TCM400 operator’s manual

TCM400
operator's
manual

TCM400 Transcutaneous pO_2 Monitoring Systems

Operator's manual

from software version 4.2

RADIOMETER

Date of issue

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Contents

Introduction

This manual describes how to operate the TCM400 system and covers the following chapters and topics:

1. Introduction

Overview

Introduction This chapter describes the intended use of the TCM400 system. It also contains the definitions of warnings, cautions and notices.

In this chapter This chapter covers the following topics:

Name, intended use and limitations

Proprietary name TCM400 Transcutaneous pO_2 Monitoring System.

Common name Multichannel tcpO_2 monitor or TCM400 system.

TCM4 Series monitors The TCM400 system is part of the TCM4 Series monitoring system.

Reference This operator's manual for the TCM400 Transcutaneous pO_2 Monitoring System is intended for use as a reference. It provides detailed operating instructions and answers to relevant questions about your transcutaneous system.

All rights reserved

Intended use The TCM400 system is a device that uses up to six non-invasive sensors placed on the patient's skin and that is intended to record transcutaneous oxygen partial pressures in adults not under gas anesthesia.

Do not use the TCM400 system in intensive care (ICU, NICU, etc.) for unattended patient monitoring, as the system has no alarms.

Measuring range Transcutaneous measurements of tcpO_2 can be performed at levels from 0 to 2000 mmHg (0 to 266.7 kPa).

Operator profile Only trained health care personnel are permitted to use the monitor.

Limitations Transcutaneous monitoring is intended only as an adjunct in patient assessment and must be used in conjunction with clinical signs and symptoms.

WARNING – *Risk of incorrect measurements*
tcpCO_2/tcpO_2 monitoring should not be used on patients in a compromised hemodynamic state as this may cause incorrect measurements.

CAUTION – *US federal law restriction*
Federal law restricts this device to sale by or on the order of a physician.

NOTICE: This equipment is not a blood gas device.

Legal notice *Instruments should be repaired by Radiometer service personnel or by Radiometer-certified representatives only.*

Symbols used in the manual

This manual contains alerts, which are important and should be read carefully before performing the related procedures. The manual also contains non-safety information.

Symbol	Signal word	Explanation
	WARNING	A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
	CAUTION	A caution alerts the reader about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or the patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to the device that may occur as a result of use or misuse.
	NOTICE	Addresses practical information that is not related to personal injury ("need-to-know information").
		Manufacturer
		Indicates that the product complies with the requirements of the Medical Device Directive 93/42/EEC June 1993. This product is a class IIb device.

2. What is what

Overview

Introduction

The transcutaneous pO_2 monitoring system includes:

- the TCM400 monitor
- the tcpO_2 sensor (E5250)

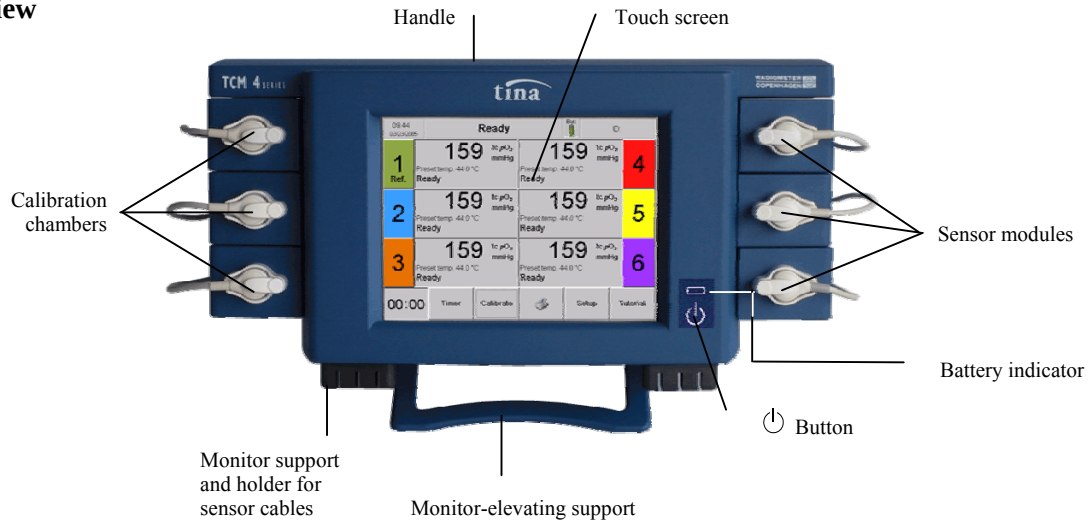
This chapter identifies the parts of the TCM400 monitor.

In this chapter

This chapter covers the following topics:

TCM400 monitor – front

Front view



Parts and functions

The following table lists the parts located on the front of the TCM400 monitor:

Part	Function
Handle	For carrying the monitor.
Calibration chambers	For sensor storage and calibration.
Touch screen	Facilitates communication between operator and monitor.
Sensor modules	For transcutaneous measurements of tcpO_2. The TCM400 monitor can contain up to six modules – see the configuration below.
Monitor support and holder for sensor cable	The support of the monitor has the capability of holding the sensor cables.
Monitor-elevating support	For supporting the monitor at an elevated angle.
⏻ button	For turning the monitor ON and OFF.
Battery indicator	For indicating whether the battery is being recharged or not. If the light is on, the battery is being recharged. **NOTICE:** Only possible if the power switch on the back of the monitor is in the ON (⏽) position.

Continued on next page

TCM400 monitor – front, *Continued*

Sensor module configurations

The TCM400 monitor allows placement of the sensor modules in many different combinations.

Example: Six sensor modules:

1		4
2		5
3		6

Example: Four sensor modules:

1		3
2		4

Automatic numbering

The TCM400 monitor will automatically give each module/sensor a number when mounted. The first module from the left will be given *number 1*, and this sensor *will always be the reference* for the other sensors when calculating the Regional Perfusion Index, RPI.

This means that RPI can only be calculated if there is a module placed in position 1.

Example: Four sensor modules:

1		3
2		4

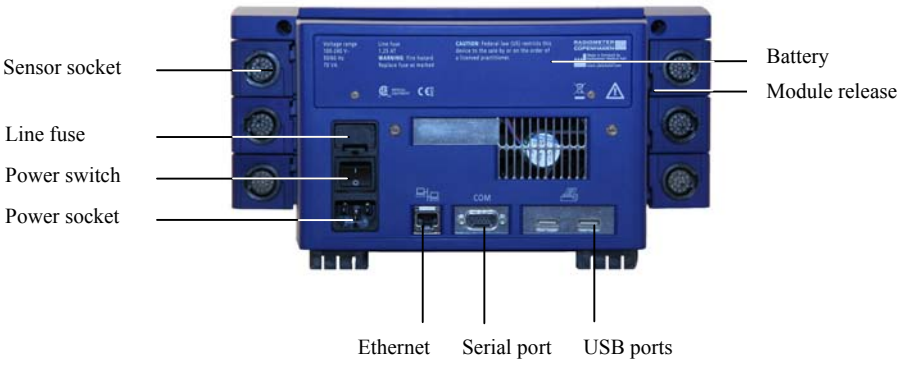
Regional Perfusion Index

The Regional Perfusion Index, RPI, is calculated as follows:

RPI = tc*p*O_2(other module) / tc*p*O_2(reference module 1)

TCM400 monitor – rear

Rear panel



Parts and functions

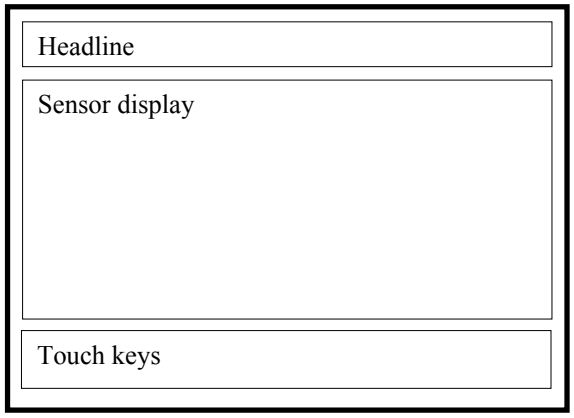
The following table lists the parts located on the rear of the TCM400 monitor:

Part	Function
Battery	For full functionality, the battery must be installed in the TCM400 monitor. It enables monitoring and storage of data during transport and prevents data loss in the event of a power failure.
Sensor socket	For connecting the sensor to the monitor.
Power socket	For connecting a power cord to the TCM400 system.
Power switch	For turning the power supply to the monitor ON and OFF. **NOTICE:** If the power supply is ON, the battery will be recharged when needed.
Line fuse	1.25 AT. For preventing a short circuit. **WARNING – *Risk of fire*** Replace fuse only as recommended by Radiometer. Otherwise you risk that the monitor catches fire.
Ethernet (serial port)	For connecting the TCM400 system to the communication system. **NOTICE***:* Not yet available.
Serial port (RS232)	For connecting the TCM400 system to an external computer.
USB ports	For connecting the TCM400 system to an external printer. **NOTICE:** It is only possible to use one of the ports at a time.
Module release	For releasing the sensor module from the monitor with a release key.

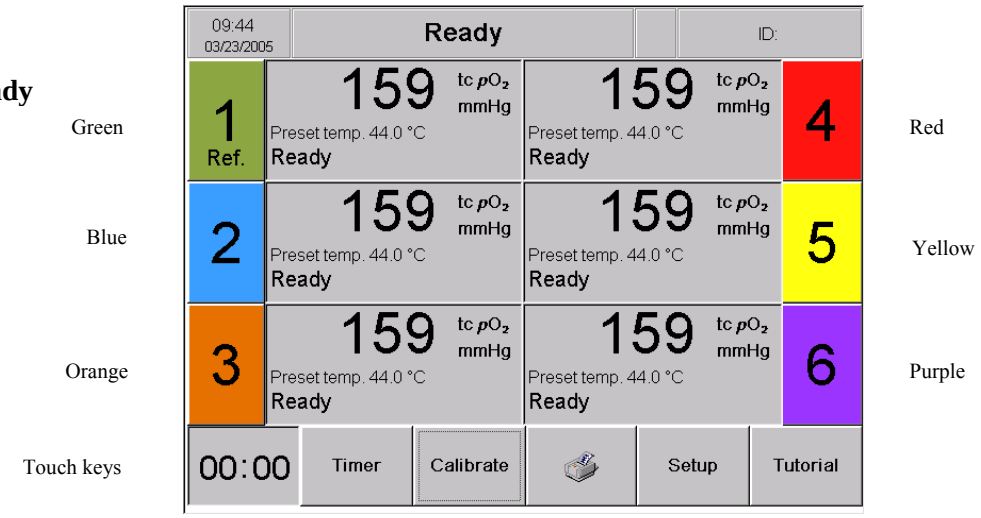
The screen: general elements

The screen configuration

There are three types of view screen (Normal, Trend table and Trend curve), and they are all divided into the following fields:



Example of Normal view screen in Ready mode



NOTICE: In Normal view, the **Event** touch key replaces the **Tutorial** touch key during Measuring mode.

Headline field

The headline field contains the following information:

Part	Shows
Time and date	The real time (24-hour cycle) and date
System status	Ready, Measuring, Calibrating or Calibration required.
Battery level indicator	Shows the battery level. The indicator is only visible when the monitor is running on battery power alone. For more details, see Chapter 4, *Installation and maintenance*. Full, almost full, low and critically low
ID	Patient identification number. Serves as a shortcut to the Patient DMS.

Continued on next page

The screen: general elements, *Continued*

Sensor display field

The sensor display field contains the following information:

Part	Shows
One to six sensor modules	Data presented as: • Numerical values (normal view) • Trend tables • Trend curves
Trend arrows	An upward/downward arrow will appear next to the result on the Normal view screen when an upward/downward trend in measuring values is detected.
Preset temp	The preset sensor temperature in each sensor display during Ready and Calibration required modes. **NOTICE:** If the sensor temperature exceeds the preset temperature, a text message appears in the sensor display.
Baro pressure	The measured barometric pressure during calibration.
pO_2 cal value	The calculated pO_2 value for calibration.
Sensor status	The status of the individual sensor, e.g. Ready, Calibration required, Calibrating, No sensor connected, etc., or an error status.
Power	Sensor power in mW.

Touch key field

The touch key field contains the following touch keys:

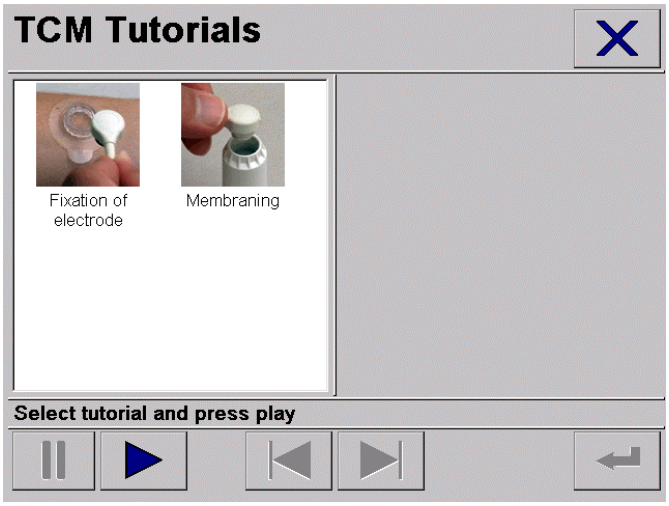
Touch Key	Function
Timer	To enter the Timer screen. Shows the actual countdown timer and its interval when active.
Calibrate	To start a calibration of all sensors.
Print	To print the measurement results.
Setup	To enter the Setup and View programs.
Event	To mark an event during monitoring. Only visible in Measuring mode and in the Trend table and Curve views.
Tutorial	To access instruction videos.

Online tutorials

Tutorials

The tutorials are short video sequences of commonly used procedures. To access the tutorials, press ***Tutorial***.

NOTICE: In Measuring mode, the **Event** touch key replaces the **Tutorial** touch key.



Touch keys

Touch key	Function
	Pauses the selected tutorial.
	Plays the selected tutorial.
 and 	Scroll backward/forward one step in the selected tutorial.
	Returns to the TCM Tutorials screen.
	Exits the tutorial and returns to Normal view.

The touch key glossary

Touch key symbols

Touch keys are designated in ***bold italic*** throughout this manual.

The glossary of all the touch keys used in the software with their description is given in alphabetical order in the table below:

Touch key	Function
	To add a check mark to the highlighted patient ID/session number (in Patient DMS).
	To see detailed information about the highlighted patient ID/session number (in Patient DMS).
	To set the printer start time and stop time. To select SmartPrint. To print one or more reports from the Patient DMS.
Advanced	To select printout of: • Events only, Timer active only and/or Print in color • pO_2, RPI or Power
Auxiliary setup	To change backlight, calibration gas mixture, humidity correction factor, pO_2 unit, serial output and date/time setup, or to bypass calibration.
Bypass calibration	To bypass the calibration in progress and force the monitor into Ready mode. **NOTICE**: If a calibration is bypassed, the monitor will be monitoring with invalid data. The option should therefore only be used for service purposes.
Calibrate	To start a calibration of all sensors.
Cancel	To return to the previous screen without making changes.
Change ID	To change the highlighted patient ID/session number (in Patient DMS) with the on-screen keyboard.
Change view	To change the view of your data to Normal, Trend table or Trend curve view, and to enter the view options.
Close	To close the Timer dialog box.
Cursor	Adds/removes a cursor in the Trend curve view.
Curve scales	To change scales for tcpO_2, power or RPI.
Curve view	To change to Trend curve view.
Date/time	To adjust Date/time settings.
Delete	To delete the patient IDs/session numbers with a check mark (in Patient DMS).

Continued on next page

The touch key glossary, *Continued*

Touch key symbols *(continued)*

Touch key	Function
Delete all	To delete all patient IDs/session numbers in the list (in Patient DMS).
Edit list	To edit the list of textual events.
Sensor no.	To start calibration of a single sensor.
Event	To mark an event during monitoring. To see which text is connected to which event number.
Export	To export the detailed information for the patient IDs/ session numbers with a check mark (in Patient DMS).
Normal view	To change to Normal numerical view.
OK	To accept the setting(s)/change(s) and return to the previous screen.
Printer setup	To enter Printer setup.
Reset	To reset the timer to 00:00.
Restore default	To restore all settings to default.
Start/stop timer	To start or stop the timer.
Start x min	To start one of the countdown timers.
Self-check	To perform self-check (see the service manual).
Service mode	To enter the Service program (see the service manual).
Setup	To enter the Setup programs and View options or to change the view or the sensor temperature.
Table view	To change to Trend table view.
Technical setup	To enter Auxiliary setup, Utilities, and Service mode.
Timer	To enter the Timer program.
Timer setup	To enter Timer setup.
Tutorial	To access instruction videos.
User setup	To enter User setup.
Utilities	To perform self-check or to restore to default settings.
View options	To change the options in the Normal, the Trend table or the Trend curve view.

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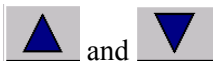
The touch key glossary, *Continued*

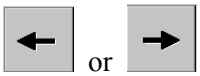
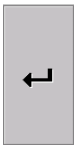
Arrow touch keys

Touch key	Function
	To scroll up/down in a list.
	To scroll left/right in a list. To add/remove events in the Edit event list.
	To scroll to the top of the Trend curve.
	To move left/right one character at a time in the Date/time settings input field.

Tutorial touch keys

Touch key	Function
	Pauses the selected tutorial.
	Plays the selected tutorial.
	Scroll backward/forward one step in the selected tutorial.
	Returns to the TCM Tutorials screen.
	Exits the tutorial and returns to Normal view.

On-screen keyboard touch keys

Touch Key	Function
	Escape. To return to the Patient DMS screen without making changes.
	To switch between different character sets.
	Backspace. To delete one character at a time from right to left.
	Shift. To shift between different keyboards in the same character set.
	To scroll left/right in the text edit field.
	Space. To add a space.
	Enter. To accept the changes made in the text edit field and return to the Patient DMS screen.

