

RADIOMETER®



TCM5

Instructions for use

From software version 1.3



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Introduction

Intended use

The TCM5 monitoring system including the TCM5 monitor, tc Sensors and accessories is intended for non-invasive continuous transcutaneous monitoring of:

- carbon dioxide partial pressure ($t_{cp}CO_2$), functional oxygen saturation (SpO_2) and pulse rate (PR), using the tc Sensor 92 applied on the earlobe, the cheek or the forehead of pediatric (>3 kg) or adult patients. On other conventional measuring sites (chest, abdomen, back, upper arm, thigh, forearm, laterally on the neck, subclavicular) only $t_{cp}CO_2$ can be monitored in pediatric or adult patients.
- carbon dioxide partial pressure ($t_{cp}CO_2$) and oxygen partial pressure ($t_{cp}O_2$) using the tc Sensor 84 applied subclavicular, on the abdomen, upper arm, forearm, inner and outer thigh or back of neonate, pediatric or adult patients. Additional application sites for pediatric and adult patients are chest, laterally on the neck and on the forehead.
- carbon dioxide partial pressure ($t_{cp}CO_2$) using the tc Sensor 54 applied on the earlobe, cheek, forehead of pediatric or adult patients. On other conventional measuring sites $t_{cp}CO_2$ can be monitored in neonate, pediatric or adult patients.

The TCM5 monitor software provides 2 preconfigured parameter sets called FLEX (full functionality) and BASIC (limited functionality).

If the BASIC parameter set is selected, the intended use is limited to non-invasive continuous transcutaneous recording of:

- carbon dioxide partial pressure ($t_{cp}CO_2$), functional oxygen saturation (SpO_2) and pulse rate (PR), using the tc Sensor 92 applied on the earlobe, the cheek or the forehead of pediatric (>3 kg) or adult patients. On other conventional measuring sites (chest, abdomen, back, upper arm, thigh, forearm, laterally on the neck, subclavicular) only $t_{cp}CO_2$ can be recorded in pediatric or adult patients.

The TCM5 monitoring system is indicated for use in hospitals, in hospital-like facilities and for use during intra-hospital patient transport. The TCM5 monitoring system is intended for use by healthcare professionals only.

The TCM5 monitoring system is for prescription use only.

Intended operators

The TCM5 monitor is intended for use by healthcare professionals over 18 years of age.

Intended medical indications

Medical conditions where the healthcare professional finds it clinically relevant to use non-invasive and continuous transcutaneous monitoring of carbon dioxide partial pressure (tcpCO_2), oxygen partial pressure (tcpO_2) functional oxygen saturation (SpO_2), and pulse rate.

Environment of use

The TCM5 monitor is intended for use in these environments:

- Hospital or clinic
- Transport within a clinical environment

Training requirements for healthcare professionals

Healthcare professionals must have received hands-on training in the procedures and functions that are relevant for their field of work and that are described in this *Instructions for use*.

First-time setup

When setting up the monitor for the first time, see *Chapter 5, Setup*.

About hazards

A hazard symbol shows which instructions an operator must obey to prevent risk to persons or equipment. There are 2 types of hazard.

Hazard type	Hazard symbol	Risk
WARNING		Death or injury to persons
CAUTION		Equipment damage or monitoring disruption

Physiological limitations

Under the following clinical situations there is, according to current knowledge¹, limited or no correlation between transcutaneous and arterial blood gas tensions:

- Profound peripheral vasoconstriction
- Compromised peripheral circulation
- Circulatory centralization (shock)
- Arterial occlusive diseases
- Arteriovenous shunts (e.g. persistent ductus arteriosus)
- Edema of the skin (e.g. Edema neonatorum) and other skin anomalies

- Hypothermia
- Use of vasoactive drugs

Like the transcutaneous technique, pulse oximetry relies on the existence of intact transport mechanisms of arterial blood to the measurement site. Whenever such transport is impaired to the extent that a sufficiently large pulse signal cannot be detected, SpO₂ monitoring is no longer feasible. Such a condition may occur in cases of circulatory centralization (shock), peripheral vasoconstriction, venous congestion or generally at low local tissue perfusion.

Furthermore, the pulse oxymetry measurement may not be valid under the following conditions:

- Excessive ambient light
- Severe electrical interference
- Excessive patient movement
- Significant levels of dysfunctional hemoglobin (e.g. COHb and metHb)
- Presence of intra-vascular dye
- Skin pigmentation
- Very low hemoglobin level
- Venous pulsation at the frequency of the patient's arterial pulse
- Venous return when the sensor is applied onto the forehead or cheek when the head is lower than the heart (Trendelenburg position)
- A pulse oximeter should NOT be used as an apnea monitor
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis.
- Inaccurate measurements or loss of pulse signal may be caused by placement of a sensor on an extremity with a blood pressure cuff, arterial catheter or intra-vascular line
- Loss of pulse signal can occur when the sensor is attached too tightly
- Loss of pulse signal can occur when there is arterial occlusion proximal to the sensor

Transcutaneous blood gas measurement should therefore not be regarded as a substitute for conventional arterial blood gas analysis. It is generally recommended that an accurate blood gas analysis be carried out prior to any decisive therapeutic measures. The use of the parameter(s) measured by the sensor cannot replace a permanent supervision of the patient by the medical personnel.

Reference list:

¹ JW. Severinghaus. The Current Status of Transcutaneous Blood Gas Analysis and Monitoring. Blood Gas News 1998. Vol. 7. No2: 4 – 9.

Sophie E. Hutmamn, Wolfram Windisch and Jan H. Storre. Techniques for the Measurement and Monitoring of Carbon Dioxide in the Blood. Ann Am Thorac Soc Vol 11, No 4, pp 645-652, May 2014.

Eberhard P. The design, use, and results of transcutaneous carbon dioxide analysis: current and future directions. Anesth Analg 2007;105 (6 Suppl):S48-S52.

Emily L. Dobyns. Chapter 39 - Assessment and Monitoring of Respiratory Function in Pediatric Critical Care (Fourth Edition), 2011.

Chan ED, Chan MM, Chan MM. Pulse oximetry: understanding its basic principles facilitates appreciation of its limitations. *Respir Med.* 2013 Jun;107(6):789-99.

Limitations of use

Note: Diagnosis should not only rely on transcutaneous monitoring. It is intended as an aid in patient assessment. It must be used in conjunction with other clinical signs and symptoms.



Risk of infection and inaccurate results

Reuse of single-use devices may lead to infection of patients and inaccurate results.



Risk of incorrect measurement

Do not use the sensors during MRI scanning. Conducted current may cause burns. Also, the sensors may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.



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 monitor. 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.



Risk of incorrect measurement

Do not measure SpO₂ or PR under very low perfusion.



Risk of incorrect measurements

Remove the sensors from the patient immediately if the system or patient is exposed to electrocautery or other high-frequency electrical signals, as these may affect the monitor and may cause injury to the patient.



Risk that the patient is not being monitored

Do not expose the monitor to heavy rain. Water can damage the monitor. In the event of exposure to heavy rain, contact a Radiometer service representative.

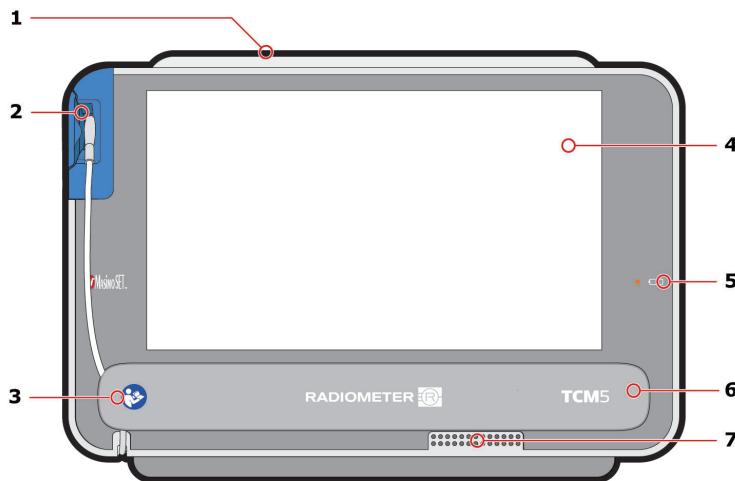
Note: This equipment is not a blood gas device. It is recommended that, prior to any decisive therapeutic measures, an accurate arterial blood gas analysis is carried out. The use of the TCM5 monitoring system cannot replace a permanent supervision of the patient by medical personnel.

Note: Monitoring a pregnant woman is limited to a maximum and accumulated period of 24 hours per pregnancy period.

