

8 *Summary Record of Care*

Recording patient encounter data can be done with the Summary Record of Care (SRoC) feature which is accessed by pressing the Event button.



The Event button.

Event general, assessment, intervention, fluid and drug names and details are organisationally configurable. The default names and details can all be changed to match the organisation's needs.

WARNING



Event naming and detailed configuration must be reviewed and checked before the Tempus Pro is deployed in service. Read the details regarding event configuration in the *Tempus Pro Configuration Utility User Guide*.

8.1 Event capture

The SRoC Events screen is displayed when the Event button is pressed.

8.1.1 General screen

The SRoC General screen allows you to quickly record a category marker or multiple events up to a maximum of 200 events. General events are a subset of events selected in the configuration from the full set of assessments, interventions, fluids and drugs. They are typically the most commonly needed events. All general events are also accessible from one of the other event tabs.

To record an event category for later editing, press one of the category markers on the left of the screen. The Tempus will record the category marker and automatically return to the monitoring screen.

Use the General screen to record events:

- To record an event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the event, press and hold the event button. The Details Editor screen is displayed.



Note If you subsequently change the time of a recorded event, the Tempus will clear the recorded vitals.

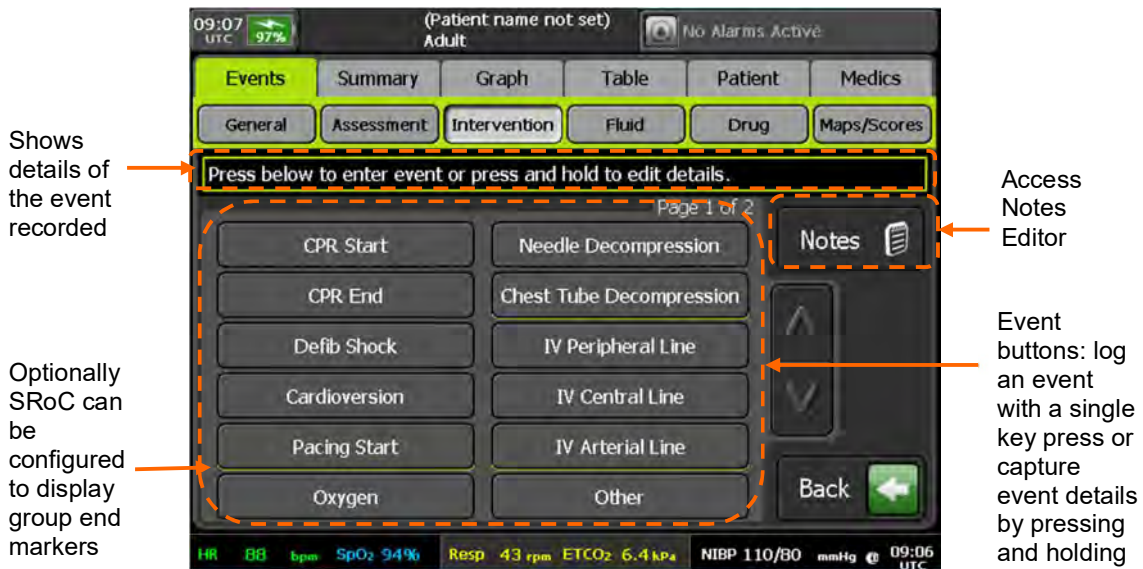


SROc General Screen

Note The Tempus Pro can be configured to display group end markers in the SROc General screen. For more information, see the *Tempus Pro Configuration Utility User Guide*.

8.1.2 Assessment, intervention, fluid and drug screens

The Assessment, Intervention, Fluid and Drug screens behave in a similar way to the General screen, allowing you to record multiple events of the corresponding type. Category markers are not available in these screens.



SROc Intervention Screen

Assessment events

Use the General or Assessment screens to record assessment events:

- To record an assessment event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the assessment event, press and hold the event button. The Assessment Details Editor screen is displayed, allowing you to edit the date and time, add an event note, or delete the event.



Intervention events

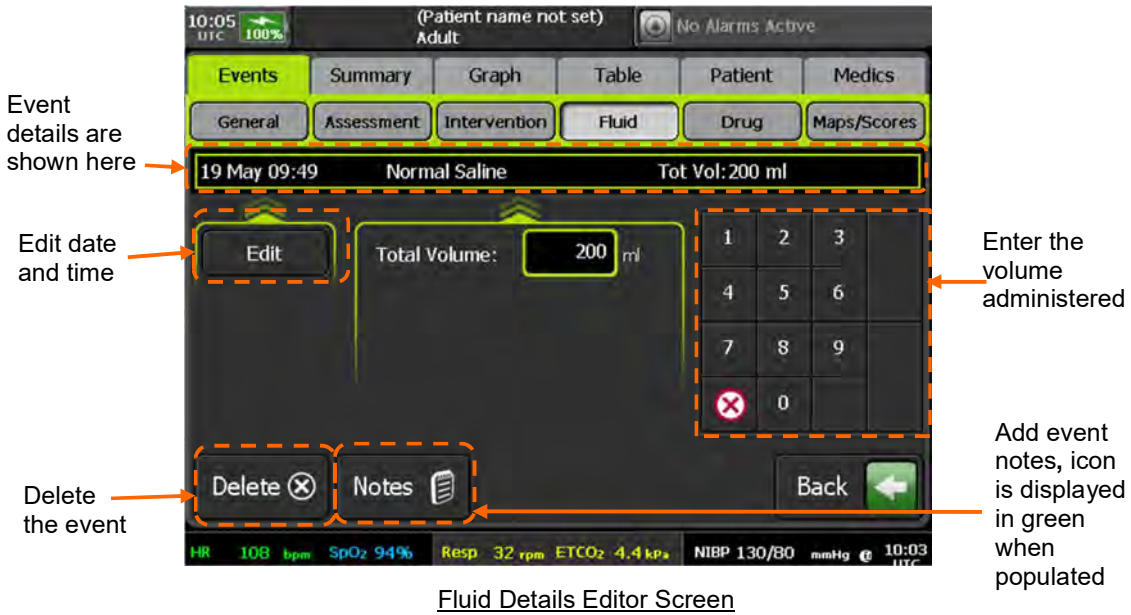
Use the General or Intervention screens to record intervention events:

- To record an intervention event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the intervention event, press and hold the event button. The Intervention Details Editor screen is displayed, allowing you to edit the date and time, add an event note, or delete the event. This screen contains the same controls as the Assessment Details Editor (above).

Fluid events

Use the General or Fluid screens to record fluid events:

- To record a fluid event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the fluid event, press and hold the event button. The Fluid Details Editor screen is displayed, allowing you to edit the date and time, edit the volume, add an event note, or delete the event.



Fluid Details Editor Screen

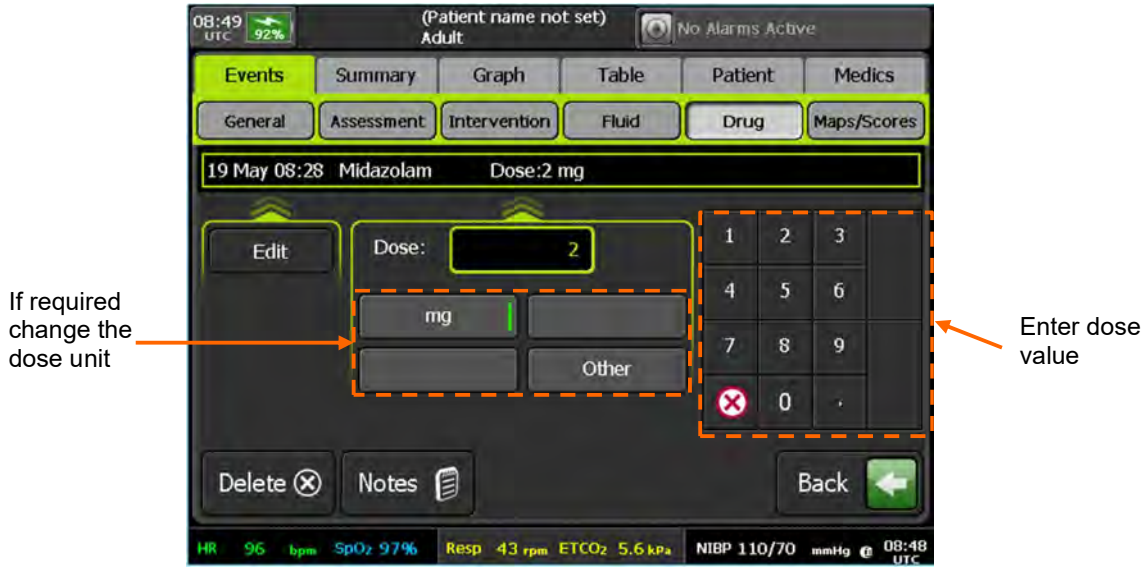
Drug events

Use the General or Drug screens to record drug events:

- To record a drug event with the current time but no other details, press and release the event button.
- To edit the time and details before recording the drug event, press and hold the event button. The Drug Details Editor screen is displayed, allowing you to edit the date and time, edit the route, edit the dose, add an event note, or delete the event.



Drug Details Editor Screen



Drug Dose Editor Screen

8.1.3 Map/score screen

The Map/Score screen provides access to the following editors:

- Glasgow Coma Scale (GCS)
- Injury Map
- Burns Map
- Dressing Map
- TQ Map



SROc Map/Score Screen

GCS screen

The Glasgow Coma Assessment (GCS) screen allows you to enter scores for Best Eye, Best Verbal and Best Motor. GCS is calculated by summation of the three scores. A 'T' verbal score indicates that the patient is intubated and provides a verbal score of 1.

CAUTION



If you exit the GCS screen without entering all three scores, then no GCS data is recorded.

The GCS score is shown here

Select best eye, verbal and motor scores

Access Event Details Editor

Enable and disable help text

GCS Assessment Screen

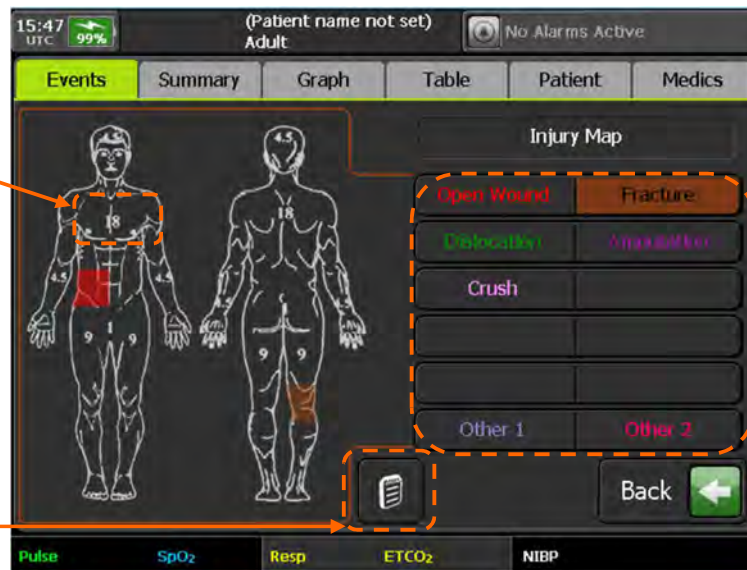
To display help text, press the Help button. When you select a score with the Help button enabled, the Tempus will automatically move to the next entry screen.

Injuries, burns and dressings maps

The Injury, Burns and Dressing Map screens allow you to record the corresponding encounter details on a body map which contains a graphical representation of the front and rear of the body. The Burns Map also allows you to record the total burns area as part of the burns assessment.

The numbers shown on the body indicate approximate percentage of the total body map area

Add Injury Assessment notes, a green icon indicates a populated note



First select injury type and then select the body map areas

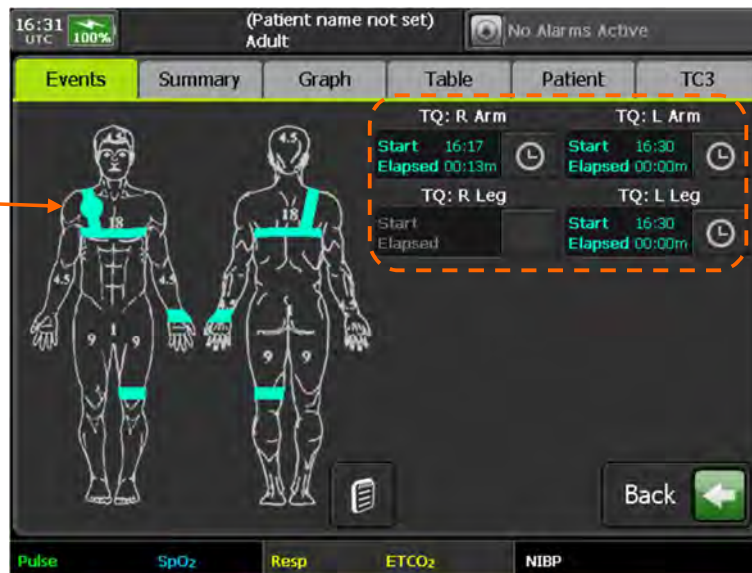
If necessary, use the Other buttons to define new injury type

Injury Map Screen

TQ map

The TQ Map screen allows you to record limb tourniquet positions and start times.

First select tourniquet positions on the body map



Then press the clock symbols to update the start times

TQ Map Screen

8.1.4 Automatic event capture

SRoC is automatically augmented with patient encounter data when:
















- An arrhythmia alarm is triggered - Tempus Pro automatically logs an event and records a waveform snapshot from 10 seconds before until 10 seconds after the event.
- A patient alarm is triggered - Tempus Pro automatically logs an event. You can also store a snapshot of the waveform at the same time, see the All Alarms menu.

- A waveform is manually captured. To manually capture a snapshot of a waveform at any time, press and release the Camera & Waveform Snapshot button.
- A 12 Lead ECG is recorded.
- A camera or laryngoscope image is recorded. For laryngoscope details refer to *Tempus Pro Laryngoscope Supplement Guide*.
- An ultrasound image is recorded. Images can be taken during general and FAST exams. Refer to *Tempus Pro Ultrasound Supplement Guide*.

If the Tempus is fitted with an internal printer and automatic printing is enabled, it will print waveforms as soon as they are captured – see “9.9.2 Internal printer configuration (optional)”.

8.2 Events summary list

The SRoC Summary screen displays a list of all the events entered by the user together with any events automatically captured. Each event is shown with the associated event icon as detailed in the table below.

Event Type	Filter button	Icon
All	Show All	All
Arrhythmia Waveform	Arrhyth or Waveform	
12 Lead ECG	ECGs	
Camera Image	Images	
Drug	Drugs	
Fluid	Fluids	
Note	Notes	
Intervention	Interven	
Laryngoscope Image	Images	
Assessment	Assess	
Waveform (Manual)	Waveform	
Medics	Medics	
Alarm Waveform	Waveform	
Injury / Burns Dressing / TQ	Maps	
GCS	Scores	
Ultrasound Image	Ultra	
Category marker: assessment, intervention, fluid or drug	Markers	Icon matches marker type

Filters allow you to select which events are shown. Pressing an event will launch the associated editor /

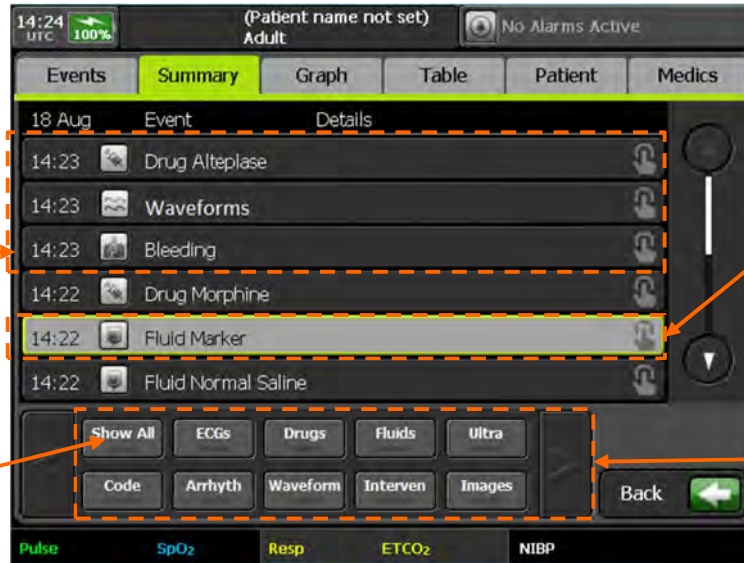
viewer, automatically recorded events can only be viewed. Category event markers can be updated by pressing on the associated row. Pressing and holding an event that is less than 72 hours old will act to launch the trend graph centred at the event time, the graph will be set to show events and set to 45 minutes zoom.

8.2.1 Summary screen

Press an event to access the associated editor or viewer

Press and hold an event to display the trend graph centred at the event time

“Show All” clears all selections and displays all events



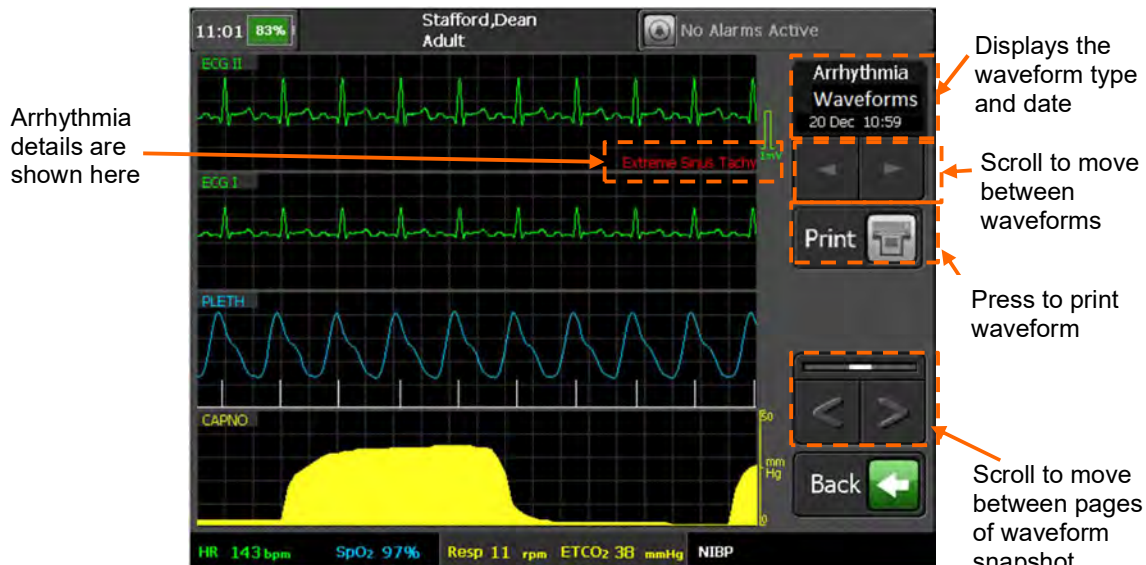
This is a category marker; press this entry to enter the event details

Press one or more of these buttons to filter by event type

SROc Summary Screen

8.2.2 Waveform viewer

To view a waveform, press the waveform event in the SROc Summary screen:



Arrhythmia details are shown here

Displays the waveform type and date

Scroll to move between waveforms

Press to print waveform

Scroll to move between pages of waveform snapshot

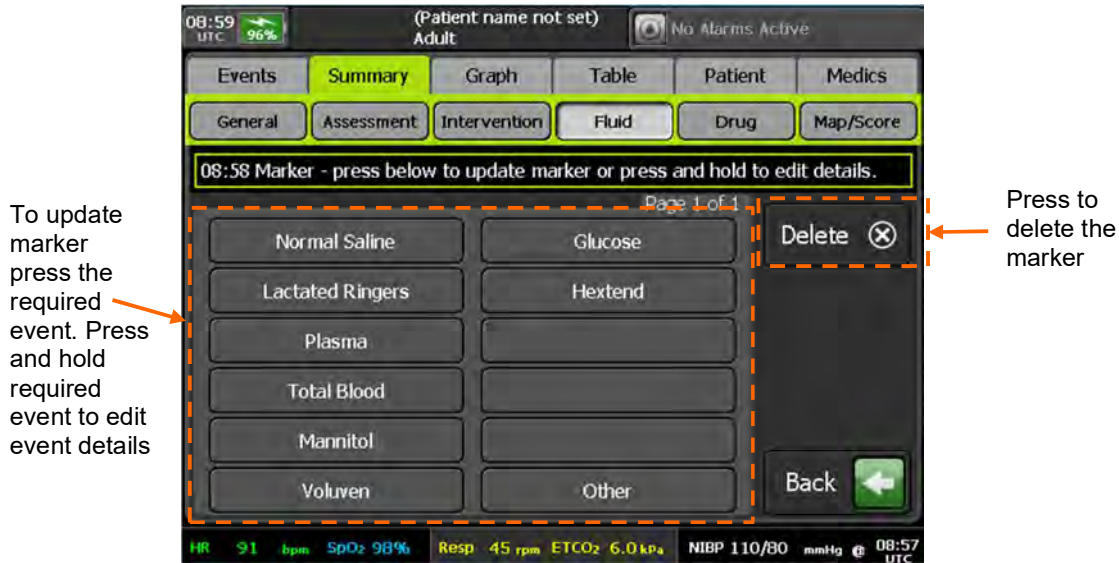
Waveform Snapshot Viewer

If the Tempus is fitted with an internal printer, you can print the waveform using the **Print** button – see “9.9.2 Internal printer configuration (optional)”.

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

8.2.3 Updating an observation category marker

To convert a category marker to a fully recorded event, press the category marker entry in the SROc Summary screen. The Tempus displays the entry screen for the relevant event category. Press an event button: this acts to update the marker. Any further events buttons pressed are recorded as new events.



Updating Observation Category Marker

8.3 Trends

Tempus automatically samples all continuous medical readings once per minute and stores these in the patient record. For readings taken less often such as Non-Invasive Blood Pressure all readings are stored in the patient record. The last 72 hours of trend data can be displayed on the Tempus as both graphical and tabular trend data. To access trend data, use one of the following methods:

- Press the Event membrane button then select the Graph or Table tab.
- Press the Trends button (displayed in all medical related menus as well as the main menu) then select the Graph or Table tab.
- Press and hold anywhere on the Home Screen. Depending on which waveform you press the graph will show you the results of that waveform.
- Press and hold on any event in the Summary tab. The graph will be centred at the time of the event you press.

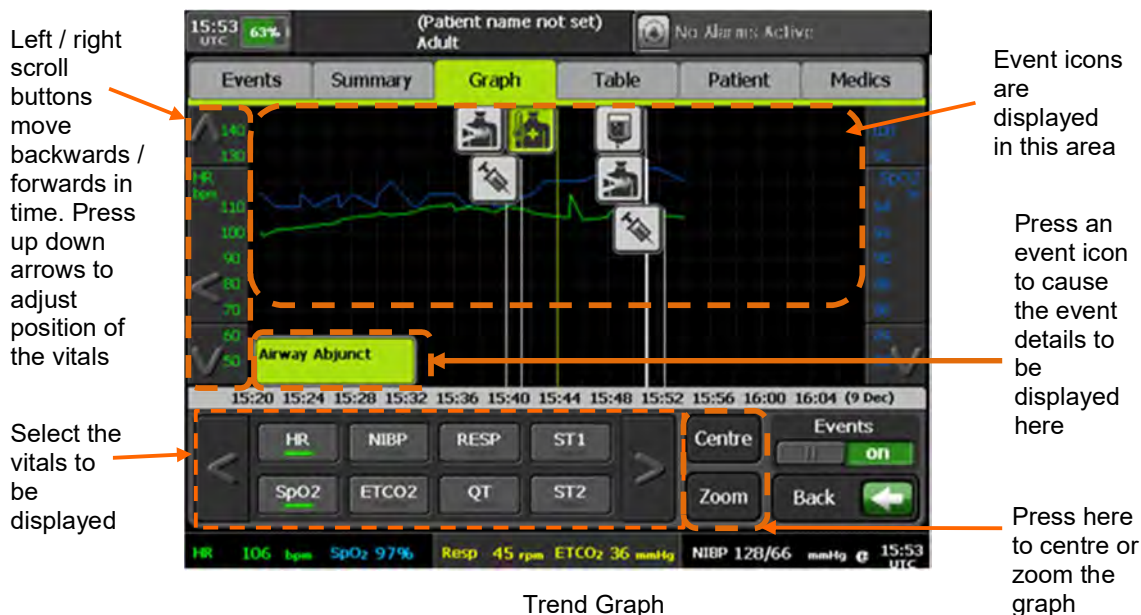
8.3.1 Trend graph

The Trend Graph allows you to select two vitals to be shown together, each vital having its own scale. The zoom button can be used to select a different time scale for the X axis. When enabled, icons for the following events are shown on the graph at the event time.