3. Menu structure and setup programs

Overview

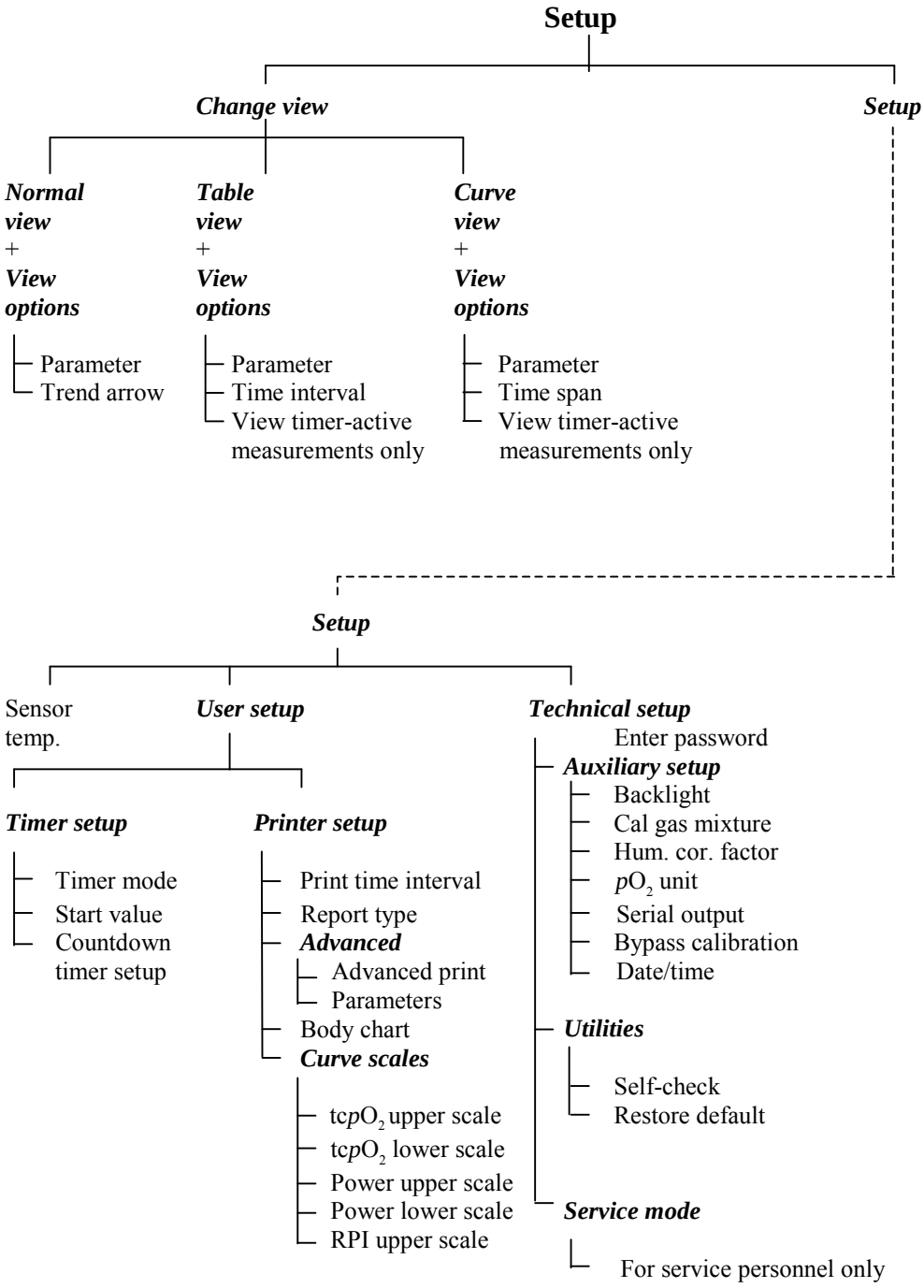
Introduction This chapter describes the view options and setup programs available on the TCM400 system.

In this chapter This chapter covers the following topics:

Menu structure

Main menu structure

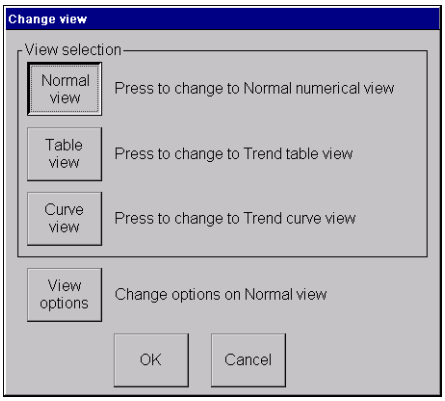
The following diagram illustrates the main menu structure of the TCM400 system:



The change view program

Introduction

The Change view program is accessed by pressing ***Setup → Change view***.



In this program, it is possible to change the view of the Main screen to Normal, Table or Curve view; and to change the options for the three different views.

Changing view

To change to another view, press one of the view selections and ***OK***.

Changing view options

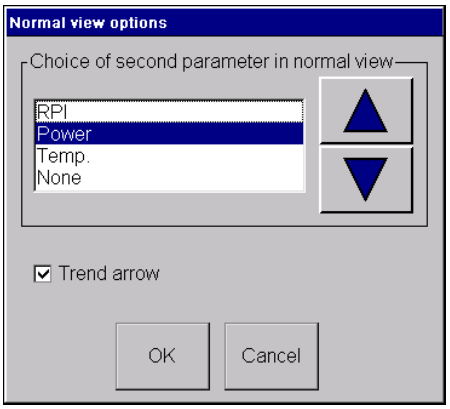
To change the options for the Normal, Table and Curve views, see the following pages:

Normal view

Changing Normal view options

Follow the steps below to change the Normal view options:

Step	Action
1.	From the Change view screen, press ***Normal view → View options***.

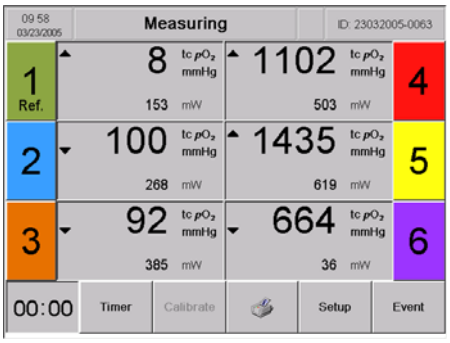


2. Use the ***Up*** and ***Down*** arrows to select the second parameter to be shown on the screen during measurement:

- RPI
- Power
- Temperature
- None

3. Press the check box to activate (check mark) or deactivate (blank) "Trend arrow". The option is activated as default.

When activated, an upward/downward arrow will appear on the Normal view screen when an upward/downward trend in measuring values is detected, as in the example below:



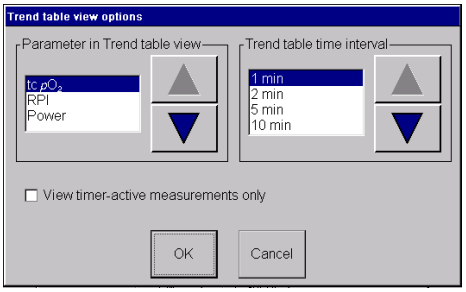
4. Press ***OK*** to accept the changes and return to the previous screen, or press ***Cancel*** to return to the previous screen without saving changes.

Trend table view

Changing Trend table view options

Follow the steps below to change the Trend table view options:

Step	Action
1.	From the Change view screen, press ***Table view → View options***.



2. Use the ***Up*** and ***Down*** arrows to select one of the following:

- tcpO_2 or RPI or Power (the table will display values for each sensor used)
- Time interval, i.e. interval between displayed values in trend tables

3. Press the check box to activate (check mark) or deactivate (blank) "View timer-active measurements only".

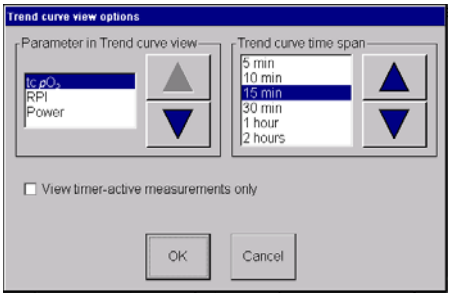
NOTICE: If the option has been activated, only the values measured while the timer was active will be shown. If the option has not been activated, then all measured values will be shown.

4. Press ***OK*** to accept the changes and return to the previous screen, or press ***Cancel*** to return to the previous screen without saving changes.

Trend curve view

Changing Trend curve view options

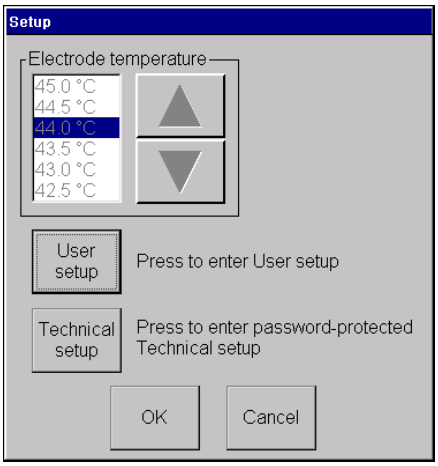
Follow the steps below to change the Trend curve view options:

Step	Action
1.	From the Change view screen, press ***Curve view → View options***. 
2.	Use the ***Up*** and ***Down*** arrows to select one of the following: • tcpO_2 or RPI or Power • Time span **NOTICE:** When loading a session from the Patient DMS into a view, and if the time span is set to e.g. 30 minutes, the system will show the latest value of the selected session and 30 minutes backward. The maximum trend curve time span is 12 hours.
3.	Press the check box to activate (check mark) or deactivate (blank) "View timer-active measurements only". **NOTICE**: If the option has been activated, only the values measured while the timer was active will be shown. If the option has not been activated, then all measured values will be shown.
4.	Press ***OK*** to accept the changes and return to the previous screen, or press ***Cancel*** to return to the previous screen without saving changes.

The setup program

Introduction

The Setup program is accessed by pressing ***Setup*** → ***Setup***.



The Setup is divided into three options:

- Sensor temperature, see below
- User setup (Timer and Printer setup)
- Technical setup (Auxiliary setup, Utilities and Service mode)

See the menu structure on the second page of this chapter.

NOTICE: It is always possible to return to the default values; see the section Default settings later in this chapter.

Adjusting sensor temperature

The sensor temperature is adjusted with the ***Up*** or ***Down*** arrows.

Available sensor temperatures range from 37.0 to 45.0 °C.

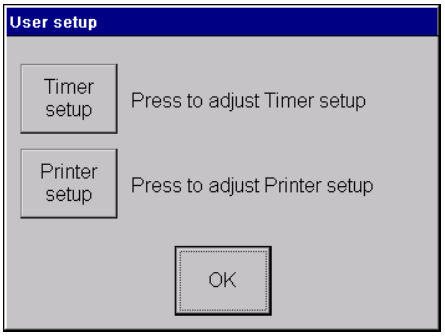
NOTICE: The temperature cannot be adjusted while the monitor is in Measuring and Ready modes. The monitor must be in Calibration required mode, or be powered off and then on to change the temperature setting.

To change the User and Technical setup, see the following pages:

User setup

Accessing User setup

The User setup is accessed by pressing ***Setup*** → ***Setup*** → ***User setup***.



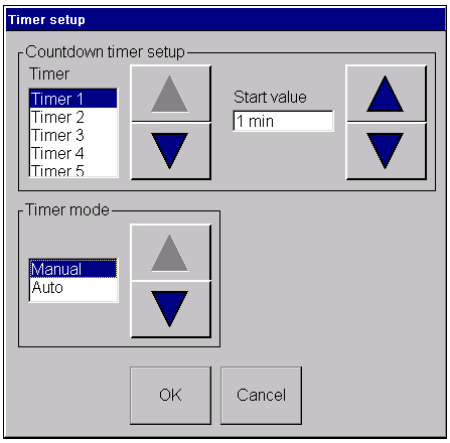
From the User setup screen it is possible to access:

- Timer setup (see below)
- Printer setup (see next page)

Timer setup

Follow the steps below to change the Timer setup:

Step	Action
1.	From the User setup screen, press ***Timer setup***.



2.	Use the ***Up*** and ***Down*** arrows to select the Countdown timer setup: • Select a Timer and the desired Start value for this timer configuration (1-60 minutes) • Repeat the procedure for the four other timers
3.	Use the ***Up*** and ***Down*** arrows to select Timer mode: • Manual – Timer must be started manually • Auto – If the monitor is in Ready mode, the timer will start automatically when the first sensor leaves the calibration chamber
4.	Press ***OK*** to accept the changes and return to the previous screen, or press ***Cancel*** to return to the previous screen without saving changes.

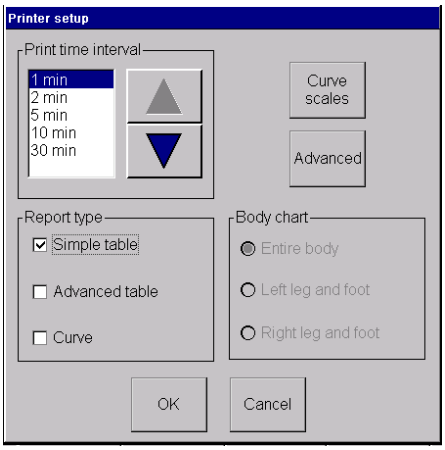
Continued on next page

User setup, *Continued*

Printer setup

Follow the steps below to change the Printer setup:

Step	Action
1.	From the User setup screen, press ***Printer setup***.

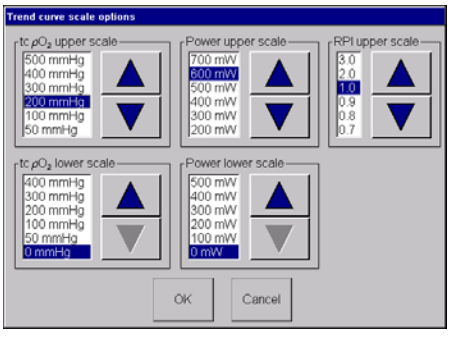


2.	Use the ***Up*** and ***Down*** arrows to select the Print time interval, i.e. the interval between the data on the printout.
3.	Press ***Curve scales*** to adjust the curve scales on the printout. See the procedure below.
4.	Press ***Advanced*** to access the Advanced printer setup. See the procedure on next page.
5.	Select one or more report types.
6.	Select a body chart. **NOTICE**: Only available if the advanced table report has been selected.
7.	Press ***OK*** to accept the new settings in Printer setup and return to the User setup screen, or press ***Cancel*** to return to the User setup screen without saving changes.

Curve scales

Follow the steps below to adjust the curve scales on the printout:

Step	Action
1.	From the Printer setup screen, press ***Curve scales***.



Continued on next page

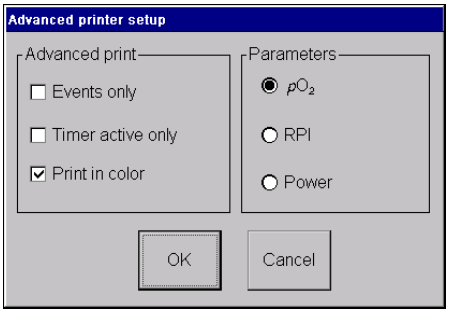
User setup, *Continued*

Curve scales *(continued)*

Step	Action
2.	Use the ***Up*** and ***Down*** arrows to select the upper and/or lower scales for the shown parameters: • tcpO_2 (**mmHg:** upper scale range is 50-2000; lower scale range is 0-1900) (**kPa:** upper scale range is 5-270; lower scale range is 0-260) • Power (Upper scale range is 100 to 700; lower scale range is 0 to 600) • RPI (Upper scale range is 0.1 to 3.0) **NOTICE**: The selected scales determine the range on the printed Trend curve report. In order for results to be printed, data must be within the upper and lower scales.
3.	Press ***OK*** to accept the changes and return to the Printer setup, or press ***Cancel*** to return to the Printer setup without saving changes.

Advanced print Follow the steps below to set the Advanced printer setup:

Step	Action
1.	From the Printer setup screen, press ***Advanced***.

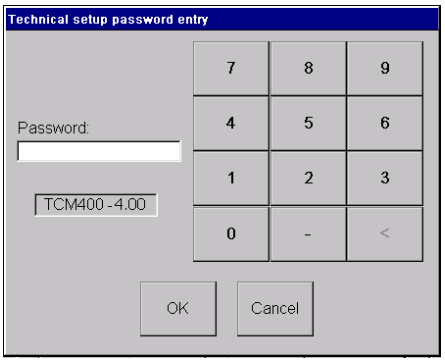


2.	Select one or more of the Advanced print options. **NOTICES**: • If "Timer active only" is selected, only the values that have been measured while the timer was active will be printed. • Only the Trend curve can be printed in color.
3.	Select the parameter you wish to print.
4.	Press ***OK*** to accept the changes and return to the Printer setup, or press ***Cancel*** to return to the Printer setup without saving changes.

Technical setup

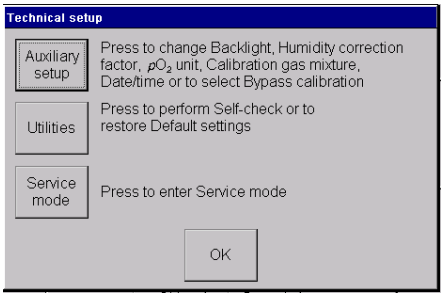
Accessing Technical setup

The Technical setup is accessed by pressing ***Setup → Setup → Technical setup***.



NOTICE: The software version is displayed on this screen.

Enter the password (19100) and press ***OK***.