Getting to know your monitor

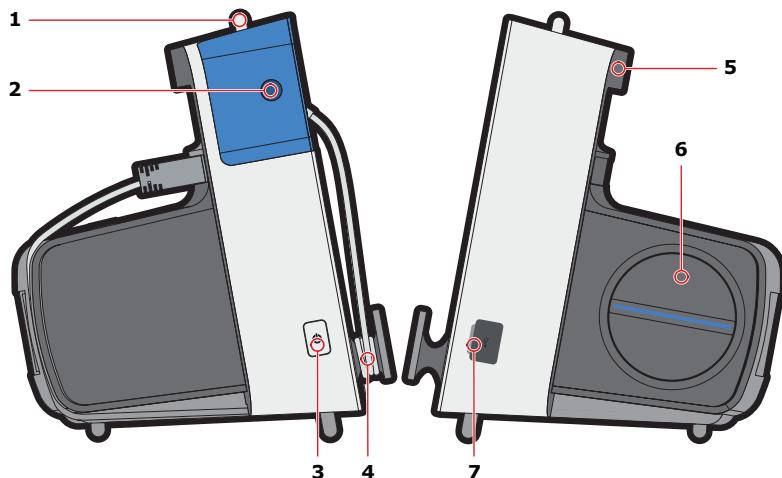
2

Front view

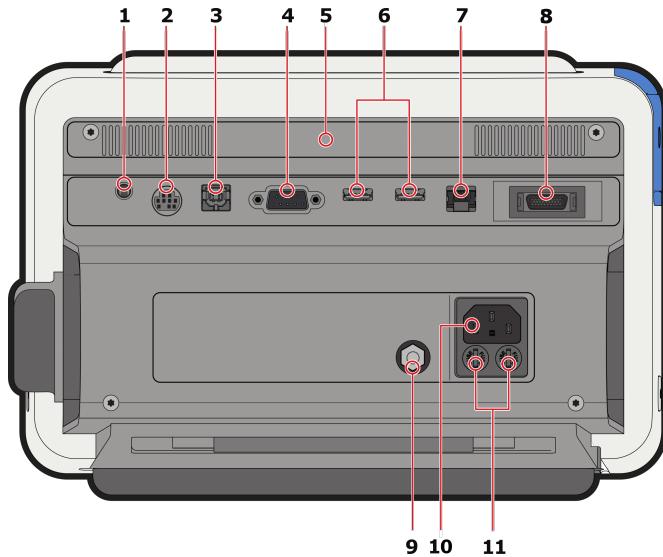


- | | | | |
|----------|--|----------|-------------------|
| 1 | Alarm bar | 5 | Battery indicator |
| 2 | Calibration chamber | 6 | Cable-wrap bar |
| 3 | Follow the <i>Instructions for use</i> | 7 | Speaker |
| 4 | Touch screen | | |

Side view

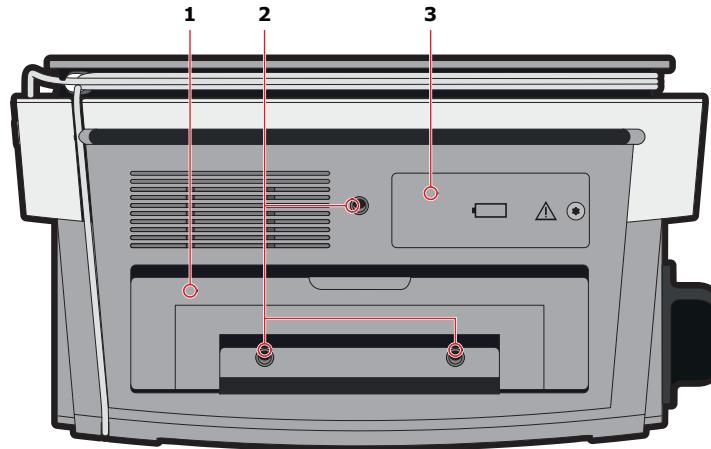


- | | | | |
|----------|---------------------|----------|------------|
| 1 | Alarm bar | 5 | Hand grip |
| 2 | Calibration chamber | 6 | Gas bottle |
| 3 | Standby button | 7 | USB port |
| 4 | Cable-wrap bar | | |

Rear view

- | | | | |
|----------|----------------------|-----------|----------------------------------|
| 1 | Nurse call | 7 | Ethernet port |
| 2 | Analog output | 8 | Sensor connector |
| 3 | USB device connector | 9 | Potential equalization connector |
| 4 | Serial port (RS232) | 10 | Mains power socket |
| 5 | Handgrip | 11 | Mains power fuses |
| 6 | USB ports | | |

Bottom view

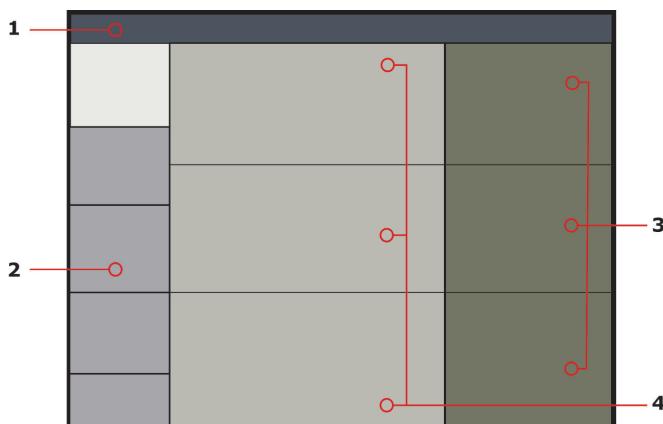


1 Retractable stand

2 Threaded inserts

3 Battery cover

Main screen – FLEX configuration



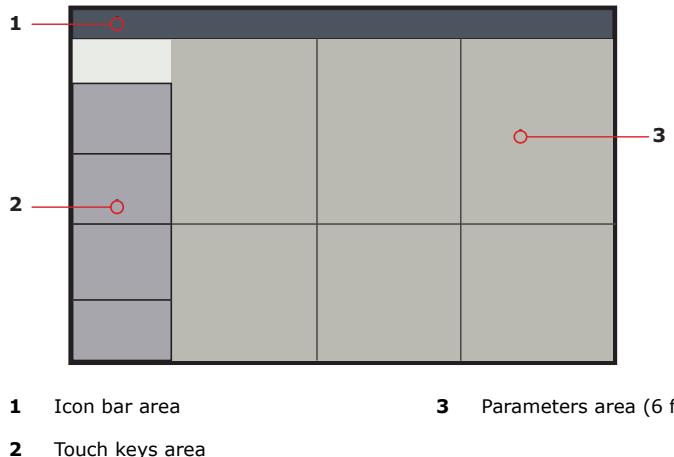
1 Icon bar area

2 Touch keys area

3 Parameters area

4 Graphs area

Main screen - BASIC configuration



1 Icon bar area

2 Touch keys area

3 Parameters area (6 fields)

Difference between BASIC and FLEX configurations

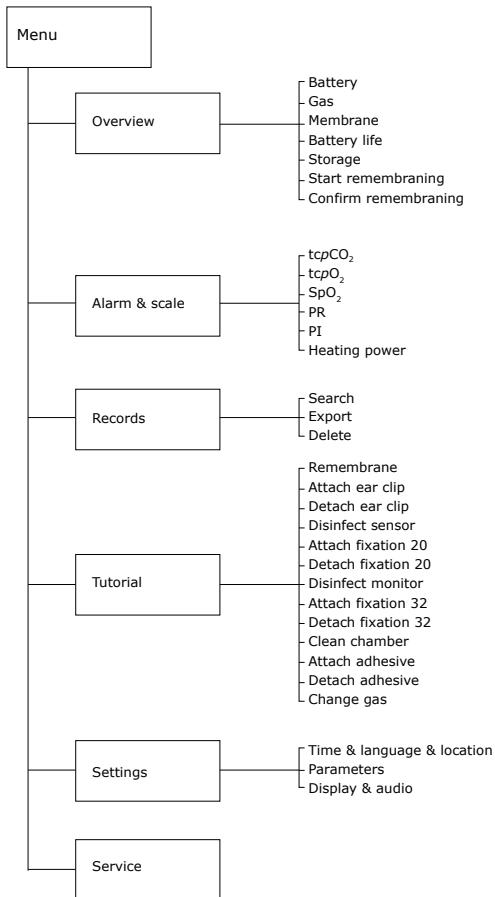
The table shows which functions are available with the BASIC and FLEX configurations.