- Arrhythmia
- 12-Lead ECG
- Drugs
- Fluids
- Assessments

- Interventions
- GCS events, but not body maps
- Laryngoscope image

A maximum of 4 events can be displayed on the graph in a 4-minute interval and there can be a delay of up to 1 minute before events are displayed.



8.3.2 Trend table

The Trend Table allows you to scroll through all the 1-minute sample readings. When enabled the following events are also displayed:

- Waveform
- Arrhythmia
- Patient Alarm
- Camera Images
- Laryngoscope Images
- 12-Lead ECG
- Drugs
- Fluids
- Assessments
- Interventions
- Body Maps and GCS
- Ultrasound Images

16:04 UTC (Patient name not set) Adult No Alarms Active

Events	Summary	Graph	Table	Patient	Medics	
Date					08 Dec	
Time	16:00	16:00	16:01	16:02	16:03	16:04
HR (bpm)	93	94	94	95	96	95
ST1 (mm)	1.5 II	1.4 II	1.4 II	1.2 II	1.3 II	1.3 II
ST2 (mm)	1.5 I	1.4 I	1.4 I	1.2 I	1.3 I	1.3 I
QT (ms)	470	470	470	470	470	470
NIBP (mmHg)	-	126/61	-	120/80	120/80	-
Resp. (rpm)	29	28	28	28	29	30
ETCO2 (mmHg)	40	39	39	37	38	39
SpO2 (%)	95	94	94	94	95	94
PI (%)	2.4	2.5	2.5	2.4	2.3	2.2
PVI (%)	27	28	28	27	24	25
SpOC (ml/d)	19	19	19	18	18	17
SpHb (g/d)	13.1	13.2	13.2	13.4	14.0	13.9
SpMet (%)	1.2	2.0	2.0	1.2	2.0	2.0
SpCO (%)	9	9	9	9	8	8

1 min 5 mins 1 hr 2 hrs Events on Back

Trend Table

An outside limits symbol placed to the right of reading indicates that the value was outside the limits set when the measurement was taken. In the case of a reading containing multiple values such as non-invasive blood pressure the alarm symbol will not show which value was outside the limits.

Outside limits symbol indicates that the adjacent measurement was outside the limits

HR (bpm)	93	94	94	95	91	94	95
ST1 (mm)	1.5 II	1.4 II	1.4 II	1.2 II	1.3 II	1.3 II	1.3 II
ST2 (mm)	1.5 I	1.4 I	1.4 I	1.2 I	1.3 I	1.3 I	1.3 I
QT (ms)	470	470	470	470	470	470	470
NIBP (mmHg)	-	126/61	-	120/80	120/80	-	-
Resp. (rpm)	29	28	28	28	29	29	30
ETCO2 (mmHg)	40	39	39	37	38	38	39
SpO2 (%)	95	94	94	94	95	95	94
PI (%)	2.4	2.5	2.5	2.4	2.3	2.3	2.2
PVI (%)	27	28	28	27	24	24	25
SpOC (ml/d)	19	19	19	18	18	18	17
SpHb (g/d)	13.1	13.2	13.2	13.4	14.0	14.0	13.9
SpMet (%)	1.2	2.0	2.0	1.2	2.0	2.0	2.0
SpCO (%)	9	9	9	9	8	8	9

Outside Limits

The outside limits symbol will only be shown for patient alarms. It will not be shown to reflect any technical alarms such as low battery, finger out of SpO2 sensor etc. It will not be shown for invasive pressure “transducer removed” but will be shown for Capnometer “zero breaths detected”. The symbol shows only that the value at the time was outside the alarm limit that was set at the time – it will not change based on subsequent editing of the alarm threshold. It will not be shown for “out of range measurements”. It will not reflect if an audible alarm was present i.e. will not differentiate if an alarm is muted, alarms suspended etc. it will merely reflect that the measured parameter was outside of the alarm threshold set at the time.

Note

The trend table shows a single reading where multiple readings may have occurred e.g. 60 individual readings for heart rate that are taken in a minute are represented as a single reading; this is the first reading recorded in that period. If a single alarm on a given parameter occurs within the time period set, then this will be shown in preference to the first reading taken within the period. If multiple alarms occur in the same period on the same parameter, then the trend table will show the first to occur.

9 Other features of the Tempus Pro

This section details the other features of the Tempus Pro.

9.1 Data input and output

9.1.1 The Data Input and Output menu



The **Data Input/Output** button.

Pressing the **Data Input/Output** button launches a menu which allows you to do the following:

Menu option	Menu screen
<p>Send patient data/report – send patient data or reports to external recipients, see “9.1.2 Send patient data/report”.</p> <p>Tempus to Tempus data handover – export and import patient data for handover to or from another Tempus, see “9.1.3 Tempus to Tempus data handover”.</p> <p>Laryngoscope – access laryngoscope functionality. For further details refer to <i>Tempus Pro Laryngoscope Supplement Guide</i>.</p> <p>Ultrasound – access ultrasound functionality, for further details refer to <i>Tempus Pro Ultrasound Supplement Guide</i>.</p>	

9.1.2 Send patient data/report

The Send patient data/report option allows you to output the SRoC patient data or report to one of four types of recipient:

- USB memory device – patient report (PDF);
- External printer – patient report;
- Email address (if the feature is installed) – patient report (PDF);
- ePCR (electronic Patient Care Reporting system) (if the feature is installed) – patient data;
- Internal printer (if fitted) - summary report or 30 second waveform.

When sending the patient report to email, USB or external printer, you can select one of the following report formats:

- 12-lead Report
- Summary Report
- Detailed report


When sending to ePCR, all patient data is sent.




The contents of the report or data depend on the report destination, as shown in the following table:

Data	USB, External Printer and Email (detailed report)	ePCR (patient data)	Internal Printer (summary report)
SRoC events	All	All	Last 100 events
Trended vitals	Up to 72 hours	All	Last 200 minutes limited to HR, NIBP, Resp, ETCO2, SpO2, T1 and T2
12-lead ECG recordings	Latest (up to 10)	Latest (up to 10)	None
Camera / intubation images	Latest (up to 10)	Latest (up to 20)	None
Image annotations	Latest (up to 10)	None	None
Waveforms	Latest (up to 20)	Latest (up to 20)	None
Ultrasound images	Latest (up to 5) and FAST exam	Latest (up to 5)	None

Detailed reports are automatically formatted such that graphs and tables are not too long. Consequently, if the recorded incident is up to 40 minutes long, all vital signs graph and table data are shown sampled at one minute intervals. Longer incidents are reformatted as follows:


- Duration 40-200 minutes: sampled at 5 minute intervals.
- Duration over 200 minutes: sampled at 5 minute intervals (latest 200 minutes only).

CAUTION 	<p>The reports created are medical records, the use and control of which may be subject to local regulations, e.g. HIPAA in the USA. It is the responsibility of the user to maintain compliance with these regulations. It is the responsibility of the individual or organisation who created the record to maintain this information in a secure and confidential state where the integrity and security of the information is not in question.</p>
---	--

CAUTION 	<p>Patient reports (PDFs) must be encrypted and password protected. The password must be preconfigured (Maintenance and Settings, Change Passwords, Patient Report Password) by following the procedure in the <i>Tempus Pro Maintenance Manual</i>. Configuration must be checked before deployment in service. The encryption type is AES128.</p>
Note 	<p>RDT recommends only Adobe® Acrobat® PDF readers that are capable of reading Acrobat V5 or later files are used.</p>
Note 	<p>RDT recommends users check that their selected PDF reader can open the created report before deploying the Tempus.</p>

Send patient report to a USB memory device

To send the SRoC patient report (PDF) to a USB memory device, press **Send patient data/report** on the Data Input/Output menu, then press **USB** on the Send Patient Data/Report screen:



Select the patient report format

Select the contents of the report (if this feature is enabled). Use the arrow buttons to scroll to next and previous pages.

Press Send to start writing to USB memory device


Send Patient Data/Report Screen (USB selected)

If handover data is required on the USB device, press **Include Tempus to Tempus Data**.

Press **Send**. The Tempus will return to the main monitoring screen. Progress information will be displayed at the top of the screen.

To check progress or cancel USB output, return to the Send Patient Data/Report screen. This screen will display a blue progress bar with status messages. If the Tempus has been configured to encrypt the SRoC patient report using a random password, then the password details will be displayed on the Send Patient Data/Report screen under the list of report formats.






Send patient report to an external printer

WARNING 	<p>Printer connections should only be made when no connections are made to a patient. Do not connect to a patient and a printer at the same time as this could cause a leakage current hazard or could affect the clinical performance of the Tempus.</p>
---	---

The screen Send Patient Data/Report screen also has an option to send the SROc patient report directly to a PCL3 compliant USB printer which operates in a similar way to sending to USB memory device. Ensure the printer is attached, switched on and provided with ink and paper before beginning. For printer instructions, see “9.9.1 External printer”.

To send the SROc patient report to an external printer, press **Send patient data/report** on the Data Input/Output menu, then press **Ext. Printer** on the Send Patient Data/Report screen.

Send patient report via email

CAUTION 	Email services are generally very reliable but do not guarantee successful delivery. Email send times vary depending upon network conditions. You should always check that an emailed patient report has been received, e.g. by phoning the recipient.
CAUTION 	The email service requires a valid email account on a server accessible from the internet. It is your responsibility to understand the local regulations regarding emailing patient data.
CAUTION 	Tempus emails must be sent using secure communications.
Note 	For email transmission, the maximum allowed patient report size is 8 megabytes. Email service provider limits may differ.
Note 	The links below provide information about HIPAA compliant email: http://www.hipaahq.com/hipaa-compliant-email-explained/ http://www.hipaahq.com/hipaa-compliant-email-providers/ .

To send the SROc patient report (PDF) via email, press **Send patient data/report** on the Data Input/Output menu, then press **Email** on the Send Patient Data/Report screen:



Send Patient Data/Report Screen (Email selected)

Press the recipient button to display the Email Recipients screen. Update email recipients and communications mode as required, then press **Back** to return to the Send Patient Data/Report screen.






Press the **Send** button. This will cause a PDF report of the selected format to be created and emailed. The Tempus will return to the main monitoring screen and display email status at the top of the screen.

To check progress or cancel emailing, return to the Send Patient Data/Report screen. This screen will display a blue progress bar with status messages. The top status area will display the PDF creation and network status details. When the email has been sent to the email server, the 'report sent' text will be displayed on the top status area for a further 30 seconds.

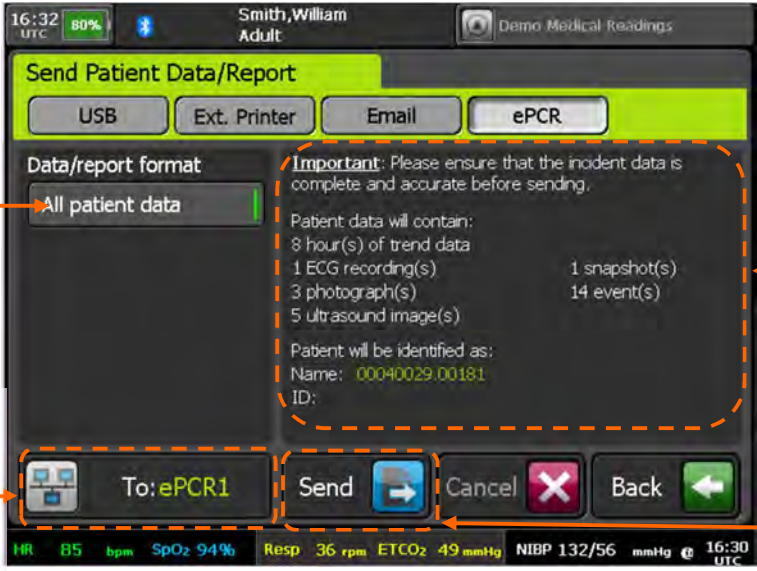
If the Tempus has been configured to use a random password, then a second email containing the random password will be sent to the recipients.

In the event of communication problems, the Tempus will attempt to resend for 20 minutes before aborting the send and displaying a warning message.

Send patient data to an electronic Patient Care Reporting System (ePCR)

<p>CAUTION</p> 	<p>Communication with the ePCR systems are generally reliable but do not guarantee successful delivery and storage of the patient data.</p>
<p>CAUTION</p> 	<p>It is your responsibility to understand the local regulations regarding sending and storing patient data.</p>
<p>Note</p> 	<p>Tempus patient data is sent using secure communications to one of the configured ePCR systems. The configuration must be checked before deployment in service.</p>
<p>Note</p> 	<p>For ePCR data transmission, the maximum allowed patient data size is 8 megabytes on the Tempus Pro.</p>
<p>Note</p> 	<p>The link below provides information about HIPAA compliant cloud storage providers: http://www.hipaahq.com/hipaa-compliant-cloud-storage-explained/.</p>

To send the SRoC patient data files to an ePCR, press **Send patient data/report** on the Data Input/Output menu, then select the **ePCR** tab on the Send Patient Data/Report screen:



All patient data is sent

To button: press here to change the ePCR system and communications mode

The contents of the patient data to be exported are shown here.

Details of the last ePCR export will be displayed below the patient details

Press here to send the patient data to the ePCR

Send Patient Data/Report Screen (ePCR selected)

Press the **To** button to display the ePCR Selection screen. Select the ePCR system and communications mode as required, then press **Back** to return to the Send Patient Data/Report screen.

Press the **Send** button. This will cause patient data to be sent to the selected ePCR system.

To cancel sending ePCR data press the **Cancel** button.

In the event of communication problems, the Tempus will attempt to resend for 20 minutes before aborting the data export and displaying a warning message.

Send patient report to the internal printer (optional)

To send the summary report or 30 second waveform to the internal printer (if fitted), press **Send patient data/report** on the Data Input/Output menu, then press **Print** on the Send Patient Data/Report screen:



Send Patient Data/Report Screen (Print selected)

Press a report type button: **Summary Report** or **30s Waveform**.

Press **Print**.

9.1.3 Tempus to Tempus data handover

The 'Tempus to Tempus data handover' screen allows you to send or receive patient data using a USB memory device or Tempus to Tempus USB data cable (part number 01-2243). The output is a complete patient data package for handover from one Tempus to another. This allows Tempus data to move with the patient and for the next level care giver to see the history of injuries and treatment in the field.

CAUTION



Do not import patient records back onto the originating Tempus (directly or once-removed). Exporting / importing is for handing over data from one Tempus to another only.

Prerequisites – ensure that you have the following:

- Tempus Pro to send patient data;
- Tempus Pro to receive patient data;
- USB memory device **or** Tempus to Tempus USB data cable (part number 01-2243).

Handover via USB memory device

To export patient data:

1. Insert a USB memory device into the sending Tempus Pro. The Tempus automatically opens the Data Input/Output Menu screen.
2. Press **Tempus to Tempus data handover**. The Tempus opens the 'Tempus to Tempus data handover' screen:



Tempus to Tempus data handover – USB memory device

3. If the PDF patient report is required by the recipient, set **Include pdf in export** to **yes**.
4. Press **Export for Handover**. If the USB device contains any existing Tempus patient data records, you will be asked if you want to keep or overwrite them.
5. The 'Tempus to Tempus data handover' screen displays a blue progress bar with status messages. When the export progress bar displays "Finished", remove the USB memory device and hand it to the next level care giver.

To import patient data:

WARNING

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

1. Insert the USB memory device into the receiving Tempus Pro. The Tempus automatically opens the Data Input/Output Menu screen.
2. Press **Tempus to Tempus data handover**. The Tempus opens the 'Tempus to Tempus data handover' screen.
3. Press **Import for Handover**. The Tempus displays a list of all patient incidents found on the USB memory device. Select the patient incident record to be imported.
4. The Tempus displays the Import Patient Record screen. Press one of the following options:
 - Merge** – this merges the imported incident data into the current patient's data record.
 - Admit as new patient** – this discharges the current patient and imports the incident data as a new patient.
5. Press **Confirm**.

The 'Tempus to Tempus data handover' screen displays a blue progress bar with status messages. When the import progress bar displays "Finished", remove the USB memory device.

Handover via USB data cable

Note

When the Tempus detects the USB data cable, it disables the **Include pdf in export** option.

To transfer the patient incident data from one Tempus to another:

1. Insert the Tempus to Tempus USB data cable (part number 01-2243) into the sending and receiving Tempus Pros.
2. Both Tempus devices automatically open the 'Tempus to Tempus data handover' screen. Either press **Export for Handover** on the sending Tempus, or press **Import for Handover** on the receiving Tempus.
3. The 'Tempus to Tempus data handover' screen displays a blue progress bar as it zips and sends the data.
4. The receiving Tempus displays the Import Patient Record screen. Press one of the following options:
 - Merge** – this merges the imported incident data into the current patient's data record.
 - Admit as new patient** – this discharges the current patient and imports the incident data as a new patient.
5. Press **Confirm**.
6. The 'Tempus to Tempus data handover' screen displays a blue progress bar with status messages. When the import progress bar displays "Finished", remove the USB data cable.



9.2 Display options

9.2.1 The Display menu



The **Display** button.

Pressing the **Display** button launches a menu which offers options on the display configuration.

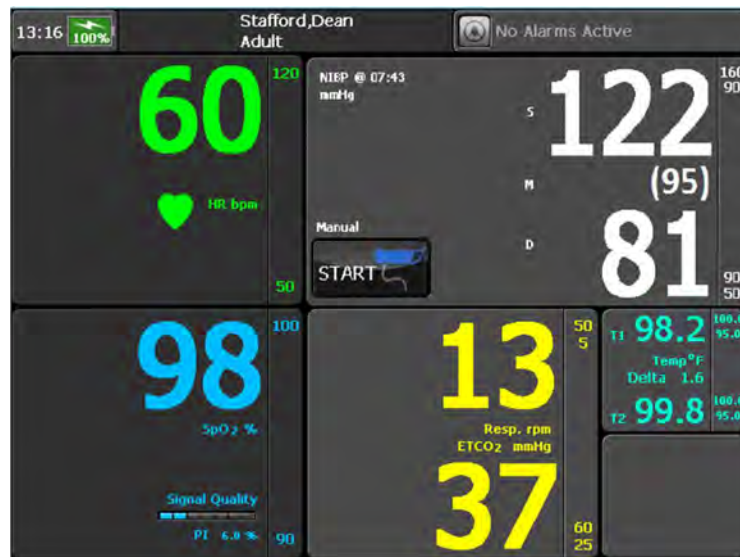
Menu option	Menu screen
<p>Select the home screen display view (from left to right):</p> <ul style="list-style-type: none"> • Four channel view (the default). • Two channel view (large ECG). • Large numeric view. • Twelve lead diagnostic view. This is only active when the 12 lead ECG cable is attached to the device. <p>See “9.2.2 Display modes”.</p> <p>High Contrast – turn high contrast display on or off, see “9.2.3 High contrast mode”.</p> <p>Waveform / Lead Selection – open the Waveform Selection Menu, see “9.2.4 Waveform and lead selection”.</p> <p>Brightness – select the screen brightness level, see “9.2.5 Brightness control”.</p>	
<p>Lock touchscreen – lock the touchscreen, see “9.2.6 Locking the touchscreen”.</p> <p>Power save mode – turn power saving on or off, see “9.2.7 Power save feature”. This setting does not persist after powering off the device.</p> <p>Corsium Crew - for use with the Corsium Crew extended display (optional). See the <i>Corsium Crew User Guide</i>.</p>	

9.2.2 Display modes

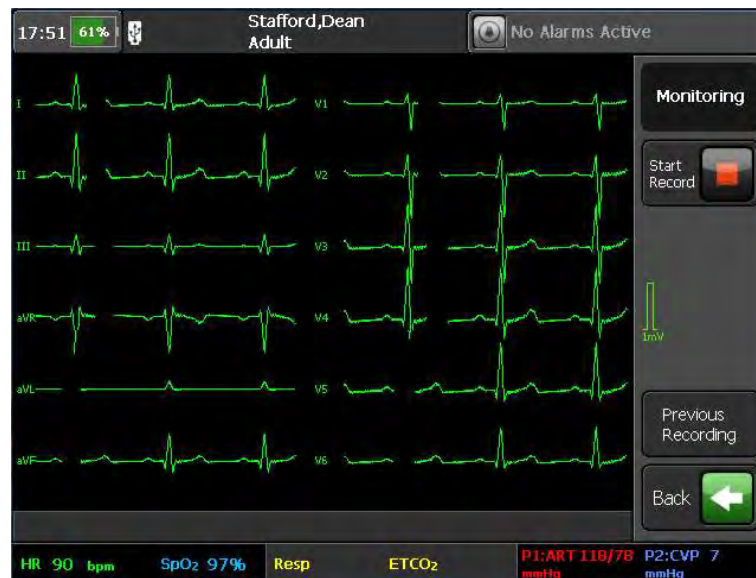
The Display Menu offers different ways to display the vital signs data on the Home screen. Each Home screen display option is shown as an icon. Pressing the icons changes the Home screen display mode. In addition to the 4 channel display (described previously), the Tempus also offers the following Home screen display options.





Large Amplitude ECG Waveform Display



Large numeric display




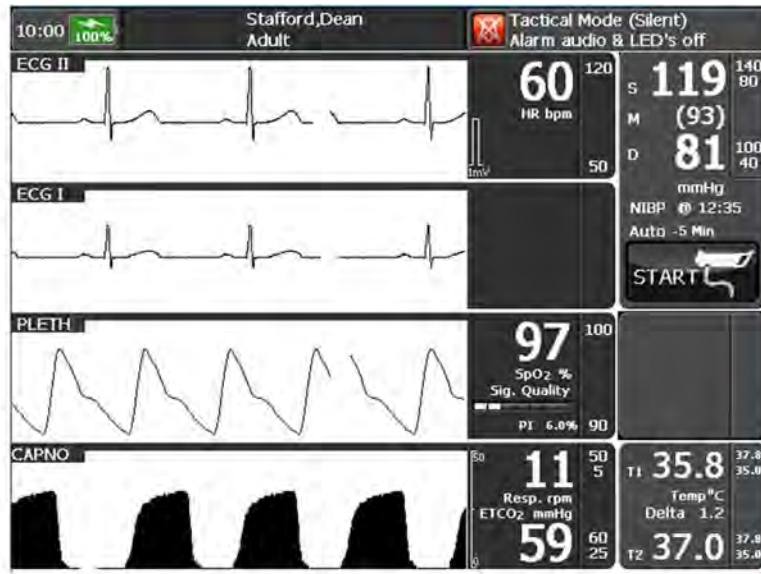
12 Lead ECG View

<p>Note</p> 	<p>The second waveform in the large ECG view defaults to display the impedance pneumography (ECG respiration) if the Capnometer is not plugged in.</p>
<p>Note</p> 	<p>When switching between the 4 waveform and the large ECG views, the ECG gain and wave speed does not change except if the gain is set to 2 mm/mV on the 4 channel view in which case the ECG will be displayed as 4 mm/mV. The user can subsequently adjust the gain settings to optimise the available waveform height. For details on changing gain settings, see “6.1.8 ECG settings”.</p>

9.2.3 High contrast mode

The first button below the different home screen views allows the user to enable a high contrast display mode on the results screen. Enabling this allows the Tempus to display vital signs data in a black on white display for high daylight conditions (shown below). The high contrast display mode can be enabled automatically by pressing and holding the button for 2 seconds. This allows the user to switch the high contrast display on by pressing a single button.