From the Technical setup screen it is possible to access:

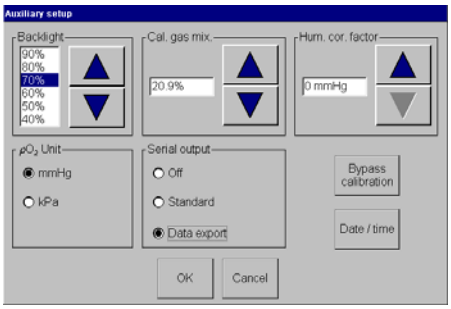
- Auxiliary setup (incl. Date/time setup) (see next page)
- Utilities (see the following pages)
- Service mode (see the following pages)

Continued on next page

Technical setup, *Continued*

Auxiliary setup Follow the steps below to change the Auxiliary setup:

Step	Action
1.	From the Technical setup screen, press ***Auxiliary setup.***



2.	Use the ***Up*** and ***Down*** arrows to select the settings for: • Backlight **NOTICE***:* Full backlight reduces the lifetime of the display. • Humidity correction factor (see chapter 5) **WARNING – *Risk of inaccurate results*** When performing an atmospheric air calibration, make sure to set the calibration gas mixture to the percentage of oxygen in atmospheric air and the humidity correction factor as described in chapter 5. Failure to do so can cause inaccurate results.
3.	Select the settings for: • pO_2 unit (kPa or mmHg) • Serial output (Off, Standard or Data export)
4.	Press ***Bypass calibration,*** if you want to bypass the calibration in progress. **NOTICE**: If a calibration is bypassed, the monitor will be monitoring with invalid data. The option should therefore only be used for service purposes.
5.	Press ***Date/time*** to adjust date and time; see procedure next page.
6.	Press ***OK*** to accept the changes and return to the previous screen, or press ***Cancel*** to return to the previous screen without saving changes.

Continued on next page

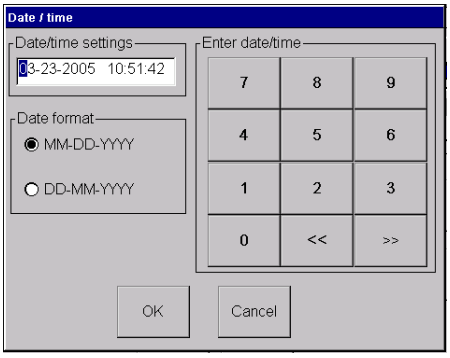
Technical setup, *Continued*

Date and time

Follow the steps below to change the Date/time setup:

NOTICE: Date and time cannot be set during measurement. Trying to do so will result in an alert.

Step	Action
1.	From the Auxiliary setup screen, press ***Date/time.***



2. Select date format:

- MM-DD-YYYY (month-day-year)
- DD-MM-YYYY (day-month-year) (default)

The clock runs on a 24-hour cycle.

3. Move one character at a time in the Date/time settings input field with the << and >> touch keys. Enter the new settings with the numeric keypad.

WARNING – *Risk of data loss*
If the Date/time settings are changed backward in time, only the measurements that have been performed *prior* to the new date/time will be kept in the memory. Other data will be deleted.

4. Press ***OK*** to accept the changes and return to the previous screen, or press ***Cancel*** to return to the previous screen without saving changes.

Continued on next page

Technical setup, *Continued*

Utilities

Follow the steps below to enter the Utilities options:

Step	Action
1.	From the Technical setup screen press ***Utilities.*** 
2.	Press one of the following touch keys: • ***Self-check***, for more information please see chapter 3: *Checkout and Adjustment* in the service manual. **NOTICE**: The Self-check program should only be entered by Radiometer service technicians. or • ***Restore default,*** if you want to set the system to Radiometer default settings. A message will be displayed on the screen, saying that current setup will be lost if the monitor is restored to default settings. **NOTICE:** If you want to use another temperature than the default sensor temperature (44.0 °C), you have to select it in the setup.
3.	Press ***OK*** to return to the previous screen.

Continued on next page

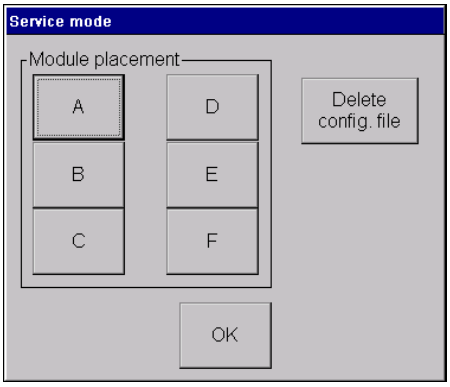
Technical setup, *Continued*

Service mode

Follow the steps below to enter the Service mode option.

NOTICE: Service mode should only be entered by Radiometer service technicians.

Step	Action
1.	From the Technical setup screen, press ***Service mode.***



2.	Press one of the touch keys to check a module.
3.	Press ***Delete config. file*** to delete the configuration file.
4.	Press ***OK*** to return to the previous screen.

See also

For more information about Service mode, please see the service manual.

Default settings

Introduction

The Radiometer default settings for the Change view and Setup programs are presented below.

Access to default settings

To restore defaults, press ***Setup*** → ***Setup*** → ***Technical setup*** → ***Utilities*** → ***Restore default***.

NOTICE: Restoring defaults during calibration will end the calibration process and cause the monitor to go into Calibration required mode.

Change view defaults

The table below lists the default settings in the Change view program:

Item	Default setting
Second parameter in Normal view	Power
Trend arrow	On
View timer-active measurements only	Off
Parameter in Trend table view	tcpO_2
Trend table time interval	1 min
Parameter in Trend curve view	tcpO_2
Trend curve time span	30 min

Setup defaults

The table below lists the default settings in the Setup program:

Item	Default setting
Sensor temperature	44.0 °C
Print start/stop time	Last 60 minutes
Print time interval	1 min
Trend curve scale options	tcpO_2 upper scale value: 200 mmHg tcpO_2 lower scale value: 0 mmHg Power upper scale value: 600 mW Power lower scale value: 0 mW RPI upper scale value: 1.0
Advanced print	Events only Off Timer active only Off Print in color On Parameters pO_2
Report type (for printout)	Simple table
Body chart (for printout)	Entire body

Continued on next page

Default settings, *Continued*

Setup defaults *(continued)*

Item	Default setting
Start values of timers	Timer 1: 1 min Timer 2: 3 min Timer 3: 5 min Timer 4: 10 min Timer 5: 20 min
Timer mode	Manual
Backlight	70 %
pO_2 unit	mmHg
Humidity correction factor	0 mmHg
Serial output	Off
Date/time	DD-MM-YYYY

4. Installation and maintenance

Overview

Introduction

This chapter describes the operating requirements and the installation of your transcutaneous pO_2 monitoring system.

As this system requires minimal maintenance, and since the installation procedure will cover most of the maintenance, it is included in this chapter as well.

In this chapter

This chapter covers the following topics:

Operating requirements

WARNING – *Risk of incorrect measurements*
Do not use the monitor adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If stacking or use adjacent to other equipment is necessary, the monitor should be observed to verify normal operation before used on patients. See the section *EMC approvals and compliance* in chapter 8.

WARNING – *Risk of incorrect measurements*
When installing, operating or servicing the monitor, special consideration should be given to the information regarding the electromagnetic precautions for this equipment given in the section *EMC approvals and compliance* in chapter 8. Otherwise the monitor may be affected by electromagnetic interference, causing incorrect measurements.

WARNING – *Risk of fire*
Do not place the monitor in an enriched oxygen atmosphere or inside a hyperbaric chamber as it may cause a fire hazard.

WARNING – *Risk of explosion*
Do not use the monitor in the presence of flammable anesthetics or gases as it may cause an explosion.

WARNING – *Risk of fire*
Do not cover the ventilator as this may cause it to seize up.

WARNING – *Risk of electrical shock*
Do not use the monitor if it is damaged as this may result in electrical shock.

Environmental requirements

The following environmental requirements must be observed at all times:

- ambient temperature: 5-40 °C
- relative humidity: 20-80 %

NOTICE: Do not operate the monitor at ambient temperatures below 5 °C or above 40 °C and relative humidity below 20 % or above 80 %. Operating the monitor outside these limits may affect the readings of the device.

Ventilation requirements

The monitor must be located in a well-ventilated, dust-free atmosphere.

Installing the monitor

Procedure Follow the steps below to install the monitor:

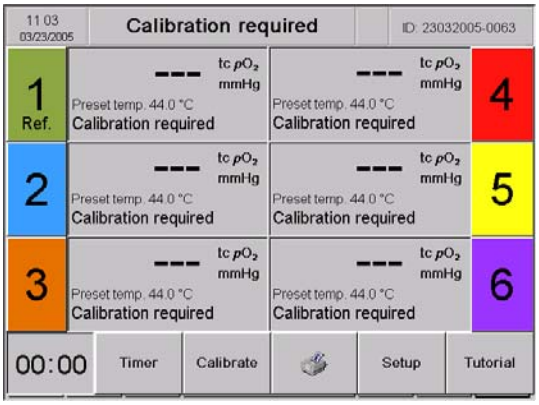
Step	Action
1.	***IMPORTANT:*** *While installing sensor modules, the monitor must be turned off.* Install the number of sensor modules needed for monitoring by pressing each module completely into the base unit until a click is heard. **NOTICES:** • To release a module, see "Releasing a sensor module" on the next page. • When interchanging the sensor modules, note that the numbering of sensors/modules changes too. See "Automatic numbering" in "TCM400 monitor – front" in Chapter 2 of this manual.
2.	Install the battery according to the procedure described later in this section under *Installing the battery.*
3.	Connect the monitor power cord to the power socket at the rear of the monitor and to an appropriate power supply.
4.	Connect the system to external equipment, if required. **WARNING – *Risk of personal injury*** Before connecting other equipment to the TCM monitor, the manufacturer of the equipment or a qualified engineer must be consulted to ensure that the equipment is compatible and that the safety of the patient, the operator or the environment will not be impaired. The resulting combined system must comply with EN 60601-1-1.
5.	Switch on the monitor by pressing the power switch to the *ON* position at the rear of the monitor. The monitor will be initializing for a few seconds.
6.	Membrane the sensor(s) as described in *Preparation and maintenance of the sensor* later in this chapter.
7.	Connect the sensor plug to the sensor socket at the rear of the sensor module. Then place the sensor in the calibration chamber at the front and swing the spring-loaded sensor retainer into position over the sensor.

Continued on next page

Installing the monitor, *continued*

Procedure *(continued)*

Step	Action
8.	Check that all sensor modules are functioning. The following screen is shown when six sensor modules are connected and calibration is required:



9.	Change View or Setup settings, if required, by pressing ***Setup***. See chapter 3: *Menu structure and setup programs*. **NOTICE**: The monitor is delivered with default settings as listed in the topic Default settings in chapter 3: Menu structure and setup programs.
10.	Check that the time and date settings correspond with the actual time and date, otherwise correct them.
11.	*Calibrate the sensor(s) as described in chapter 5:* Calibration.

Reconfiguration of sensor modules

IMPORTANT: *In order not to jeopardize the integrity of the patient data stored before the reconfiguration, you must save your data by making a data export and/or printout prior to reconfiguring the modules.*

Follow the steps below to reconfigure the sensor modules:

Step	Action
1.	Turn the monitor off.
2.	Install/remove the necessary sensor module(s) (see procedures on the previous page and the next page).
3.	Turn the monitor on.

Continued on next page

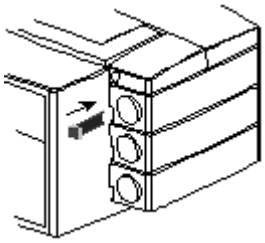
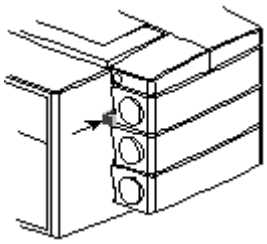
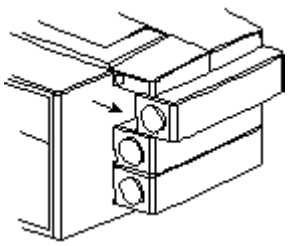
Installing the monitor, *continued*

Reconfiguration of sensor modules *(continued)*

Step	Action
4.	A dialog box will be displayed, giving you the following options: 1. Shut down and revert to previous configuration to back up data. 2. Delete all patient data and allow new configuration. Select one of the options and press ***OK***. **NOTICES:** • In case you have not made a backup of the existing patient data, it is possible to abort the configuration by selecting the first option. Then save your data and follow steps 1-4 in this procedure. • Reconfiguration of the electrode modules does not affect the setup.

Releasing a sensor module

Follow the steps below to release a sensor module:

Step		Action
1.		Slide the release key into the module release at the rear of the module.
2.		Press the release key while releasing the module sideways.
3.		Remove the release key and pull out the sensor module.

Continued on next page

Installing the monitor, *continued*

Battery

The following battery type must be installed on the monitor: Standard 12 V 2AH lead-acid battery (code number: 431-018, available from Radiometer)

Contact your local battery supplier for available type.

CAUTION – *Risk of patient not being monitored*
For data safety reasons, a battery must always be connected to the system.

CAUTION – *Risk of patient not being monitored*
Replace battery only with the types recommended by Radiometer.

CAUTION – *Handling of biohazardous waste*
Dispose of the battery according to local procedures to avoid personal injury or pollution of the environment.

Installing the battery

To install the battery, follow the steps below:

Step	Action
1.	Using a 2 mm hex- or Allen key, remove the two screws from the battery cover at the rear of the monitor.
2.	Remove the cover.
3.	Clip the connector cable to the battery.
4.	Slide the battery onto the battery shelf in the monitor.
5.	Reattach the battery cover.

Running the monitor on battery power alone

The monitor can function for approximately one hour on battery power alone. The battery power level can be read from the battery level indicator on the monitor screen – for more details see *Headline field* in *The screen: general elements* in Chapter 2, *What is what*.

The battery level indicator (on the screen) starts blinking when the battery level is getting low. If the monitor continues to be run on battery power alone, the battery level will continue to fall and the monitor will sound an alarm and display an alert message about connecting the monitor to a mains power supply as soon as possible (see Chapter 7, *Troubleshooting*).

If the monitor continues to be run on battery power alone, the monitor will automatically switch off before the battery power reaches a critically low level. This not only prevents loss of any measurement data, it also prevents the battery being damaged by being completely discharged.

CAUTION – *Risk of patient not being monitored*
Make sure the battery level never becomes critically low, as this will prevent data from being saved onto the disk.

Recharging the battery

Reconnect the monitor to the mains as soon as possible after the battery level indicator starts to flash to recharge the battery. Recharging the battery takes approximately eight hours.

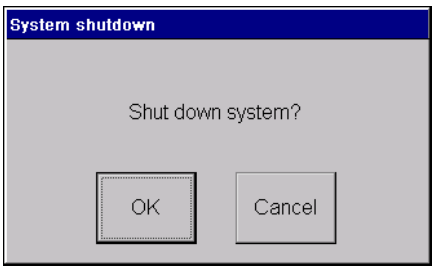
Changing the battery

To change the battery, follow the steps below:

Step	Action
1.	Using a 2 mm hex- or Allen key, remove the two screws from the battery cover at the rear of the monitor.
2.	Remove the cover.
3.	Detach the battery from the connector cable.
4.	Attach a new battery to the connector cable.
5.	Slide the battery onto the battery shelf in the monitor.
6.	Reattach the battery cover.

Shutting down the monitor

Procedure Follow the steps below to shut down the monitor:

Step	Action
1.	Press the ⏻ button on the front of the monitor. The following dialog box will be displayed: 
2.	Press ***OK*** to shut down the monitor or ***Cancel*** to return to the main screen without shutting down the monitor.

Cleaning the monitor

NOTICE Do not spray, pour or spill any liquid on the monitor or any of the accessories, connectors, switches or openings in the chassis.

Cleaning the exterior

To clean the monitor exterior:

Step	Action
1.	Shut down the monitor by following the procedure described earlier in this chapter.
2.	Use a soft cloth or tissue moistened with a mild detergent to wipe the exterior. **NOTICE**: Do not use abrasive cleaners or pads, otherwise you may damage the finish. **NOTICE**: Do not use aggressive detergents as extensive use may cause the plastic to become brittle and crack.
3.	Use clean tissues moistened with water to remove any remaining detergent from the surfaces.
4.	Use clean tissues to remove any remaining moisture.

Cleaning the touch screen

A dry or lightly dampened soft, lint-free cloth may be used to clean the monitor's touch screen. Simply wipe the screen gently to remove fingerprints and/or dirt. To avoid streaking, an approved screen cleaner is recommended.

Cleaning the calibration chamber

The calibration chamber must be cleaned whenever it has been exposed to contact liquid. The procedure is as follows:

Step	Action
1.	Use a soft cloth or tissue moistened with either water or a mild detergent to clean the chamber.
2.	If a mild detergent has been used, use clean tissues moistened with water to remove any remaining detergent from the chamber.
3.	Use clean tissues to remove any remaining moisture from the chamber.

Recommended disinfection solutions

The following disinfectants, dissolved in water, may be used to disinfect the monitor exterior and touch screen:

- 70 % isopropyl alcohol
- 70 % ethanol
- 4 % Diversol BX

Continued on next page

Cleaning the monitor, *continued*

Disinfection procedures and frequency

The need for disinfection of the monitor exterior and touch screen is governed by local requirements as well as monitor use.

Disinfecting outer surfaces

IMPORTANT: *It is important that you consult the hygiene committee at your hospital to establish the correct disinfection procedures for your hospital.*

To disinfect the monitor exterior and touch screen:

Step	Action
1.	Shut down the monitor by following the procedure described earlier in this chapter.
2.	Use a soft cloth or tissue moistened with one of the recommended disinfection solutions to wipe the outer surfaces of the monitor. **NOTICE**: Follow legal requirements and local rules for safe work practices with chemicals.
3.	Use clean tissues moistened with water to remove any remaining disinfection solution from the surfaces.
4.	Use clean tissues to remove any remaining moisture.

Preparation and maintenance of the sensor

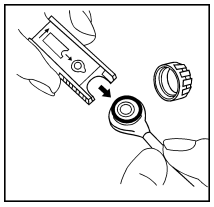
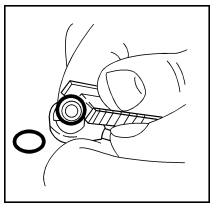
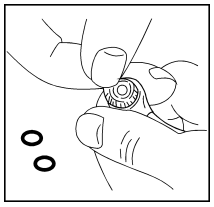
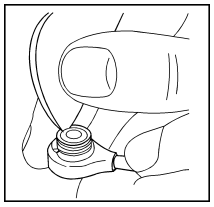
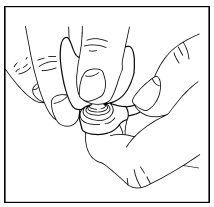
General information

To obtain reliable measurements, the sensor should be remembraned every week.

After a sensor has been remembraned, connect the sensor plug to the sensor socket at the rear of the monitor. Check that the system shows "Calibration required" and calibrate the sensor twice as described in chapter 5: *Calibration*.