Function	FLEX	BASIC
NICU mode	✓	✗
Adult mode	✓	✓
Sleep mode	✓	✓
Site time/temperature management	✓	✓
Tutorials	✓	✓
Interactive remembranring guide	✓	✓
Event marker	✓	✓
Standby mode	✓	✓

Function	FLEX	BASIC
Protocol for Philips Intelli-Bridge	✓	✓
Detail view	✓	✗
Trend graphs	✓	✗
Parameter alarms	✓	✗
Technical alarms	✓	✓
tc Sensor 54 compatible	✓	✗
tc Sensor 84 compatible	✓	✗
tc Sensor 92 compatible	✓	✓

Note: The sensor compatibility also depends on the use modes. For more information See *Use modes and sensor compatibility*.

Menu structure



Explanation of symbols

These are the symbols and abbreviations you might see on the housing, packaging and on the accessories of the TCM5 monitoring system.

Symbol/Text	Explanation
2797	CE marking of conformity
	CE marking of conformity
	Medical Device
	Manufacturer
	Date of manufacture
Patents: www.radiometer.com/en/legal/patents www.masimo.com\patents.htm	Patents
	Lot no.
	Catalog no. (product code)
	Serial no.
Storage/Transport -20°C / -4°F to 50°C / 122°F	Storage and transport temperature range for the monitor
Operation 41°F to 5°C / 104°F	Operation temperature range for the monitor

Symbol/Text	Explanation
	Storage temperature range for sensor or accessories
	Consult instructions for use
	Use-by date
	Warning, consult accompanying documents for important safety information
	Caution, consult accompanying documents for important safety information
	Refer to instruction manual/booklet
 	<p>This symbol indicates that Radiometer Medical A/S and its distributors within the European Union (EU) and associated states have taken the necessary steps to comply with the "DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste of electrical and electronic equipment (WEEE)".</p> <p>Equipment marked with this symbol must not be disposed of as household waste but as electronic waste in accordance with local legislation.</p> <p>Please note that equipment contaminated with potentially infectious substances, such as body fluids, must be decontaminated before recycling. If this is not possible, the equipment must be disposed of as biohazardous material.</p> <p>Contact your local Radiometer representative for instructions.</p>

Symbol/Text	Explanation
IP 32	IP Code: Degree of protection against harmful ingress of solids and water
	Fuse
	Battery
	Standby button
IOIOI	Serial port (RS232)
SENSOR	Sensor connector
	Nurse call
	Graphical recorder (Analog output)
	USB
	Ethernet connector
	Degree of protection against electrical shock: Defibrillation-proof Type BF applied part
	Alternating current (AC)
	<p>Potential equalization connector for providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation</p> <p>The requirements for the Potential equalization connector are in accordance with IEC 60601-1: 8.6.7</p>

Symbol/Text	Explanation
	Single use - do not reuse
Rx only	US FDA prescription device Caution: Federal law restricts this device to sale by or on the order of a physician
	Compressed Gas Non-flammable Gas
	Warning for Electrolyte Harmful if swallowed May cause damage to organs (kidneys) through prolonged or repeated exposure Do not eat, drink or smoke when using this product Get medical advice/attention if you feel unwell Dispose of contents/container in accordance with local regulations Contains: cis-1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride May produce an allergic reaction
	Keep dry
	This side up
	Fragile, handle with care
	Humidity limitation

Symbol/Text	Explanation
	Atmospheric pressure limitation

Explanation of graphical symbols on the screen

These are the symbols you might see in the TCM5 monitor's graphical user interface.

Symbol	Explanation
	NICU (Neonatal Intensive Care Unit) mode (Available with FLEX configuration only)
	Adult (Intensive Care Unit) mode
	Sleep mode
	Audio off
	Alarm off button
	Audio paused
	Alarm limits button
	SmartHeat on
	Notification message - Atmospheric pressure is set manually or Severinghaus correction is disabled

Symbol	Explanation
	LAN cable connected
	LAN cable disconnected
	LAN Alert
	Gas bottle status 0-100 %
	Only the mains power supply is in use
	Battery charge 75-100 %
	Battery charge 50-74 %
	Battery charge 25-49 %
	Battery charge 5-24 %
	Battery charge 0-4 %
	No battery installed
	Detail view – Expand button (Available with FLEX configuration only)
	Detail view – Forward button (Available with FLEX configuration only)

Symbol	Explanation
	Detail view – Back button (Available with FLEX configuration only)
	Open drop-down list button
	Close drop-down list button
	Back button
	Table button
	Selected
	Deselected
	Auto decreased Site time
	Remaining membrane lifetime 0-23 hours
	Event
	Multiple events
	Consult instructions for use

Explanation of battery indicator

A LED (Light-emitting diode) indicates the mains power connection and battery charge status, as follows:

Mains power status	Battery status	LED color
Connected	Low battery	Solid red
Connected	Charging	Solid orange
Connected	Fully charged	Solid green
Connected	Battery fault or missing	Toggle orange/green at 0.5 Hz
Disconnected	Low battery	Solid red
Disconnected	Battery OK	Off
Disconnected	Battery fault or missing	Off

Note: In case of an interruption or loss of power supply, the TCM5 monitor automatically switches to battery operation. A fully charged battery lasts for a maximum of 4 hours.

Use modes

You can select from 3 different use modes:

- **NICU** (Neonatal Intensive Care Unit)
- **Sleep mode**
- **Adult mode**

WARNING – Risk of incorrect monitoring

Selection of an inappropriate use mode can result in missing alarms. Check use mode selection before each application.

Use modes and sensor compatibility

The tables below show the sensors that are compatible with the different Use modes.

BASIC configuration		
Sensor	Adult	Sleep
tc Sensor 92	✓	✓
tc Sensor 54	✗	✗
tc Sensor 84	✗	✗

FLEX configuration			
Sensor	NICU	Adult	Sleep
tc Sensor 54	✓	✓	✓
tc Sensor 84	✓	✓	✗
tc Sensor 92	✗	✓	✓

To select a Use mode

Prerequisite(s)

- You must have a password for the **Service** menu

- Tap **Menu > Service**.
- Enter your password for the **Service** menu.
- Tap the **Done** button.
- Tap **Settings > Usage > Use mode**.
- Select a mode.
- Tap the **Apply** button.

Tutorials

Tutorials that illustrate each step of a task are available on the monitor. Available tutorials are:

- Remembrane
- Attach ear clip
- Detach ear clip
- Disinfect sensor
- Attach fixation 20
- Detach fixation 20
- Disinfect monitor
- Attach fixation 32
- Detach fixation 32
- Clean chamber
- Attach adhesive
- Detach adhesive
- Change gas

To start a tutorial

- Tap **Menu > Tutorial**.
- Select a tutorial.

Patient monitoring

Before monitoring

Start of measurement

The measurement starts when the sensor is removed from the calibration chamber.

Preparing to monitor a patient

When you prepare to monitor a new patient, do these tasks:

- Prepare the monitor
- Prepare the sensor
- Check the sensor temperature and site time
- Set the alarm limits*
- Set the parameter scales*
- Set the graph display times*
- Enter patient information

* Available with FLEX configuration only

WARNING – Risk of incorrect monitoring

Make sure to select the alarm limits carefully. Setting alarm limits to extreme values can render the alarm system useless.

WARNING – Risk of incorrect measurement

Do not use the sensors during MRI scanning. Conducted current may cause burns. Also, the sensors may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.

WARNING – Risk of personal injury

Make sure to select the upper alarm limit for oxygen saturation carefully and in accordance with accepted clinical standards. High oxygen levels may predispose a premature infant to develop retinopathy.

WARNING – Risk of incorrect measurement

Do not measure SpO₂ or PR under very low perfusion.

WARNING – Risk of incorrect measurement

Always select the measuring site carefully to avoid selecting a site with low perfusion or low signal quality, which can cause incorrect measurements.

**WARNING – Risk of skin damage**

Do not apply pressure on the sensor for prolonged periods as this might lead to burns or pressure injuries.

**WARNING – Risk of incorrect measurements**

Certain patient conditions such as shock, hypotension and severe vasoconstriction can impair a measurement.

**WARNING – Risk of incorrect measurements**

Make sure the sensor is applied correctly. Incorrect application of the sensor can cause incorrect measurements.

**WARNING – Risk of incorrect measurement**

The TCM5 monitor is protected against defibrillator discharge delivered by external emergency defibrillator and implanted defibrillator devices. The measurement values may temporarily be affected during defibrillation but will recover rapidly. Use only sensor cables and extension cables provided by Radiometer and follow instructions for use of the defibrillator.