<p>Note</p> 	<p>The high contrast display is available for all Home screen display modes.</p>
--	--



High Contrast Display Activated

9.2.4 Waveform and lead selection

Use the Waveform / Lead Selection screen to customise the display of waveforms in the four-waveform home screen. To access this screen, either press the **Display** button and then press **Waveform / Lead Selection**, or from the ECG Settings menu press **Waveform / Lead selection**.

The screenshot shows the 'Waveform / Lead Selection' screen with the following annotations:

- Press the waveform region that you want to update (the first is reserved for ECG)**: Points to the 'Waveform 1 (ECG)' region.
- Press the ECG lead that you wish to display in the selected waveform region (ECG cable dependent)**: Points to the 'ECG - II' lead selection.
- Press to display plethysmogram or capnogram in the selected waveform region**: Points to the 'PLETH' and 'CAPNO' buttons.
- Press to display AA gas vitals (optional)**: Points to the 'AA' and 'O2' buttons.
- Press the IP sensor that you wish to display in the selected waveform region (P1 to P4 as available)**: Points to the 'P1' through 'P4' buttons.

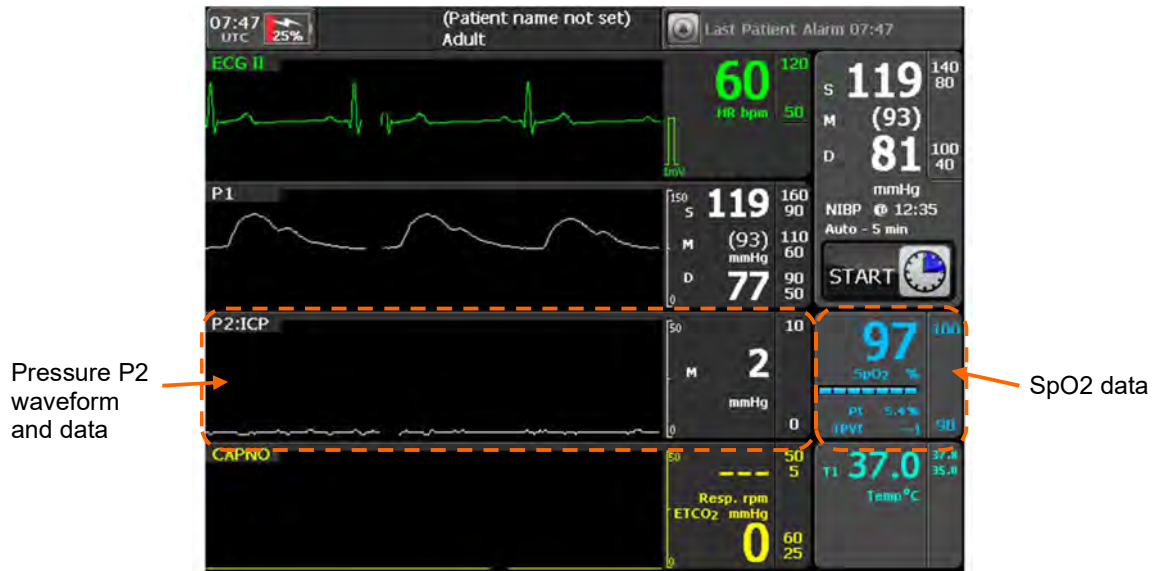
At the bottom of the screen, the following vital signs are displayed: HR 90 bpm, SpO₂ 94%, Resp 13 rpm, ETCO₂ 45 mmHg, NIBP 110/80 mmHg, 11:24.

Waveform Selection

Note If Corsium Crew is enabled, the Waveform / Lead Selection screen will include 'Crew App' waveforms. See the *Corsium Crew User Guide*.

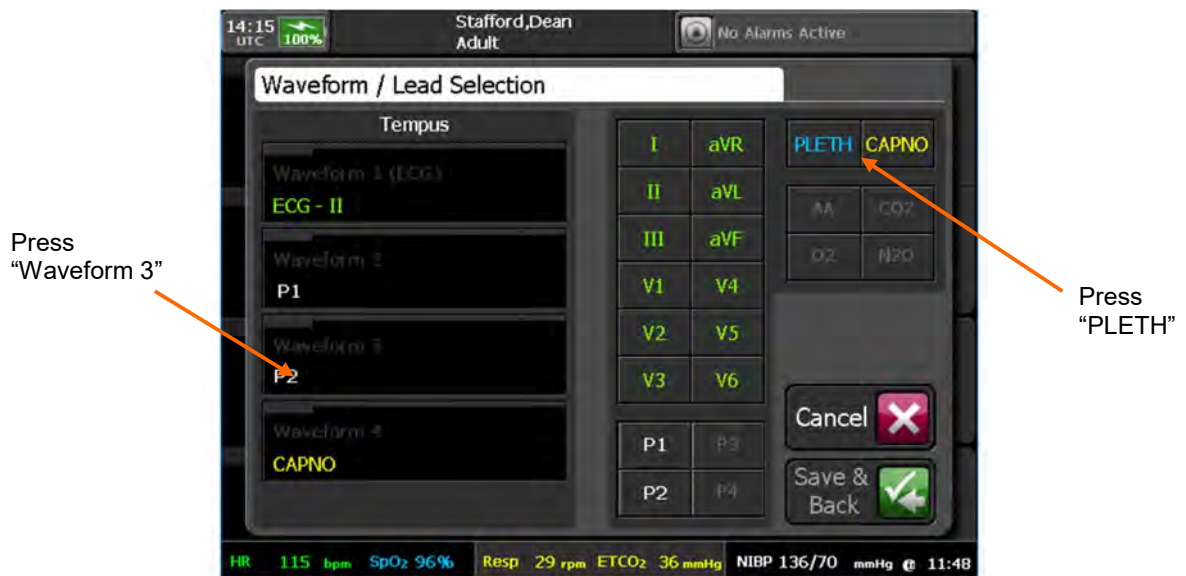
For example, you may want to move pressure P2 to a numeric area and display the plethysmogram waveform instead:

- Before this change is made, the home screen looks like this:



Standard home screen with 2 IP channels connected

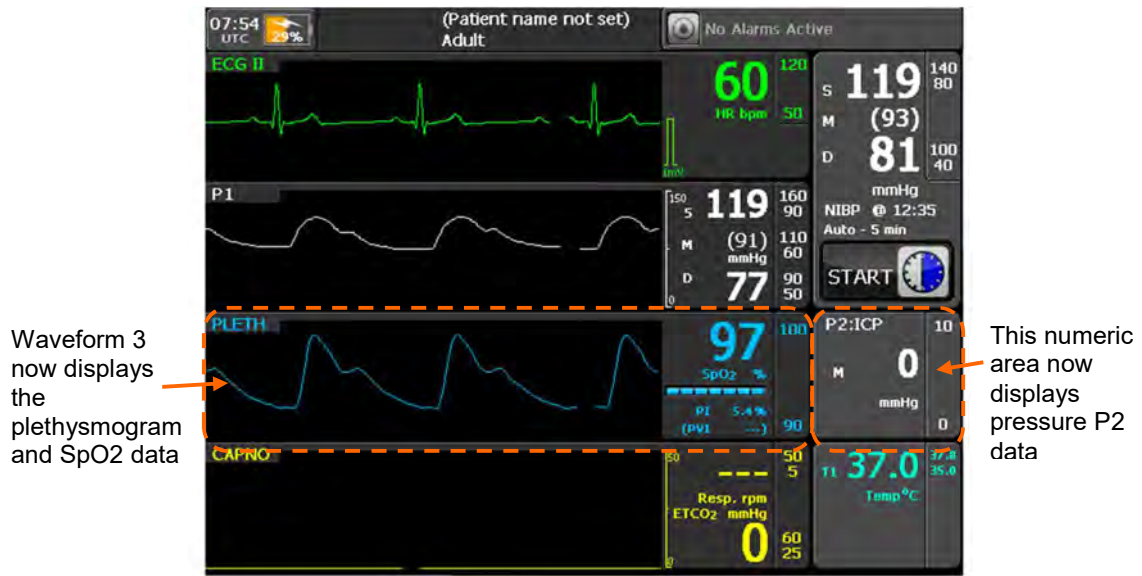
- From the Display Menu, press “Waveform Selection”. On the Waveform Selection screen, change the Waveform 3 setting from P2 to PLETH:




Setting Waveform 3 to PLETH

•

- After this change, the home screen looks like this:



Home Screen with Plethysmogram in Waveform 3



<p>Note</p> 	<p>You can swap two waveforms around by selecting both waveform regions. The waveform selection feature is not available when iAssist Mode is activated</p>
--	---

9.2.5 Brightness control

The Display Menu includes a screen brightness control. The screen’s brightness has five available settings as follows:

- Min – 10%;
- Low – 30%;
- Mid (default) – 60%;
- High – 80%;
- Max – 100%.

Using a lower brightness setting will improve battery life.

<p>WARNING</p> 	<p>The low display settings are intended for use by military and civilian pre-hospital care users for scenarios where low emitted light is required or desired. Users are reminded that while these functions are enabled, the device will present a display that may be too dim to see in daylight conditions. Users should therefore ensure that they use this feature only when required and recognise that greater levels of patient care and supervision will be required.</p>
<p>Note</p> 	<p>Min, Low and Mid are compatible with NVGs (night vision goggles) – see “4.3.2 Tactical mode (optional)”. The Max setting should only be used for strong sunlight applications.</p>

9.2.6 Locking the touchscreen

The Lock Touchscreen function allows the touchscreen to be intentionally disabled. If this feature is activated the Tempus will display the message shown below:



Touchscreen Lock Activated

This message stays on the screen for 2 seconds. After that point, if any button, control or the touchscreen are pressed the following message will be displayed. Some technical alarm conditions allow you access to the touch screen but once you return to the home screen the lock will still be active.

To disable the touchscreen lock, simply press the buttons marked "1" then "2" within 3 seconds of each other. If neither button is pressed, or the buttons are not pressed in the correct sequence, then the message will leave the screen after 5 seconds.



Touchscreen Lock Deactivate

9.2.7 Power save feature

When power save is activated the display turns to 'min' brightness after 3 minutes of no use (i.e. no user controls or alarms). If there is a further 2 minutes of no use the display turns off. The Tempus Pro continues monitoring etc. whilst the screen is off and the device's display will come back on at its original brightness as soon as an alarm is triggered, the touch screen is pressed or a keypad button is pressed.

This control can be used to extend the battery life of the Tempus.


9.3 Patient information

9.3.1 The patient menu




The Patient button

Pressing the **Patient** button launches a menu which will offer options on the management of patient data. This menu allows you to:

Menu option	Menu screen
<p>TC3 card – complete an electronic version of the military Tactical Combat Casualty Care (TCCC) card, see “9.3.2 Updating the TCCC card”.</p> <p>Patient details – enter the patient’s name, ID and allergies, see “9.3.5 Entering patient details”.</p> <p>Discharge/admit patient – discharge the current patient and admit a new patient, see “9.3.3 Admitting a new patient”.</p> <p>Switch to a previous patient – switch to a previously monitored patient, see “9.3.4 Switching to a previous patient”.</p> <p>Medics - enter details of medics (first responders).</p> <p>End of shift – allows you to clear the patient list. This means that you will not have access to previous patient incidents.</p>	 <p>Note: The TC3 card option is only available on Tempus units sold to military users.</p>

9.3.2 Updating the TCCC card

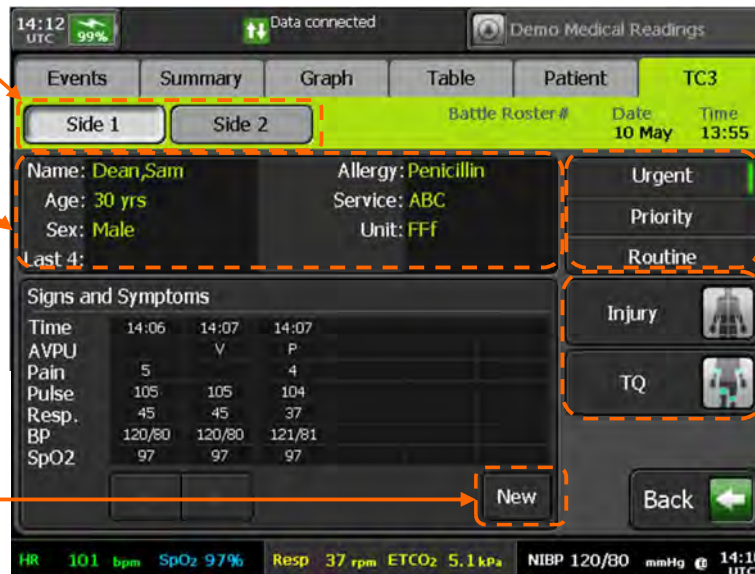
Pressing the **TC3 Card** button allows you to complete an electronic version of the military TCCC card. This feature is designed to replace the paper version used in the field. The screen is therefore laid out like a two-sided card and behaves the same way: you can insert, amend and delete TCCC data until the card is exported to a USB stick.

WARNING  It is the user's responsibility to ensure the information recorded in the TCCC is accurate and complete. Omissions or inaccuracies could lead to mis-diagnosis resulting in death or serious injury.

Press these buttons to switch between Side 1 and Side 2 of the card

Press this area to enter or edit the patient's name and details

Press the New button to bring up AVPU and Pain buttons to select from (time and vitals are recorded automatically)



Press one of these buttons to record the urgency of the casualty

Press these buttons to record injuries and TQ locations

TCCC Card Side 1

Press this area to record ABC and other interventions

Press this button to enter medics details

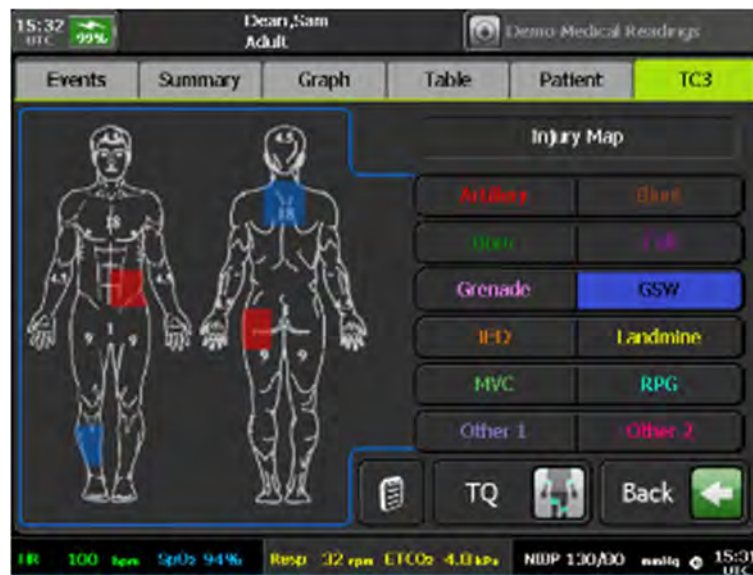


Press these buttons to enter fluids or drugs

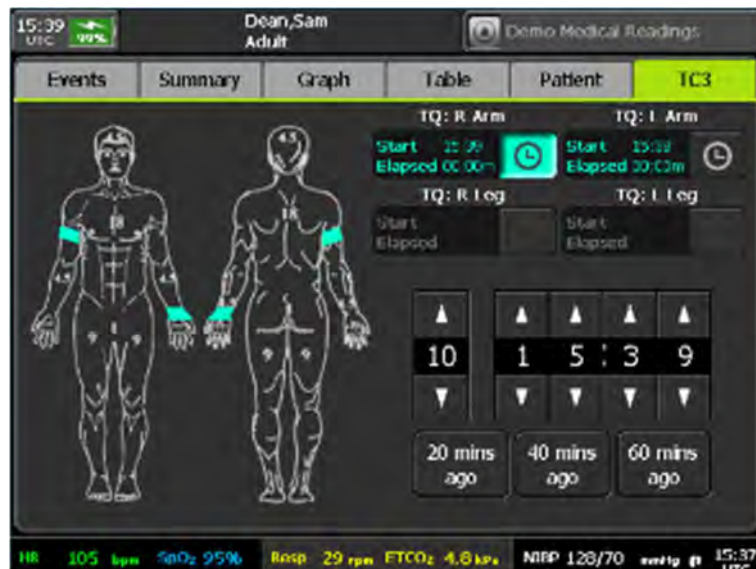
Press this button to enter notes

TCCC Card Side 2

The TCCC Injury and TQ editors provide body maps on which injuries and tourniquets may be recorded.



TCCC Injury Map

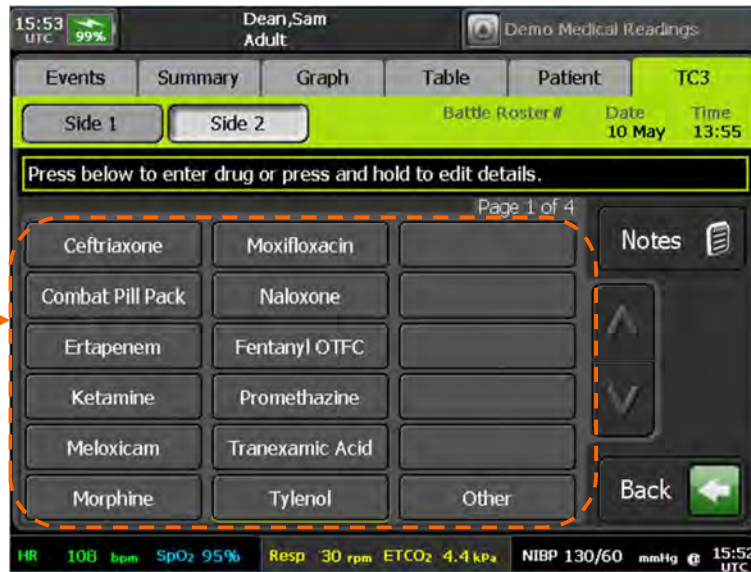


TCCC TQ Map

The drugs editor can be configured to contain all the drugs provided by the military for standard medics. The dosages and routes can be edited, but by default should be those most commonly used.

Press and release a drug button to record a drug you have administered with the default time, route and dose.

Press and hold a drug button to edit the time, dose or route of a drug before it is recorded.



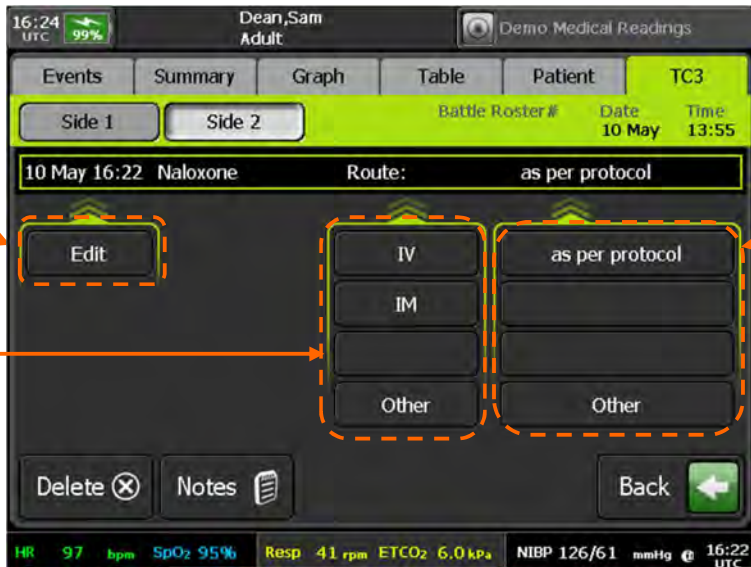
TCCC Drugs Editor

To edit the time, dose or route of administration of a drug before it is recorded, press and hold the drug button. This brings up an editor which allows any time (in the last 24 hours) to be selected and for the dose and route to be edited.

Press this button to enter the time of administration.

Press one of these buttons to enter the route of administration.

Press one of these buttons to enter the dose.



TCCC Drugs Time, Does and Route Editor

The fluids editor can be configured to contain all the fluids provided by the military for standard medics. The volumes can be edited, but by default should be those most commonly used.

Press and release a fluid button to record a fluid you have administered with the default time and volume.

Press and hold a fluid button to edit the time or volume of a fluid before it is recorded.



TCCC Fluids Editor



To edit the time or volume of a fluid before it is recorded, press and hold the fluid button. This brings up an editor which allows any time (in the last 24 hours) to be selected and the volume to be edited.

Press this button to enter the time of administration.

Use the keypad to enter the volume.



TCCC Fluids Time and Volume Editor

<p>Note</p> 	<p>If GPS is turned on and a fix is available, drug records will be geo-tagged with the location when the record is entered – see “9.5 GPS location”.</p>
<p>Note</p> 	<p>REMEMBER the TCCC card is a paper replacement system. Like a piece of paper, all information in the TCCC card can be edited or deleted up until the point the data is exported onto a USB stick – see “9.1.3 Tempus to Tempus data handover”.</p> <p>Switching to a previous patient will allow the user to re-access the previous TCCC card and edit it – see “9.3.4 Switching to a previous patient”.</p> <p>If the Tempus is connected to a response centre they will not be able to see the TCCC card being edited but will be able to see a fixed update of the TCCC card on their system every 2 minutes. The response centre user is not able to edit the TCCC card, only view it – see “9.6.5 Interacting with the Response Centre”.</p>

9.3.3 Admitting a new patient





If the **Discharge/admit patient** button is pressed, the Tempus will bring up a new dialog which asks you to confirm if the patient is new or not and gives the options to enter the new patient's name immediately or later. A warning is displayed if the current patient is still being monitored (see below).



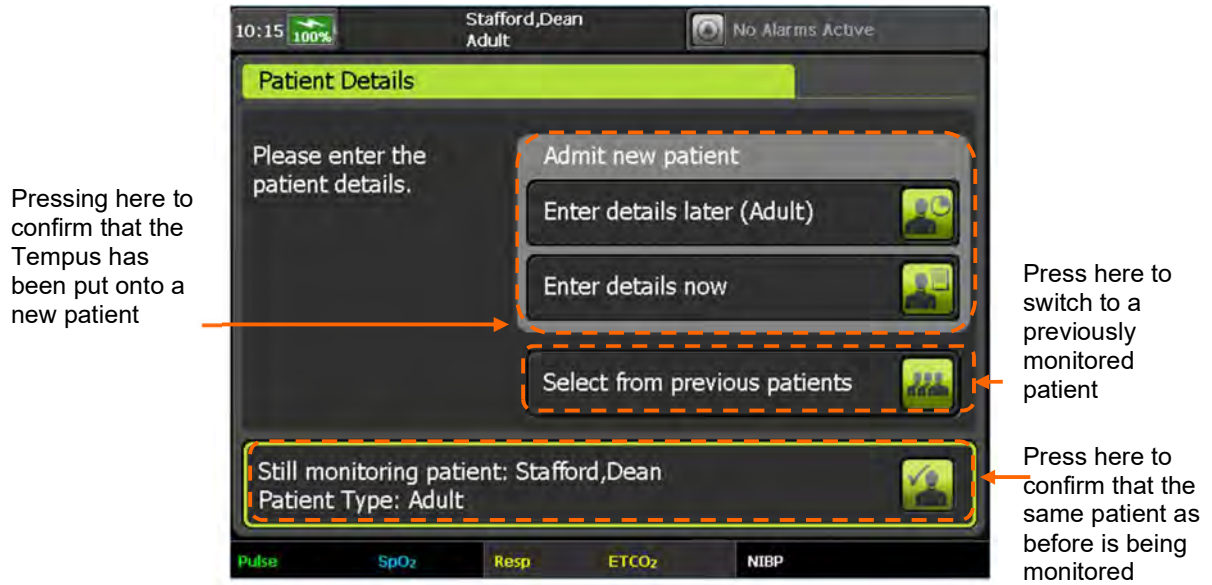
Admitting a New Patient

If a connection has not been established to a Response Centre, all data for that patient can be transmitted later so long as a new patient is not admitted. For details on communications with a Response Centre, see “9.6 Connecting to an alternate location”.