Preparing a sensor

Follow the steps below to prepare the sensor for membraning:

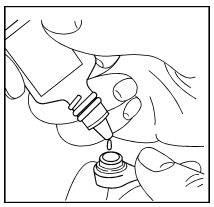
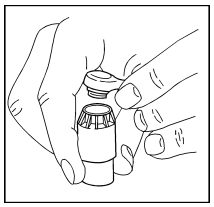
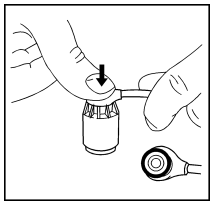
Step		Action
1.		Remove the protection cap. Then remove the old O-rings by sliding the O-ring remover under the O-rings, just above the arrow on the sensor house.
2.		Turn the O-ring remover clockwise to release the two O-rings.
3.		Peel off the old membrane and check that the entire membrane has been removed.
4.		Clean the sensor surface: Absorb the old electrolyte solution with a piece of cleaning paper.
5.		Rub the sensor measuring surface carefully two or three times to remove the thin layer of silver that has precipitated on the sensor.
6.		Membrane the sensor as described in steps 1-3 in the membraning procedure on the next page.

Continued on next page

Preparation and maintenance of the sensor, *Continued*

Membraning a sensor

Use the D826 membraning kit and follow the steps below to membrane a sensor:

Step		Action
1.		Apply two drops of the tcpO_2 electrolyte solution on the surface of the sensor. **NOTICE**: Check that the electrolyte solution covers the entire surface without air bubbles.
2.		Place the membrane unit on a hard and stable surface. Turn the sensor slowly so that the measuring surface faces downwards. Insert the sensor head into the top of the white tcpO_2 membrane unit.
3.		Press the sensor firmly into the unit until a click is heard. Remove the sensor from the unit and wipe off the surplus electrolyte solution with the piece of cleaning paper.

Cleaning the sensor and cable

Clean the sensor and cable as follows:

Step	Action
1.	Use a soft cloth or tissue moistened with water to wipe the sensor and cable.
2.	Use clean tissues to remove any remaining moisture.

Continued on next page

Preparation and maintenance of the sensor, *continued*

Recommended disinfection solutions

As the number of available disinfection solutions is increasing and varies from country to country and from hospital to hospital, it is not possible to come up with a complete list of water-based disinfection solutions that may be used to disinfect the sensor and cable. However, Radiometer suggests that one of the following water-based disinfection solutions is used:

- MadaCide-FD (MADA Inc.)
- Control III (Maril Products Inc.)
- Hi-Tor Plus (Ecolab Inc.)

NOTICE: Constant use of hand lotion containing isopropanol/propylalcohol and alcohol prior to handling the sensor may damage the cable. To avoid transferring lotion to the cable, dry hands prior to handling the sensor.

Disinfecting the sensor and first part of the cable

IMPORTANT: *It is important that you consult the hygiene committee at your hospital to establish the correct disinfection procedures for your hospital.*

Disinfection of a sensor and the first part of the attached cable (that closest to the sensor) is carried out with a membraned sensor prior to calibration.

WARNING – *Risk of infection*
Due to the nature and seriousness of diseases such as the Human Immunodeficiency Virus (HIV) (the causative agent of AIDS) and Hepatitis B, always regard equipment and accessories that can come into contact with human or animal tissues or fluids (particularly blood) as contaminated and potentially hazardous to avoid the risk of infection.

WARNING – *Risk of incorrect measurements (sensor failure)*
Do not immerse the sensor plug in disinfection solution. Immersing the sensor plug in disinfection solution will cause the sensor to fail.

WARNING – *Risk of incorrect measurements (sensor failure)*
Do not heat sterilize as the sensor cannot tolerate temperatures exceeding 70 °C. Heat sterilization of the sensor will cause it to fail.

Step	Action
1.	Immerse the sensor and only the first part of the cable in one of the recommended water-based disinfection solutions.
2.	Use clean tissues moistened with water to remove any remaining disinfectant from the sensor and cable.
3.	Use clean tissues to remove any remaining moisture.

Continued on next page

Preparation and maintenance of the sensor, *continued*

Disinfecting the last part of the sensor cable

Disinfect the last part of the sensor cable (the part closest to the plug) as follows:

Step	Action
1.	Use a soft cloth or tissue moistened with one of the recommended disinfection solutions to wipe the cable.
2.	Use clean tissues moistened with water to remove any remaining disinfectant from the cable.
3.	Use clean tissues to remove any remaining moisture.

Storing the sensor

If the sensor needs to be stored for less than one week, it may be stored in the calibration chamber.

However, for storage periods longer than 1 week, the sensor should be kept covered by its protective cap (after placing 2 drops of electrolyte solution in it).

5. Calibration

Overview

Introduction This chapter describes the calibration of the tcpO_2 sensor(s) with atmospheric air. The sensor zero current check is also described.

In this chapter This chapter covers the following topics:

General information

Calibration materials

To calibrate the tcpO_2 sensor, use atmospheric air (room air).

Calibration frequency

Radiometer recommends performing a calibration:

- prior to each monitoring period
- when changing measuring sites
- every four hours
- every time a sensor has been remembraned

NOTICE: After an eight-hour monitoring period, the monitor will go into Calibration required mode, i.e. it will be necessary to perform a calibration in order to be able to monitor.

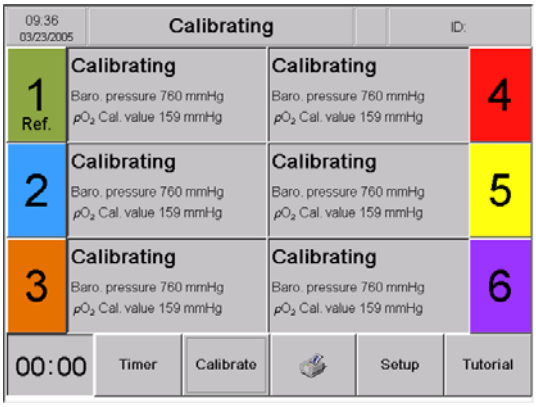
Recommen-dation

Check the monitor's barometer against a known calibrated barometer periodically. See ranges in chapter 8: *Specifications and ordering information*.

Calibration with atmospheric air

Procedure Follow the steps below to calibrate the tcpO_2 sensor(s) with atmospheric air:

Step	Action
1.	Connect the tcpO_2 sensor to the sensor socket on the monitor.
2.	Check that the calibration chamber is clean. If it is not, clean it. See the procedure *Cleaning the calibration chamber* in Chapter 4.
3.	Clean the sensor. See the procedure *Cleaning the sensor* in Chapter 4.
4.	Insert the membraned sensor into the calibration chamber on the monitor.
5.	Swing the sensor retainer into position over the sensor.
6.	Adjust the humidity correction factor, if required, by pressing ***Setup*** → ***Setup*** → ***Technical setup*** → ***Auxiliary setup.***
7a.	To calibrate all connected sensors simultaneously, press ***Calibrate***.
	If six sensors are connected, the following screen appears:

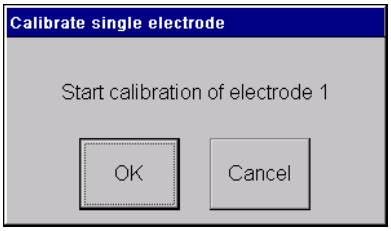


Continued on next page

Calibration with atmospheric air, *continued*

Procedure *(continued)*

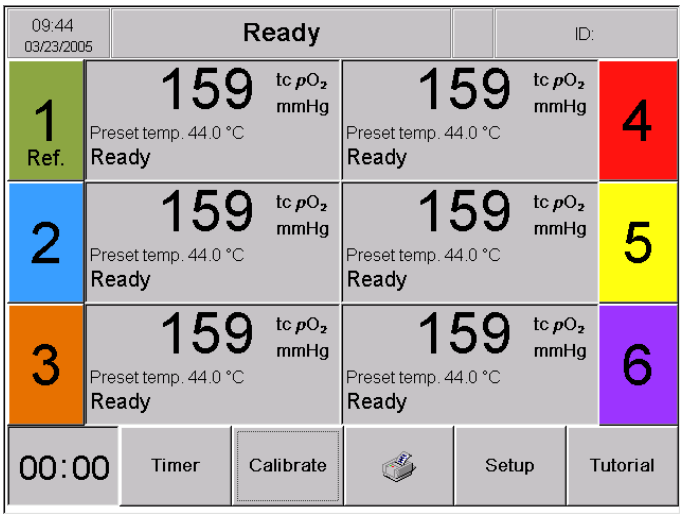
Step	Action
7b.	To calibrate one sensor at a time, press the number of the relevant sensor.



Press **OK** *to start calibration, or press* **Cancel** *to return to the previous screen without initiating the calibration.***NOTICE:** While calibrating a single sensor, it is possible to monitor with the other sensors.

8. Wait for the calibration to finish.

RESULT: There is a beep, and the calibration values are displayed:



NOTICES

- If the sensor has been remembraned prior to the calibration, leave the sensor in the calibration chamber for 30 minutes and then press Calibrate again.
- If the sensor is not removed from the calibration chamber within 30 minutes after Ready, the heat to the sensor will be switched off minimizing electrolyte drying-out. A new calibration will be required.
- The temperature cannot be adjusted while the monitor is in Measuring and Ready modes. The monitor must be in Calibration required mode, or be powered off and then on to change the temperature setting.

Continued on next page

Calibration with atmospheric air, *continued*

Calculating the calibration value

When using atmospheric air, the tcpO_2 calibration value is calculated according to the following formula:

$$pO_2(\text{CAL}) = (B - pH_2O(\text{temp})) \times \frac{FO_2(\text{atm.air})}{100}, \text{ where}$$

B	= barometric pressure in mmHg or kPa
FO_2(atm.air)	= percentage of oxygen in atmospheric air (default 20.9 %)
pH_2O(temp)	= humidity correction factor
	= actual water vapor pressure in mmHg or kPa in atmospheric air at room temperature, temp (°C):

$$pH_2O(\text{temp}) = \frac{\text{RH}}{100} \times pH_2O(\text{sat}, \text{temp}) \text{, where}$$

RH is the actual percentage of relative humidity in atmospheric air. pH_2O (sat, temp) is the saturated water vapor pressure at room temperature.

Causes of error

Calibration can be performed in atmospheric air without compensating for fluctuations in relative humidity or barometric pressure. However, this may lead to some inaccuracies.

Example: relative humidity

If no compensation for relative humidity is made, the following inaccuracy can be estimated:

Barometric pressure, B = 760 mmHg

Room temperature, temp = 21 °C

Relative humidity, RH = 60 %

Saturated water vapor pressure at room temperature,

pH_2O(sat,21°C) = 18.7 mmHg

Percentage of oxygen in atmospheric air, FO_2(atm.air) = 20.9 %.

$$pO_2(\text{CAL}) = \left(760 - \frac{60}{100} \times 18.7\right) \times \frac{20.9}{100} = 156.5 \text{ mmHg}$$

This means that a calibration value of 156.5 mmHg would be right.

If the pO_2(CAL) value of 159 mmHg is used instead, the inaccuracy will be:

$$\%\ \text{inaccuracy} = \frac{159 - 156.5}{159} \times 100\ \% = 1.6\ \%$$

This means that the tcpO_2 values during measurement will be 1.6 % too high.

Continued on next page

Calibration with atmospheric air, *continued*

Saturated water vapor pressure

The table below shows saturated water vapor pressure at different temperatures:

Saturated water vapor pressure		
°C	**mmHg**	**kPa**
20	17.5	2.33
21	18.7	2.49
22	19.8	2.64
23	21.1	2.81
24	22.4	3.00
25	23.8	3.17
26	25.2	3.36
27	26.7	3.56
28	28.3	3.77
29	30.0	4.00
30	31.8	4.24

1 kPa = 7.50 mmHg

The humidity correction factor used in the TCM400 system is calculated by multiplying the saturated water vapor pressure found in the table with the relative humidity. If, for example, the temperature is 22 °C and the relative humidity is 70 %, the humidity correction factor to be used is:

Humidity correction factor = 19.8 × 70 / 100 = 13.9 ≈ 14

Checking the sensor zero current

Items required

The following items are required to check the sensor zero current:

- CAL2 standard calibration gas (10% CO_2 with N_2 as balance).
- Gas adapter for CAL2 gas.

Recommendation

Check the sensor zero current:

- once a month
- if the sensor performance appears to deteriorate

Procedure

Follow the steps below to check the sensor zero current:

Step	Action
1.	Calibrate the sensor. See the procedure in *Calibration with atmospheric air* in this chapter.
2.	Attach the adapter to the CAL2 gas cylinder and place the sensor in the calibration chamber of the gas adapter.
3.	Wait 3-5 minutes for the tcpO_2 reading to stabilize.
4.	Read the tcpO_2 value on the screen: • If under 5 mmHg (0.7 kPa), the sensor is in good condition. • If equal to or above 5 mmHg (0.7 kPa), the sensor must be remembraned and recalibrated. Then repeat steps 1 to 3 of this procedure. **NOTICE:** If the tcpO2 reading is still e qual to or above 5 mmHg(0.7 kPa), the sensor is defective.
5.	After zero current has been checked , unscrew the CAL2 gas c ylinder from the gas adapter.

6. In vivo monitoring

Overview

Introduction This chapter describes the application of the tcpO_2 sensor on a patient and in vivo monitoring. Graphical presentations of the results are also described in this chapter.

In this chapter This chapter covers the following topics:

General Information

Restricted use The use of the equipment is restricted to one patient at a time.

Measuring sites Clinical studies have shown the abdomen and chest to be the best measuring sites for adults.

Measuring temperature A measuring temperature between 43 and 45 °C is recommended for adults.

WARNING – *Risk of burns*
Do not allow the sensor temperature to exceed 44 °C when sensors are attached to skin for more than four hours as this may otherwise cause burns.

General alerts

WARNING – *Risk of incorrect measurements*
Remove the sensor(s) from the patient immediately, if the TCM400 system or patient is exposed to a defibrillator, electrocautery, or other high-frequency electrical signals, as this may affect the device and may cause injury to the patient.

WARNING – *Risk of strangulation*
As with all medical equipment, carefully route and affix patient cabling using the cable clip to reduce the possibility of patient entanglement or strangulation.

WARNING – *Risk of incorrect measurements*
tcpO2 monitoring should not be used on patients in a compromised hemodynamic state as this may cause incorrect measurements.

WARNING – *Risk of skin damage*
Long-term hyperthermia may blister skin. When producing local hyperemia by means of hyperthermia, a certain risk of applying temperatures harmful to the skin is always present, although the risk is limited due to the control system of the instrument. Always pay attention to the use of hyperthermia for special patients – e.g. patients in shock, patients with low blood pressure and patients with vascular constrictions.

WARNING – *Risk of bruises*
When applying a fixation ring to a patient, make sure to place it so that the patient does not lie on top of it, as this may cause the fixation ring to leave bruises on the patient.

WARNING – *Risk of fire*
Do not place the TCM400 system in an enriched oxygen atmosphere or inside a hyperbaric chamber as it may cause a fire hazard.

WARNING – *Risk of incorrect measurements*
Do not use the TCM400 system adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If stacking or use adjacent to other equipment is necessary, the TCM400 system should be observed to verify normal operation before being used on patients. See the section EMC approvals and compliance in chapter 8.

WARNING – *Risk of incorrect measurements*
When installing, operating or servicing the TCM400 system, special consideration should be given to the information regarding the electromagnetic precautions for this equipment given in the section EMC approvals and compliance in chapter 8.Otherwise the TCM400 system may be affected by electromagnetic interference, causing incorrect measurements.

- **NOTICE:** The TCM400 system is not a blood gas device.

In vivo monitoring

Required materials

The following items, included in the fixation kit, are required to affix a tcpO_2 sensor to a patient:

- Fixation ring

WARNING – *Risk of infection and inaccurate results*
Reuse of single-use devices may lead to infection of patients and inaccurate results.

- Contact liquid

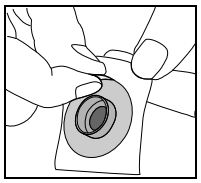
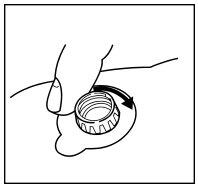
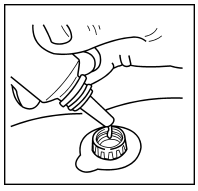
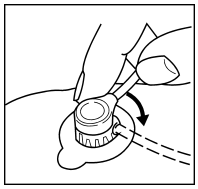
Prior to sensor application

Follow the steps below prior to affixing a sensor to a patient:

Step	Action
1.	Calibrate the sensor as described in chapter 5: *Calibration*.
2.	Clean the selected measuring site with alcohol or other skin-preparation solution.
3.	Dry the site well with a gauze pad.

Application procedure

Follow the steps below to affix a tcpO_2 sensor to a patient:

Step		Action
1.		Take a fixation ring and remove the fixation ring from the protection film.
2.		Apply the fixation ring to the measuring site by pressing the center of the fixation ring onto the measuring site with a finger and then running a finger around the rim circumference. **NOTICE**: Press firmly to prevent leaks.
3.		Fill the hole in the fixation ring with 3-5 drops of the contact liquid.
4.		Remove the sensor from the calibration chamber, align the arrow on the sensor with one of the marks on the fixation ring, and turn the sensor a quarter of a turn clockwise to fasten it in the fixation ring.
5.		Repeat steps 1-4 if more sensors are to be applied.