**WARNING – Risk of incorrect measurements**

Remove the sensors from the patient immediately if the system or patient is exposed to electrocautery or other high-frequency electrical signals, as these may affect the monitor and may cause injury to the patient.

**WARNING – Risk of incorrect diagnosis**

This device is not intended to detect dysrhythmias.

**WARNING – Risk of strangulation**

When you attach the sensor to the patient, use the cable clip to reduce the risk of patient entanglement or strangulation.

**WARNING – Risk of incorrect measurements**

When the patient is in the Trendelenburg position, the measurement of SpO₂ and pulse is not reliable.

To turn on the monitor

1. Plug the power cord into the AC outlet.
2. Facing the front of the monitor, find the **Standby** button on the left side of the monitor.
3. Press the **Standby** button.

Note: Make sure the monitor is connected to mains.

Note: When you turn on the monitor, the system performs a sensor calibration.

To start a measurement

The measurement and data collection starts when the sensor is removed from the calibration chamber.

1. Remove the sensor from the calibration chamber.

Session

A session is a collection of patient data. It starts when the sensor is removed from the calibration chamber and ends when the sensor is placed back in the calibration chamber.

Each session gets a unique number. This number can be linked to a patient ID. You can link several sessions to the same patient ID.

Patient information

Patient information is entered in the **Patient** menu and stored in the **Records** menu. You enter information with the virtual keyboard. The virtual keyboard is shown wherever information can be entered.

To enter patient information

1. Tap **Patient**.
2. Tap a field and enter the information.
3. When finished, tap the **Done** button.

Sensor temperature and application time

tc Sensor 92 or the tc Sensor 54

When you use the tc Sensor 92 or the tc Sensor 54 on the earlobe, a sensor temperature of 42 °C is recommended. The maximum application time along with the sensor temperature are indicated in the table below:

Patient age	Set sensor temperature	Corresponding maximum sensor-skin interface temperature	Recommended maximum application time
Up to a year	42 °C	41 °C	10 hours
More than 1 year	42 °C	41 °C	12 hours
	43 °C	42 °C	8 hours
	44 °C	43 °C	4 hours

tc Sensor 84

When you use the tc Sensor 84, a sensor temperature of 43-44 °C is recommended. The best correlation between arterial and transcutaneous pO_2 is found at the highest possible sensor temperature tolerated by the skin over an acceptable period of time. A compromise must be made between sensor temperature, exposure time of the sensor to the skin and the quality of the correlation. The application time must be selected according to this. To get the maximum correlation between arterial and transcutaneous pO_2 , the recommended maximum application time at elevated sensor temperatures is indicated in the table below:

Patient age	Set sensor temperature	Corresponding maximum sensor-skin interface temperature	Recommended maximum application time
Preterm infants	43 °C	42 °C	4 hours
Neonates (excluding preterm infants) and adults	44 °C	43 °C	4 hours

SmartHeat



WARNING – Risk of burns

Do not turn on SmartHeat unless instructed. Increased temperatures resulting from SmartHeat can cause burns.

Available in **Adult mode** and **Sleep mode**.

For **Sensor 54**, **tc Sensor 84** and **tc Sensor 92**:

If SmartHeat is set to ON, it adds +2 °C (max. temp. 44 °C) to the set sensor temperature for the first 20 minutes after the sensor has been removed from the calibration chamber.

If SmartHeat is on, the SmartHeat symbol appears on the Icon bar.

To set the sensor temperature

1. Tap **Timer**.
2. Select from the values in **Temperature** on the screen.
3. Tap the **Apply** button.

Site timer

The site timer shows how much measuring time remains. It counts down to zero at 1-minute intervals. When it reaches zero, an alarm sounds.

Moving the sensor from one ear to the other

When you monitor for a long time, you can move the sensor from one ear to the other. A maximum application time of 8-12 hours, at a sensor temperature of 42 °C,

is recommended. You can leave the clip on the earlobe for 24 hours and use it for other sensor applications. After 24 hours, the clip must be removed and discarded, and the earlobe kept free of adhesive for 8-12 hours.

Related information

To set the site time, page 25

To set the site time

1. Tap **Timer**.
2. Select from the values in **Site time** on the screen.
3. Tap the **Apply** button.

Related information

Moving the sensor from one ear to the other, page 24

Alarm system versus use mode

Use mode	FLEX	BASIC
NICU	Medium-priority alarms: available	N/A
	Low-priority alarms: available	N/A
Adult	Medium-priority alarms: available	Medium-priority alarms: not available
	Low-priority alarms: available	Low-priority alarms: available
Sleep	Medium-priority alarms: available	Medium-priority alarms: not available
	Low-priority alarms: available	Low-priority alarms: available

Alarm limits

The alarm limits are shown in the **Parameters** area of the main screen after the **Alarm limits** symbol.



WARNING – Risk of incorrect measurements

Check that the alarm setting is appropriate for each patient.

Parameter	Alarm low limit	Alarm high limit
tcpCO ₂	5-100 mmHg	6-200 mmHg
	0.7-13.3 kPa	0.8-26.7 kPa

Parameter	Alarm low limit	Alarm high limit
tcpO ₂	0-600 mmHg	1-800 mmHg
	0.0-80 kPa	0.1-106.7 kPa
SpO ₂	50-99 %	51-100 %; OFF
Pulse rate	25-235 bpm	30-240 bpm
PI	0.1-2.0 %	N/A

Note: Available with FLEX configuration only.

To turn on the parameter alarms

1. Tap **Menu > Alarm & scale**.
2. Tap the **Edit** button.
3. Select a parameter.
4. Tap the  button.

Note: If parameter alarms are switched off, the **Alarm off** button is displayed in the main display in the parameter section. Neither auditory nor visual alarms will be activated and respective alarm limits cannot be selected.

To turn off the parameter alarms

1. Tap **Menu > Alarm & scale**.
2. Tap the **Edit** button.
3. Select a parameter.
4. Tap the  button.

To set the upper and lower alarm limits

1. Tap **Menu > Alarm & scale**.
2. Tap the **Edit** button.
3. Use the arrows to set a high or low limit.
4. Tap the **Apply** button.

Note: You can set the alarm limits directly by tapping on the alarm values of the parameter section in the main screen. (Available with FLEX configuration only)

To turn on audio pause

Prerequisite(s)

- You must have a password to enter the **Service menu**
1. Tap **Menu > Service**.
 2. Enter your password for service menu.
 3. Tap the **Done** button.
 4. Tap **Settings > Usage**.
 5. Tap the button next to **Audio pause**.
 6. Tap the **Apply** button.

To set the upper and lower graph scales

1. Tap **Menu > Alarm & scale**.
2. Tap the **Edit** button.
3. Use the arrows to set an upper and lower point.
4. Tap the **Done** button.

To set the graph display time

1. Tap **Menu > Alarm & scale**.
2. Tap the **Time** button.
3. Tap **Display duration** button.
4. Use the arrows to set the display time.
5. Tap the **Apply** button.

To connect a sensor to the monitor

1. Connect the sensor to the sensor socket at the rear of the monitor.

Calibration

The TCM5 monitor calibrates automatically whenever the sensor is placed in the calibration chamber. In the case that the sensor was calibrated within the last 30 minutes, no calibration occurs. If the TCM5 monitoring system failed to calibrate and there is no sensor failure detected, a second calibration starts.

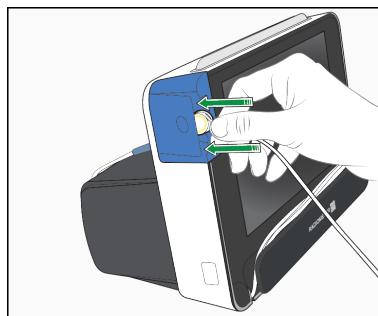
To calibrate the sensor

WARNING – Risk of incorrect measurement

Use an alcohol swab to remove contact gel from the sensor before you put it in the calibration chamber. The contact gel can result in incorrect calibration values, which can cause incorrect measurements.

1. Put the sensor in the calibration chamber.

Calibrating is shown on the screen. When the calibration status reaches 100 %, the sensor is ready for use.



Note: When the sensor is calibrating, the parameters and graphs area turns blue and the calibration status is displayed.

Stabilization

The main purpose of stabilization is to stabilize the sensor condition after remembraning. Stabilization of a sensor takes between 40 minutes and 8:20 hours. During stabilization, the sensor temperature is automatically reduced to the ambient temperature (minimum: 20 °C).

A secondary purpose of stabilization is to inform you when it is time to remembrane the sensor again. In this case, stabilization of the sensor takes 40 minutes. If the stabilization was unsuccessful, the user is asked to either remembrane the sensor or to contact the service personnel.