Once a new patient is admitted, the recorded data cannot be transmitted to the Response Centre.

<p>WARNING</p> 	<p>Ensure that the Tempus Pro is disconnected from the old patient before confirming that a new patient is being monitored. Failing to do so will mean that real-time vital signs data from the old patient will be entered with the record for the new patient.</p>
<p>CAUTION</p> 	<p>If the Tempus is connected to a Response Centre, discharging the old patient and starting to monitor a new one will create a new patient record at the Response Centre also. Ensure the Response Centre user understands who is being monitored.</p>
<p>CAUTION</p> 	<p>Admitting a new patient will reset all alarm settings to the factory defaults – see “7 Alarms”.</p>
<p>Note</p> 	<p>Do not attempt to connect the Tempus Pro to other medical systems until such functionality is properly supported in software.</p>

It should be noted that if the patient is removed from all real-time sensors then the Tempus will lose its real-time detection of the patient's presence. This scenario could be caused by users needing to move the Tempus from one patient (cease monitoring that patient) as they intend to start monitoring a new patient. In the instance that all real-time patient signals are lost for more than 5 minutes, the Tempus will anticipate that the user could be moving from one patient to a different one. It will therefore automatically give the user the option of switching to a new patient without having to press the Patient button (as described earlier in this section).



Patient Reset Options

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





9.3.4 Switching to a previous patient

The Tempus allows you to switch between the current patient and a patient that has been monitored on the same Tempus device within the previous 72 hours. The Tempus will also show patients admitted more than 72 hours ago, but only up to a total of 20. This feature may be used, for example, in multi-casualty situations.

To switch between patients, simply press the **Switch to a previous patient** button and then select from any patient that is shown in the list. If no patients are shown, then there are no records to select from.



Selecting From Previous Patients

WARNING 	Ensure that you select the correct patient record. Records can be identified by patient name (last and first), ID number, or incident start time. If you are not sure if the record you wish to select is the correct one, then select new patient. Mixing different patient's records could lead to confusion and misdiagnosis.
WARNING 	Ensure that the Tempus Pro is disconnected from the old patient before confirming that a new patient is being monitored. Failing to do so will mean that real-time vital signs data from the old patient will be entered with the record for the new patient.
CAUTION 	If the Tempus is connected to a Response Centre, discharging the old patient and starting to monitor a new one will create a new patient record at the Response Centre also. Ensure the Response Centre user understands who is being monitored.
CAUTION 	Admitting a new patient will reset all alarm settings to the factory defaults – see “7 Alarms”.

9.3.5 Entering patient details

Pressing the **Patient Details** button allows the patient's name, ID and allergies to be entered.



Entering Patient Details

The patient's age (or age group) and sex can be entered at any time. If the age (in years) is entered by the user, the Tempus calculates the age group. If the patient's age is not known or is less than 1 year, the user can select the patient's age group. The Tempus uses the selected age group to update alarm limits.

WARNING



Patient age group is an important factor for determining the correct initial inflation pressure (and maximum inflation pressure) for non-invasive blood pressure measurements in children of 12 years and under and also for neonates (28 days old or less) – see “6.2.3 NIBP settings”.

Failure to set the correct age group for these patients may result in them being subject to higher inflation pressures than is warranted. For new patients, the default settings are Adult/Male. Always check and enter the patient's age or select the correct age group.

CAUTION



Patient age affects the settings used in some medical modules.



Weight and height are included in the patient report but do not affect any monitoring settings in the Tempus Pro medical parameters.

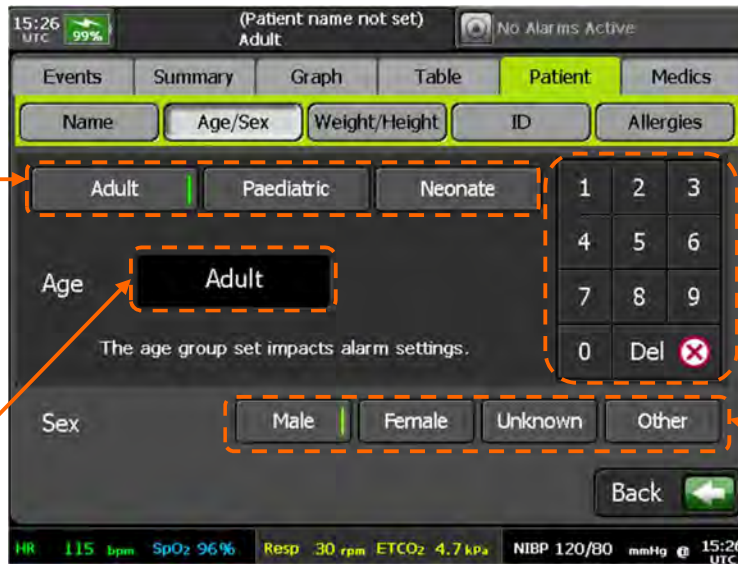
If patient's age is not known or is less than 1 year, press here to select the patient's age group:

Adult: > 12 years

Paediatric: 29 days to 12 years

Neonate: < 29 days

The entered age or selected age group is shown here



If patient's age is known, use this keypad to enter age in years (zero is interpreted as Paediatric)

Press here to record the patient's sex

Entering Patient Age & Sex

9.4 Digital camera





the Camera & Waveform Snapshot button.

Holding the **Camera & Waveform Snapshot** button for more than 2 seconds launches a camera screen. The camera screen can also be launched from the main menu camera button. This shows the viewfinder of the camera and provides buttons to take a still picture, turn on the backlight or transmit video.




It is possible to capture and send still digital pictures using the camera built into the device. If the Tempus is connected to a Response Centre, then the image is sent immediately automatically. If it is not connected, the image is stored and can be uploaded later if a connection to the Response Centre is made. Digital pictures are shown live on the Tempus Pro 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. After pressing the "Take a photo" button the Tempus will display a 3 second countdown during which time the photo can be cancelled without being saved or transmitted.

A backlight is provided to help light the subject.

Real-time video can be transmitted if a data connection with sufficient bandwidth is connected to the Response Centre.

<p>Note</p> 	<p>Do not look directly at the backlight or shine in eyes unnecessarily.</p>
<p>Note</p> 	<p>The camera is intended to allow photos of the patient to be taken (as part of the care record) or to be transmitted to enable the user at the Response Centre to see the patient (e.g. helping to decide the best care path and options will be aided by being able to see the patient). The Tempus Pro is NOT a teledermatology system or similar device.</p>



<p>Note</p> 	<p>Moving video is intended to give the Response Centre the ability to see the patient moving or to see around the patient's environment. Users should remember that the resolution and quality of the received video stream will not be the same as they see on the screen of the Tempus Pro 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 <i>slowly</i>. If rapid movement of the camera is necessary then the received image is likely to 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.</p>
<p>Note</p> 	<p>The overall image quality and resolution of the camera is greater for still pictures than moving video. If the Response Centre require an image with a reasonable level of detail (such as a close-up image) then a still photo would probably be more suitable.</p>
<p>Note</p> 	<p>Unlike still photos, moving video images are not stored on either the Tempus or at the Response Centre. They are "real-time" images only.</p>

9.4.1 Annotation of digital pictures

Images transmitted from the Tempus Pro can be altered using the software at the Response Centre. The altered image can then be sent back to the Tempus Pro 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:

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



9.5 GPS location

The Tempus Pro has a built-in GPS receiver. You can access this feature from the Main Menu – see “5.2.1 The main menu”.

The GPS may take up to 4 minutes to display a fix. If it is unable to obtain a fix (if the view of the sky is obstructed or if the unit is used indoors) then it will display an error. The most recent fix (with the time and date of the fix) is always displayed.

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



<p>Note</p> 	<p>The GPS operation will be limited if the Tempus Pro is not used outside with a clear view of the sky.</p>
<p>Note</p> 	<p>The GPS is intended to provide the User and the Response Centre with the patient's location. It should not be used as a guidance or navigation device.</p>

9.6 Connecting to an alternate location

This section describes how to connect the Tempus Pro to an alternate location to share data, typically a telemedicine support centre or response centre.




i2i ReachBak (optional)

In addition to being used as a vital signs monitor, the Tempus Pro can also be used to transmit the patient's vital signs, photos, moving video or position to an i2i Response Centre (if the i2i ReachBak feature is enabled). The user of the Tempus can also speak to the Response Centre with the Tempus.


To do this you will need to:

- Ensure the device is set to use an appropriate Communications Mode. The Tempus can connect to the same Response Centre through a number of different, pre-set configuration Modes e.g. using Ethernet, WiFi or GSM (cellular data) over a specific communications device. Normally the Tempus should be pre-configured to the correct mode but it may be necessary to change this from time to time – see “9.6.4 Communications modes”.
- Make the data connection from the Tempus Pro to the Response Centre.
- Fit the Headset comfortably in your ear.

The Tempus Pro can be left running with the data link connected but with 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 voice link open with Tempus Pro User. In this case the voice link can be reconnected at any time by pressing the Connect button.

<p>Note</p> 	<p>Users are reminded that a valid cell phone network SIM card is required to be fitted to the Tempus in order to support cell phone connections.</p>
<p>Note</p> 	<p>The characteristics of the communications network in use must be sufficient to enable the Tempus to communicate. Details of the Tempus' communications specifications are provided in “14.4 Communications”.</p> <p>Ensure that the network is sufficient to enable the device's communications to operate as described in this manual.</p>
<p>Note</p> 	<p>Should the communications network not be sufficient to enable reliable communications, the Tempus will attempt to re-establish communications for a limited number of attempts and will then show an error message. This situation is not hazardous but will prevent communications from occurring. In this situation the connection to the network should be checked, the network operation should be verified and if necessary/possible the network re-started before attempting communications with the Tempus again.</p>

If the network fails during transmission the user can expect to see intermittent data transfer (complete failure or intermittent performance of data, voice or video). Again this is not hazardous in nature but users should wait to see if the network performance improves and then consider taking the steps detailed above to fix the problem.

<p>CAUTION</p> 	<p>In accordance with IEC60601-1 clause 14.13, responsible organisations should be conscious of the potential risks to patients e.g. risk of electric shock through the use of un-isolated electrical devices, the potential increase in summed leakage currents through the connection of devices etc. that could occur from connecting medical devices to communications networks. In addition, the impact of the use of the Tempus should be considered (e.g. bandwidth allocation). When making changes to the network (including adding or removing, updating or upgrading components), those responsible should take into account the bandwidth and other technical requirements (such as addressing and maintaining the appropriate ports in an open state) of the Tempus and ensure that these requirements are maintained. For details see “14.4 Communications”.</p>
---	--


9.6.1 Making the data connection



The iAssist help processes on your Tempus Pro 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'



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



Example Data Connection Process

Once the data connection process has been completed, press the Dial Data button to start the data connection process.



These instructions are provided in iAssist format – see “9.7 iAssist processes”.

In the event that an alarm occurs, the Tempus will immediately revert back to the Home screen so that the alarm condition can be seen.



The instructions shown above are examples, the on-screen instructions may differ depending on what Connection Mode the Tempus Pro is in. Users are reminded to read and follow the instructions on screen paying attention to both the written instructions and the graphics which show how to perform different elements of the task.

If the Response Centre cannot be contacted, this could be due to errors in the way that the connection has been attempted. Help will be given in the form of an iAssist help process, follow the instructions given and wait for a few minutes before trying again. For Troubleshooting information, see “11.5 Troubleshooting”.

If the Tempus cannot connect to the Response Centre first time, it will automatically make a number of redial attempts (typically 3). The system will indicate the redial process by displaying a number over the Data Link status indicator.

9.6.2 Fitting the headset and making the voice connection

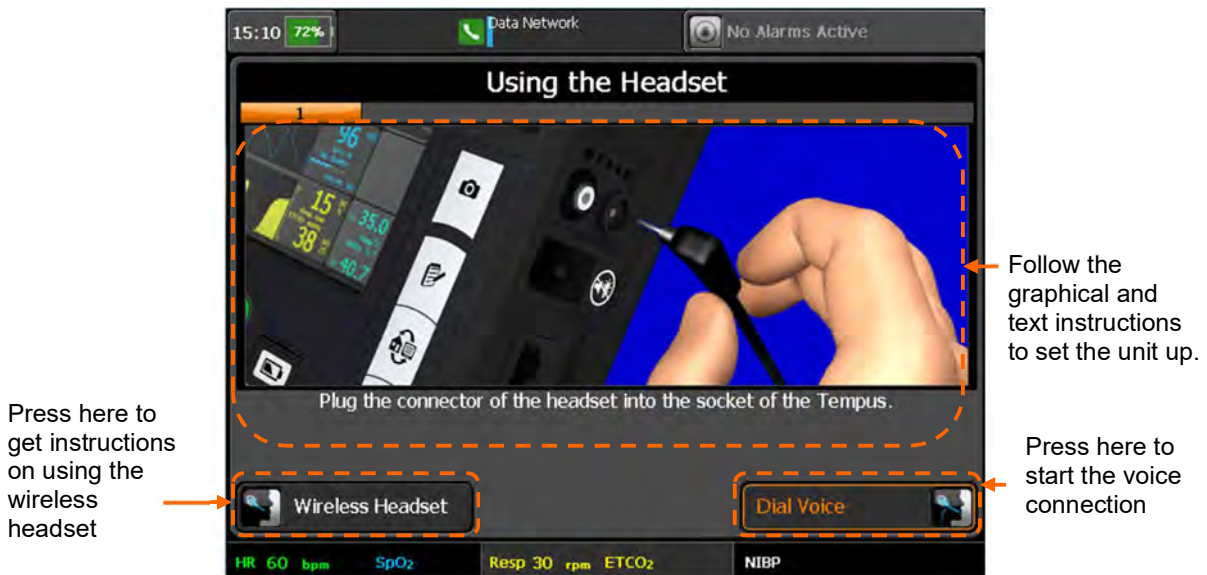
After starting the data connection, the Tempus will bring up instructions to make the voice connection. If a voice connection is not required press the Home button. The voice connection can be made using either the pre-attached Bluetooth® headset or the wired headset (accessory).

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

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

The voice connection can be setup only if the data connection is established first. The voice connection can be disconnected (hung up) while the data connection remains established but a voice connection cannot be made without a data connection. The voice connection is essentially a VoIP call. This is routed directly to a laptop/PC. Additional third-party hardware can be purchased to route the VoIP call to a landline – if this is required RDT should be contacted for technical support.

The voice connection is typically the means for the Tempus user to alert the personnel receiving the data that there is data to be received. Other means (such as a radio) can be used to notify personnel of an incoming data connection.



Voice Connection Process Using a Wired Headset Adaptor Cable



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

Once the voice connection process has been completed, press the Dial Voice button to start the voice connection process.



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

Using the wireless headset

The Tempus Pro uses the Presence or VMX200 Bluetooth headset provided by Sennheiser®. Note that the headset will be supplied in a charged state and its charge level is automatically maintained so long as it is regularly docked on the charging pin on the back of the device.

It should also be noted that the headset is a Sennheiser® wireless device. It is supplied “paired” with the Tempus Pro. You cannot use different wireless headsets with the Tempus Pro and RDT recommends that you do not attempt to use the headset supplied with the Tempus Pro with any other wireless devices (including other Tempus Pros or other communications devices such as mobile phones).

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

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

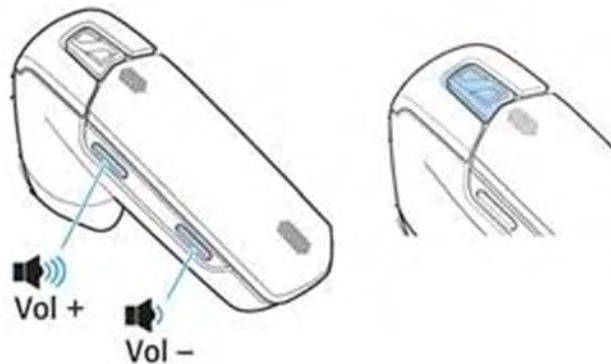
Introduction

The headset has 3 buttons:

- Volume up
- Volume down
- Multi-function button



Sennheiser Presence



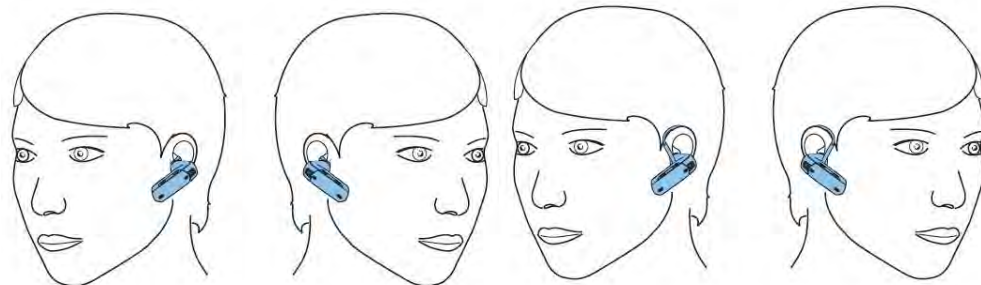
Sennheiser VMX200



Note Users should avoid using the headset speaker volume controls. The speaker volume can be controlled through the Tempus and is preset to maximum.

Wearing the headset

To put the headset on, follow the instructions given on screen. Simply put the headset into your ear (either ear). It is small and light and should not require the use of an ear hook but this can be fitted if required (see Sennheiser instruction manual provided with the Tempus). You should ensure the speaker is well seated in your ear so it feels stable.




Controlling the wireless headset

To use the headset:

- Press the green dial button.
- Following the on-screen instructions, remove the headset from its dock.
- Following the on-screen instructions, press the Multi-function button once (for 1 second or less). The light on the headset will flash blue.



The Tempus will go through a process to link to the headset via Bluetooth®.

- Following the on-screen instructions put the headset into your ear.
- Following the on-screen instructions press the Connection button on the touchscreen.


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

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

You do not need to switch the headset off; this is achieved by docking the headset back onto the Tempus Pro. If you do wish to turn the headset off, press and hold the Multi-function button for 3 seconds until the LED flashes blue three times.

<p>Note</p> 	<p>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 Pro and then re-initiate the connection again following the on-screen instructions.</p>
<p>Note</p> 	<p>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.</p>

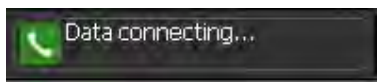
To adjust the volume during a call, press the “vol+” button or “vol-“ button on the headset as shown above.

<p>Note</p> 	<p>If you press and hold the “vol-” button for 1 second you will mute the headset. 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.</p>
--	--

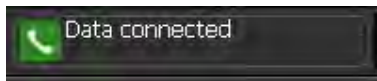
9.6.3 Connection status indicators

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

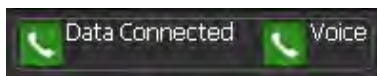
The following symbols indicate the state of the links:



Data connection started (icon will flash)



Data connection to Data centre (gateway) completed (icon solid), data not picked up by Response Centre



Data connection to Response Centre completed (icon solid and capital “C” on “Connected”).

Voice connection in progress (icon flashing) or connected (icon solid)

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

Once the voice connection is in progress the User can hear its status through the headset e.g. ringing, connected etc.

WARNING

When connected the patient name and age are not displayed.

9.6.4 Communications modes

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



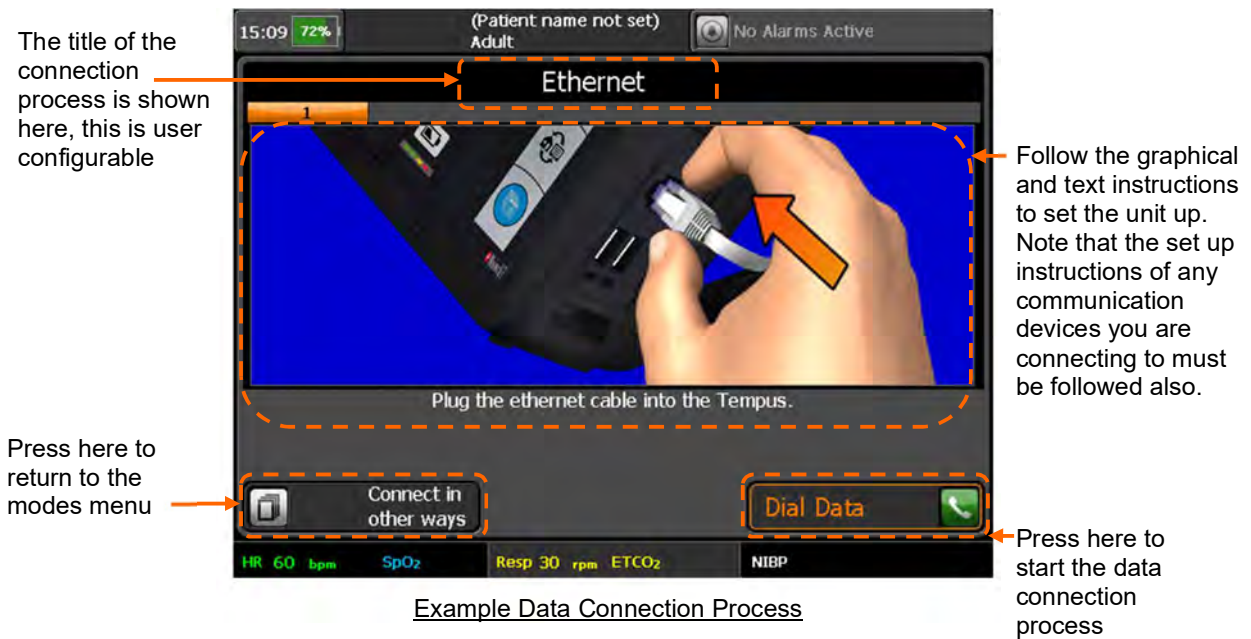
The Tempus can only be pre-set to connect to a single Response Centre. Configuring it to connect to new Response Centre requires the support of RDT.

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 make it easy to switch between these types of connections, the Tempus Pro 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 Pro shows what Mode it is in with a banner at the top of the Connection iAssist help process.

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



Changing modes

You can change the Communications Mode by pressing the “Connect in other ways” button. This will bring up the Communications Modes Menu. This can also be reached through the “Communications Modes” button in the Main Menu – see “5.2.1 The main menu”.



Example Modes Menu

The Mode that the Tempus is set to use will be indicated with a lit bar. To change Mode, press the required Mode. The instructions for that Mode will be brought up on screen. The title of the new instructions will show what Mode the Tempus is now set to use.

The Modes that are available on each Tempus Pro are dependent on the requirements of each User. Refer to the Modes Menu on your Tempus Pro 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.

Once the mode is selected the Tempus will display the instructions for connecting in that mode.

Changing headset settings

The performance of the headset can be changed if required. The headset settings are accessed using the Headset Settings button on the Communications Settings menu – see “5.2.2 Printer and Headset menu”.




The headset settings are pre-set for the best performance for use in environments with a range of ambient noise levels. Users should change the settings if they are struggling to hear or be heard.

