaning and re-packing help screen shown below.



Cleaning and Re-packing Help Screen

Press one of the following buttons to get additional help:

To get help on removing and disposing of the capnometer cannula.

To get help on cleaning and re-packing the wrist keypad.

To get help on re-packing the telephone leads.

To get help on cleaning and re-packing the blood pressure cuff and pulse oximeter.

To get help on cleaning and re-packing the ECG electrodes.

Press the green button on the temperature probe to get help on cleaning and re-packing the temperature probe.

Press this button to return to the main help screen.

6.2 Cleaning the Tempus 2000

It is necessary to clean the Tempus 2000 after use.

The outer case of the Tempus 2000 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.

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.

If the Tempus 2000 is heavily soiled, or if the inside is soiled or contaminated, arrangements must be made to return the unit to the manufacturer.

The Tempus 2000 instruments must be cleaned during the re-packing process described in the following section.

6.3 Re-packing for Re-use

This section describes the steps necessary to clean and re-pack the Tempus 2000 after use.

Suitable cleaning wipes labelled "Alcowipe" or “DisCide” are provided within the Tempus 2000. The help screen shows the location of the wipes in the highlighted area on the first picture. These wipes should be used when cleaning the Tempus 2000 earpiece, ECG electrode apron, the Pulse Oximeter probe and the Blood Pressure cuffs. Since there are only a limited number of wipes within the Tempus 2000, care should be taken to ensure that each wipe is used as much as it can be on each part before it is disposed of.

It should be noted that the cleaning wipes are provided with written instructions on their packaging. Read this information before using the wipe. In addition, please note:

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 should be returned to RDT.

WARNINGS

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

Warning: flammable, keep away from open flame.

6.3.1 Blood Pressure Cuff

This procedure describes how to clean and re-pack the blood pressure cuff.

Follow the instructions given in the helpscreen to complete this activity.

6.3.2 ECG Apron

This procedure describes how to clean and re-pack the ECG apron. It is important to follow this procedure carefully in order for the apron to fit properly into its designated space.

Follow the instructions given in the helpscreen to complete this activity.

6.3.3 Capnometer Cannula

Follow the instructions given in the helpscreen to complete this activity.

The capnometer cannula must be disposed of after use.

6.3.4 Temperature Probe

This procedure describes how to re-pack the temperature probe.

Follow the instructions given in the helpscreen to complete this activity.

6.3.5 Phone Cables

This procedure describes how to re-pack the phone cables.

Follow the instructions given in the helpscreen to complete this activity.

6.3.6 Wrist Keypad

This procedure describes how to re-pack the wrist keypad.

Follow the instructions given in the helpscreen to complete this activity.

6.3.7 Pulse Oximeter

This procedure describes how to re-pack the pulse oximeter.

Follow the instructions given in the helpscreen to complete this activity.

6.4 Single-use Devices

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

Part number	Description
01-0004	Alcohol Wipes (Box of 100)
01-0006	Nail Varnish Remover Swabs (Box of 100)
01-0007	ECG Spray
01-0009	Thermometer Cover Dispenser (Dispenser of 25)
01-0016	Capnometer Cannula/Filter
01-0022	Tempus 2000 Repack Kit
01-0028	Earpiece Covers (Pack of 60)