Note: When the sensor enters stabilization mode, the parameters and graphs area turns blue and the stabilization status is displayed.

Standby

When in **Standby**, the sensor temperature is automatically reduced to the ambient temperature (minimum: 20 °C). This helps to extend the lifetime of both the membrane and the sensor.

Standby also saves power when the TCM5 monitor is not in use.

When in **Standby**, the monitor still has power and is ready to use after a short automatic calibration is completed.

Automatic Standby

If **Automatic Standby** is activated, the TCM5 monitor enters this mode when the monitor has not been used for 30 minutes.

If **Automatic Standby** is not activated, you can activate **Standby** manually.

To enter Standby manually

1. Facing the front of the monitor, find the **Standby** button on the left side of the monitor.
2. Press the **Standby** button.
3. Tap **Standby** on the screen.

To exit Standby

1. Facing the front of the monitor, find the **Standby** button on the left side of the monitor.
2. Press the **Standby** button.

Note: When you exit **Standby**, the system performs a calibration.

To activate Automatic Standby

Prerequisite(s)

- You must have a password for the **Service** menu

1. Tap **Menu > Service**.
2. Enter your password for the **Service** menu.
3. Tap the **Done** button.
4. Tap **Settings > Usage**.
5. Tap the button next to **Automatic standby** to activate.
6. Tap the **Apply** button.

To deactivate Automatic Standby

Prerequisite(s)

- You must have a password for the **Service** menu

1. Tap **Menu > Service**.
2. Enter your password for the **Service** menu.
3. Tap the **Done** button.
4. Tap **Settings > Usage**.

5. Tap the  button next to **Automatic standby** to deactivate.

6. Tap the **Apply** button.

Measuring sites and use modes

Sensor	Parameter	Patient population	Sensor fixation	Sensor application site
tc Sensor 92	tcpCO ₂ , SpO ₂ and PR	Adults, pediatrics (>3 kg)	Attachment clip (ear clip)	Earlobe
		Adults, pediatrics (>3 kg)	Fixation ring 32	Cheek, forehead
	tcpCO ₂ only	Adults, pediatrics	Fixation ring 32	Chest, abdomen, back, upper arm, thigh, forearm, laterally on the neck, subclavicular
tc Sensor 84	tcpCO ₂ tcpO ₂	Adults, pediatrics	Fixation ring 32	Subclavicular, chest, abdomen, back, upper arm or thigh, forehead, forearm, laterally on the neck
		Neonates	Fixation ring N20 or Adhesive ring N20	Subclavicular, abdomen, back, upper arm, inner and outer thigh, forearm
tc Sensor 54	tcpCO ₂	Adults, pediatrics	Attachment clip (ear clip)	Earlobe
		Adults, pediatrics	Fixation ring 32	Subclavicular, chest, abdomen, back, upper arm or thigh, forehead, forearm, laterally on the neck
		Neonates	Fixation ring N20 or Adhesive ring N20	Subclavicular, abdomen, back, upper arm, inner and outer thigh, forearm

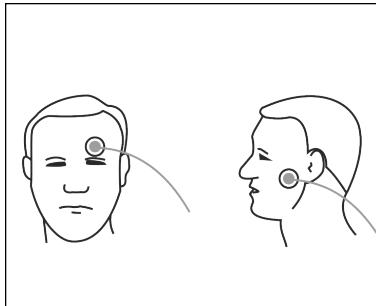
Note: TCM5 BASIC configuration supports the tc Sensor 92 only.

⚠ WARNING – Risk of incorrect measurement

The measurement of SpO₂ and pulse rate is only reliable when the sensor is applied on the earlobe, the forehead or the cheek. To avoid incorrect readings and false alarms of SpO₂ and pulse rate when using the Sensor 92 on other application sites, these parameters must be turned off.

Alternative sites for Sensor 92 only

For monitoring of tcpCO₂ and SpO₂, the Sensor 92 can be applied to the forehead and cheekbone of pediatrics and adults. You must use a 32 mm fixation ring.

**⚠ WARNING – Risk of infection and inaccurate results**

Reuse of single-use devices may lead to infection of patients and inaccurate results.

To see the membrane status

1. Tap Menu > Overview.

To attach a sensor with an ear clip**Required item(s)**

Sensor	Ear clip	Alcohol swab	Contact gel

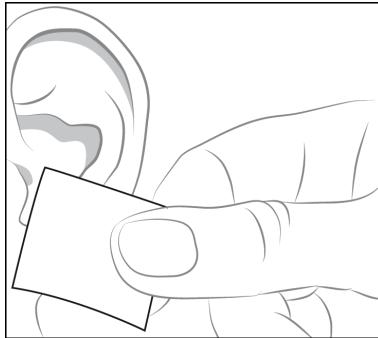
⚠ WARNING – Risk of allergic reaction

The contact gel and electrolyte solutions may cause allergic reactions in some patients.

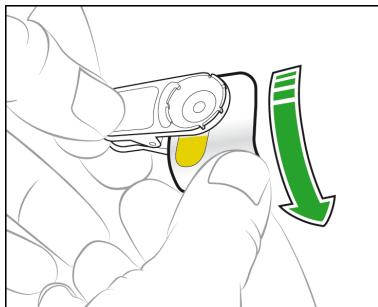
***WARNING – Risk of infection and inaccurate results***

Reuse of single-use devices may lead to infection of patients and inaccurate results.

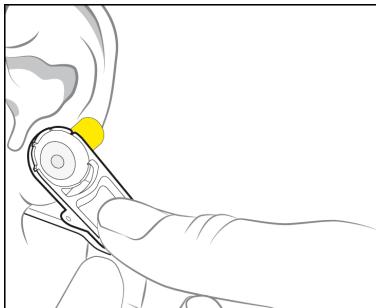
1. To remove grease, oil and lotions on the skin surface, clean and dry the measuring site according to your local procedures.



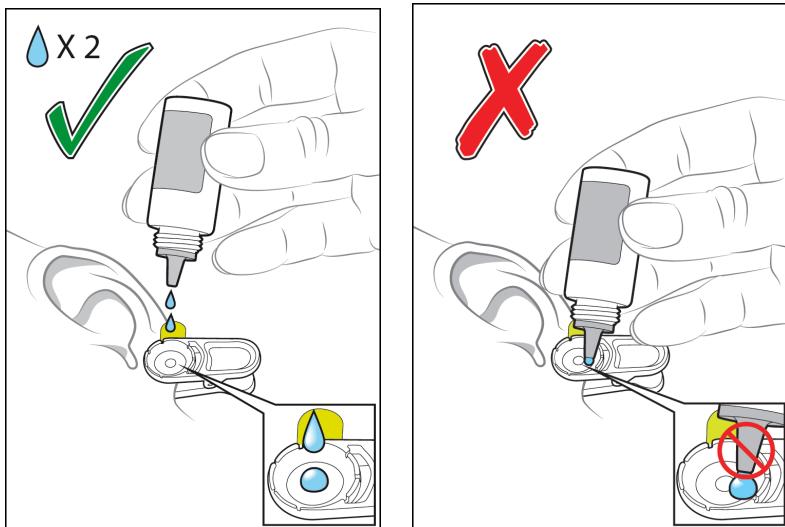
2. Open the jaws of the ear clip and remove the paper.



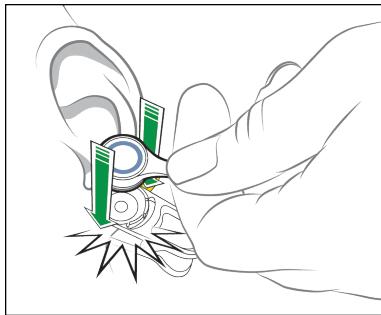
3. Attach the ear clip to the earlobe with the retainer ring facing outwards. Press gently to make sure that the adhesive area sticks to the earlobe. Make sure that there is no air under the adhesive area.



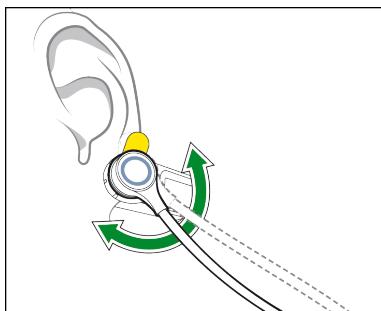
4. Apply 2 drops of contact gel to the skin in the center of the retainer ring.



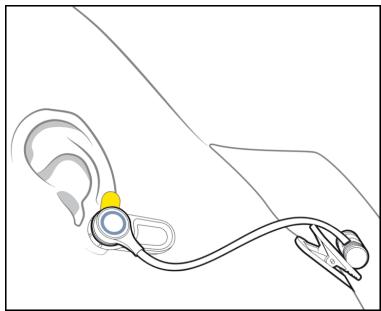
5. Put the sensor into the retainer ring and press gently until it snaps into place.