9.6.5 Interacting with the Response Centre


The Response Centre

Each Tempus Pro device is pre-configured to dial automatically to a specific Response Centre. The centre should be staffed 24 hours a day, 365 days a year and should always be able to receive your connection. If a connection cannot be established, you should wait a short time and attempt to connect again.


<p>Note</p> 	<p>It is the User's responsibility to ensure their Response Centre is properly staffed and equipped.</p>
--	--



When interacting with the Response Centre staff, you should also realise that they may be operating in a different time zone to the one where the incident is taking place. However, the clocks (and displayed times) of the both the Tempus Pro and the i2i software are synchronised.

Remote viewing and control

<p>WARNING</p> 	<p>The alarm functions of the Tempus are intended to be used by the attendant user only. If the device is connected to a Response Centre this is for the purpose of sharing vital signs data in real time, between two users for the purpose of obtaining additional clinical support. The system is not a distributed alarm system (e.g. nurse monitoring station system) in the terms of IEC60601-1-8. The i2i system at the Response Centre is not equipped with alarm silencing or suspending controls.</p>
---	--

The Response Centre operators will have exactly the same information on their screens as displayed on the Tempus Pro. Should the Tempus Pro display change e.g. if a new help screen is brought up, new data is displayed or an error message appears, the Response Centre system will display exactly the same information a few seconds later. The only exceptions to this are when you are taking a digital picture or when you are monitoring or recording a 12 Lead ECG, in these situations the Response Centre only see that you are in the process of recording the ECG or taking the photo but they don't see the ECG or photo until it has been downloaded.

<p>WARNING</p> 	<p>Users are reminded that the i2i system at the Response Centre is not equipped with alarm silencing or suspending controls. The i2i user is able to see the alarm condition through the on-screen visual alarm manifestations but they are not provided with audible alarms (it is not a distributed alarm system) and they are not equipped with means to silence or suspend the alarms. Managing the alarm state of the product is the responsibility of the Tempus User.</p>
---	--

<p>Note</p> 	<p>While the i2i will display the same information as the Tempus, user should note that the actual display size and aspect ratio of waveforms will vary slightly depending on the native resolution of the display that the i2i user has i.e. the i2i user's display may have differently sized and shaped pixels to the display of the Tempus and so very minor differences may be present between the two displays.</p>
<p>Note</p> 	<p>If the waveform or video stop appearing on the i2i application stop the connection and reconnect the Tempus.</p>

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

9.6.6 Recording data off-line and transmitting on-line

If a connection has not been established to a Response Centre, all data for that patient can be transmitted later so long as a new patient is not admitted. Once a new patient is admitted, the recorded data cannot be transmitted to the Response Centre. For details on discharging the patient, see “9.3.3 Admitting a new patient”.

9.7 iAssist processes



The iAssist help processes on your Tempus Pro 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 Tempus can provide additional on-screen instructions on how to use the device. This feature is called iAssist Mode. iAssist Mode is intended to be set by more experienced users in order that they can pass the Tempus to less experienced colleagues knowing that their operation of the device will be supported by on-screen instructions. If iAssist is activated on the Main Menu, the second ECG Lead waveform will be removed and the Plethysmogram and Capnogram will be moved up to make room for a row of graphical buttons in the bottom-most waveform of the Tempus Home Screen – see “5.2.1 The main menu”.

The first button is the ECG button

Each button is a graphical cue to allow the less experienced user to get on-screen instructions on how to deploy that particular parameter.

Home Screen in iAssist Mode



ECG – pressing this brings up instructions on how to use the ECG



Blood pressure – pressing this brings up instructions on how to take non-invasive blood pressure measurements



Pulse oximeter – pressing this brings up instructions on how to take blood oxygen measurements



Capnometer – pressing this brings up instructions on how to take Capnometry measurements

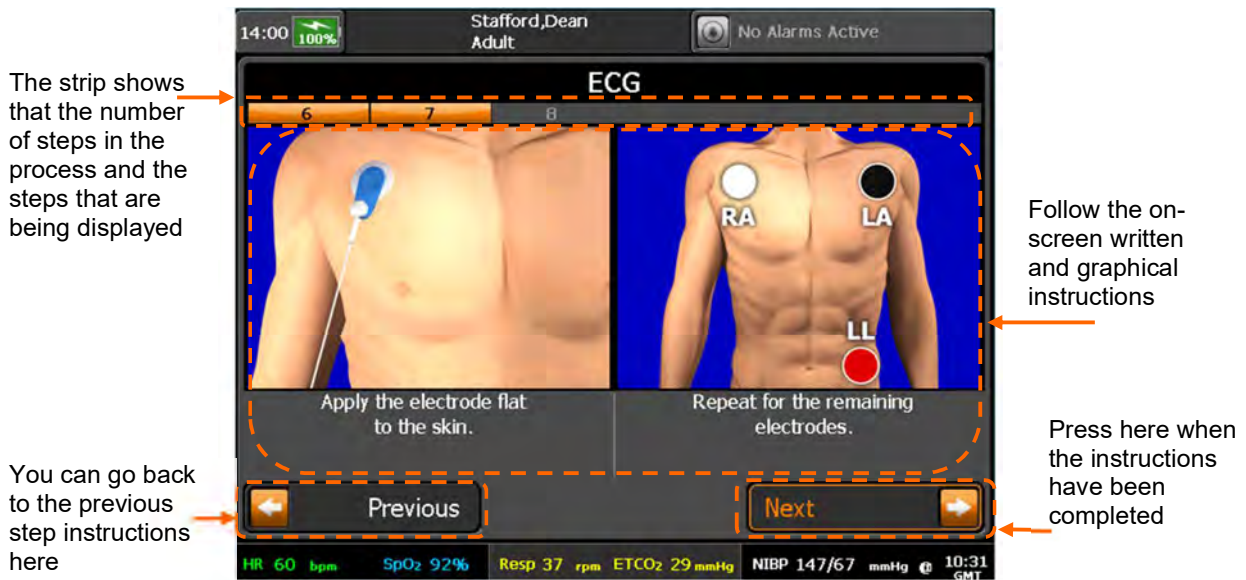


Temperature – pressing this brings up instructions on how to take temperature measurements

When in iAssist Mode, the Tempus Pro 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 to use the parameter.

The example iAssist process shown below shows there are two distinct areas on the screen that give different types of information.

- Process Instructions - This area contains the graphical pictures and text instructions that show you how to use the device. This takes the user through each activity one or two steps at a time.
- Touch Screen Buttons - In this example there are two buttons at the bottom of the touchscreen. In all cases the user will press the button on the **bottom right** of the screen to progress onto the next step in the process.



Example iAssist Process

When in iAssist Mode, the Tempus Pro 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.

In the example shown above, the screen shows that the process has 8 steps and that the device is showing steps 6-7.

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.

9.7.1 Monitoring ECG




To begin monitoring an ECG, 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.

9.7.2 Taking blood pressure measurements




To take Blood Pressure measurements, press the  button on the device. The first step in the Blood Pressure help process will appear.

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

9.7.3 Taking pulse oximetry measurements



To take Pulse Oximetry measurements, press the  button on the device. The first step in the Pulse Oximeter help process will appear.

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

9.7.4 Taking capnometry readings




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.

9.7.5 Taking temperature readings



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.

9.7.6 Using the camera



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 Pro display in the position shown in the following picture.

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

9.8 View installed features

Use the Main Menu option **View Installed Features** to view a list of features installed on Tempus Pro.



9.9 Printer maintenance

9.9.1 External printer configuration

You can use an external USB printer to print patient reports – see “9.1.2 Send patient data/report”.


To configure an external printer:

1. Select **Main Menu > Printer and Headset > External Printer Settings**.
2. Select the setting to change:
Printer Type - PCL3 or PCL3-GUI.
Paper - A4 or Letter (8.5 x 11”).
3. Press **Test Page** and check the resulting test print.
4. Press **Back**.

9.9.2 Internal printer configuration (optional)

You can use the internal printer (if fitted) to print:

- Waveform snapshots – see “8.2.2 Waveform viewer”.
- 12 lead ECG recordings – see “6.1.6 Performing a diagnostic ECG”.

Note 	<p>Always store the Tempus Pro with a paper roll fitted to the printer.</p> <p>Printing on the internal printer is not possible whilst the ultrasound is being used.</p>
--	--

To configure the internal printer:

1. Select **Main Menu > Printer and Headset > Internal Printer Settings**.
2. Select the setting to change:
Paper - Plain or Grid.
Auto Print Snapshots - 'yes' means that waveform snapshots will be printed as soon as they are captured.
3. Press **Test Page** and check the resulting test print.
4. Press **Back**.

9.9.3 Changing the paper roll (internal printer only)

**Note**

To ensure ease of access to the printer roll, place the Tempus Pro on a flat surface, lying on its front.

Do not force the lid to open at an angle greater than 90° from the back of the unit. Excessive force will detach the lid from the printer body: if this happens see "9.9.4 Fitting the printer lid".

To change the paper roll in the internal printer, proceed as follows:

1. Open printer lid by depressing the button in the printer housing. Open the lid to an angle not greater than 90° from the back of the unit. Do not force it to open any more than this:



2. Remove the old paper roll spindle:



3. Free the end of the new roll:



4. Place the roll into the housing, with the outside face of the paper against the printer mechanism:



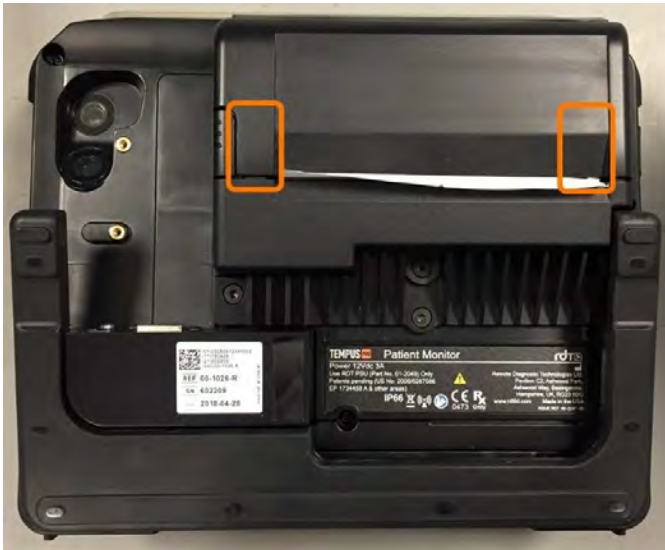
5. Feed in one side of the roll, then the other:



6. Ensure the roll spindle is centred on the fixing springs, pull the roll to ensure it rotates freely:



7. Close the lid and press it down on both corners, listening for a click. Tear off any extra paper:

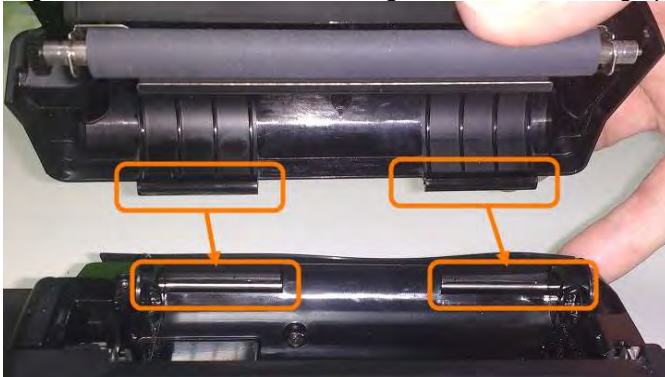


8. Set the paper type (Plain or Grid). If required, print a test page - for instruction see “[9.9.2 Internal printer configuration \(optional\)](#)”.

9.9.4 Fitting the printer lid (internal printer only)

If the lid becomes detached from the printer housing, refit it as follows:

1. Align the slotted ends of the lid hinges with the steel hinge pins in the printer housing:



2. Lower the lid onto the printer housing, ensuring that the top rubber seal is not trapped. Do not press the lid into position yet:



3. (a) Hold the lid open at an angle of not more than 45° to the back of the unit.



- (b) Place your thumbs on both lid hinges:

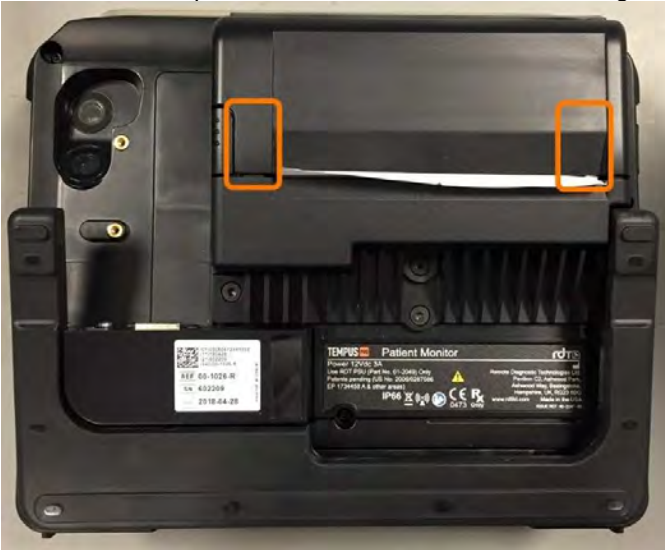


4. Push the slotted ends of the lid hinges down onto the steel hinge pins in the printer housing, ensuring they both click into place.

Important - ensure that the lid rotates freely on its hinges to open and close.






5. Close the lid and press it down on both corners, listening for a click:

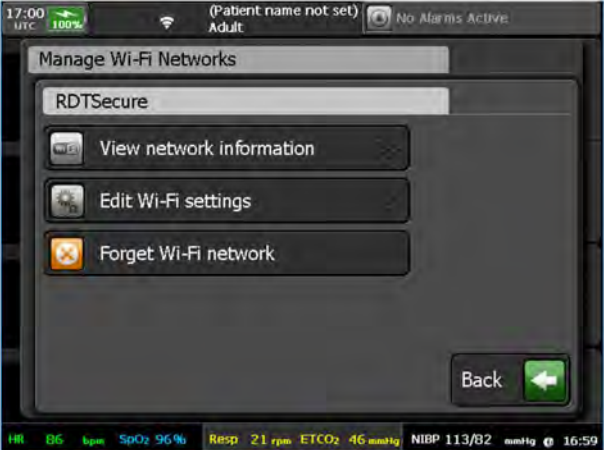






9.10 Managing Wi-Fi networks

If Wi-Fi is the communication mode for your Tempus Pro, you can scan and connect to available Wi-Fi networks. Smart management of Wi-Fi enables Tempus Pro to automatically connect to any Wi-Fi network that it finds in range where the configuration details are already stored.

To manage your Wi-Fi networks, proceed as follows:

Step	Description	Screen
1.	<p>Go to the Main menu .</p> <p>In the Wireless Enabled control area, ensure that Wi-Fi is set to 'yes'.</p> <p>Press Manage Wi-Fi Networks.</p>	
2.	<p>Tempus Pro displays the Manage Wi-Fi Networks menu. It may take up to 30 seconds to scan for and display the available networks. Each network is displayed with its connection status:</p> <p>Connecting... - Tempus Pro is attempting to connect to this network.</p> <p>Authenticated - Tempus Pro is now connected to this network. Press this button to view settings, update settings or forget the network (step 3a).</p> <p>Saved - Tempus Pro knows the key for this network. Press this button to connect to the network, update settings or forget the network (step 3b).</p> <p>Key required - Tempus Pro does not know the key for this network. Press this button to connect to the network (step 3c).</p> <p>You can also connect to a hidden network (if you know its key and other settings) - press Add a Wi-Fi network (step 3d).</p>	

Step	Description	Screen
3a.	<p>If you have selected the Authenticated network, choose an option:</p> <p>View network information - view IP address, IP subnet and IP gateway/DNS.</p> <p>Edit Wi-Fi Settings - edit SSID, network key and hidden status.</p> <p>Forget Wi-Fi Network - if you forget this network the Tempus will no longer be able to connect to it automatically.</p> <p>Press Back.</p>	
3b.	<p>If you have selected a Saved network, choose an option:</p> <p>Connect to Wi-Fi network - press this button to connect. Tempus Pro redisplay the Manage Wi-Fi Networks menu showing the status of this network as Connecting.... If connection is successful, status changes to Authenticated.</p> <p>Edit Wi-Fi Settings - edit SSID, network key and hidden status.</p> <p>Forget Wi-Fi Network - if you forget this network the Tempus will no longer be able to connect to it automatically.</p>	
3c.	<p>If you have selected a Key required network, choose this option:</p> <p>Connect to Wi-Fi network:</p> <ul style="list-style-type: none"> • Press this button. • Enter the network key. • Press Connect. <p>Tempus Pro redisplay the Manage Wi-Fi Networks menu showing the status of this network as Connecting.... If connection is successful, status changes to Authenticated.</p> <p> Note: If the "Wi-Fi error" message appears, check the connection assumptions in Edit Wi-Fi settings and try to connect again. If this does not help, press Forget Wi-Fi network, power cycle Tempus Pro and restart the connection to the required network.</p>	

Step	Description	Screen
<p>3d.</p>	<p>If you have selected Add a Wi-Fi Network:</p> <p>Enter the SSID, network key, hidden status and other details as requested.</p> <p>Press Save.</p> <p>Press Back.</p>	

10 After using the Tempus Pro


10.1 Inspecting the Tempus Pro

After using the Tempus, always inspect the device, its accessories (including power supplies, mains cable, batteries and charger) for signs of damage or wear. While doing this ensure that you 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. Also remember to check connector covers (if fitted) and particularly the Capnometer door, to ensure they close and latch acceptably.

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



At least once per year completely inspect the whole device and 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 device function within specification and within locally prescribed safety limits.

Note 	Users should note that particular calibration curves exist for use of specific SpO ₂ simulators with the Tempus' Masimo [®] pulse oximeter. Please contact RDT for details. Such functional testers should not be used to determine the accuracy of the device, only its correspondence to the particular calibration curve provided by the tester.
--	---

10.2 Cleaning the Tempus Pro

It is necessary to clean the Tempus Pro after use.

CAUTION 	If you suspect that dirt or fluids have entered the battery compartment, see the <i>Tempus Pro Maintenance Manual</i> .
Note 	If the Tempus is soiled, it is the user's responsibility to ensure it is withdrawn from use and properly decontaminated prior to re-deployment. In this instance users are recommended to replace the handle – for the appropriate part number, see “12 Accessories list of the Tempus Pro”.

10.2.1 Cleaning the case of the Tempus Pro

To clean the Tempus, use a clean and dry cloth using an agent from the table below. Ensure that connector pins are covered during cleaning and remain dry. Wipe off any excess cleaning agent from the device with a different clean and dry cloth.

Approved Cleaning Agents:

- Warm water

- Liquid soap
- Wex-cide®
- Windex®

Never use any other cleaning agent than those described above. Use of more aggressive agents such as alcohols, acetone and other solvents is not permitted.

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

In the event of contamination of the Tempus from human fluids or other waste matter the product should be thoroughly decontaminated and disinfected. In this event the handle should be removed and discarded and replaced with a new part sourced from RDT.

CAUTION

If the Tempus requires cleaning, users are advised to ensure that stiff or sharp objects are NOT used to remove detritus from underneath the louvered vents in the front and rear panels of the device. Doing so could compromise the IP66 sealing of the product.

The front panel vent is located where shown in the image below. The rear panel vents are located behind the accessory pockets.



Position of Vent

10.2.2 Cleaning the display

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. It should be noted that the anti-reflective (AR) coating of the touchscreen may be impaired if unsuitable materials are used to clean the touchscreen. The table below lists different cleaning materials and their effect on the AR coating after a 30-minute exposure under ambient conditions:

Chemicals	Result
NaOH 3% aq. solution	Unchanged
Na4OH 3% aq. solution	Unchanged
HCl 3% aq. solution	Unchanged
Kitchen cleaner 5% aq. solution	Unchanged
Glass cleaner	Unchanged

CAUTION

Under no circumstances should any abrasive substance be applied to the screen.

10.2.3 Cleaning connectors

If connectors are wet, they should be rinsed with tap water and then dried. All solid material (e.g. dust or sand), should be removed with compressed air.

Cables or connectors with corroded contacts should be replaced.

10.2.4 Cleaning the NIBP cuffs and hose

The NIBP hose and reusable cuffs should be cleaned with a clean cloth after use with a disinfectant such as Clorox® (1:10 solution).

Ensure that any cleaning solution does not enter the hose or bladder. Ensure the cuff is completely dry before it is reused.

The cuffs may be machine washed at 40-50 °C (after plugging the air connector to prevent water entering the bladder).

10.2.5 Cleaning the SpO2, ECG and invasive pressure cables

Clean the sensor cables with a clean cloth after use with a disinfectant such as Clorox® (1:10 solution). Do not immerse any cables. Ensure the cables are completely dry before they are reused.

CAUTION

No cables or parts of the Tempus should be sterilised using any process (Steam, EO, Radiation etc.).

Never immerse ECG cables, doing so could reduce the performance of defibrillation protection devices within the cable'

10.2.6 Cleaning the battery contacts

Remove the battery once a week. Inspect the electrical contacts of the Tempus Pro battery compartment and of the battery itself. If any battery contacts are dirty, clean them as described:

Approved cleaning agents:


- Isopropyl alcohol electronic cleaning solvent.

Cleaning:

1. Moisten a clean, dry cloth with the approved cleaning agent and wipe the battery contacts.
2. Wipe off any excess cleaning agent with a clean, dry cloth.
3. Refit the battery.

10.3 Disposal at end of life



The WEEE logo  on the Tempus and its battery 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.

Note



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

10.3.1 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.

11 Maintenance, servicing and troubleshooting

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

More details on maintenance are given in the *Tempus Pro Maintenance Manual*, which is available from RDT, see "[RDT contact details](#)".

The *Tempus Pro Maintenance Manual* contains the necessary technical information, schematics, parts designation and process description for specified maintenance and testing to be performed.

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 such parts are not subject to wear, fraying, tears, knots or other signs of damage. Damaged or worn parts should be replaced.
CAUTION 	The ECG cables contain components to protect against the effect of a defibrillator. The ECG cables should be measured on an annual basis (or more frequently at the user's discretion if they are subject to a high number of defibrillation discharges) to ensure that they retain a resistance of $1\text{ k}\Omega \pm 10\%$ as per AAMI EC53. Cables should be replaced if this resistance is not maintained.
Note 	If the Tempus Pro 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.

11.1 Tempus Pro battery

11.1.1 The battery

The Tempus Pro contains a removable, rechargeable battery.





Example of the Battery Front





Example of the Battery Rear

In normal usage, the rechargeable battery provides power for at least 9 hours' continuous use when fully charged.

<p>Note</p> 	<p>Assessment of use is based on projections of reasonable device usage within a patient incident made by RDT.</p>
<p>Note</p> 	<p>Do not attempt to fit batteries from previous RDT products (Tempus IC or Tempus IC Professional) into the Tempus Pro, they will not fit.</p>

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

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

<p>Note</p> 	<p>RDT recommends that the battery charge status should be checked at least every month and recharged if necessary. If the device is being used regularly then the battery should be checked, weekly or daily depending on the frequency of use. RDT also recommends that the battery be completely discharged and recharged once a year.</p>
<p>Note</p> 	<p>The User should remember that battery capacity of older batteries will not be the same as new batteries.</p>

By monitoring the remaining battery life, situations where the battery is too weak to power the Tempus Pro 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.

The power of the battery can be extended by enabling a screen-saving feature on the Tempus. Enabling this feature will make the display switch off if 5 minutes pass with no operator intervention or alarms triggering. The Tempus will remain on and performing any monitoring function it has been set to do. If any patient or technical alarms occur, the Tempus display will come back on and the alarm functions sound as normal. While the display is off, if any operator controls are used then the display will come back in immediately.

Using the power save feature will enable the battery life to be extended significantly.