In vivo monitoring

Follow the steps below to start the in vivo monitoring with one or more sensors:

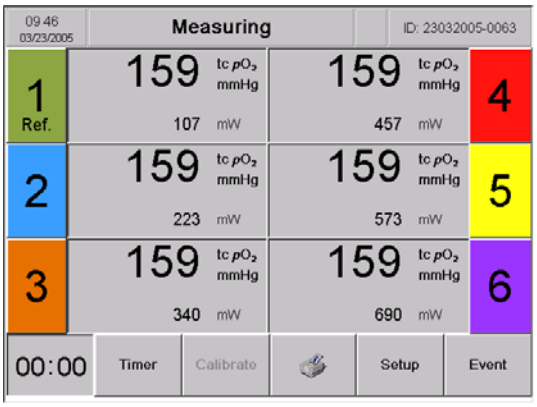
Step	Action
1.	Wait for a stable reading after the sensor has been affixed to the patient. **NOTICE***:* The physiological stabilization time of a patient is 10-20 minutes for the tcpO2 reading. Longer time may indicate an incorrect attachment of the sensor or a poorly selected measuring site.
2.	Press ***Timer***, if required. See the procedure later in this topic. **NOTICE***:* If Timer mode has been set to Auto in the Setup program, the timer will start automatically when the first sensor is removed from the calibration chamber.
3.	Press ***Event***, if required. See the procedure later in this topic. **NOTICE**: The Event touch key can, among other things, be used to record the time when starting a new monitoring period.
4.	Link the session in progress to a specific patient ID. See the topics "Accessing Patient DMS" and "Session" on the following page.
5.	View the readings and adjust the settings, if necessary. See the topic *Menu structure* in chapter 3": *Menu structure and setup programs*.
6.	When the patient no longer needs to be monitored, remove the sensor by turning it in an anticlockwise direction (through a quarter of a turn), until the arrow on the sensor aligns with one of the marks on the fixation ring, and lift it out.
7.	Clean the sensor using a soft cloth or tissue moistened with water, then use a dry tissue to remove any remaining moisture, then place it in the calibration chamber. **WARNING – *Risk of skin damage*** The sensor must be moved to a new site at least every four hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site. **NOTICE:** After an eight-hour monitoring period, the monitor will go into Calibration required mode, i.e. it will be necessary to perform a calibration in order to be able to monitor.

Continued on next page

In vivo monitoring, *continued*

Screen during monitoring

The following is an example of a screen picture during monitoring:



Patient DMS

The Patient DMS manages all session/patient ID data, and it helps reducing the risk of patient data mix-up.

From the Patient DMS screen it is possible to:

- change the automatically generated session number to a unique patient ID
- view data from a session in the Trend table or Trend curve view
- print one or more reports
- export one or more sessions
- delete sessions
- see detailed information about a session

Session

A session is a collection of data starting when the first sensor is removed from the calibration chamber and ending when the last sensor is placed back in the calibration chamber.

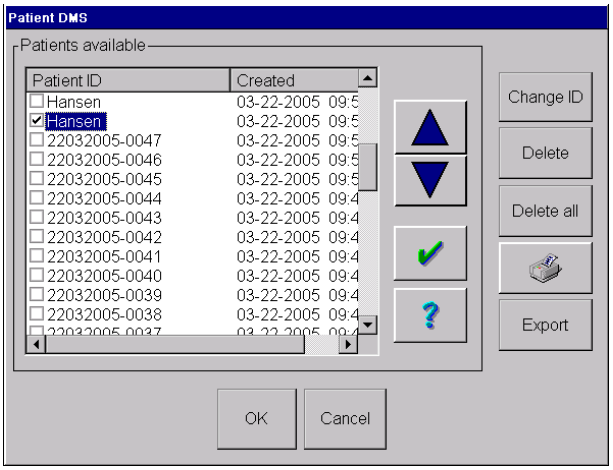
Each session gets a unique number, which can be linked to a specific patient ID at any time. It is thereby possible to link several sessions to the same patient ID.

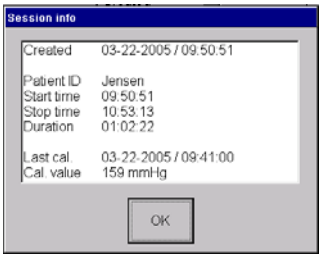
Continued on next page

In vivo monitoring, *continued*

Accessing Patient DMS

Press the ID field in the top right corner of the view screens to enter the Patient DMS (Data Management System).



Touch key	Function
 and 	Scroll between the patient IDs/session numbers in the list.
	Adds a check mark to the highlighted patient ID/session no. **NOTICE**: Only patient IDs/session numbers with a check mark can be viewed, deleted, printed and exported.
	Shows detailed information about the highlighted patient ID/session number. 
Change ID	Enables changing the highlighted patient ID/session number with the on-screen keyboard (see next page). Maximum 64 characters. **NOTICE**: When changing a patient ID/session number, make sure to change it to something unique for each patient. If the same ID is used for two patients, the DMS will not be able to tell them apart.
Delete	Deletes the patient IDs/session numbers with a check mark. **NOTICES:** • A dialog warns users that the action cannot be undone. • The session in progress cannot be deleted.

In vivo monitoring, *continued*

Accessing Patient DMS *(continued)*

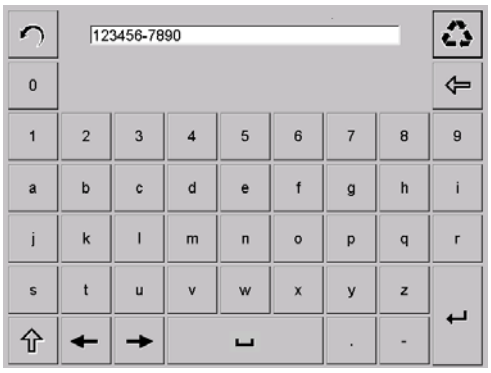
Touch key	Function
Delete all	Deletes all patient IDs/session numbers in the list. **NOTICES:** • A dialog warns users that the action cannot be undone. • The session in progress cannot be deleted.
Print	Prints a report (one or more report types) for the patient IDs/session numbers with a check mark.
Export	Exports the patient information and measuring data for the patient IDs/session numbers with a check mark (see the section *Serial data output: data export* later in this chapter).
OK	Loads sessions with a check mark into the Trend table and Trend curve views. **NOTICES:** • Sessions with the same patient ID can be loaded into the same view. • If changes are made to the sessions that have been loaded into a view, all the sessions will have to be loaded into the view again.

Accessing Patient DMS *(continued)*

Touch key	Function
Cancel	Returns to the view screen.

On-screen keyboard

The following screen shows the basic keyboard layout:

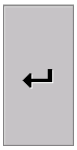


Touch Key	Function
	Escape. To return to the Patient DMS screen without making changes.

Continued on next page

In vivo monitoring, *continued*

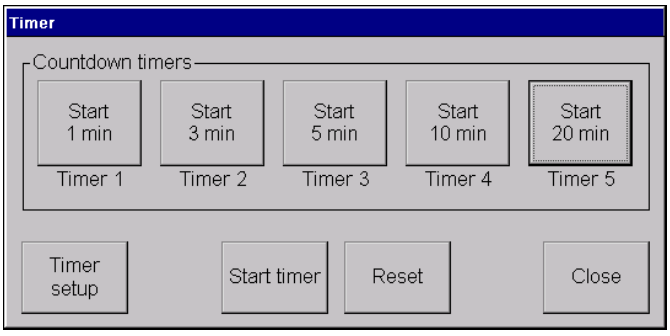
On-screen keyboard *(continued)*

Touch Key	Function
	To switch between different character sets.
	Backspace. To delete one character at a time from right to left.
	Shift. To shift between different keyboards in the same character set.
 or 	To scroll left/right in the text edit field.
	Space. To add a space.
	Enter. To accept the changes made in the text edit field and return to the Patient DMS screen.

Starting and stopping timer

Follow the steps below to start and stop the Timer:

Step	Action
1.	Press ***Timer***.



Continued on next page

In vivo monitoring, *continued*

Starting and stopping timer *(continued)*

Step	Action
2.	Press the desired countdown timer to start the timer counting down. **NOTICE:** When the timer reaches 00:00, the monitor will make a beep sound. Or Press ***Start timer*** when the timer is at 00:00 to start the timer counting up. **NOTICES:** • When the timer has been started, the text on the Start timer touch key will change to Stop timer. • During the first hour, the countup timer shows time in minutes and seconds (59:59), then it changes to hours and minutes. The maximum countup time is 99 hours and 59 minutes. • If the timer has been activated and one of the five countdown timers is selected, this will cause the timer in progress to stop and the new one to start.
3.	Press ***Stop timer*** to stop the countdown/countup. **NOTICE:** The text on the touch key will change to Start timer. If Start timer is pressed, the timer will continue the countdown/countup from where it stopped.
4.	To change the timer configurations, press ***Timer setup*** – the Timer setup screen will appear. (See *Timer setup* in chapter 3: *Menu structure and setup programs*).
5.	To reset the timer to 00:00, press ***Reset***.
6.	To close the dialog box, press ***Close***.

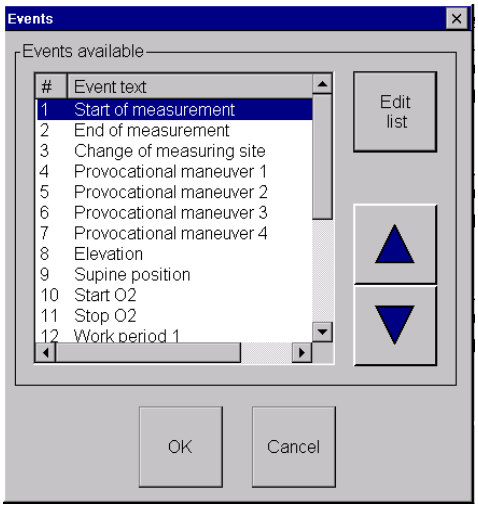
Continued on next page

In vivo monitoring, *continued*

Marking of event

Follow the steps below to mark an event while monitoring:

Step	Action
1.	Press ***Event***.



2.	Select a textual event from the list.
3.	Press ***OK*** to mark the event, or press ***Cancel*** to return to the previous screen without marking the event.

List of available events

The following predefined events are available:

1. Start of measurement
2. End of measurement
3. Change of measuring site
4. Provocational maneuver 1
5. Provocational maneuver 2
6. Provocational maneuver 3
7. Provocational maneuver 4
8. Elevation
9. Supine position
10. Start O_2
11. Stop O_2
12. Work period 1
13. Work period 2
14. Work period 3
15. Stasis
16. Stable point
17. Change HBO condition
18. Other 1
19. Other 2
20. Other 3

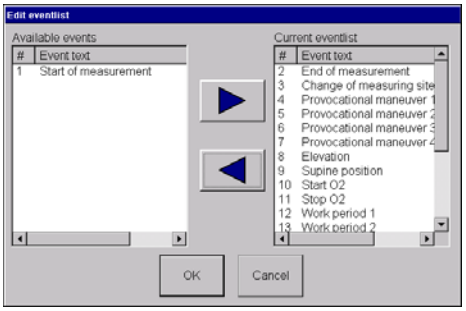
Continued on next page

In vivo monitoring, *Continued*

Configuration of event list

Follow the steps below to edit the list of events:

Step	Action
1.	Press ***Edit list***.

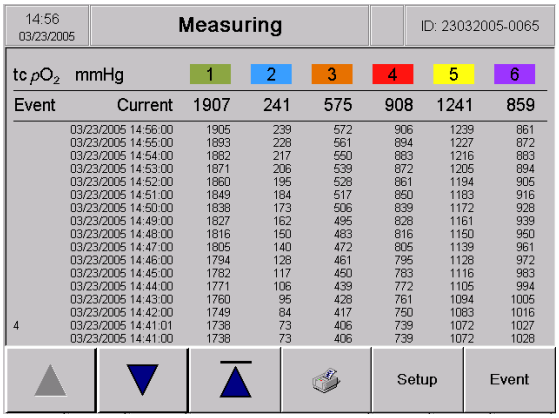


2.	The available events are listed to the left, and the events that have been selected are listed to the right. Events are added to/removed from the list to the right with the ***Left*** and ***Right*** arrows.
3.	Press ***OK*** to accept the changes or press ***Cancel*** to return to the Events screen without saving changes.

Trend table view

How to view a trend table

To view a Trend table, press ***Setup → Change view → Table view → OK.***



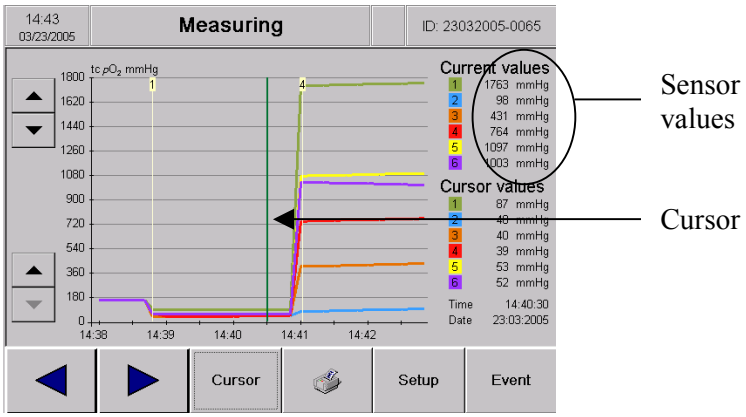
NOTICE: If the temperature of a sensor exceeds the preset temperature, the sensor value will be flashing.

Step	Action
1.	To scroll through the results, press the ***Up*** and ***Down*** arrows. If the arrows are held down, they scroll an entire screen. When scrolling is activated, the view becomes static and data will not automatically be updated when the monitor receives new data. By scrolling to the latest results, the view becomes dynamic and data will be updated when the monitor receives new data.
2.	To mark an event, press ***Event*** and select from a list of textual events. **NOTICE:** Events can only be inserted during Measuring mode.
3.	To print the results, press ***Print***. The printed report can be made in accordance with the Printer setup or as a SmartPrint (see the section *How to print* later in this chapter and chapter 3: *Menu structure and setup programs*). **NOTICES**: • The monitor must be connected to an HP printer with PCL3 protocol. • The memory function stores up to 48 hours of accumulated measuring data. • To view data in the Trend table view, it is necessary to be monitoring or to select a patient ID/session number into the view. • If measurement data is not available for all sensors, or if some measurements are missing for a specific sensor, a dash is shown in the specific field(s) in the table.

Trend curve view

Trend curve

To view a Trend curve, press ***Setup*** → ***Change view*** → ***Curve view*** → ***OK***.



NOTICE: If the temperature of a sensor exceeds the preset temperature, the sensor value will be flashing.

Step	Action
1.	To scroll through the results, press the ***Left*** and ***Right*** arrows. If the arrows are pressed, they scroll an entire time span (e.g. 1 hour); and if held down, they scroll normally but with built-in acceleration. When scrolling is activated, the view becomes static and data will not automatically be updated when the monitor receives new data. By scrolling to the latest results, the view becomes dynamic and data will be updated when the monitor receives new data.
2.	To display the cursor, press ***Cursor***. This will also change the function of the ***Left*** and ***Right*** arrow keys: they now move the cursor instead of time. If the cursor is moved all the way to one side, the time axis moves, which makes it possible to go back and forth in time. Cursor values as well as current values are shown to the right of the trend curve. Cursor values are always static. To remove the cursor from the screen, press ***Cursor***.
3.	To mark an event, press ***Event*** and select from a list of textual events. **NOTICE:** Events can only be inserted during Measuring mode.
4.	To adjust the high and low values of the parameter ranges shown in the Trend curve view, press the vertical arrow keys. When leaving the view, the monitor will remember the new range values.

Continued on next page

Trend curve view, *Continued*

Trend curve *(continued)*

Step	Action
5.	To print the results, press ***Print***. The printed report can be made in accordance with the Printer setup or as a SmartPrint (see the section *How to print* later in this chapter and chapter 3: *Menu structure and setup programs*). **NOTICES:** • The monitor must be connected to an HP printer with PCL3 protocol. • The memory function stores up to 48 hours of accumulated measuring data. • To view data in the Trend curve view, it is necessary to be monitoring or to select a patient ID/session number into the view. • If measurement data for a sensor is not available or if it is out of scale, the line reflecting the results of that sensor will not be shown.

How to print

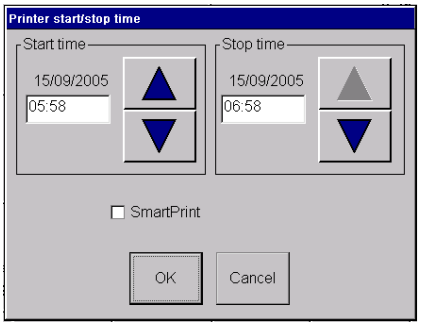
Connecting printer

Follow the steps below to connect a printer to the monitor:

Step	Action
1.	Shut down the monitor by following the procedure described in chapter 4: *Installation and maintenance*.
2.	Connect an HP printer with PCL3 protocol to one of the USB ports on the rear of the monitor. **NOTICE:** It is also possible to connect a printer to a TCM400 monitor with parallel port.
3.	Switch the monitor on and select the printer settings in Printer setup (see chapter 3: *Menu structure and setup programs*).

Printing

Follow the steps below to make a printout:

Step	Action
1.	Press ***Print***. 
2a.	To get a printout using the printer settings, set the Start and Stop time. **NOTICES:** • The memory function stores up to 48 hours of accumulated measuring data. • The default settings for printer Start time/Stop time for a session in progress are the last 60 minutes; and for an older session, they are the time of the last value in that session and 60 minutes backward. The default settings for Print time interval is 1 min.
2b.	To print a dump (i.e. what you see is what you get) of the actual view in Table or Curve view, activate SmartPrint. SmartPrint uses the view settings (range, span, interval, parameter, etc.) and is only available in the Table and Curve views; and if selected, the Start and Stop time input fields are grayed.

Continued on next page

How to print, *Continued*

Printing *(continued)*

Step	Action
3.	Press ***OK*** to make a printout and return to the previous screen, or press ***Cancel*** to return to the previous screen without making a printout. **NOTICES:** • It can take up to 30-60 seconds to generate the report(s) for printout, and during this time the Print touch key is grayed. • Even if several report types have been selected in Printer setup, only one "Comments" page will be printed. • If a report contains one or more events, the event numbers and texts are listed on a separate page at the end of each report.