6. Hold the sensor neck and gently twist the sensor into the best position. Make sure that the sensor cable is loose and cannot cause entanglement or strangulation.



7. Use the cable clip to attach the sensor cable to the patient's clothing.



To attach a sensor with a fixation ring**Required item(s)**

				
Sensor	Fixation rings	Alcohol swab	Tape	Contact gel

⚠ WARNING – Risk of allergic reaction

The contact gel and electrolyte solutions may cause allergic reactions in some patients.

⚠ WARNING – Risk of skin damage

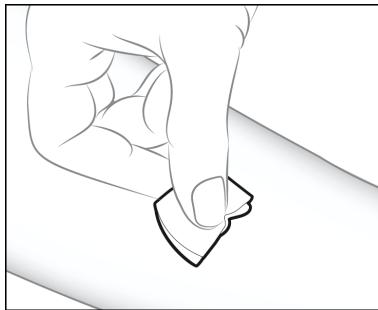
Change the measuring site periodically. Failure to do so can result in skin damage.

⚠ WARNING – Risk of infection and inaccurate results

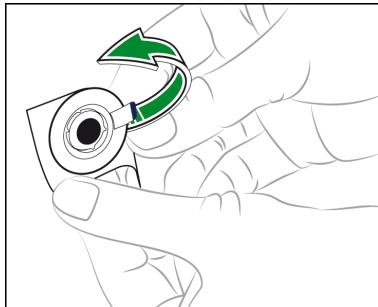
Reuse of single-use devices may lead to infection of patients and inaccurate results.

Note: Change the application site of fixation rings periodically. Failure to do so can result in skin damage.

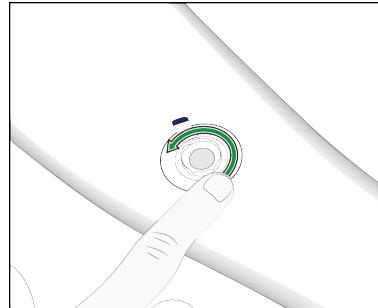
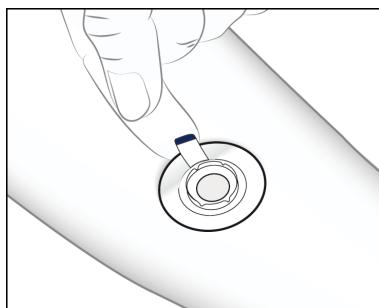
1. To remove grease, oil and lotions on the skin surface, clean and dry the measuring site according to your local procedures.



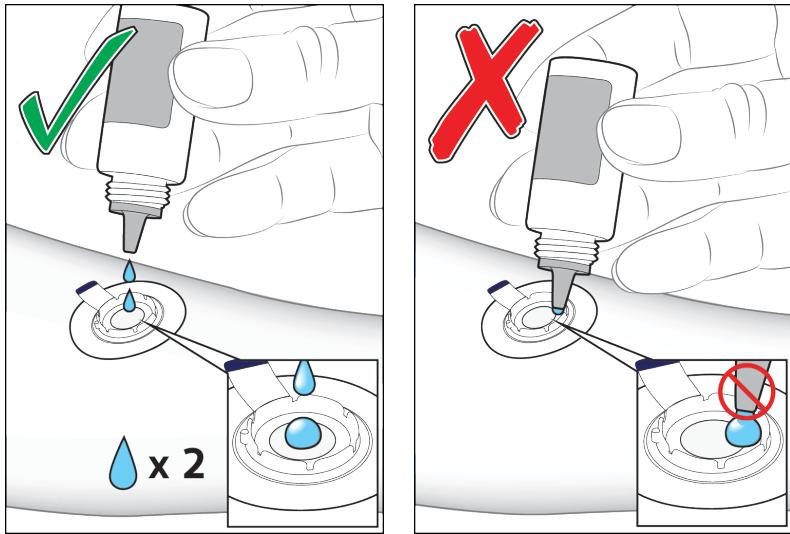
2. Remove a fixation ring from its cover.



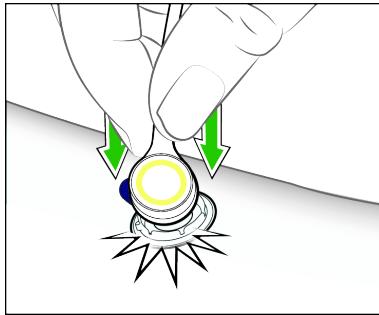
3. Attach the fixation ring to the measuring site and gently press around the edge to prevent leaks.



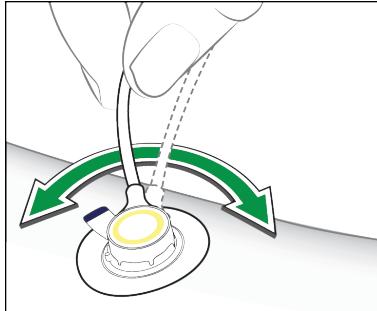
4. Apply 2 drops of contact gel to the skin area in the center of the fixation ring.



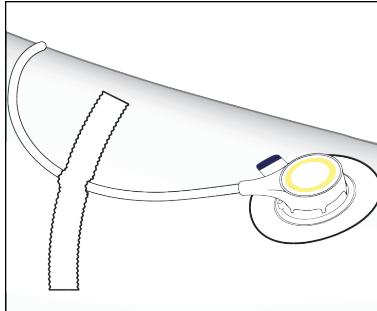
5. Hold the sensor neck and put the sensor into the fixation ring. Press the sensor gently until it snaps into the fixation ring.



6. Hold the sensor neck and twist the sensor into the best position.

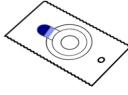


7. Use adhesive tape to keep the sensor cable in position.



To attach a sensor with an adhesive ring

Required item(s)

			
Sensor	Adhesive ring	Alcohol swab	Contact gel

 **WARNING – Risk of allergic reaction**

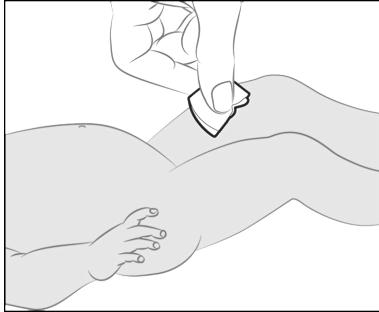
The contact gel and electrolyte solutions may cause allergic reactions in some patients.

 **WARNING – Risk of infection and inaccurate results**

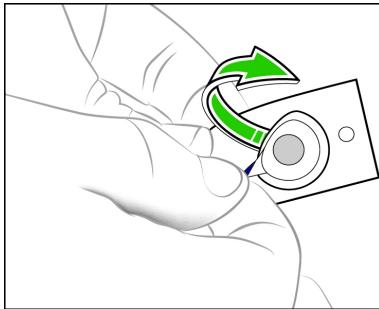
Reuse of single-use devices may lead to infection of patients and inaccurate results.

Note: Change the application site of adhesive rings periodically. Failure to do so can result in skin damage.

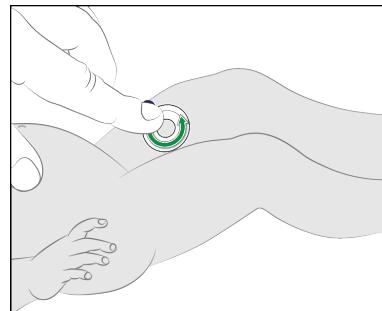
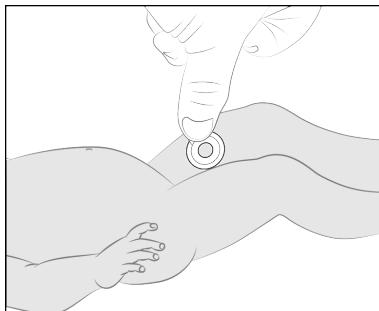
1. To remove grease, oil and lotions on the skin surface, clean and dry the measuring site according to your local procedures.



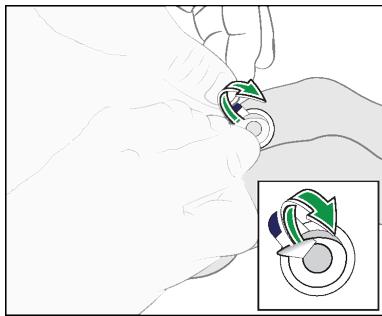
2. Pull the blue tab to remove the adhesive ring.