To enable this feature, go to the Display Menu and then turn Power Save to on – see “9.2.7 Power save feature”.

Checking the charge of the battery





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

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

- Four green LEDs – 76-100%
- Three green LEDs – 51-75%
- Two green LEDs – 26-50%
- One green LED – 1-25%
- One green flashing LED – less than 10%
- No LEDs – no power due to deep discharge

Battery status is always displayed in the status bar – see “5.1.3 Battery status indicator”.



<p>CAUTION</p> 	<p>When the battery is low it should be recharged soon after use. Starting a Tempus on an empty battery or leaving batteries in a low or empty state for prolonged periods may put the battery into a deep-discharged state. In this state the battery LEDs will not light and the battery will require a prolonged period on charge in order to return it to normal operation.</p>
<p>CAUTION</p> 	<p>If none of the LEDs light, then the battery may have been deep-discharged. It should be left on-charge on an external charger for 24 hours to bring the battery out of this state.</p>


These will light cumulatively when the battery button is pressed i.e. only the one green light will light if the charge state is 1-25% after which the 2nd green light will light as well.

The Tempus Pro does not need to be turned on to check the battery.

If batteries do not retain their charge state, users should try charging them fully on an external charger. As batteries become old and over many charge/discharge cycles, users should expect to see a reduction in their capacity. Such batteries should be replaced at the user's discretion.

11.1.2 Removing the battery from the Tempus Pro

<p>WARNING</p> 	<p>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.</p>
<p>WARNING</p> 	<p>Ensure the latches on both sides of the battery are fully engaged prior to using the Tempus - an incorrectly fitted battery could result in the Tempus losing power during use.</p>

<p>Note</p> 	<p>Before removing the battery, you must switch off the Tempus Pro by pressing the power button.</p> <p>If necessary, you can force a hard shut-down by pressing and holding the power button for 10 seconds.</p> <p>Remember that the battery cannot be removed until the lamp on the front panel has gone out.</p> <p>The Tempus Pro should not be used without the battery fitted.</p>
--	---

To replace the battery:

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



Example of the Battery Indicator

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





Battery Removal

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

Battery Insertion

11.1.3 Charging the battery

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




<p>WARNING</p> 	<p>Do not attempt to charge the battery using any charger other than those supplied by RDT.</p>
<p>CAUTION</p> 	<p>When the battery is low it should be recharged soon after use. Starting a Tempus on an empty battery or leaving batteries in a low or empty state for prolonged periods may put the battery into a deep-discharged state. In this state the battery LEDs will not light and the battery will require a prolonged period on charge in order to return it to normal operation.</p>
<p>CAUTION</p> 	<p>If none of the LEDs light, then the battery may have been deep-discharged. It should be left on-charge on an external charger for 24 hours to bring the battery out of this state.</p>
<p>Note</p> 	<p>Users are reminded that the Tempus (when using its external power supply) should not be used to recharge batteries above 40°C – see “14.2 Physical characteristics and environmental specifications”.</p>

Charging the battery when attached to the Tempus Pro

When fitted to the Tempus Pro, the battery can be charged by connecting the power supply (part number 01-2049) to the connector on the right hand side of the Tempus.

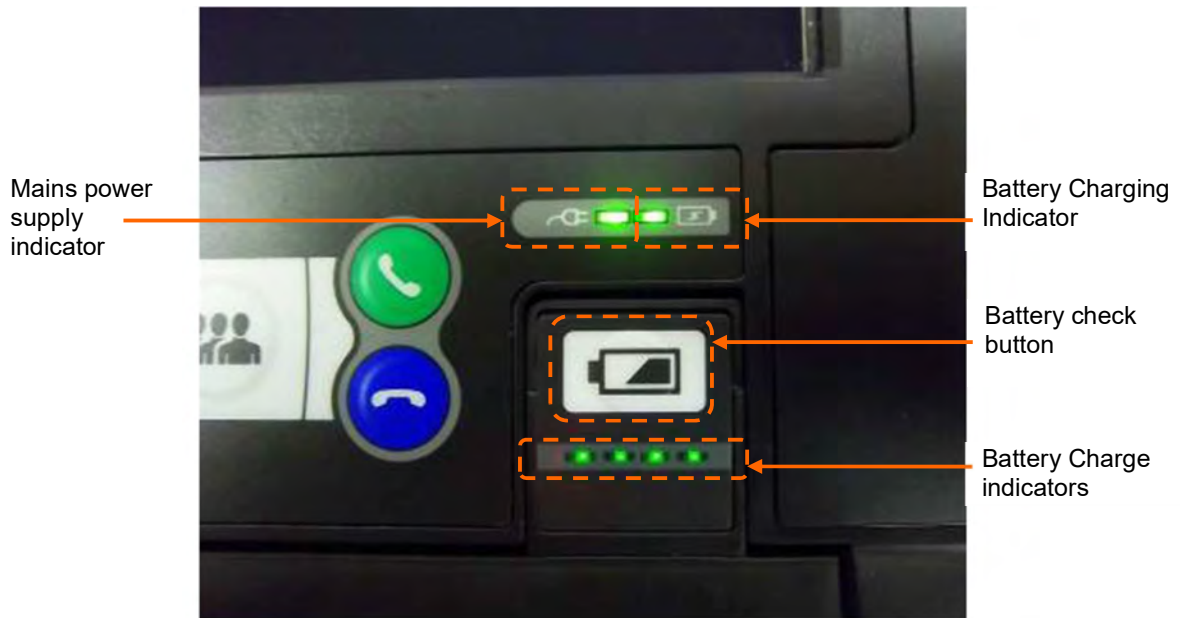





The PSU Plug Attached to the Tempus Pro Connector

<p>CAUTION</p> 	<p>If the Tempus is powered using the mains power supply, ensure the mains power supply is accessible so the mains lead can be disconnected in the event that the device needs to be isolated from mains power. The means of isolation of mains power is to disconnect the mains lead from the power supply.</p>
<p>CAUTION</p> 	<p>Where the integrity of the external protective conductor (earth) in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source.</p>
<p>Note</p> 	<p>Interruption of the supply mains for short periods e.g. 30 seconds, will not cause a problem, as the Tempus will automatically switch to battery power. In the event that a battery is not fitted (or is completely flat) the device will shut down immediately. In this case no patient data will be lost. If the device is restarted within 30 seconds it will resume with all patient settings unchanged. If power is resupplied after that it will resume as normal with default settings in place. In this case the user can switch back to monitoring the previous patient (and continue completing their record) as described in sections 4.3.3 and 9.3.4.</p>

When the power supply is attached to the Tempus Pro, the green power light on the Tempus Pro 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.



CAUTION 	<p>When the battery is low it should be recharged soon after use. Starting a Tempus on an empty battery or leaving batteries in a low or empty state for prolonged periods may put the battery into a deep-discharged state. In this state the battery LEDs will not light and the battery will require a prolonged period on charge in order to return it to normal operation.</p>
CAUTION 	<p>If none of the LEDs light, then the battery may have been deep-discharged. It should be left on-charge attached to a battery charger (separate from the Tempus) for 24 hours to bring the battery out of this state.</p>
Note 	<p>Charge times of the battery will vary depending on the how the Tempus Pro is being used. If the Tempus is switched off charging will be faster than if the Tempus is on and all features are being used. Charging a completely empty battery will take 6 hours when the Tempus Pro is switched off.</p>

Using the battery charger

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






The Battery Connector Attached to the Battery

Clip the charger to the battery (the clip only attaches in one way).

Attach the charger to the main supply.

The LED on the charger 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.

<p>CAUTION</p> 	<p>When the battery is low it should be recharged soon after use. Starting a Tempus on an empty battery or leaving batteries in a low or empty state for prolonged periods may put the battery into a deep-discharged state. In this state the battery LEDs will not light and the battery will require a prolonged period on charge in order to return it to normal operation.</p>
<p>CAUTION</p> 	<p>If none of the LEDs light, then the battery may have been deep-discharged. It should be left on-charge attached to a battery charger (separate from the Tempus) for 24 hours to bring the battery out of this state.</p>

<p>Note</p> 	<p>Battery charger is rated at 100-240 V 50-60 Hz 0.9 A.</p> <p>Recharging the battery takes up to 6 hours for a fully discharged battery. Charging to 90% capacity takes 5 hours.</p>
--	--

11.2 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.

11.2.1 Charging the headset



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

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

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

Placing the headset onto the docking pin enables the Tempus Pro to recharge it. The Tempus Pro recharges the headset for up to 9 hours (approx.) every time the headset is replaced. The charging cycle will continue regardless if the Tempus Pro is switched on or off. Charging is started as soon as the headset is fitted to the docking pin. The indicator light on the headset will light red for the duration of the charging process. Once the headset is charged its LED will flash blue every 5 seconds. The indicator lights will go off when charge cycle is complete (9 hours).

In addition, the Tempus Pro will top up the charge of the headset approximately every 97 days. This occurs when the Tempus is switched off and lasts for up to 9 hours (approximately).

<p>CAUTION</p> 	<p>Always maintain a level of at least 10% in the Tempus battery. Leaving the Tempus battery in a low charge state can risk it being depleted by the headset charging process.</p>
<p>CAUTION</p> 	<p>Do not attempt to charge the headset using any other charging device. This will automatically suspend the warranty and could be dangerous.</p>

11.2.2 General guidelines for safe use

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

Do not expose the headset to liquid or moisture. Unlike the Tempus, the headset has no protection against ingress of solids or liquids.

Do not expose your headset to extreme temperatures. The temperature range of the headset is 10-40 °C.

Do not try to disassembly your headset. Service and Maintenance can only be performed by RDT.

Do not let children play with the headset since it contains small parts that could become detached and create a choking hazard.

WARNING



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

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.

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

11.2.3 Disposal of batteries

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

Note



In most countries, it is illegal to dispose of used batteries in residual waste (landfill). Users are required to dispose of used batteries through the proper channels, for example through not-for-profit organisations mandated by local governments.

11.3 Daily checks

RDT recommends that the following daily checks are performed on the Tempus, its cables and accessories:

- Ensure they are clean (with no fluid spills) and free of visible damage. Clean and replace as required.
- Check for signs of damage, excessive wear (cuts in insulation, fraying, broken wires, dirty or bent connector pins). Replace if damaged.
- Ensure that the device is equipped with appropriate quantities of all disposable supplies (e.g. ECG monitoring electrodes etc.).
- Ensure that any accessories or consumables are within the shelf life printed on their packages.
- Ensure that the internal printer (if fitted) contains sufficient paper for at least one day's use.
- Verify that a charged battery is fully inserted into the Tempus.
- Ideally ensure that a fully charged spare battery is available.
- Ensure the Tempus powers on and that all controls (as described in section 5.1) operate as described.

11.4 Weekly checks

RDT recommends that the following weekly checks are performed on the Tempus:

CAUTION



To prevent battery failure, perform this check every week when the Tempus Pro is in use.

- Remove the battery from the Tempus Pro and inspect its contacts. If contacts are damaged, replace the battery. If contacts are dirty, clean them - see "1.1.6 Cleaning the battery contacts".
- Perform a test print.

11.5 Troubleshooting

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

12 Accessories list of the Tempus Pro

12.1 Parts list

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

12.1.1 Temperature accessories

Product name & description	Part number
YSI-400 Series Reusable 401AC ContactTemp Probe Autoclavable	01-2153
YSI-400 Series Disposable 4492 12hr Contact Temp Probe	01-2078
YSI-400 Series 4940 Contact Temperature Adaptor Cable	01-2079

12.1.2 Invasive pressure accessories

Product name & description	Part number
<i>Part numbers 01-2048 and 01-2052 connect directly to the Tempus Pro:</i>	
Invasive Pressure Adaptor 2 Channel - Utah Deltran 8 ft	01-2048
Invasive Pressure Cable 2 Channel - Edwards TruWave 8ft	01-2052
<i>Part number 01-2113 and the Fogg adapter cables connect to the Tempus Pro only via the universal cable (part number 01-2108). Part number 01-2108 accepts up to two adaptor cables for two IBP channels:</i>	
Tempus Pro 2-Channel Invasive Pressure Universal Cable	01-2108
Transpac & Art-Line Transducer Adaptor Cable	01-2113
2 Channel Invasive Pressure Module	01-2017

The following invasive pressure transducers are approved for use with the Tempus Pro:

Transducer manufacturer	Transducer model	Adaptor cable
ICU Medical (Abbott)	Transpac IV or IT	RDT P/N: 01-2113
Biometrix	Art-Line	RDT P/N: 01-2113
Smiths-Medical (Medex)	TranStar	RDT P/N: 01-2113
Smiths-Medical (Medex)	LogiCal	Fogg P/N: 0386-2516:L16
Merit Medical (Argon Medical / BD)	Meritrans / DTXPlus	Fogg P/N: 0444-2516:L16
Codan PVB (ITL Healthcare)	Xtrans (DPT 9000)	Fogg P/N: 0461-2516:L16
Codan PVB (ITL Healthcare)	DPT-6000	Fogg P/N: 0460-2516:L16

Transducer manufacturer	Transducer model	Adaptor cable
Utah Medical	Deltran	Fogg P/N: 0412-2516:L16
Biosensors International	Biotrans	Fogg P/N: 0412-2516:L16
Biosensors International	Accutrans	Fogg P/N: 0412-2516:L16
Edwards Lifesciences (Baxter)	TruWave	Fogg P/N: 0395-2516:L16
Fluke Biomedical	ProSim 8 Vital Signs Simulator	Fogg P/N: 0450-2516:L16

12.1.3 Non-invasive blood pressure accessories

Product name & description	Part number
Tempus Blood Pressure Cuff – adult cuff (23 – 33 cm)	01-1002
Tempus Blood Pressure Cuff – large adult cuff (31 – 40 cm)	01-1003
Tempus Blood Pressure Cuff – child cuff (12 – 19 cm)	01-1004
Tempus Blood Pressure Cuff – small adult cuff (17-25cm)	01-2119
Tempus Blood Pressure Cuff – infant (8 - 13 cm)	01-2021
Tempus Blood Pressure Cuff – adult thigh cuff (38 – 50 cm)	01-1032
Tempus Neonate Patient Hose Adaptor CPC/Luer	01-2067
Tempus Blood Pressure Cuff – neonate cuff (3 – 6 cm) Single Use (Box of 20)	01-2030
Tempus Blood Pressure Cuff – neonate cuff (4 – 8 cm) Single Use (Box of 20)	01-2031
Tempus Blood Pressure Cuff – neonate cuff (6 – 11 cm) Single Use (Box of 20)	01-2032
Tempus Blood Pressure Cuff – neonate cuff (7 – 13 cm) Single Use (Box of 20)	01-2033
Tempus Blood Pressure Cuff – neonate cuff (8 – 15 cm) Single Use (Box of 20)	01-2034
Tempus Blood Pressure Hose 4ft	01-1006
Tempus Pro NIBP Cuff Kit (adult, large adult, thigh and child cuffs)	01-2155
Tempus Pro Blood Pressure Hose 8ft	01-2074
NIBP Infant Disposable Cuff (Box of 20)	01-2230
NIBP Child Disposable Cuff (Box of 20)	01-2231
NIBP Small Adult Disposable Cuff (Box of 20)	01-2232
NIBP Adult Disposable Cuff (Box of 20)	01-2233
NIBP Large Adult Disposable Cuff (Box of 20)	01-2234
NIBP Thigh Disposable Cuff (Box of 20)	01-2235

12.1.4 Masimo accessories

Product name & description	Part number
MasimoSET Rainbow cables	
MasimoSET Rainbow Patient Cable 12 ft 25-Pin R/A RC12 RA	01-2138
MasimoSET Rainbow Patient Cable 4ft 25-Pin R/A RC4 RA	01-2088
Masimo Rainbow DCI	
Masimo Rainbow DCI Adt 3ft (SpO2, SpCO, SpMet) [1] - Clip	01-2086
Masimo Rainbow DCI SC-400 Adt 3ft (SpO2, SpHb, SpMET) [1] - Clip	01-2092

Product name & description	Part number
Masimo Rainbow DCIP	
Masimo Rainbow DCIP SC-400 Ped 3ft (SpO2, SPCO, SpMet)[1] - Clip	01-2136
Masimo Rainbow DCIP Ped 3ft (SpO2, SpCO, SpMet) [1] - Clip	01-2137
Masimo Rainbow R1	
Masimo Rainbow R1 25 Adt 1ft (SpO2, SpHb, SpMET) [10] - Adh	01-2128
Masimo Rainbow R1 20 Ped 1ft (SpO2, SpHb, SpMET) [10] - Adh	01-2129
Masimo Rainbow R1 20L Inf 1ft (SpO2, SpHb, SpMET) [10] - Adh	01-2130
Masimo Rainbow R1 25L Neo/Adt 1ft (SpO2, SpHb, SpMET) [10] - Adh	01-2131
Masimo Rainbow R20	
Masimo Rainbow R20 Ped 1ft (SpO2, SpCO, SpMET) [10] - Adh	01-2133
Masimo Rainbow R20-L Inf 1ft (SpO2, SpCO, SpMET) [10] - Adh	01-2134
Masimo Rainbow R25	
Masimo Rainbow R25 Adt 1ft (SpO2, SpCO, SpMET) [10] - Adh	01-2132
Masimo Rainbow R25-L Neo/Adt 1ft (SpO2, SpCO, SpMET) [10] - Adh	01-2135
MasimoSET M-LNCS	
MasimoSET M-LNCS DBI Adt SpO2 Reusable Sensor [1] - Boot	01-2089
MasimoSET® M-LNCS Adtx-3 Adult Sensor (20 box)	01-2090
MasimoSET® M-LNCS Neo-3 Neonatal/Adult Sensor (20 box)	01-2091
MasimoSET M-LNCS Pdtx-3 Ped 3ft [20] - Adh	01-2095
MasimoSET M-LNCS DCI Adt 3ft [1] - Clip	01-2123
MasimoSET M-LNCS DCIP Ped 3ft [1] - Clip	01-2124
MasimoSET M-LNCS INF-3 Inf 3ft [20] - Adh	01-2126
MasimoSET M-LNCS NEOPT-3 Neo 3ft [20] - Adh	01-2127
MasimoSET Rainbow Sample Pk (All M-LNCS-Adtx-3, pdtx-3, Neo-3)	01-2140
Masimo E1 (Adult Single Use Ear Sensor)	01-2205

12.1.5 Masimo Rainbow field upgrades

Product name & description	Part number
Masimo Rbow Total Haemoglobin (SpHb+SpOC) Field License Kit	01-2328
Masimo Rbow Methaemoglobin (SpMet) Field License Kit	01-2329
Masimo Rbow Carboxyhaemoglobin (SpCO) Field License Kit	01-2330
Masimo Rbow Pleth Variability Index (PVI) Field License Kit	01-2331

12.1.6 Ultrasound accessories

Product name & description	Part number
Tempus Pro USB 3.5 MHz General Abdominal Ultrasound Probe (GP)	01-2008
Tempus Pro USB 7.5 MHz Vascular Ultrasound Probe (LP)	01-2042

12.1.7 Video laryngoscope accessories

Product name & description	Part number
Tempus Pro USB C-MAC S Imager Video Laryngoscope	01-2044
Video Laryngoscope Single Use D blade (pack of 10)	01-2063
Video Laryngoscope Single Use Size 3 Macintosh blade (pack of 10)	01-2010
Video Laryngoscope Single Use Size 4 Macintosh blade (pack of 10)	01-2011

12.1.8 Capnometer accessories

Product name & description	Part number
Smart CapnoLine Plus Adult/Intermediate 02 25UN (P/N 015018)	01-2143
Smart CapnoLine Pediatric 02 25units (P/N 015027)	01-2144
VitaLine H Set Adult/Pediatric 25units (P/N 015026)	01-2145
FilterLine H Set Adult/Pediatric 25units (P/N 015016)	01-2146
FilterLine Set Adult/Pediatric 25units (P/N 015021)	01-2147
FilterLine H Set Infant/Neonates 25units (P/N 015028)	01-2148
Filter Set ADU/PED 25UN	01-2150
Smart CapnoLine Plus Adult/Intermediate 02 25UN (P/N009822)	01-2151
Smart CapnoLine 02 PED 25UN	01-2247
Smart CapnoLine Pediatric 02 25units (P/N007269)	01-2248
VitaLine H Set Adult/Pediatric 25units (P/N010787)	01-2249
FilterLine H Set Adult/Pediatric 25units (P/NXS04624)	01-2250
FilterLine H Set Infant/Neonates 25 units (P/N006324)	01-2252

12.1.9 Electrocardiogram accessories

Product name & description	Part number
Tempus Pro 3-Lead ECG Cable (AAMI) 8 ft	01-2068
Tempus Pro 5-Lead ECG Cable (AAMI) 8 ft	01-2069
Tempus Pro 12 Lead ECG Cable (AAMI) 8 ft	01-2070
Tempus Pro 5-Lead ECG Cable (AAMI) 10ft.	01-2084
Tempus Pro 3-Lead Neonatal ECG Cable (AAMI) 6ft	01-2203
Tempus Pro 4-Lead ECG Modular Trunk Cable (AAMI) 8 ft	01-2177
Tempus Pro 6-Lead ECG Limb Leads for Modular Cable (AAMI)	01-2179
Tempus Pro 12-Lead (4+6) ECG Modular Cable (AAMI) 8 ft	01-2182
Tempus Pro 3-Lead ECG Cable (IEC) 8 ft	01-2071
Tempus Pro 5-Lead ECG Cable (IEC) 8 ft	01-2072
Tempus Pro 12 Lead ECG Cable (IEC) 8 ft	01-2073
Tempus Pro 3-Lead Neonatal ECG Cable (IEC) 6ft	01-2202
Tempus Pro 4-Lead ECG Modular Cable (IEC) 8 ft	01-2181
Tempus Pro 6-Lead ECG Limb Leads for Modular Cable (IEC)	01-2183

Product name & description	Part number
Tempus Pro 12-Lead (4+6) ECG Modular Cable (IEC) 8 ft	01-2178
Ambu BlueSensor 'T' Adult Foam ECG Electrode - 10 Pack	01-2080
Ambu BlueSensor R 25units (P/N 1559024)	01-2152

12.1.10 Power and charging accessories

Product name & description	Part number
Tempus Lithium-ion Battery – one supplied with unit	01-2051
Tempus Mains Power Supply (PSU) – one supplied with unit	01-2049
<i>When ordering a PSU, select the mains cable for the country of operation:</i>	
• Switzerland	01-2058
• UK	01-2056
• Euro/Schuko	01-2057
• USA	01-2055
• Australia	01-2060
• Nigeria (as per UK)	01-2056
• Israel	01-2062
• South Africa	01-2054
Tempus Battery Charger (including 2-core figure 8 mains cable)	01-1012
<i>When ordering a battery charger, select the mains cable for the country of operation:</i>	
• Switzerland	01-2059
• UK	01-2159
• Euro/Schuko	01-2160
• USA	01-2161
• Australia	01-2061
• Nigeria (as per UK)	01-2159
• Israel	01-2160
• South Africa	01-2162
Tempus DC Vehicle Power Supply	01-2053

12.1.11 Tempus Pro ReachBak real-time telemedicine accessories

Product name & description	Part number
Sennheiser Presence Bluetooth® Headset (Tempus Pro Kit)	01-2254
Tempus Wired Headset	01-1019
Tempus Ethernet Cable	01-2025
Tempus Pro Tactical Headset Adaptor Cable	01-2041

12.1.12 Miscellaneous accessories

Product name & description	Part number
Tempus Pro Litter Mount	01-2035
Tempus Pro Hard Transit Case	01-2400
Tempus Soft Transit Bag	01-2037
Tempus to Tempus USB Data Cable	01-2243

Product name & description	Part number
Tempus Pro SMART mount (order PSU and power cable separately)	01-2244
Tempus Pro Printer paper blank 100mm (1x roll)	01-2184
Tempus Pro Printer paper with grid 100mm (1x roll)	01-2186
Tempus Pro shoulder strap (with locking mech) and 20G fixings kit	01-2197
Tempus Pro shoulder strap only (with locking mech)	01-2200
Tempus Pro Left Pouch with partition (medical side)	01-2241

12.1.13 Anaesthetic gas monitoring accessories

Product name & description	Part number
ISA OR+ sidestream Analyser	01-2167
Tempus to ISA OR+ adaptor cable	01-2168
Nomoline 2.0m (Box of 25) Sampling line with male luer lock connector, single-patient use, Adult/Pediatric/Infant. Requires T adaptor	01-2169
Nomoline Adapter 0.1m (Box of 25) Sampling line with female luer lock connector. Adult/Pediatric/Infant. Requires Nomo Extension and T adaptor	01-2170
Nomoline Airway Adapter Set 2.0m (Box of 20) Sampling line with straight airway adapter, single-patient use, Adult/Pediatric	01-2171
Nomo Extension 2.0m (Box of 25) Sampling line with male luer lock connector	01-2172
Nomo Extension 3.0m (Box of 25) Sampling line with male luer lock connector	01-2173
T-adaptor (Box of 25) Airway adapter with female luer lock connector, Adult/Pediatric	01-2174
AA gas exhaust port kit (Masimo #4409)	01-2255
ISA OR+ Ferno Mount Bracket	01-2258

12.1.14 Corsium Crew accessories

Product name & description	Part number
Extended Display Tablet Cable (USB-A to USB-C)	01-2252

12.1.15 Manuals and software accessories

Product name & description	Part number
Tempus Pro User Manual Set (CD-ROM) – includes Configuration Utility software	43-2001
Tempus Pro Maintenance Manual CD-ROM)	43-2003

13 Configuring the Tempus Pro

For information on configuring communications settings and pairing Bluetooth® peripherals, see the *Tempus Pro Maintenance Manual*.