Printout of timer-active measurements

There are two ways to print only the values that have been measured while the timer was active:

- In the Advanced printer setup, select "Timer active only"
- In the Trend table or Trend curve view options, select "View timer-active measurements only", go into Trend or Curve view and make a SmartPrint

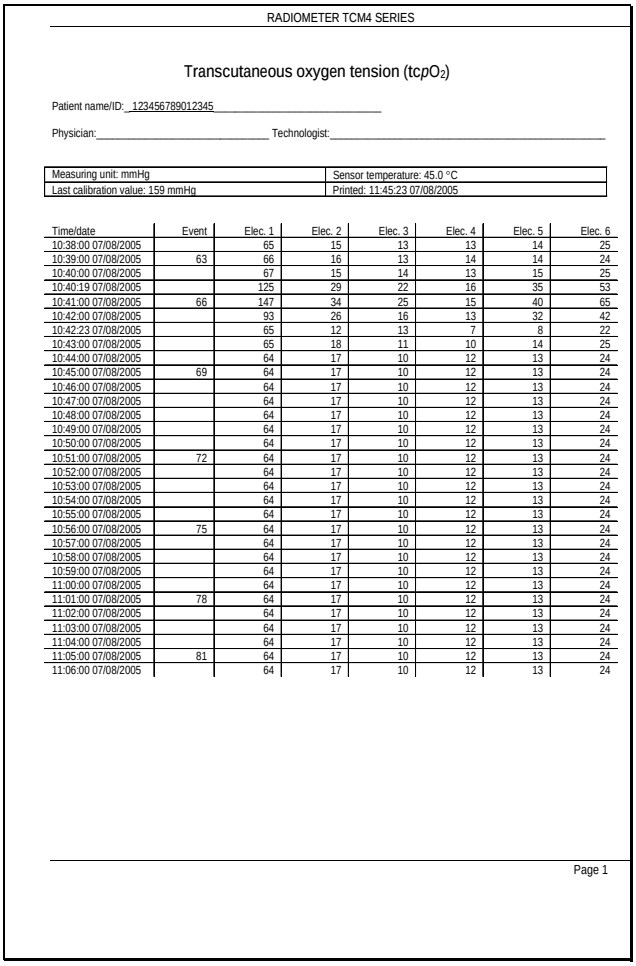
Examples of table and curve reports are shown on the following pages.

Continued on next page

How to print, *Continued*

Simple trend table

Below is an example of a simple trend table report for tcpO_2:



RADIOMETER TCM4 SERIES

Transcutaneous oxygen tension (tcpO_2)

Patient name/ID: 123456789012345

Physician:_____ Technologist:_____

Measuring unit: mmHg	Sensor temperature: 45.0 °C
Last calibration value: 159 mmHg	Printed: 11:45:23 07/08/2005

Time/date	Event	Elec. 1	Elec. 2	Elec. 3	Elec. 4	Elec. 5	Elec. 6
10:38:00 07/08/2005		65	15	13	13	14	25
10:39:00 07/08/2005	63	66	16	13	14	14	24
10:40:00 07/08/2005		67	15	14	13	15	25
10:40:19 07/08/2005		125	29	22	16	35	53
10:41:00 07/08/2005	66	147	34	25	15	40	65
10:42:00 07/08/2005		93	26	16	13	32	42
10:42:23 07/08/2005		65	12	13	7	8	22
10:43:00 07/08/2005		65	18	11	10	14	25
10:44:00 07/08/2005		64	17	10	12	13	24
10:45:00 07/08/2005	69	64	17	10	12	13	24
10:46:00 07/08/2005		64	17	10	12	13	24
10:47:00 07/08/2005		64	17	10	12	13	24
10:48:00 07/08/2005		64	17	10	12	13	24
10:49:00 07/08/2005		64	17	10	12	13	24
10:50:00 07/08/2005		64	17	10	12	13	24
10:51:00 07/08/2005	72	64	17	10	12	13	24
10:52:00 07/08/2005		64	17	10	12	13	24
10:53:00 07/08/2005		64	17	10	12	13	24
10:54:00 07/08/2005		64	17	10	12	13	24
10:55:00 07/08/2005		64	17	10	12	13	24
10:56:00 07/08/2005	75	64	17	10	12	13	24
10:57:00 07/08/2005		64	17	10	12	13	24
10:58:00 07/08/2005		64	17	10	12	13	24
10:59:00 07/08/2005		64	17	10	12	13	24
11:00:00 07/08/2005		64	17	10	12	13	24
11:01:00 07/08/2005	78	64	17	10	12	13	24
11:02:00 07/08/2005		64	17	10	12	13	24
11:03:00 07/08/2005		64	17	10	12	13	24
11:04:00 07/08/2005		64	17	10	12	13	24
11:05:00 07/08/2005	81	64	17	10	12	13	24
11:06:00 07/08/2005		64	17	10	12	13	24

Page 1

The simple trend table report contains the following:

- Space for adding: Signatures (of physician and technologist)
- Information about: Patient name/ID (from the Patient DMS)
  Measuring unit
  Sensor temperature
  Value of the last calibration that was completed successfully before the session started
  Time and date of printout
- Table of measurement data

  NOTICE: If measurement data is not available for all sensors, or if some measurements are missing for a specific sensor, a dash is printed in the specific field(s) in the table.
- Page number (if data stretch over more pages, page headers and page numbers are added to all pages)

Continued on next page

How to print, *Continued*

Advanced trend table

Below is an example of an advanced trend table report for tcpO_2:

RADIOMETER TCM4 SERIES

Transcutaneous oxygen tension (tcpO_2)

Patient name/ID: 123456789012345

Physician: _____ Technologist: _____

Measuring unit: mmHg	Sensor temperature: 45.0 °C
Last calibration value: 159 mmHg	Printed: 11:45:23 07/08/2005

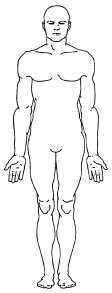
Time/date	Event	Elec. 1	Elec. 2	Elec. 3	Elec. 4	Elec. 5	Elec. 6
10:38:00 07/08/2005		65	15	13	13	14	25
10:39:00 07/08/2005	63	66	16	13	14	14	24
10:40:00 07/08/2005		67	15	14	13	15	25
10:40:19 07/08/2005		125	29	22	16	35	53
10:41:00 07/08/2005	66	147	34	25	15	40	65
10:42:00 07/08/2005		93	26	16	13	32	42
10:42:23 07/08/2005		65	12	13	7	8	22
10:43:00 07/08/2005		65	18	11	10	14	25
10:44:00 07/08/2005		64	17	10	12	13	24
10:45:00 07/08/2005	69	64	17	10	12	13	24
10:46:00 07/08/2005		64	17	10	12	13	24
10:47:00 07/08/2005		64	17	10	12	13	24
10:48:00 07/08/2005		64	17	10	12	13	24
10:49:00 07/08/2005		64	17	10	12	13	24
10:50:00 07/08/2005		64	17	10	12	13	24
10:51:00 07/08/2005	72	64	17	10	12	13	24
10:52:00 07/08/2005		64	17	10	12	13	24
10:53:00 07/08/2005		64	17	10	12	13	24
10:54:00 07/08/2005		64	17	10	12	13	24
10:55:00 07/08/2005		64	17	10	12	13	24
10:56:00 07/08/2005	75	64	17	10	12	13	24
10:57:00 07/08/2005		64	17	10	12	13	24
10:58:00 07/08/2005		64	17	10	12	13	24
10:59:00 07/08/2005		64	17	10	12	13	24
11:00:00 07/08/2005		64	17	10	12	13	24
11:01:00 07/08/2005	78	64	17	10	12	13	24
11:02:00 07/08/2005		64	17	10	12	13	24
11:03:00 07/08/2005		64	17	10	12	13	24
11:04:00 07/08/2005		64	17	10	12	13	24
11:05:00 07/08/2005	81	64	17	10	12	13	24
11:06:00 07/08/2005		64	17	10	12	13	24

Page 1

RADIOMETER TCM4 SERIES

Transcutaneous oxygen tension (tcpO_2)

Patient name/ID: 123456789012345



Technologist's comments:

Physician's interpretation:

Physician's signature: Date:

Page 2

The advanced trend table report contains the following:

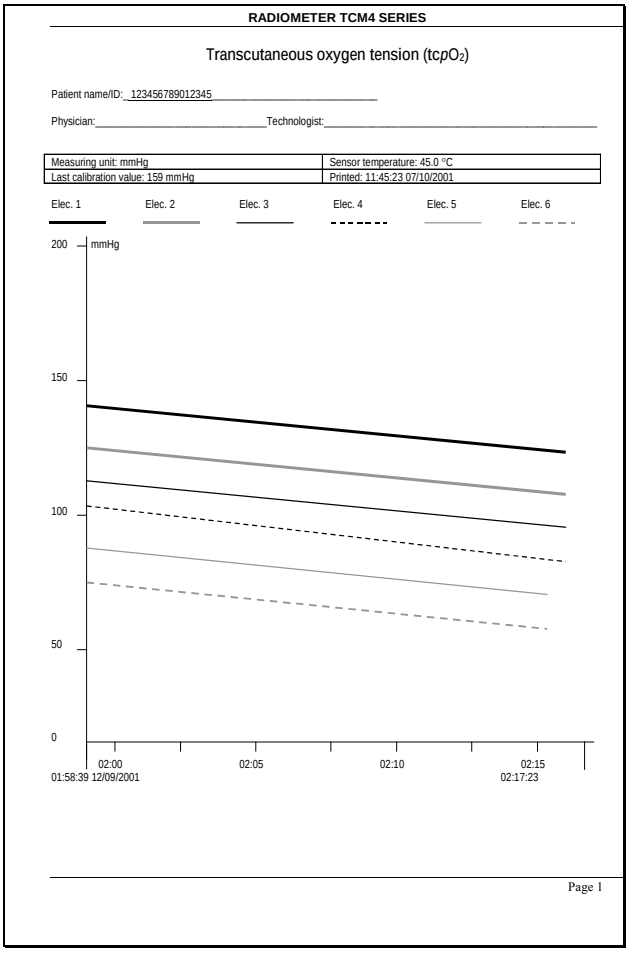
- Space for adding: Signatures (of physician and technologist)
- Information about: Patient name/ID (from the Patient DMS)
  Measuring unit
  Sensor temperature
  Value of the last calibration that was completed successfully before the session started
  Time and date of printout
- Table of measurement data

  NOTICE: If measurement data is not available for all sensors, or if some measurements are missing for a specific sensor, a dash is printed in the specific field(s) in the table.
- Body chart (of entire body, left leg and feet or right leg and feet) on which the sensor sites can be marked.
- Space for notes, physician's signature and date
- Page number

Continued on next page

How to print, *Continued*

Trend curve Below is an example of a trend curve report tcpO_2:



The above example shows a report in monochrome. When the printout of the report is in color, the colors of the lines are the same as on the display.

The trend curve report contains the following:

- Space for adding: Signatures (of physician and technologist)
- Information about: Patient name/ID (from the Patient DMS)
  Measuring unit
  Sensor temperature
  Value of the last calibration that was completed successfully before the session started
  Time and date of printout
- Data-versus-Time graph of measurement data

  NOTICE: If measurement data for a sensor is not available or if it is out of scale, the line reflecting the results of that sensor will not be shown.
- Page number

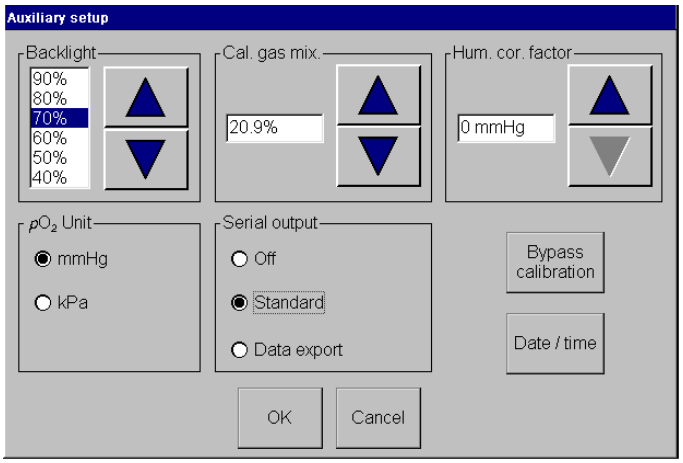
Serial data output: standard

Introduction

The TCM400 monitor is equipped with a continuous data output for direct connection to an external PC. The transmitted data consists of the current values, i.e. the values displayed in Normal view. This means that values for sensors that are in Ready mode are also transmitted.

Procedure

Follow the steps below to connect the monitor directly to an external PC:

Step	Action
1.	Connect the TCM4xx ETX serial adapter (code no. 636-649) to the serial port on the TCM400 monitor and to the PC (e.g. the COM1 port). The RS232 output from the TCM400 monitor is transmitted continuously every two seconds in ASCII code in the following format: [Timestamp]; [Sensor no.]; [O_2]; [RPI]; [Heater power]; [Temperature]
2.	On the TCM400 monitor, press ***Setup*** → ***Setup*** → ***Technical*** and enter the password.
3.	Press ***Auxiliary setup***, select "Standard" and press ***OK***. 

Continued on next page

Serial data output: standard, *continued*

Procedure *(continued)*

Step	Action
4.	On the PC, select: ***Start*** → ***Programs*** → ***Accessories*** → ***Communications*** → ***HyperTerminal***.

Type in a name for the connection, e.g. TcData, and then click ***OK***.

5.

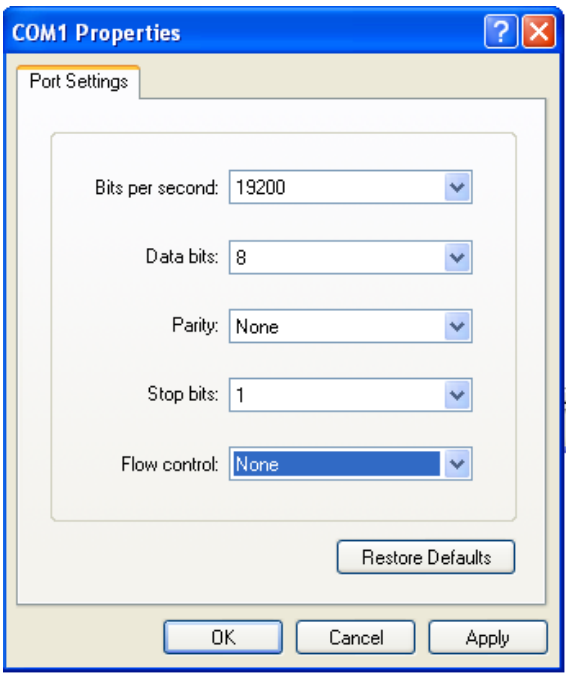
Connect using: COM1 and click ***OK***.

Continued on next page

Serial data output: standard, *continued*

Procedure ***(continued)***

Step	Action
6.	Select the following port settings and click ***OK***.



7.	Collect the data in HyperTerminal: • select ***Transfer*** → ***Capture text*** • name the file, e.g. CAPTURE.txt • click ***Start***

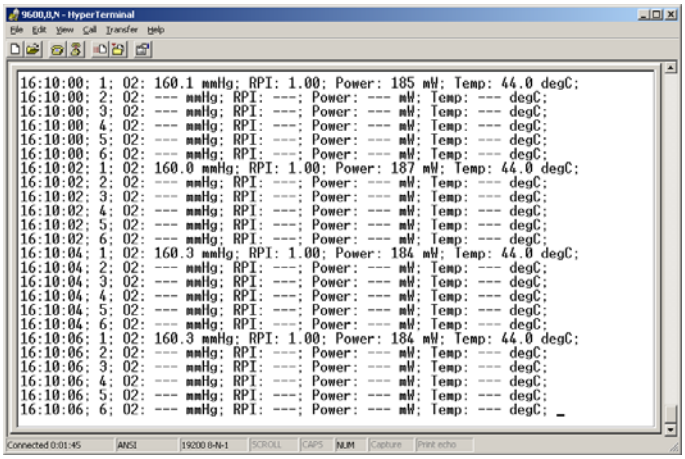
Continued on next page

Serial data output: standard, *Continued*

Procedure ***(continued)***

Step	Action
8.	Stop the collection of data to the file in HyperTerminal by selecting ***Transfer*** → ***Capture text*** → ***Stop***.

The following shows a screen from HyperTerminal:



NOTICE: Data is easily imported into other programs, e.g. Microsoft Excel (see procedure under Data export).

Serial data output: data export

Introduction With the data export option, a dump of the trend data can be exported to an external PC and presented in spreadsheet format.

Procedure Follow the steps below to export data from the TCM400 monitor to a PC. In the example below, HyperTerminal version 690170 with Excel version 97 SR-2 is used:

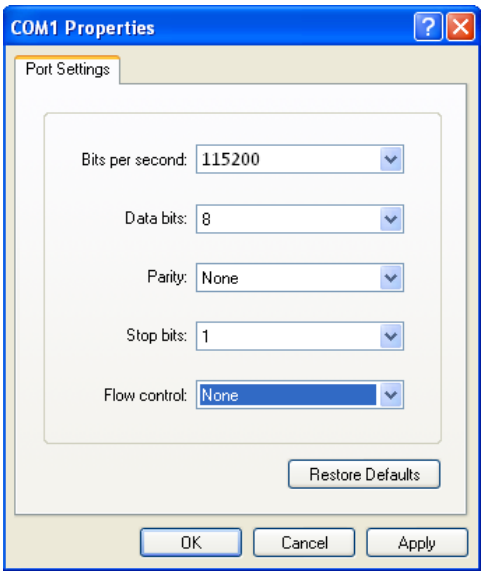
Step	Action
1.	Connect the TCM4xx ETX serial adapter (code no. 636-649) to the serial port on the TCM400 monitor and to the PC (e.g. the COM1 port).
2.	On the PC, select: ***Start*** → ***Programs*** → ***Accessories*** → ***Communications*** → ***HyperTerminal***.  Type in a name for the connection, e.g. TcData, and click ***OK***.
3.	 Connect using: COM1 and click ***OK***.

Continued on next page

Serial data output: data export, *Continued*

Procedure *(continued)*

Step	Action
4.	Select the following port settings and click ***OK***.