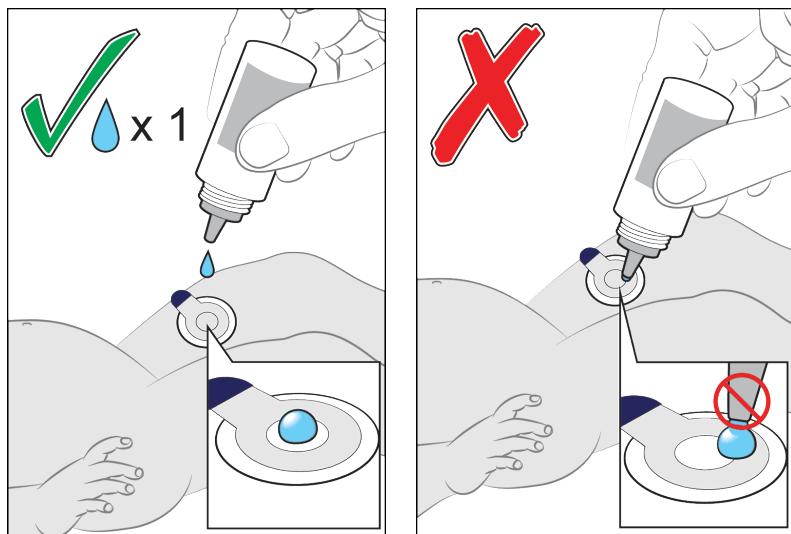
3. Place the adhesive ring on the measuring site and gently press around the edge to prevent leaks.



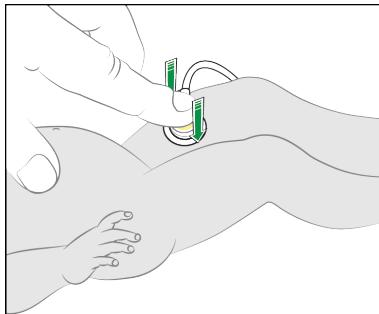
4. Press down the blue tab and lift the inner cover ring.



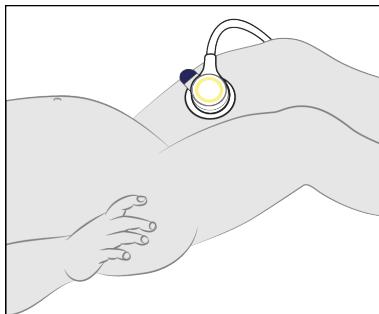
5. Apply one drop of contact gel to the skin in the center of the adhesive ring.



6. Attach the sensor to the adhesive layer in the center of the ring and press the sensor gently.



7. Make sure that the sensor cable is loose and cannot cause entanglement or strangulation.



During monitoring

Alarms

The TCM5 monitor uses visual and auditory alarm signals to alert the user when a parameter is above or below a specified value (parameter alarm limit - available with FLEX configuration only), when the site time has elapsed or when technical conditions require user attention.

Notifications are used for information and user guidance. Alarm messages and notifications are displayed in the status bar. If several alarm conditions exist at the same time, the alarm with the highest priority is displayed. If 2 alarms have the same priority, the alarm triggered by the most recent event is displayed.

Alarm and Notification priority	Description	Status bar	Alarm bar	Audio/Sound
Medium-priority alarm	Parameter alarms (high/low)	Yellow	Yellow blinking	Medium-priority alarm melody
Low-priority alarm	Technical alarms	Yellow	Yellow steady	Low-priority alarm melody
Notification	User guidance	Gray	Off	Beep

For parameter alarms, in addition to the alarm signals described above, the numeric value for the respective parameter and the respective alarm limit blinks.

Alarm signals are switched off automatically when the alarm condition no longer exists.

For a complete list of alarm messages and notifications, see *Chapter 4, Maintenance and troubleshooting*.



WARNING – Risk of incorrect monitoring

Make sure to select the alarm limits carefully. Setting alarm limits to extreme values can render the alarm system useless.

Note: The alarms are deactivated during the arterialization phase. During this phase the graph and the values are shown in opaque gray.

Note: Low-priority alarms and notifications may not be visible when a medium-priority alarm is active.

Silencing alarms

Depending on the alarm setting, the auditory alarm signal for an active alarm condition can be paused or permanently switched off. If the alarm is paused, the auditory alarm signal is activated again after 2 minutes.

Depending on the **Audio pause** setting, one or 2 buttons appear in the alarm status bar when a low or medium-priority alarm sounds. You can use either button to silence the alarm:

- **Audio pause:** Pauses the complete audio alarm system for 2 minutes (actual and upcoming alarms). During these 2 minutes, the audio pause symbol appears on the yellow alarm status bar (or if the alarm disappears: on the icon bar). The alarm text will still be displayed with normal text font. A countdown clock appears next to audio pause symbol which indicates the remaining time before the alarm sounds again. The volume increases each time the alarm reappears.
- **Alarm reset:** Silences the active alarm only. The alarm text appears in italic font after being reset. Any additional medium or low-priority alarms will appear with the audio signal.

The visual alarm signals cannot be paused or switched off for a currently active alarm. For more information about alarm settings, see *Chapter 5, Setup*.

To audio pause the complete alarm system for 2 minutes

1. Tap the **Audio pause** button on the yellow alarm status bar.

To silence the active alarm

1. Tap the **Alarm Reset** button on the yellow alarm status bar.

Events

You can add events that occur when you monitor a patient. If you add more than 99 events, the oldest event is deleted.

List of events

These predefined events are available:

- Arterial blood gas sample
- Toilet break
- Medication
- Other

To create a new event

1. Tap **Event**.
2. Select an event type from the drop-down list.
3. Tap **Event time** and select a time.
4. Tap the **Notes** field if you want to add information to the event.
5. Enter the information.
6. Tap the **Done** button.
7. Tap the **Apply** button.

To view an event

1. Tap the **Event > Previous event**.

After monitoring

End of measurement

The measurement ends when the sensor is placed in the calibration chamber or when the site time set by the healthcare professional elapses.

Note: If **Night mode** is not activated, a blue screen appears with the message **CALIBRATING** when you place the sensor in the calibration chamber.

Removal of a sensor after the site time has expired

Remove the sensor from the site at the end of the site time.

With the TCM5 monitoring system, a site time change is possible without calibration as long as the accumulated site times are below 12 hours.

To stop the measurement

The recording of the measurement stops, once the sensor is placed in the calibration chamber.

- 1.** Put the sensor in the calibration chamber.

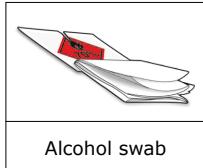
To change the application site

When you have changed the application site on the patient, make sure to confirm the site change on the monitor.

- 1.** Tap **Timer**.
- 2.** Tap the **Site changed** button.

To detach the sensor from the ear clip

Required item(s)

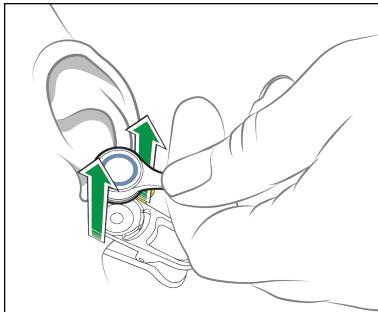


Alcohol swab

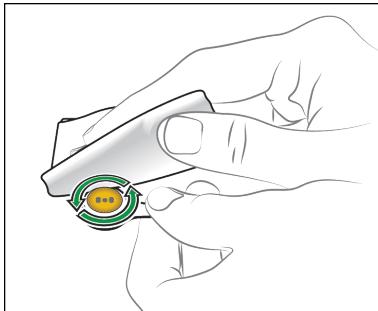
⚠ WARNING – Risk of incorrect measurement

Use an alcohol swab to remove contact gel from the sensor before you put it in the calibration chamber. The contact gel can result in incorrect calibration values, which can cause incorrect measurements.

1. Hold the ear clip in one hand and the sensor in your other hand.
2. Gently remove the sensor from the ear clip.

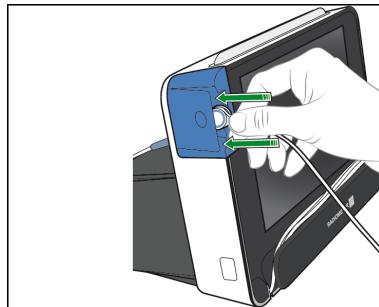


3. Clean the sensor with an alcohol swab.

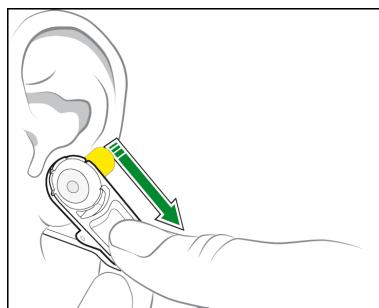


4. Put the sensor in the calibration chamber.

Note: The measurement automatically stops when the sensor is placed in the calibration chamber.