13.1 Demonstration and training

The Tempus can be set so that it can be used in a training environment. Once set for this purpose, the Tempus can simulate:

- All medical readings including ECG monitoring and recording - – in this case the readings are randomly generated by the Tempus regardless of whether a patient is connected or not;
- All other features such as the transmission of photos, videos, GPS positioning etc. – in this case the readings are randomly generated by the Tempus;
- Data and voice connections – where the device simulates the appearance of a connection even when none has been made.

WARNING



Training and demonstration features are only for use in non-clinical settings i.e. training environments. Activation of these features in clinical settings could lead to confusion of the patient's real vital signs.

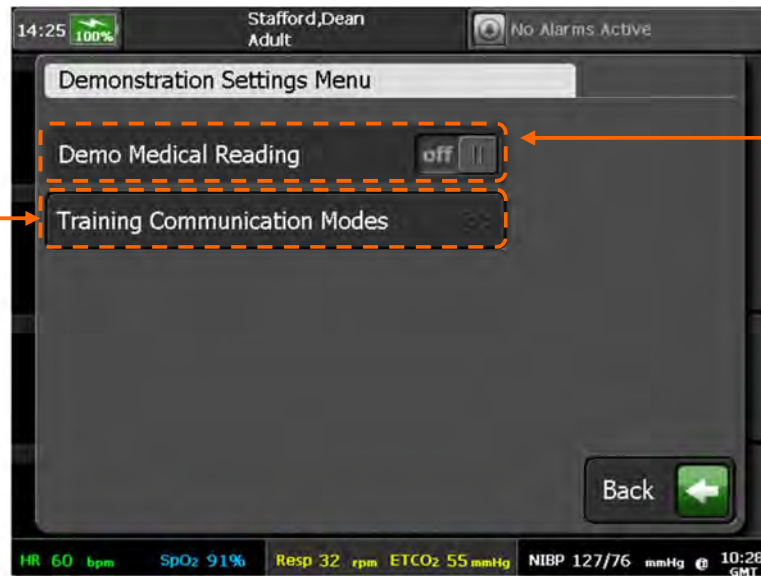
From the Main Menu, press Demonstration and Training button - the Tempus will display a caution.



Demonstration and Training Caution

Clearing this message brings up the Demonstration and Training menu.

Pressing here brings up the Training Modes Menu. This gives a range of communication modes for use in training, in which the Tempus simulates a full data and voice connection but does not require any real equipment to connect to



Pressing here turns ALL the medical and non-medical readings to demo mode – all readings will be simulated

Demonstration and Training Menu

If the Tempus is set to operate in Demonstration Mode, there will be a label “Demo” placed on the home screen and on the 12 Lead ECG recording screen (where the 50/60Hz mains filter buttons would normally be).

If the Tempus is put into a Training Communications Mode, this will be indicated by the word “Training” to the left of the iAssist connection process instruction.

In either case, the Tempus can be put back into normal operational mode by returning to the Demonstration and Training Menu and resetting Demo Mode to “Off”. The correct communications mode can be reset by accessing the Communications Mode Menu from the Main Menu.

WARNING




If a Tempus is set into either Demonstration or Training mode, it will remain set in this way after the power has been cycled and after a new patient has been admitted.

14 Specifications and standards

14.1 Specifications

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

14.1.1 ECG monitoring

	<p>These specifications relate to the performance of the product when it is configured to display only one or two ECG waveforms, for example when the default home screen is selected.</p>
---	--

Regulatory standard	Meets ANSI/AAMI EC13:2007 & IEC60601-2-25:2011
Cable	For use with RDT's proprietary 3-, 4-, 5- and 12-lead cables with 4mm snap disposable electrodes
Gain/Sensitivity	2, 4, 5, 10 (default), 1, 20, 30 & 50 mm/mV (scale 8:10)
Input Range	±5 mV
Input Impedance	>100 MΩ
DC Offset	±300 mVdc
Time bases	12.5, 25, 50 mm/s
Aspect ratio range	5:50 – 20:12.5 (mm/mV : mm/s) (scale 8:10)
Heart rate detection range	30 – 300 bpm
Accuracy	±3%
Acquisition sample rate	500 Hz
Monitoring bandwidth	0.5 Hz – 35 Hz : Monitor 0.05 Hz – 150 Hz : Diagnostic 0.05 Hz – 35 Hz: Filtered diagnostic
Frequency response	0.05 to 175 Hz ±3 dB
Defibrillator protection	Patient leads are isolated from system and operator, with 5kV protection
Electrosurgery protection	Protected
Common Mode Rejection	95 dB
Leads Off Indicators	Connection status for each lead is shown on acquisition screen
Permanent Filters	High Pass: 0.05 Hz 1st order

	Low Pass: 150 Hz 1st order Baseline Wander: Baseline reset by adaptive zeroing algorithm
Notch filter (Mains Noise Rejection)	50 Hz 4th order Butterworth, 49.1Hz - 50.9 Hz, 60 Hz 4th order Butterworth, 59.1 Hz - 60.9 Hz
Low pass (Muscle Artifact Filter)	35 Hz 4th order
ST measurement range	-10 mm to 10 mm (-1 to 1 mV)
ST accuracy	±0.53 mm (±53 µV)
ST resolution	0.1 mm
ST measurement definition	J+80 ms (for heart rates < 115 bpm) J+60 ms (for heart rates > 115 bpm) ISO electric line taken from PQ segment
QT measurement range	10 ms - 1990 ms
QT accuracy	±25 ms mean 30 ms standard deviation
QT resolution	1 ms
Compliance	IEC60601-2-25:2011 AAMI EC57

14.1.2 12-lead diagnostic ECG viewing and recording



These specifications relate to the performance of the product when it is configured to display and record the 12 lead diagnostic ECG view.

Regulatory standard	Meets ANSI/AAMI EC11:1991 inc R:2001 & IEC60601-2-27:2011
Cable	For use with RDT's proprietary 12 lead (10 wire) cable with 4mm snap disposable electrodes
Gain/Sensitivity	2, 4, 5, 10 (default), 1, 20, 30 & 50 mm/mV
Input Range	±5 mV
Input Impedance	>100 MΩ
DC Offset	±300 mVdc
Acquisition sample rate	500 Hz
Diagnostic bandwidth	0.05 Hz – 40 Hz : Filtered diagnostic 0.05 Hz – 175 Hz : Diagnostic Note ECG tested at 150 Hz per EC11 and with a 175 Hz 3dB bandwidth measurement.
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
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, 49.1Hz - 50.9 Hz, 60 Hz 4th order Butterworth, 59.1 Hz - 60.9 Hz
Low pass (Muscle Artifact Filter)	35 Hz 4th order

14.1.3 Impedance pneumography (respiration)

Range:	30-150 rpm
Accuracy	± 2 rpm or $\pm 2\%$ whichever is greater
Excitation current	$< 20 \mu\text{A}$
Excitation frequency	56 kHz
Measurement Leads available	Lead I & Lead II

14.1.4 ETCO₂ sensor

The Capnometer is automatically compensated for local atmospheric pressure.

CO ₂ Units	mmHg or kPa
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) Note  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 71-120 bpm: ±2 bpm 121-149 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	Annual performance verification may be performed if required and calibration then performed if the system requires. Calibration required after 4000 hours' usage of the Capnometer.

14.1.5 Non-invasive blood pressure

Range:	Adult Systolic 40 - 260 mmHg
	Paediatric Systolic 40-230 mmHg
	Neonate Systolic 40-130 mmHg
	Adult Diastolic 20 - 200 mmHg
	Paediatric Diastolic 20-160 mmHg
	Neonate Diastolic 20-100 mmHg
	Adult MAP 26 - 220 mmHg
	Paediatric MAP 26-183 mmHg
	Neonate MAP 26-110 mmHg
Accuracy:	± 3 mmHg
Resolution:	1 mmHg
Pulse rate range:	30-220 bpm ± 2% or ±3 bpm (whichever is greater)
Maximum inflation:	300 mmHg (150 mmHg neonate)

Initial inflation pressure:	160 mmHg adult, 140 mmHg paediatric, 90 mmHg neonate
Method:	Oscillometric, diastolic values correspond to Phase 5 Korotkoff sounds

14.1.6 Invasive pressure

Channels	up to 4 (2 as standard)
Sensitivity	5 μ V/V/mmHg
Bridge	180 Ω minimum
Response	0-20 Hz (-3 dB)
Filters	50-60 Hz notch
Range:	-99 – 310 mmHg
Accuracy:	\pm 2% or \pm 2 digits including RDT's adaptor cable but excluding the transducer
Resolution:	1 mmHg
Warm up time	10 seconds

14.1.7 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 \leq 3 digits, motion \leq 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 \pm 2 digits 70-100%, motion \pm 3 digits 70-100% Accuracy (neonate): motion, no motion and low perfusion \pm 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%
Response	<1 second delay
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 (other probe types are available from Masimo®)

SpO₂ was determined by testing on healthy adult volunteers in the range 60%-100% SpO₂ against a laboratory CO-Oximeter. SpO₂ 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 kg. Seventy-nine (79) data samples were collected over a range of 70 - 100% SaO₂ with a resultant accuracy of 2.9% SpO₂.

The arterial oxygen saturation accuracy during no motion only applies to LNOP® Blue SpO₂ 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% SpO₂ 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 was 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% SpO₂ 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.

14.1.8 Masimo Set rainbow

Carboxyhemoglobin (SpCO)	
Measurement Range:	0 – 99%
Accuracy (Adults/Paediatrics/Infants):	1 – 40% ± 3%
Resolution:	1%
Alarm:	1-98%
Methaemoglobin saturation (SpMet)	
Measurement Range:	0 – 99.9%
Accuracy (Adults/Paediatrics/Infants/Neonates):	1 – 15% ± 1%
Resolution:	0.1%
Alarm:	1-99.5%
Total haemoglobin concentration (SpHb)	
Measurement Range:	0 – 25 g/dL
Accuracy (Adults/Paediatrics):	8 – 17 g/dL ±1 g/dL (arterial or venous)
Resolution:	0.1 g/dL
Alarm:	1-24.5 g/dL
Total oxygen content (SpOC)	
Measurement Range:	0 – 35ml of O ₂ /dL of blood

SpO₂, SpCO, and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60% - 100% SpO₂, 0% - 40% SpCO, and 0% - 15% SpMet against a laboratory CO-Oximeter. SpO₂ and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO₂ and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO₂ and 0.9% SpMet.

The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO₂ 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.

The 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 0.2% and 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.

The 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.

SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8-17 g/dl SpHb against a laboratory CO-oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

The following substances may interfere with pulse CO-Oximetry measurements:


- Elevated levels of Methaemoglobin (MetHb) may lead to inaccurate SpO₂ and SpCO measurements
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO₂ measurements
- Very low arterial Oxygen Saturation (SpO₂) levels may cause inaccurate SpCO and SpMet measurements
- Severe anaemia may cause erroneous SpO₂ readings

- Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Elevated levels of total bilirubin may lead to inaccurate SpO₂, SpMet, SpCO and SpHb readings.

14.1.9 Contact temperature

Channels	2 (first standard, second is optional)
Compatibility:	YSI series 400
Measurement range:	20-45 °C / 68-113 °F
Accuracy:	±0.1 °C / ±0.2 °F
Resolution:	±0.1 °C / ±0.2 °F
Measurement time	<10 seconds

14.2 Physical characteristics and environmental specifications

Size and weight – non-printer model:	<p>Standalone size and weight of Tempus Pro part number 00-1004-R with its battery and RapidPak clip but without external cables, sensors or accessories:</p> <p>263 mm (10.3") x 216 mm (8.5") high x 100 mm (3.9") (width x height x depth)</p> <p>2.9 kg (6.4 lb) nominal</p> <p>The non-printer model with a Bluetooth headset is slightly heavier (part number 00-1007-R).</p>
Size and weight – printer model:	<p>Standalone size and weight of Tempus Pro part number 00-1026-R with its battery and printer but without external cables, sensors or accessories:</p> <p>263 mm (10.3 ") x 216 mm (8.5 ") x 102 mm (4 ") (width x height x depth)</p> <p>3.2 kg (7 lb) nominal</p> <p>Printer models without invasive pressure are slightly lighter (part number 00-1024-R).</p>
Altitude:	<p>-200 to 5486 m (-656 to 18000 ft)</p> <p>(can be used at higher physical altitudes provided the local atmosphere is no higher than 5486 m, e.g. in a pressurised aircraft cabin)</p> <p>Note</p> <p> The power supply's altitude rating must be adhered to. Do not use the power supply outside of its specifications.</p>
Relative humidity:	15%-95% (non-condensing)
Operating temperature range:	<p>0° C to 50° C all functions, 0° C to 40° C charging</p> <p>Short term operating low -20 °C for 60 mins after being stored at room temperature</p>
Transport/Storage temperature range:	-37° C to +73.3° C
Transport/Storage pressure range:	<p>-200 to 5486 m (-656 to 18000 ft)</p> <p>104 kPa to 53 kPa</p>
Start-up time in normal use	Time for switching on or starting until the equipment is ready for normal use: 42 seconds
Start-up time from storage	<p>Time required for the equipment to warm from the minimum storage temperature between uses until the equipment is ready for intended use at 20°C: 180 minutes</p> <p>Time required for the equipment to cool from the maximum storage temperature between uses until the equipment is ready for its intended use at 20°C: 180 minutes</p>

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 objects (the first numeral) and water (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 means the device is protected against the ingress of 100 l/m of water "jetting" at the device from 2.5 to 3 m.

14.2.1 Environmental performance and certification

Drop	1 m drop per IEC60601-1
Transit Drop	1.22 m (4 ft) MIL 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 steel ball from 1.3 m as per IEC60601 including the display

Temperature & altitude:

Category:	A1
Test Standard,	Temperature, RTCA/DO-160E Section 4, Para 4.5.1 to 4.5.4
Test Standard, Altitude,	RTCA/DO-160E Section 4, Para 4.6.1 and 4.6.2
Temperature:	Operating: 0 °C to +50 °C Storage: -37 °C to +73.3 °C Short Term High: +50 °C
Rapid Decompression:	2438 m to 5486 m (8,000 ft to 18000 ft) in 15 seconds

Temperature variation:

Test Standard:	RTCA/DO-160E Section 5 Cat C
Rate of Variation:	2 °C per minute.

Humidity:

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

Operational shocks & crash safety:

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

Vibration:

Test Standard: Test Standard: MIL-STD-810G rotary, fixed wing (jet and turboprop profile)

Explosion proofness:

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

Water proofness:

Not tested to RTCA/DO-160G Section 10
Commercial qualification:

Fluids susceptibility:

Not applicable.

Sand & dust:

Commercial qualification: IP66 (dust ingress under pressure) – whole device (excluding internal printer, which is IP43)

Fungus resistance:

Not applicable.

Salt spray:

Not applicable.

Magnetic effect:

Not applicable.

Power input:

Not tested to RTCA/DO-160E Section 16.

Commercial qualification:	EN61000-3-2:2006 inc A1/A2:2009 Mains harmonics
	EN61000-3-3:2008 Mains flicker
	EN61000-4-11:2004 voltage dips and interruptions

Voltage spike:

Not tested to RTCA/DO-160G Section 17.
Commercial qualification: IEC61000-4-4:2012 Fast transient bursts

Audio frequency conducted susceptibility – power inputs:

Not tested to RTCA/DO-160G Section 18.
Commercial qualification: IEC61000-4-5:2006 Surges

Induced signal susceptibility:

Not tested to RTCA/DO-160G Section 19.
Commercial qualification: IEC61000-4-6:2013 Conducted RF field

Radio frequency susceptibility (radiated & conducted):

Not tested to RTCA/DO-160G Section 20.
Commercial qualification: IEC61000-4-3:2006 inc A2:2010 Radiated RF Interference

Emission of radio frequency energy:

Test Standard: RTCA/DO-160G Section 21 Cat M.

Lightning induced transient susceptibility:

Not applicable.

Lightning direct effects:

Not applicable.

Icing:

Not applicable.

ESD:

Not tested to RTCA/DO-160G Section 25.


Commercial qualification: IEC61000-4-2:2008 ESD




Fire and smoke hazards:

Main case material:	PC-ABS
Flame:	UL94V-0
Overmould material:	TPU (*)

(*) Contains 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol.

14.2.2 Use in high ambient temperatures

CAUTION 	<p>Since the Tempus is rated for use in high ambient temperatures, users are reminded to give consideration to the potential for outer surfaces of the Tempus 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.</p>
---	--

Note 	<p>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.</p>
Note 	<p>Users are reminded that the Tempus (when using its external power supply) should not be used to recharge batteries above 40°C – see “14.2 Physical characteristics and environmental specifications”.</p>
Note 	<p>Users are reminded that the specification of the power supply limits its use to 40°C maximum – see “14.3 Miscellaneous features and specifications”.</p>

14.3 Miscellaneous features and specifications

14.3.1 Invasive pressure USB module 01-2017 (optional)

Channels	2
Sensitivity	5 μ V/V/mmHg
Bridge	180 Ω minimum
Response	0-20 Hz (-3 dB)
Filters	50/100/150 Hz & 50-60 Hz notch
Range:	-99 – 310 mmHg
Accuracy:	\pm 2% or \pm 2 digits including RDT's adaptor cable but excluding the transducer
Resolution:	1 mmHg
Warm up time	10 seconds
Ingress protection	IP56
Size	108 mm x 63 mm x 36 mm
Weight	116g
EMC	IEC 60601-1-2:2014 Class B
Altitude:	-200 to 5486 m (-656 to 18000 ft)
	(can be used at higher physical altitudes provided the local atmosphere is no higher than 5486 m, e.g. in a pressurised aircraft cabin)
Relative humidity:	15%-95% (non-condensing)
Operating temperature range:	0° C to 40° C due to transducer specifications
Transport/Storage temperature range:	-37° C to +73.3° C
Transport/Storage pressure range:	-200 to 5486 m (-656 to 18000 ft); 104 kPa to 53 kPa
Drop	1 m drop per IEC60601-1
Transit Drop	1.22 m (4 ft) MIL 810G, 26 drops all corners, faces and edges with and without accessories connected (when not connected to the Tempus Pro)
Impact	500 g steel ball from 1.3 m as per IEC60601
Emission of radio Frequency energy:	RTCA/DO-160G Section 21 Cat M.
Temperature & Altitude:	
Category:	A1
Test Standard, Temperature,	RTCA/DO-160E Section 4, Para 4.5.1 to 4.5.4
Test Standard, Altitude,	RTCA/DO-160E Section 4, Para 4.6.1 and 4.6.2
Temperature:	Operating: 0 °C to +40 °C Storage: -37 °C to +73.3 °C
Rapid Decompression:	2438 m to 15545 m (8,000 ft to 51,000 ft) in 1 second

Temperature Variation:	
Test Standard:	RTCA/DO-160E Section 5 Cat C
Rate of Variation:	2 °C per minute.
Humidity:	
Test Standard:	RTCA/DO-160E Section 6 Cat A
Transport/Storage:	15 to 95% RH Non-condensing (tested for 48 hours at 38-50 °C)
Operating:	15 to 95% RH Non-condensing (tested at the end of the storage cycle)
Operational Shocks & Crash Safety:	
Test Standard:	RTCA/DO-160E Section 7 Cat B
Operational Shock:	Para 7.2 (6g for 11ms saw-tooth wave, repeated 3 times in all axis).
Crash Safety:	20g in all directions (sustained).
Vibration:	
Test Standard:	MIL-810-F rotary, fixed wing (jet and turboprop profile)
Main case material:	PC-ABS
Flame:	UL94V-0


14.3.2 Rechargeable battery


Battery life	At least 10¼ hours with display brightness at 60% (default), ECG, SpO ₂ , ETCO ₂ , IP x 2, temp x 2 and NIBP every 15 minutes.
	At least 11½ hours with display brightness at 30%, ECG, SpO ₂ , ETCO ₂ , IP x 2, temp x 2 and NIBP every 15 minutes.
	Up to 14 hours with battery saving mode activated (display at default 60% brightness) – typically 12½ hours with the display active 50% of the time.
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 x 42 x 62 mm max
Shelf life	Approximately 75% remaining after 1 year (before the charge indicator light turns to Amber)
Operating temperature	-20°C to +60°C


Note


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.

14.3.3 Mains power supply

Note 	Only the RDT mains power supply (part number 01-2049) can be used with the Tempus Pro.
--	--

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	133 x 60.7 x 41 mm (5.24" x 2.39" x 1.62")
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  The power supply's altitude rating of 4000m must be adhered to. Do not use the power supply outside of its specifications.

14.3.4 Battery charger

Note 	Only the RDT Battery Charger (part number 01-1012) can be used with the Tempus Pro.
--	---

Mains input voltage	100-240 V
Frequency	50-60 Hz
Input current	0.9 A max (at 100 V approx.)
Output voltage	8.4 V dc
Output current	<2.73 A
Charge time (from empty)	6 hours
Weight	0.25 kg nominal
Dimensions	107 x 67 x 36.5 mm

14.3.5 Vehicle power supply

Battery input voltage	11V dc – 27 Vdc
Input connector type	Cigar plug
Output voltage	12 Vdc \pm 5%
Output current max	6 A
Rated Power	72 W
Efficiency	>85%
Operating temperature range:	0° C to 40° C
Transport/Storage temperature range:	-20° C to +85° C
Weight	0.21 kg nominal
Dimensions	105 x 40 x 26.5 mm
Operational shock	10g
Non-operational shock	60g

14.3.6 GPS

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

14.3.7 Other features

Display	Colour 165 mm (6.5”) 640x480 pixels 130 klux daylight readable display
Printer (*)	High resolution 113 mm (4”) integrated thermal printer
Integral digital camera	Color 3.2M pixel camera Takes still pictures or video using the H264 algorithm (bandwidth dependent)

(*) Optional, additional feature

14.4 Communications

14.4.1 i2i ReachBak communications

When connecting to a Response Centre via i2i ReachBak, the Tempus has the following communications requirements:



Tempus Connection – all data AES encrypted: Ethernet; WiFi – WEP, WPA, WPA-2; Cell – 3G.