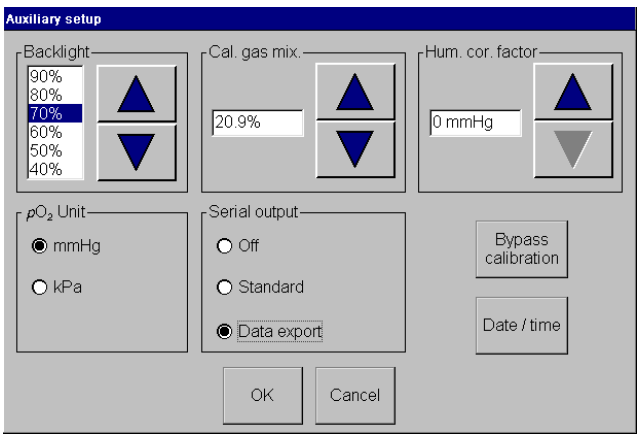


5. Collect the data in HyperTerminal:

- select ***Transfer*** → ***Capture text***
- name the file, e.g. CAPTURE.txt
- click ***Start***

6. On the TCM400 monitor, press ***Setup*** → ***Setup*** → ***Technical setup*** and enter password.

7. Press ***Auxiliary setup***, select "Data export" and press ***OK***.



8. Go into the Patient DMS and add a check mark to the session(s) you want to export. Press ***Export*** and wait for the data to be transmitted.

NOTICE: During data transmission, the Export touch key is grayed.

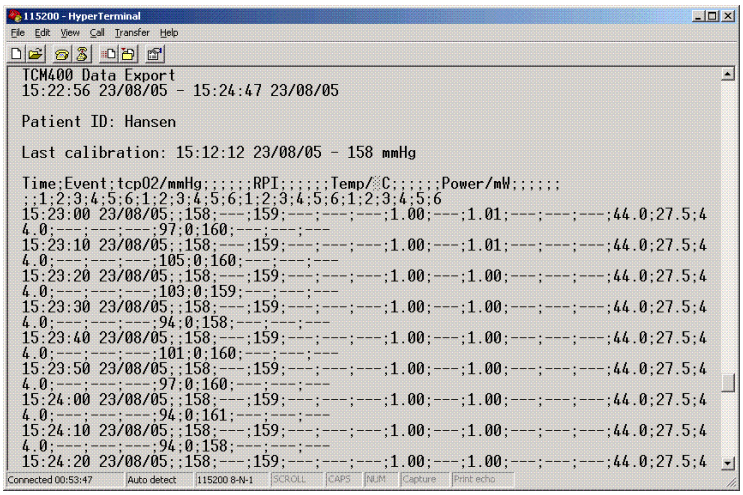
Continued on next page

Serial data output: data export, *Continued*

Procedure *(continued)*

Step	Action
9.	On the PC, stop the collection of data to the file in HyperTerminal by selecting ***Transfer → Capture text → Stop***.

The following shows an extract of a screen from HyperTerminal:



NOTICE: If measurement data is not available for all sensors, or if some measurements are missing for a specific sensor, a dash is shown in the specific field(s).

General information about exporting data to Microsoft Excel

Before exporting data to Microsoft Excel, please note the following:

Control characters:

The patient data has been prepared for data handling programs that separate and organize data. It therefore contains control characters to mark the beginning and end of a session, the patient ID, etc. This, however, causes a problem with regard to Excel, as the control characters will not be filtered out of the exported data but be displayed as "□□□" (see the screen in step 6 in the procedure below).

NOTICE: After exporting data to Excel, you have the option of deleting the "□" characters from your Excel file.

Patient ID:

Patient IDs are Unicode characters exported in byte format. Therefore they are displayed in Excel in one of the following ways:

- For languages based on a standard ASCII character set (Basic Latin), a space is added in front of each character, e.g. " S m i t h"
- For Japanese, Greek and Russian, all characters in the patient ID are replaced with non-readable characters – unless the patient ID is composed of numerical values only

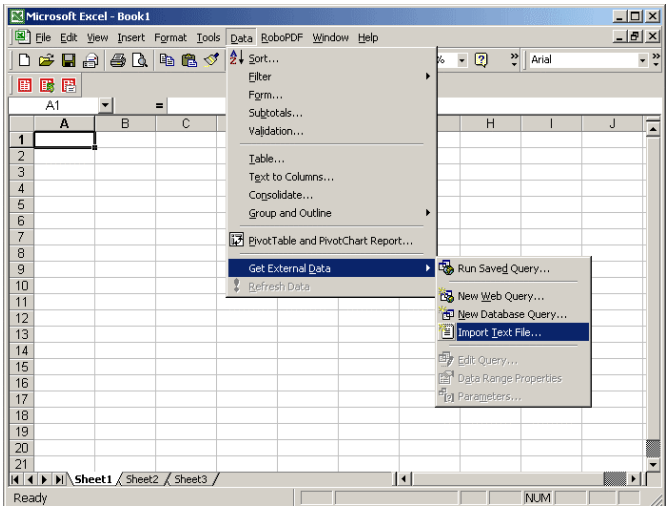
Continued on next page

Serial data output: data export, *Continued*

Data files in Microsoft Excel

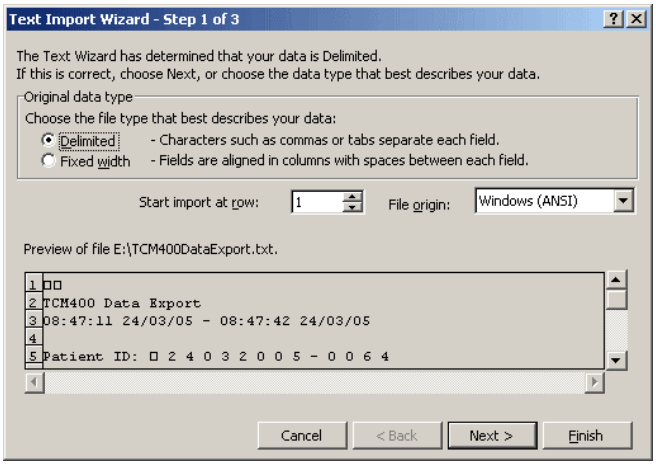
Step	Action

1. Open Excel and select ***Data → Get External Data → Import Text File***.

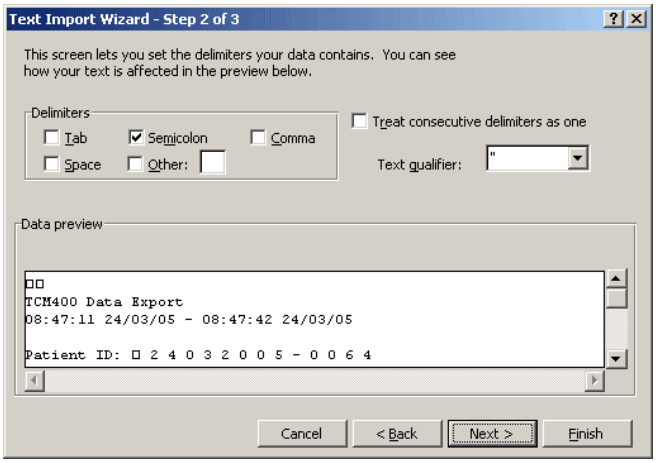


2. Select the file CAPTURE.txt and click ***Import***.

3. Select the following settings and click ***Next***.



4. Select the following settings and click ***Finish***.

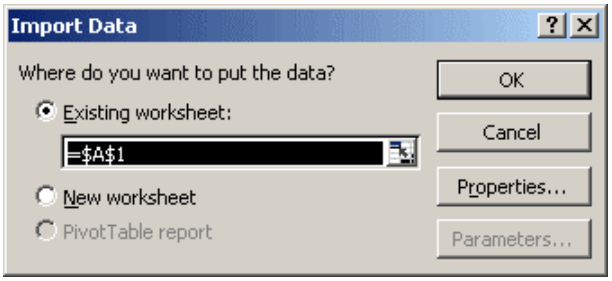


Continued on next page

Serial data output: data export, *Continued*

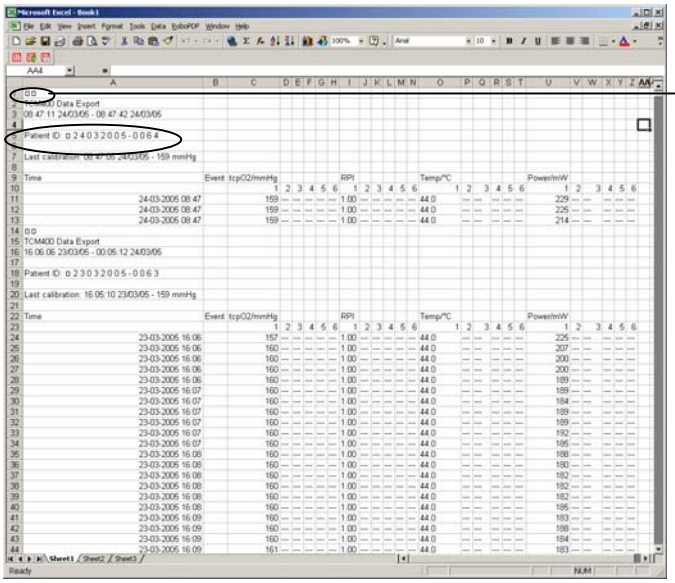
Data files in Microsoft Excel *(continued)*

Step	Action
5.	Select the following settings and click ***OK***.



6. Data is imported to Excel.

The following shows an extract of a screen from Excel:



7. Save (Log Excel worksheet).

7. Troubleshooting

Overview

Introduction This chapter describes the errors, their causes, and the recommended operator actions.

In this chapter This chapter covers the following topics:

The monitor

Introduction

The status of the system is continuously monitored during operation. When problems or errors occur, they are automatically recorded and presented to the operator on the screen.

This chapter describes the errors, their causes and the recommended operator actions.

Error symptoms

The following table lists the errors symptoms for the monitor:

Symptom	Cause	Recommended actions
Measured values drift when sensor is measuring on cal gas (in vitro) or air	• Insufficient removal of old electrolyte during membraning procedure • Air bubbles in electrolyte • The sensor membrane has not been changed regularly • Sensor zero current check has not been performed regularly • Defective sensor membrane (holes or scratches) • Defective O-rings (one or both O-rings broken)	Remembrane the sensor
Measured values drift constantly without any physiological cause when sensor is mounted on patient (in vivo)	• Improper attachment of the sensor • Improper attachment of the fixation ring • An inappropriate measurement site has been selected • Inadequate vasodilation	• Detach the sensor and reapply correctly • Detach the fixation ring and reapply correctly
Measured values not stable or out of limits 20 minutes after application	• Patient status unstable • Inadequate vasodilation • Improper attachment of the sensor	• Evaluate patient status • Remount the sensor

Continued on next page

The monitor, *Continued*

Error symptoms *(continued)*

Symptom	Cause	Recommended Actions
Measured values change suddenly without any physiological cause	• Artifact due to patient movements • Air leakage under fixation ring • Self-adhesive ring does not stick to the skin	Recalibrate and reapply sensor to the skin, possibly selecting a new measuring site
Noise appears on the tension readout	Interference from nearby equipment	Increase the distance from the interfering equipment
Monitor not operational	• Monitor is defective • Battery is exhausted • Monitor is not connected to mains	• Check the connection • Contact authorized service personnel
Battery low (battery bar and “High” and “Low” are flashing)	Battery level is low	Connect the monitor to the mains
Battery low (battery bar and “High” and “Low” are flashing and a continuous alert sound is heard)	Battery level is critically low	Connect the monitor to the mains immediately

Error messages The following table lists the error messages for the monitor in alphabetical order:

Error message	Cause	Recommended actions
Cal error, barometer	Barometer value invalid when collected at start of calibration	• Start a new calibration • If error remains, contact authorized service personnel
Cal error, chamber	No sensor detected in the calibration chamber at start of or during calibration	Place a tcpO_2 sensor in the chamber
Cal error, drift	The sensor is rejected during the drift check	• Start a new calibration • If error remains, remembrane the sensor and start a new calibration. • If error still remains, the sensor is defective. Replace with a new one.

Continued on next page

The monitor, *continued*

Error messages *(continued)*

Error message	Cause	Recommended actions
Cal error, sensitivity	The sensor sensitivity is outside the specifications	• Remembrane the sensor and start a new calibration • The sensor is defective. Replace with a new one.
Cal error, temperature	The selected sensor temperature value cannot be reached	• Calibrate the sensor • If error remains, the sensor is defective. Replace with a new one.
Calibration required	• The last calibration has been aborted • Eight hours have passed since the last successful calibration	Perform a calibration
Heater failure	• The sensor has been subject to excessive heating • The measured power is outside the measuring range	• Calibrate the sensor • If error remains, the sensor is defective. Replace with a new one.
Module disappeared	For unknown reasons, the communication between the monitor and the module has not been satisfactory	• Turn the monitor off and on • If error remains, try with another module • If error still remains, contact authorized service personnel
No sensor connected	• No sensor detected in the calibration chamber • The sensor in the calibration chamber is not functioning	Connect a functional tcpO_2 sensor
Out of range	The measured tcpO_2 value is outside the measuring range	• Replace the sensor with a new one • Recalibrate the sensor

Continued on next page

The monitor, *continued*

Error messages *(continued)*

Error message	Cause	Recommended actions
Temp. error	• Measured temperature is outside the measuring range • The two sensor thermistors give different temperatures • The selected sensor temperature cannot be reached • The sensor temperature is too high	• Calibrate the sensor • If error remains, the sensor is defective. Replace with a new one.
Temp. warning	The selected sensor temperature cannot be reached	Wait until it is reached

Dialog box messages

A number of messages (system messages and alerts) appear in dialog boxes. The following table lists these messages in alphabetical order:

System message	Cause	Recommended actions
Battery level is critically low. Data and setup changes cannot be saved on disk.	There is less than 5 minutes running time left on the battery	Connect monitor to the mains
Battery not connected. Data and setup changes cannot be saved on disk.	No battery connected	Attach a battery and connect the monitor to the mains
Changing date/time backward in time results in loss of data. Only data from before the new time will be available.	The date/time settings are changed backward in time	• Press ***OK*** to accept the new settings • Press ***Cancel*** to abort
Data from more than one patient cannot be selected into a view	The user has tried to load sessions from different patient IDs into a view	Select only sessions linked to the same patient ID
Date and time cannot be set during measurement	The user has tried to enter the Date/time setup during measurement	Press ***OK*** to abort

Continued on next page

The monitor, *Continued*

Dialog box messages *(continued)*

System message	Cause	Recommended actions
Incorrect password. Try again.	Wrong password entered in Technical setup	Try again or use 19100
Incorrect time. Try again.	The user has entered an incorrect time format	Enter a valid time format (see the topic *Date and time* in chapter 3)
Memory low	The PC has run out of memory	• Close irrelevant programs • Turn the monitor off and on
Monitor temperature too high. Please shut down system immediately.	The temperature in the CPU is too high, possibly because the fan has stopped or is blocked.	Turn off the monitor and contact authorized service personnel
No sessions selected. Please select one or more sessions.	The user has tried to view session information without selecting a session	Press ***OK*** to abort
One or more sessions will be deleted from the system. This action cannot be undone.	The user has selected one or more sessions in the Patient DMS and pressed ***Delete*** or ***Delete all***	• Press ***OK*** to delete the sessions • Press ***Cancel*** to keep the sessions
The monitor is measuring. Current session cannot be deleted.	The user has tried to delete the session in progress	Press ***OK*** to abort
The monitor is measuring. No other sessions can be loaded into the view.	The user has tried to select one or more sessions – other than the one in progress – into a view	Press ***OK*** to abort

System status messages

The following table lists the system status messages in alphabetical order:

System message	Cause
Calibrating	All sensors are being calibrated
Calibration required	At least one of the sensors must be calibrated
Measuring	At least one of the sensors is measuring
Ready	All sensors have been calibrated and are ready for use

8. Specifications and ordering information

Overview

Introduction This chapter contains the specifications and ordering information for the TCM400 transcutaneous pO_2 monitoring system.

In this chapter This chapter covers the following topics:

Specifications

TCM400 monitor

The table below lists the specifications for the TCM400 monitor:

Item	Description
Parameters	Measured: tcpO_2 and sensor heating power Derived/calculated: RPI – Regional Perfusion Index
tcpO_2 range	0-2000 mmHg or 0-266.7 kPa
RPI	0-3
Accuracy	Better than ± 2 mmHg or 0.2 kPa ± 0.1 % of reading at 25 °C (excluding sensor)
Polarization voltage	–680 mV ± 5 mV
Sensor heating power range	10-500 mW Displayed accuracy: ± 3 %
Temperature settings in °C	37.0 to 45.0 °C in steps of 0.5 °C Accuracy better than ± 0.1 °C (excluding sensor)
Barometer	Built-in: 375-825 mmHg or 50-110 kPa Accuracy: ± 5 mmHg or 0.67 kPa
Calibration	Atmospheric air
Ambient relative humidity	20-80 %
Ambient temperature	Monitor: 5-40 °C tc sensors: 15-40 °C **NOTICE:** The ambient temperature must always be at least 3 °C lower than the set sensor temperature.
Data storage	Up to 48 hours of accumulated measuring data from six tcpO_2 sensor modules in 10-second data intervals
Computer	Screen: 6½" color touch TFT, full VGA (640 × 480) CPU: AMD ETX LX800, 500 MHz (Pentium Class) Software platform: Windows CE 5.0
Dimensions of monitor	Height: 16 cm 6.3 in Width: 30.8 cm 12.1 in Depth: 23 cm 8.7 in Weight: 4 kg (including battery) 8.8 lbs
Dimensions of sensor module	Height: 3.5 cm 1.4 in Width: 14.5 cm 5.7 in Depth: 14.8 cm 5.8 in Weight: 0.22 kg 0.5 lb
Power supply	100-240 V 50-60 Hz

Power consumption	70 VA	
Interface connection	Serial output	EIA232, (RS232)
	Printer output	USB 2.0 (Compliant with USB 1.1)
Battery	Rechargeable Pb battery	Under normal conditions, the battery can operate for 1 hour with three modules before recharging is needed

EMC approvals and compliance

The TCM400 system is intended for use in the electromagnetic environment specified in the tables below. The customer or user of the TCM400 system should assure that it is used in such an environment. The TCM400 system complies with IEC 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	TCM400 system's RF emissions are very low and they are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The TCM400 system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Continued on next page

Specifications, *Continued*

EMC approvals and compliance *(continued)*

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % drop in U_T) for 0.5 cycle 40 % U_T (60 % drop in U_T) for 5 cycles 70 % U_T (30 % drop in U_T) for 25 cycles < 5 % U_T (> 95 % drop in U_T) for 5 seconds	Not applicable, as the TCM400 monitor has battery backup	None
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	None

NOTICE: UT is the AC mains voltage prior to application of the test level.