Database – all PHI AES 256 encrypted.

Tempus to Data Centre (Gateway)	Destination Port (FIPS 140-2 enabled)	Minimum data rate required		Response Centre to Data Centre (Gateway)	Destination Port (FIPS 140-2 enabled)	Minimum data rate required	
Medical Data (1)	TCP 2169	3 kbps	3 kbps	Medical Data (1)	TCP 52169	3 kbps	3 kbps
Waveforms (2)	UDP (SRTP) port 52508	6 kbps		Waveforms (2)	UDP (SRTP) port 52509	6 kbps	
Voice (VOIP) (3)	UDP (SRTP) 52505	12 kbps	12 kbps	Voice (VOIP) (3)	UDP (SRTP) 52511	12 kbps	12 kbps
Video (4)	UDP (SRTP) port 52506		40 kbps	Video (4)	UDP (SRTP) port 52507		40 kbps
Total (5)		21 kbps	55 kbps	Total (5)		21 kbps	55 kbps

Notes:

(1) Medical Data means heart rate, non-invasive blood pressure, SpO₂, ETCO₂, invasive pressure, respiration rate and temperature with still photos and 12 Lead ECG recordings transmitted on a store-and-forward basis and TCCC card data sent every 30 seconds.

(2) Waveforms means 1-2 channels of ECG, Plethysmogram and Capnogram and 1-2 channels of invasive pressure.

(3) VOIP - Speex codec .

(4) Video - H264 format CIF image transmitted at 5 frames per second - this provides a low-bandwidth video solution.

(5) Total rate is on a lossless data transfer; the bandwidth is likely to increase if data retry attempts are required due to packet loss on the network.

(6) The Data Centre application is installed on the first or primary PC to use the i2i application. The Data Centre application is simply installed (selected) during the i2i installation process. Ports will need to be opened on firewalls in and out of the DC and RC.

(7) A shared database is recommended between all RC installations. This requires a local wired network.

(8) Web access is optional and allows users with i2i installed on a PC (with internet access) to share the data elements of the real time display with other users via the web who don't have i2i. Web access is automatically terminated when the Tempus disconnects from the i2i.

I2i transmission rates

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

- 12 lead ECG – < 30 seconds
- Digital photographs – < 30 seconds

These times are for guidance only and are based on a typical Ethernet network. Times may vary depending on network equipment, configuration and usage.

14.4.2 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

14.4.3 WiFi specification

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

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 WiFi technology has the following features:

WiFi Specification	
The WiFi module has the following specifications:	
Range	~ 91 m (300 ft)
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

14.4.4 Integral 2G and 3G cell phone specification

The Cell Phone (GSM) technology used by the Tempus 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
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.

14.4.5 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:

Indoor Range	~ 9 m (30 ft) (typical office environment)
<i>Data Rate:</i>	V2.0 up to 1 Mb/s EDR: 2.3 Mb/s
Baseband Modulation	V2.0: GFSK EDR: Pi/4 DQPSK, 8DPSK

14.4.6 Bluetooth® headset specification

The Tempus Pro uses the Sennheiser® Presence or VMX200 wireless headset. This is unmodified by RDT and is provided under FCC part 15C and an Industry Canada License 2099D. Users are reminded to refer to the Sennheiser user guide (attached to the CD-ROM provided with the Tempus) that provides instructions for use of the headset. These include environmental performance specifications which may differ from those of the Tempus.

Description	General Specifications
Bluetooth® type	V4.0 class 1 (Presence) V3.0 class 2 (VMX200)
Range	10 m max in an open field
Transmission frequency	2402 – 2480 MHz
Bluetooth® Profiles	HSP, HFP, A2DP (Presence) HSP, HFP (VMX200)
Weight	13 g (Presence) 10 g (VMX200)
Size	51 x 19 x 23 mm (Presence) 55 x 26 x 58 mm (VMX200) (WxHxD)
Talk time	Up to 4 hours* (Presence) Up to 6 hours* (VMX200)
Stand by time	Up to 240 hours*
Operating temperature range	10 – 40 °C
Operating humidity range	20 – 85% non-condensing
Storage temperature range	-20 to +60 °C
Storage humidity range	10-95% non-condensing

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

14.4.7 Communications security specification

The Tempus Pro is (optionally) provided with Mocana Federal Information Processing Standard (FIPS) 140-2 cryptographic module. This provides US government certified encryption on the voice, data and video transmission.

The FIPS 140-2 encryption provided on the Tempus Pro is Level 1 as specified by the FIPS 140-2 standard.

14.4.8 FCC and Industry Canada compliance

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 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.

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.

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.

FCC compliance

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. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This device complies with Part 15 of the FCC rules. 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.

IC compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Industry Canada Standard ICES-003. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

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

14.5 Tempus Pro 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 Pro 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 are designated as Patient Applied Parts per IEC60601-1.
- The Tempus Pro 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) and with dust covers fitted or not fitted and with the battery mated or unmated.
- 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.

14.5.1 Standards compliance

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

Standard	Title
IEC 60601-1 3 rd edition	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2 4 th edition	Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6	Medical electrical equipment -- Part 1-6: General requirements for safety - Collateral standard: Usability
EN 60601-1-8	Medical electrical equipment -- Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-49	Medical electrical equipment -- Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
ISO 80601-2-56	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN 60601-2-34	Medical electrical equipment -- Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

Standard	Title
EN 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN 80601-2-61	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN 80601-2-55	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN 62304	Medical device software -- Software life cycle processes
EN 62366	Medical devices -- Part 1: Application of usability engineering to medical devices

14.6 EMC information

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

14.6.1 Cable length of the sensors and the accessories

	RDT Part Number	Cable Length (typ.)	Tested Length
Ethernet cable	01-2025	2.1m	2.1m
SpO2 sensor	01-2014	2.4m	2.4m
3-lead ECG cable	Various	2.4m	2.4m
4-lead ECG cable	Various	2.4m	2.4m
5-lead ECG cable	Various	2.4m	2.4m
12-lead ECG cable	Various	2.4m	2.4m
IBP adaptor cable	Various	2.4m	2.4m
Wired headset	01-1019	1.2m	1.2m
Mains Power supply	01-2049	0.45m	0.45m
Mains lead	01-2055	2m	2m

WARNING



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

CAUTION

For the purposes of compliance with IEC60601-1-2, all vital signs and communications functions were regarded as essential performance.

14.6.2 Manufacturer's Declarations

Electromagnetic Emissions (IEC EN 60601-1-2)

The Tempus Pro 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 Pro must emit RF energy in order to perform its function. Nearby electronic devices may be affected. Note that the Tempus Pro can be configured for not to emit RF energy in which case it will be group 1 and will not be likely to cause any interference in nearby electronic equipment.
HF emissions acc. to CISPR11	Class B	The Tempus Pro 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	

Electromagnetic Emissions (IEC EN 60601-1-2)


The Tempus Pro 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	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 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	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should conform to a typical business or clinic environment.
Surge voltage acc. to IEC 6100-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV normal mode voltage ± 2 kV common mode voltage	Mains power should be that of a typical hospital or commercial environment.

Interference Resistance Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidelines
Voltage drops, short interruptions and variations in supply voltage acc. to IEC 61000-4-11	<p>< 5 % U_T (>95 % break of U_T) for 0.5 period</p> <p>40 % U_T (60% break of U_T) for 5 periods</p> <p>70 % U_T (30% break of U_T) for 25 periods</p> <p>< 5 % U_T (>95 % break of U_T) for 5 seconds</p>	<p>< 5 % U_T (>95 % break of U_T) for 0.5 period</p> <p>40 % U_T (60% break of U_T) for 5 periods</p> <p>70 % U_T (30% break of U_T) for 25 periods</p> <p>< 5 % U_T (>95 % break of U_T) for 5 seconds</p>	Mains power should be that of a typical hospital or commercial environment. If the user of the Tempus Pro 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	30 A/m	100 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			

Electromagnetic Interference Resistance (IEC EN 60601-1-2)

The Tempus Pro 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. to IEC61000-4-6	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. Recommended safety distance $d = 1.2\sqrt{P}$
Radiated RF disturbances acc. to IEC61000-4-3	6 Vrms in ISM bands (*1) 3 V/m 80 MHz to 2.7 GHz Frequency spots as listed below (*4)	6 Vrms 3 V/m for all parameters & 20 V/m for all parameters except invasive pressure per EN 1789 Frequency spots as listed below (*4)	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.7 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 (*2) (*3). Interference may occur in the vicinity of devices with the following symbol: 
NOTE 1: For 80 Hz and 800 MHz the higher frequency range applies.			
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.			

(*1) The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

(*2) The field strength of stationary transmitters such as fixed parts of cellular phones and mobile radio sets, amateur radio stations, AM and FM radio and television cannot be determined exactly in theory. To detect the electromagnetic environment in regard to stationary transmitters a study of the location should be considered. If the measured field strength at the location where the device is being used exceeds the Compliance level above the device should be watched to verify the proper functions. If unusual features are watched additional actions might be necessary such as a modified orientation or another location of the device.

(*3) For the frequency range of 150 kHz to 80 MHz, the field strength should be lower than 10 V/m.

(*4) Immunity to proximity fields from RF wireless communications equipment:

Test frequency (MHz)	Service	Modulation	Immunity test level (V/m)
385	TETRA 400	Pulse modulation 18 Hz	27
450	GMRS 460, FR 460	FM \pm 5 kHz deviation 1 kHz sine	28
710	LTE Band 13, 17	Pulse modulation 217 Hz	9
745			
780			
810	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870			
930			
1720	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845			
1970			
2450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500			
5785			

14.6.3 Recommended safety distances

Recommended Safety Distances between portable and mobile RF Telecommunication Devices and the Tempus Pro (Tab. 206 according to IEC EN 60601-1-2).

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

Safety Distance Depending on the Frequency in m			
Nominal power of the transmitter (W)	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters with a maximum nominal power not mentioned above: To detect the recommended safety distance use the equitation in the corresponding column. P is the maximum nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer.			
NOTE 1: For 80 Hz and 800 MHz the higher frequency range applies.			
NOTE 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.			

14.7 Factory default settings








Setting	Range	Factory Default
Communications mode	Various – customer specific	Uppermost listed mode within the customer specific communications mode menu
Patient	Neonate, Child, Adult	Adult
NIBP mode	Manual, Auto, Rapid Cuff	Auto
NIBP automatic measurement interval	2, 3, 5, 10, 15, 30 and 60 minutes	Automatic - 3 minutes
QRS volume	0-100% in steps of 20	0%
ECG waveform 1	Lead I-III – 3-lead ECG cable Lead I-III, aVL, aVR & aVF – 4-lead ECG cable Lead I-III, aVL, aVR, aVF & V – 5-lead ECG cable Lead I-III, aVL, aVR, aVF, V1-6 – 12-lead ECG cable	Lead II










Setting	Range	Factory Default
ECG waveform 2	Lead I-III, aVL, aVR & aVF – 4-lead ECG cable Lead I-III, aVL, aVR, aVF & V – 5-lead ECG cable Lead I-III, aVL, aVR, aVF, V1-6 – 12-lead ECG cable	Lead I
ECG wave speed	12.5, 25, 50 mm/s	25mm/s
ECG Gain	2, 4, 5, 10, 15, 20, 30 and 50 mm/mV	10mm/mV
ECG Monitoring filter	Monitor (0.5 Hz – 35 Hz) Filtered diagnostic (0.05 Hz – 35 Hz) Diagnostic (0.05 Hz – 150 Hz)	Monitor (0.5 Hz – 35 Hz)
ECG Mains filter	ON-OFF	ON
Arrhythmia detection	ON-OFF	ON
Mains frequency	50-60 Hz	50Hz (this value is retained and not reset after 8 hours or for a new patient)
Pulse Oximeter plethysmogram wave speed	12.5, 25, 50 mm/s	25mm/s
Capnograph wave speed	3.1, 6.25, 12.5 mm/s	6.25mm/s
Temperature readings	°C - °F	°C
Invasive pressure	See “6.6.4 Configuring the transducer / channel”.	P1 – White with arterial settings P2 – White with arterial settings P3 – White with arterial settings P4 – White with arterial settings


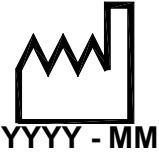
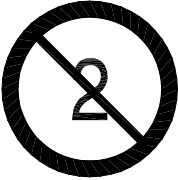



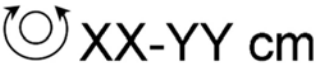


15 Symbols used on the Tempus Pro








15.1 Symbols used









The following symbols are used on the Tempus Pro:



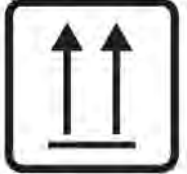


Symbol	Description
	Symbol for pausing audible alarms temporarily
	Symbol for pausing all alarm manifestations (visual and audible) temporarily
	Alarm off (either individual parameter or all parameters)
	General alarm symbol
	Defibrillation proof type CF applied part,
	Capnometer inlet
	ECG Socket


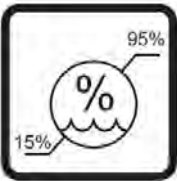

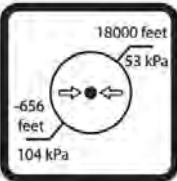
Symbol	Description
	Pulse oximeter socket
	Contact temperature sockets
	NIBP socket
	Attention, consult accompanying documents
	Attention, consult accompanying documents
	Tactical Mode
	Not for use with YSI 700 series sensors
	Battery Charge indicator – flashes green when the battery is on charge
	Battery power level

Symbol	Description
	System power on/off (push/push)
	Date of manufacture, where the year that the item was manufactured is represented by the year and then the month e.g. 2002 06 is June 2002.
	Single use device only, discard item after use
	Capnometer Cannula inlet connection
	These symbols are used to check that the blood pressure cuff is the correct size, once wrapped around the arm the INDEX mark should be between the RANGE marks
	Centre 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)

Symbol	Description
	<p>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 objects (the first numeral) and water (the second numeral). The first numeral “65” means the device is “dust-proof” against the ingress of dust to a size <math><75 \mu\text{m}</math>. The second numeral means the device is protected against the ingress of 100 l/m of water “jetting” at the device from 2.5 to 3 m.</p>
	<p>The device has been declared by the manufacturer to be in accordance with the requirements of the European Union Medical Devices Directive 93/42/EEC (as amended) as transposed by UK national legislation.</p> <p>For class IIa and IIb devices.</p>
	<p>The device has been declared by the manufacturer to be in accordance with the requirements of the European Union Medical Devices Directive 93/42/EEC as transposed by UK national legislation.</p> <p>For class I devices.</p>
	<p>Shelf life, where the time that the unit must be used by is represented by the year and then the month e.g. 2004 06 is June 2004.</p>
<p>LOT YYYY - MM</p>	<p>Where the year that the item was manufactured as a part of a larger batch is represented by the year and then the month e.g. 2002 06 is June 2002.</p>
	<p>This product should not be discarded as general waste and must be disposed of as electrical and electronic waste.</p>
	<p>Communications connections</p>
	<p>WiFi connection mode to Response Centre</p>

Symbol	Description
	Bluetooth® connection to medical modules
	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)

Symbol	Description
	Camera Backlight
	Device contains wireless transmitters
	DC connector
	Packing box to be stored upright
	Packing box contains breakable items – handle with care
	Recyclable packaging
	Packaging should not be discarded

Symbol	Description
	<p>Packing box should not be exposed to rain/water/moisture</p>
	<p>Packing box storage humidity range</p>
	<p>Packing box storage temperature range</p>
	<p>Packing box storage pressure/altitude range</p>

16 End user license agreement

16.1 Tempus Pro EULA

This license covers RDT's Tempus Pro 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 Pro 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 Pro 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 Pro 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 Pro 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 Pro to any third party. However, users of the Tempus Pro 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 Pro. RDT gives you a personal, revocable, non-assignable, and non-exclusive license to use the Tempus Pro.

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

software product. Some jurisdictions do not allow the exclusion of implied warranties, so the above exclusion may not apply to you. This warranty gives you specific legal rights and you may have other rights that vary from region to region.

RDT's Terms and Conditions apply.

RDT and its distributors make no representations with respect to the merchantability or fitness of the Tempus Pro software and the product is supplied "as is", without any warranty of any kind. Further, RDT reserves the right to revise its publications and program(s) without obligation to notify customer of such a revision.

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.

16.2 Mocana EULA

This license covers the Mocana FIPS 140-2 security technology.

CUSTOMER LICENSE AGREEMENT MINIMUM TERMS

1. **No Warranty.** RDT does not extend to its customers (on Mocana's behalf) any warranty – express, implied or statutory – including without limitation the implied warranties of title, non-infringement, merchantability, fitness for a particular purpose, accuracy, and quiet enjoyment.
2. **No Liability.** RDT does not extend to its customers (on Mocana's behalf) any liability, including liability for any incidental, special, consequential, indirect or direct damages of any kind (including damages for interruption of business, procurement of substitute goods, lost data, lost profits, or the like) regardless of the form of action, whether in contract, tort (including negligence), strict product liability, or any other legal or equitable theory.
3. **No Reverse Engineering.** Users are not permitted to in any way reverse engineer, decompile, or modify the Tempus Pro software, the i2i software or the Mocana software.
4. **Export Control.** The Tempus Pro (including the Mocana FIPS 140-2 encryption software) contains certain cryptographic functionality, the export and re-export of which is restricted under U.S. law.



The Mocana FIPS security algorithm is provided as an option only and is not standard on all Tempus Pro devices.

16.3 MPEG4 EULA

NOTICE REGARDING VIDEO STANDARDS.

THIS PRODUCT IS LICENSED UNDER ONE OR MORE VIDEO PATENT PORTFOLIO LICENSES SUCH AS AND WITHOUT LIMITATION VC-1 AND MPEG4 PART2 VISUAL FOR THE PERSONAL AND NON-COMMERCIAL USE OF A CONSUMER TO:

(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.

SUCH LICENSE EXTENDS TO THIS PRODUCT ONLY AND ONLY TO THE EXTENT OF OTHER NOTICES WHICH MAY BE INCLUDED IN THIS DOCUMENT. THE LICENSE DOES NOT EXTEND TO ANY OTHER PRODUCT REGARDLESS OF WHETHER SUCH PRODUCT IS INCLUDED WITH THIS LICENSED PRODUCT IN A SINGLE ARTICLE. NO LICENSE IS GRANTED OR SHALL BE IMPLIED FOR ANY OTHER USE. ADDITIONAL INFORMATION MAY BE OBTAINED FROM MPEG LA, L.L.C. SEE [HTTP://WWW.MPEGLA.COM](http://www.mpegla.com).

16.4 Masimo® EULA

THIS DOCUMENT IS A LEGAL AGREEMENT BETWEEN YOU, THE "PURCHASER," AND RDT. IF YOU DO NOT AGREE TO THE TERMS OF THIS AGREEMENT, PROMPTLY RETURN THE ENTIRE PACKAGE, INCLUDING ALL ACCESSORIES, IN THEIR ORIGINAL PACKAGE, WITH YOUR SALES RECEIPT TO RDT FOR A FULL REFUND.

1. Grant of License. In consideration of payment of the license fee, which is part of the price paid for this product, RDT grants to Purchaser a nonexclusive, non-transferable license, without right to sublicense, to use the copy of the incorporated software/firmware, and documentation in connection with Purchaser's use of the Masimo Products for their labelled purpose. RDT reserves all rights not expressly granted to Purchaser.
2. Ownership of Software/Firmware. Title to, ownership of, and all rights and interests in, any MASIMO software and/or firmware and the documentation, and all copies thereof, remain at all times vested in MASIMO Corporation, licensor to RDT, and they do not pass to Purchaser.
3. Assignment. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise, without RDT's prior written consent; any attempt without such consent, to assign any rights, duties or obligations arising hereunder shall be void.
4. Copy Restrictions. The software/firmware, mask works, circuit board layouts, and accompanying written materials are copyrighted. Unauthorized copying of the software, including software that has been modified, merged, or included with other software, or other written materials is expressly forbidden. You may be held legally responsible for any copyright infringement that is cause or incurred by your failure to abide by the terms of this license. Nothing in this license provides any rights beyond those provided by 17 U.S.C. §117.
5. Use Restriction. As the Purchaser, you may physically transfer the products from one location to another provided that the software/firmware is not copied. You may not electronically transfer the software/firmware from the products to any other device. You may not disclose, publish, translate, release distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Masimo Product, the software/firmware, or the written materials without the prior written consent of RDT. Masimo Sensors that are designated for single use are licensed under Masimo patents for use on a single patient only, and are not sold. There is no license, implied or otherwise, that would allow use of single use Masimo Sensors beyond their intended single use. After use of single use Masimo Sensors, there is no further license granted by Masimo to use the sensors and they must be discarded.
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.

7. **Beneficiary.** Masimo Corporation is a Beneficiary of this Agreement and has the right to enforce its provisions.

U.S. Government Rights: If you are acquiring software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the software is deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this agreement.

16.5 Firebird – Interbase Public License

The product includes open source code executables without modification. The original code was created by Interbase Software Corp and its successors. Portions created by Borland/Inprise and copyright Borland/Inprise. This software is distributed on an "as is" basis, without warranty of any kind, either express or implied. The source code of the covered code is available under the terms of its license.

16.6 Info-Zip License

Copyright (c) 1990-2007 Info-ZIP. All rights reserved.

For the purposes of this copyright and license, "Info-ZIP" is defined as the following set of individuals:

Mark Adler, John Bush, Karl Davis, Harald Denker, Jean-Michel Dubois,
Jean-loup Gailly, Hunter Goatley, Ed Gordon, Ian Gorman, Chris Herborth,
Dirk Haase, Greg Hartwig, Robert Heath, Jonathan Hudson, Paul Kienitz,
David Kirschbaum, Johnny Lee, Onno van der Linden, Igor Mandrichenko,
Steve P. Miller, Sergio Monesi, Keith Owens, George Petrov, Greg Roelofs,
Kai Uwe Rommel, Steve Salisbury, Dave Smith, Steven M. Schweda,
Christian Spieler, Cosmin Truta, Antoine Verheijen, Paul von Behren,
Rich Wales, Mike White.

This software is provided "as is," without warranty of any kind, express or implied. In no event shall Info-ZIP or its contributors be held liable for any direct, indirect, incidental, special or consequential damages arising out of the use of or inability to use this software.

16.7 OpenSSL License

The product includes software developed by the OpenSSL Project for use in the OpenSSL Toolkit (<http://www.openssl.org/>). Copyright © 1998-2011 The OpenSSL Project. All rights reserved.

16.8 US Government Devices – US Department of Defense (DoD) Notice and Consent Banner

The following statement is applicable to devices purchased by US government employees and which are used on SPR networks.

You are accessing a U.S. Government (USG) Information System (IS) that is provided for USG-authorized use only. By using this IS (which includes any device attached to this IS), you consent to the following conditions:

1. The USG routinely intercepts and monitors communications on this IS for purposes including, but not limited to, penetration testing, COMSEC monitoring, network operations and defense, personnel misconduct (PM), law enforcement (LE), and counterintelligence (CI) investigations.
2. At any time, the USG may inspect and seize data stored on this IS.
3. Communications using, or data stored on, this IS are not private, are subject to routine monitoring, interception, and search, and may be disclosed or used for any USG-authorized purpose.
4. This IS includes security measures (e.g., authentication and access controls) to protect USG interests--not for your personal benefit or privacy.
5. Notwithstanding the above, using this IS does not constitute consent to PM, LE or CI investigative searching or monitoring of the content of privileged communications, or work product, related to personal representation or services by attorneys, psychotherapists, or clergy, and their assistants. Such communications and work product are private and confidential.