WARNING – *Risk of incorrect measurements*
Do not use the monitor adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If stacking or use adjacent to other equipment is necessary, the monitor should be observed to verify normal operation before used on patients. See the section *EMC approvals and compliance* in chapter 8.

WARNING – *Risk of incorrect measurements*
When installing, operating or servicing the monitor, special consideration should be given to the information regarding the electromagnetic precautions for this equipment given in the section *EMC approvals and compliance*. Otherwise the monitor may be affected by electromagnetic interference, causing incorrect measurements.

Specifications, *Continued*

EMC approvals and compliance *(continued)*

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the TCM400 monitor, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TCM400 system is used exceeds the applicable RF compliance level noted above, the TCM400 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TCM400 system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTICE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTICE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Continued on next page

Specifications, *Continued*

EMC approvals and compliance *(continued)*

Recommended separation distances between portable and mobile RF communications equipment and the TCM400 system

The TCM400 system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the TCM400 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TCM400 system as recommended below, according to the maximum output power of the communications equipment.

Rated output power of transmitter Watts	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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 rated at an output power not listed above, the recommended separation distance *d* in meters can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in the corresponding column.

NOTICE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTICE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Other approvals and compliance

Item	Description
Patient safety	• The instrument complies with IEC 60601-1 and IEC 60601-2-23. • The following test house has approved the instrument: CSA in Canada according to CAN/CSA-C22.2 No. 601.1-M90, 601.1S1-94, 601.1B-98, and UL std. No. 601.2.23-02 and 60601-1.

Continued on next page

Specifications, *Continued*

Other approvals and compliance *(continued)*

Item	Description
Compliance	The TCM400 system complies with: • IEC-60601-1, Medical electrical equipment – Part 1: General requirements for safety • IEC-60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests • IEC-60601-2-23, Medical Electrical Equipment – Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment • IEC-60601-3-1, Medical Electrical Equipment Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment • Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (tc*p*CO_2) and Oxygen (tc*p*O_2) Monitors; Guidance for Industry and FDA (December 13, 2002)
IEC 60601-3-1 Performance Specifications	**Linearity** The IEC 60601-3-1 requirement to linearity (± 5 mmHg/ ± 0.66 kPa) is fulfilled for gas concentration between 2 % O_2 and 20.9 % O_2. * At zero % O_2 the linearity is better than 1 mmHg * At 90 % O_2 the linearity is better than 25 mmHg (equal to 4 %) The above linearity data was obtained at an sensor temperature of 43 °C.

Continued on next page

Specifications, *Continued*

Other approvals and compliance *(continued)*

Item	Description
IEC 60601-3-1 Performance Specifications (continued)	**Drift** The IEC 60601-3-1 requirement to drift ≤ 5 % of initial reading over the calibration interval is fulfilled. The following max. drift per hour has been measured at a sensor temperature of 43 °C. Max. drift per hour at 10% O_2: 1.0 % Max drift per hour at 20% O_2: 0.7 % **Response time (10 % to 90 % response)** The following max. response times have been measured at a sensor temperature of 43 °C. 2 % O_2 to 20.9 % O_2: 11 seconds 20.9% O_2 to 2 % O_2: 11 seconds **Test conditions** All tests have been performed after preparation and calibration of the sensor according to the operator's manual. The linearity tests have been performed using the calibration chamber as a test chamber. The test gases used for the tests were dry gases fed to the calibration chamber at a flow rate of 10-15 mL/min. The drift tests have been performed simulating "in vivo" conditions, i.e. with the sensor in contact liquid as during in vivo monitoring. These test conditions have been obtained by placing the sensor in the sensor protection cap filled with contact liquid for four hours (the calibration interval). The drift value calculation is based upon the gas readings before and after the four hours. The gas readings are obtained using the calibration chamber as test chamber feeding the dry test gas to the calibration chamber at a flow rate of 10-15 mL/min. The temperature of the test gases corresponds to the ambient temperature (21-23 °C).

Continued on next page

Specifications, *Continued*

Other approvals and compliance *(continued)*

Item	Description
Known sources of interference	After an hour's exposure, halothane (4 % evaporated into Carrier Gas) will interfere with the tc*p*O_2 readings of the E5250 sensor and thereby also influence the combined effects of non-linearity and hysteresis (beyond ±6 mmHg/±0.8 kPa). Furthermore, if the patient is treated with Halothane, this may cause changes in the skin blood flow and in this way interfere with the tc*p*O_2 readings. The following substances have been tested and shown not to influence the combined effects of non-linearity and hysteresis (within ±6 mmHg/±0.8 kPa): • Nitrous oxide (in a gas mixture of 60 % N_2O, 20.9 % O_2, 5 % CO_2, balance N_2). In the following referred to as Carrier Gas. • Enflurane: 5 % evaporated into Carrier Gas. • Isoflurane: 5 % evaporated into Carrier Gas. • Sevoflurane: 5 % evaporated into Carrier Gas. • Desflurane: 12 % evaporated into Carrier Gas.
Biocompatibility	The suitability of the fixation ring adhesives for use on intact human skin is supported by a series of in vitro and in vivo evaluations. The fixation ring adhesives meet the requirements of the ISO 10993-1, "Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing" for surface devices contacting intact human skin. The evaluations include cell cytotoxicity, skin irritation and sensitization potential.

Materials and accessories

All materials and accessories	All materials and accessories are latex-free.

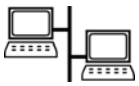
E5250 tc*p*O_2 sensor

The table below lists the specifications for the tc*p*O_2 sensor:

Item	Description
Dimensions	Diameter: • Sensor housing: 15 mm 0.6 in • Silver body: 9.1 mm 0.36 in Height: 11.3 mm 0.44 in Weight: 2.9 g 0.1 oz
Pressure on skin	0.015 g/mm^2 0.05 4 lb/sq.in
Sensor cable length	2.25 m 88.6 in

Specifications, *Continued*

List of symbols The following symbols are used with the TCM4 Series monitoring system:

Symbol	Explanation
	Barcode
	CSA approved
	COM (communication) port
	Printer
	Battery
	Ethernet interface connection to network. Not for phone connection.
	Power switch - Standby
	Manufactured by
	Type BF (body floating) equipment

Continued on next page

Specifications, *continued*

List of symbols *(continued)*

Symbol	Explanation
CE 0459	Product complies with the requirements of the Medical Device Directive 93/42/EEC June 1993. This product is a class IIa device.
	Caution, consult accompanying documents
	**Waste of Electrical and Electronic Equipment (WEEE)** The symbol indicates that: • Radiometer Medical ApS and its distributors within the European Union (EU) and associated states have taken the necessary steps to comply with the directive, 2002/96/EC on waste electrical and electronic equipment (WEEE) • The instrument, when reaching its end of life, must be collected and recycled separately from other waste according to national requirements. Please contact your local Radiometer distributor for instructions. Environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health.
	Store between the temperatures shown on the symbol. Example shows the temperature range between 10 and 25°C.
	Lot number
	Expiry date. Do not use after this date.
	See instructions for use

Accessories

TCM400 system accessories

Type	Description	Code no.
E5250	tcpO_2 sensor	945-605
D826	tcpO_2 accessory kit that contains: • tcpO_2 electrolyte solution • 12 white membrane units with PP membrane • O-ring remover key • Cleaning paper, bag with 20 pieces	904-308
D282	Fixation kit that contains: • 4 × 25 disposable fixation rings • 4 × 20 mL contact liquid	904-891

Line cords

Description	Code no.
Line Cord 115–120V, USA and JPN	615-407
Line Cord 230V, UK	615-312
Line Cord 230V, ITA	615-313
Line Cord 230V, DK	615-314
Line Cord 230V, ISR	615-315
Line Cord 230V, CHE	615-316
Line Cord 230V, other 230V countries	615-303
Line Cord 230V, AUS and NZA	615-317
Line Cord 230V, ZAF and IND	615-318

TCM400 documentation

Item	Code no.
Operator's manual, English	989-592
TCM4 Series service manual, English	989-579
CD-ROM with TCM400 operator's manual, English	990-590

Continued on next page

Accessories, *Continued*

Additional items In addition, the following accessories are available:

Description	Code no.
CAL2 standard calibration gas: 10 % CO_2, balance N_2, 999 m L	962-154
Protection cap for E5250 sensor, white	940-419
Color code kit, 18 tags	940-844
tc*p*O_2 sensor module incl. release key	902-564
TCM4xx ETX serial adapter	636-649
12V 2AH lead-acid battery	431-018
Unassembled connector kit for hyperbaric chamber	905-660
Connector kit for ETC hyperbaric chamber	905-688
Passthrough cable	905-751
Extension cable for tc*p*O_2 sensor. Length: 3 meters (118.1 in). **NOTICE:** The total length of cable between the sensor and the TCM400 monitor must not exceed 10 meters.	617-853
Extension cable for tc*p*O_2 sensor. Length: 6 meters (236.2 in). **NOTICE:** The total length of cable between the sensor and the TCM400 monitor must not exceed 10 meters.	617-864

9. Functional description

Overview

Introduction

This chapter gives functional descriptions of:

- the construction of the tcpO_2 sensor and the theory behind its calibration and measurement
- the solutions used with the system and their approximate compositions

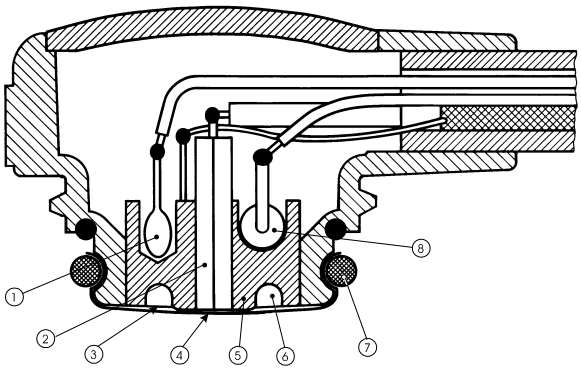
In this chapter

This chapter covers the following topics:

The tcpO_2 sensor

The sensor components

The E5250 tcpO_2 sensor combines a heating element, temperature sensors and a Clark-type oxygen sensor in a single unit.



Number	Component
1	2 NTC resistors – temperature sensors
2	Platinum cathode
3	Electrolyte covering the sensor surface
4	O_2 permeable membrane
5	Ag reference sensor
6	Electrolyte reservoir
7	Two O-rings to secure the membrane
8	Heating element

The NTC resistors

The temperature of the sensor is sensed by the NTC resistors incorporated in the Ag reference sensor. Due to the high thermal conductivity of the silver body, the NTC resistors respond quickly to any changes in temperature. The thermostatting system will keep the sensor at the preset temperature.

Local vasodilation

When the sensor is attached to the skin, the generated heat is transferred from the heating element via the silver body to the skin surface. The heating produces local vasodilation and increases the permeability of the skin to oxygen, thus making a measurement on the skin surface possible.

Measurement

Definition

The measurement of pO_2 is defined as the partial pressure (or tension) of oxygen. It is performed as a direct polarographic measurement based on an electro-chemical sensor chain consisting of the platinum cathode (the electrode sensor) and the silver anode (the reference sensor).

Measurement principle

The sensor tip is covered with a thin membrane, which stabilizes the conditions of diffusion to the sensor. Oxygen diffuses through this membrane to the cathode where a reduction of oxygen occurs as a result of the current-generating process:

$$O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$$

At the anode the following reaction takes place:

$$4Ag + 4Cl^- \rightarrow 4AgCl + 4e^-$$

The reduction of oxygen at the sensor's cathode generates a current, which is fed into the pO_2 channel where it is converted into a voltage and digitized. This digitized signal is then passed on to the microcomputer where it is reconverted to display pO_2 in mmHg or kPa.

Patient safety features

In order to satisfy the requirements for patient safety, the circuitry that is interconnected with the sensor is galvanically isolated from the rest of the system.

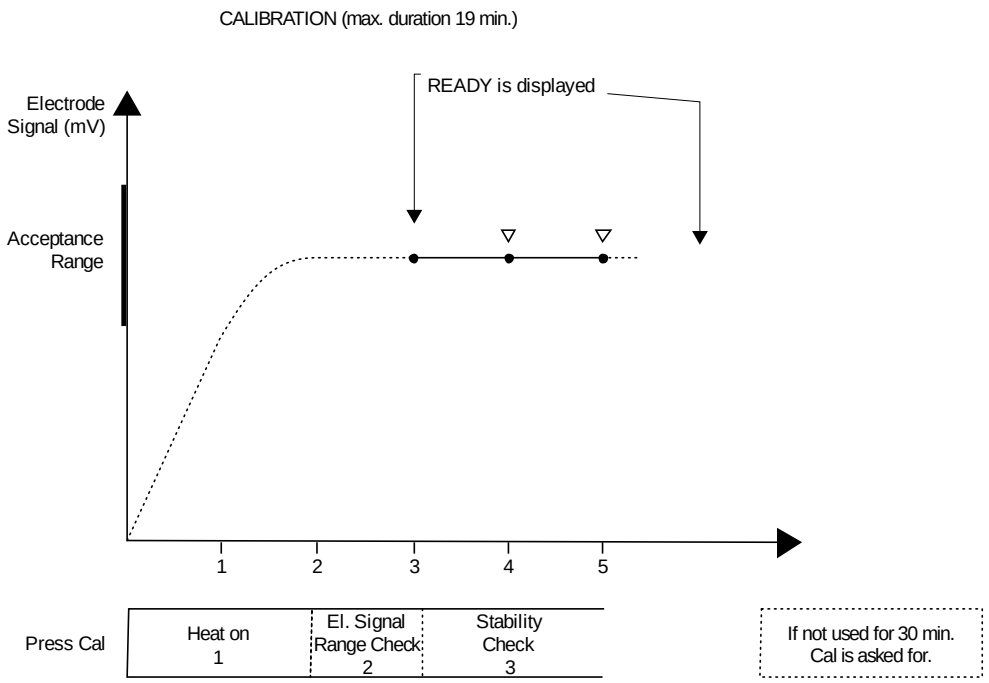
The TCM400 system is equipped with an extensive safety system for controlling and for continuous surveillance of the sensor temperature:

- The microprocessor program gives an audiovisual alarm if the sensor temperature deviates ± 0.3 °C from the preset value. The error message *Temp. error* is displayed.
- The sensor power consumption is permanently supervised. If it exceeds maximum effect for more than two minutes during a measurement, the heat switches off. The error message *Heater failure* is displayed. Although it is an effective safety feature, it may cause problems if the sensor has been immersed for more than 2 minutes in a cold disinfectant solution after calibration. The only remedy is to raise the temperature of the solution.
- If the sensor temperature reaches 46 °C, this could indicate a short or an open circuit in the thermostatting control loop. In this case, the monitor utilizes one of several hardware controls to shut off immediately and permanently.

Calibration

Calibration process

The calibration process includes the stages described in the table:



Stage	Description
Heating of the sensor	The sensor will typically be heated to the preset temperature within one minute. If it has not reached this temperature within three minutes, the computer will reject the sensor and the error message *Cal error, temperature* will be displayed.
Checking the sensor signal range	When the sensor has reached the preset temperature, the TCM400 system checks the sensor pO_2 signals. If they are not within a specified range within 1 minute, the monitor rejects the sensor and the error message *Cal error, sensitivity* will be displayed.
pO_2 value adjustment	The pO_2 measurement is performed on atmospheric air, and the pO_2 value is adjusted to the pO_2 value of atmospheric air.

Continued on next page

Calibration, *Continued*

Calibration process *(continued)*

Stage	Description
Sensor stability check	The TCM400 system checks the sensor stability for maximum 10 minutes until the change in the sensor signal is less than 1 % compared with the signals registered 1 minute and 30 seconds earlier. If the stability criterion is not fulfilled, the TCM400 system rejects the sensor and the error message *Cal error, drift* is displayed. If the stability is accepted, the TCM400 system displays *Ready*. The sensor signal range check continues during the stability check. If, during the stability check, the pO_2 signal exceeds the sensor signal range limits, the error message *Cal error, drift* will be displayed.

Solutions and calibration gas

Solutions

The following solutions are used with the TCM400 system:

Solution	Description	
tcpO_2 electrolyte solution, 10 mL	Use:	To be applied on the clean sensor surface.
	Composition:	1,2-propanediol, potassium chloride, sodium hydrogen carbonate and deionized water.
	Storage:	At room temperature or below.
	Stability:	Expiration date and lot no. are printed on a separate label on the bottle.
Contact liquid, 20 mL	Use:	To establish contact between the skin and the sensor during in vivo measurements.
	Composition:	1,2-propanediol and deionized water.
	Storage:	At room temperature or below.
	Stability:	Expiration date and lot no. are printed on a separate label on the bottle.

NOTICE: Keep the bottle caps on when bottles are not in use.

Zero point check gas

The CAL2 standard calibration gas:

Use:	To check the sensor zero current.
Composition:	10 % CO_2, with N_2 as balance gas.
Storage:	At room temperature.
Volume:	1 L cylinder (blue label).
Stability:	Expiration date and lot no. are printed on a separate label on the cylinder.

WARNING – *Risk of explosion*
Calibration gas cylinder: Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 50 °C may cause contents to vent or cause bursting. Never discard container into fire or incinerator as it may cause an explosion.

WARNING – *Risk of explosion*
Before discarding an empty calibration gas cylinder, remove the safety valve using the valve key (code no. 922-509). If you do not do this, the calibration gas cylinder may burst if exposed to heat.

Traceability certificate

Certificate of Traceability

Product name: CAL2 standard calibration gas

Type: 10 % CO_2, balance N_2, 999 mL

Code: 962-096

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
CO_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	±0.02
O_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	±0.03

Certification: Each lot of this product has been tested, and the nominal values, specified on the label of this product, have been established with the above traceability.

Bjarne Kristensen

H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

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Date of issue

Radiometer representative:

Manufacturer:

RADIOMETER

If you have any questions or need assistance, please contact your local Radiometer representative.

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TCM400 Transcutaneous pO_2 Monitoring System operator's manual

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