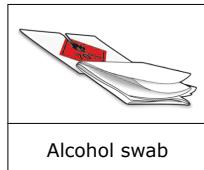


5. Remove the ear clip.



To detach the sensor and the fixation ring

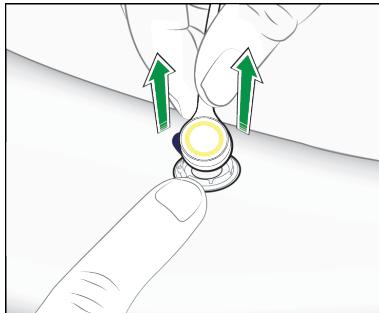
Required item(s)



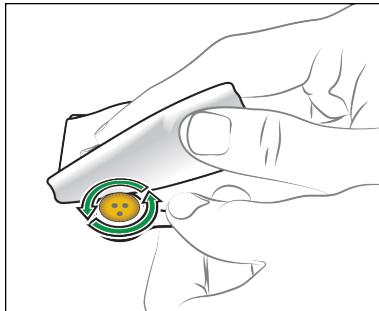
⚠ WARNING – Risk of incorrect measurement

Use an alcohol swab to remove contact gel from the sensor before you put it in the calibration chamber. The contact gel can result in incorrect calibration values, which can cause incorrect measurements.

1. While pressing down on the outer part of the fixation ring, hold the sensor neck and pull the sensor head upwards.

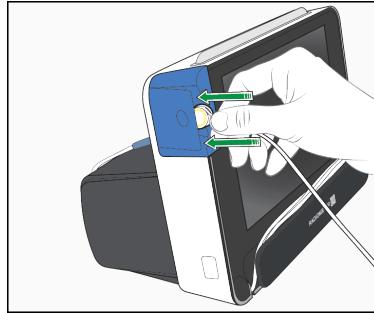


2. Clean the sensor with an alcohol swab.

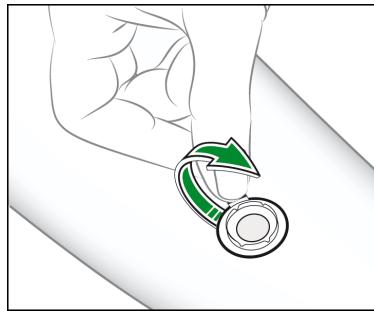


3. Put the sensor in the calibration chamber.

Note: The measurement automatically stops when the sensor is placed in the calibration chamber.

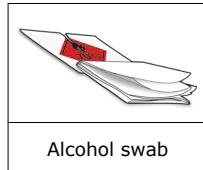


4. Remove the fixation ring.



To detach the sensor and adhesive ring

Required item(s)



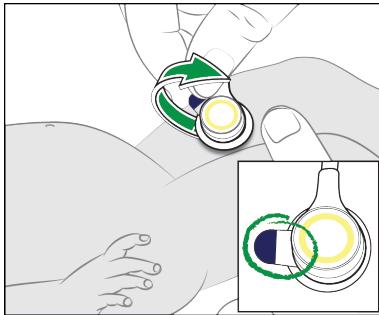
WARNING – Risk of infection and inaccurate results

Reuse of single-use devices may lead to infection of patients and inaccurate results.

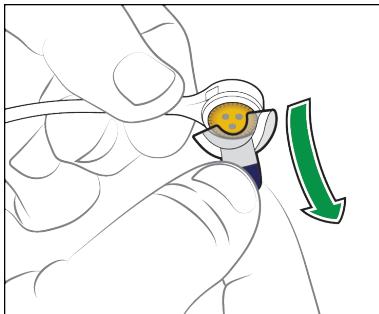
⚠️ WARNING – Risk of incorrect measurement

Use an alcohol swab to remove contact gel from the sensor before you put it in the calibration chamber. The contact gel can result in incorrect calibration values, which can cause incorrect measurements.

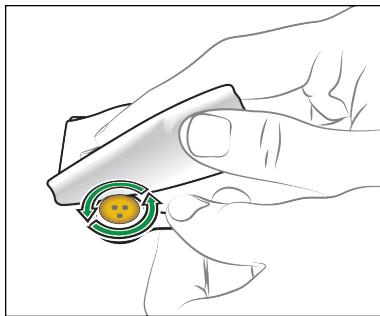
1. Lift the blue tab to remove the sensor together with the adhesive ring.



2. Hold the sensor neck and remove the adhesive ring from the sensor.

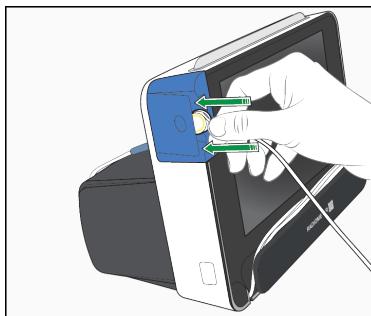


3. Clean the sensor with an alcohol swab.



4. Put the sensor in the calibration chamber.

Note: The measurement automatically stops when the sensor is placed in the calibration chamber.



Exporting records

You can export a patient's record to an external PC or a USB stick. The record will be exported as a .csv file.

To select an export format

1. Tap **Menu > Service**.
2. Enter your password for the **Service** menu.
3. Tap the **Done** button.
4. Tap **Connectivity > Serial**.
5. Select **Protocol**.

6. Select **CSV Format**.
7. Tap the **Apply** button.

To export a patient record

1. Tap **Menu > Records**.
2. Select from the list.
3. Tap the **Export** button.

To delete a patient record

1. Tap **Menu > Records**.
2. Select from the list.
3. Tap the **Delete** button.

To shut down the monitor

1. Facing the front of the monitor, find the **Standby** button on the left side of the monitor.
2. Press the **Standby** button.
3. Tap the **Shutdown** button.

Maintenance and troubleshooting

4

Maintenance

Decontamination



WARNING – Risk of infection

Contaminated equipment and accessories must be decontaminated in accordance with the hospital decontamination and disinfection procedures appropriate for the device.

Decontamination must be carried out by properly trained staff. If you are in any doubt regarding contamination or decontamination, consult your local infection control officer.

Calibration gas

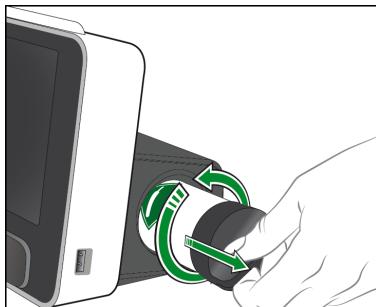
Use the TCM5 Calibration Gas mixture (CO₂: 7.5 %, O₂: 12.0 %, N: 80.5 %) to calibrate the sensor.

To change the gas bottle

⚠ WARNING – Risk of explosion

Pressurised container: May burst if heated. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

1. Turn the gas bottle counterclockwise and pull it out.



2. Put the new gas bottle into the chamber and turn it clockwise.



To see the gas status

1. Tap **Menu > Overview**.

Routine maintenance of sensor

Routine maintenance should be performed monthly.

To maintain the sensor

1. Check sensor and cable assembly for any signs of mechanical damage. In case of any damage, replace sensor. Do not attempt to repair.
2. Clean the membraned sensor and the cable.
3. Remembrane the sensor if required.

Note: See *To remembrane the sensor* or *To clean and disinfect the sensor*.

To do a tcpO₂ and tcpCO₂ function test of a sensor

1. After a calibration, expose the sensor to ambient air for approximately 1-2 minutes.
2. Read off the displayed tcpO₂ and tcpCO₂ values. tcpO₂ should be >145 mmHg (21.0 kPa), and tcpCO₂ should be <5 mmHg (0.7 kPa).
3. If these values are not met, the sensor should be remembraned and the test repeated.
4. If the values are still not met, authorized service personnel should check the sensor.

Note: This test can be carried out on a daily basis by healthcare professionals to check the functionality of the system.

Note: During the test, alarms may occur.

To do an SpO₂/PR function test of a sensor

1. Remove the tc Sensor 92 from the calibration chamber.
2. Check to see if the red sensor LED is visibly blinking.
3. Apply the tc Sensor 92 sensor to the earlobe of a healthy person and check if SpO₂ and PR readings can be obtained.
4. If the red sensor LED is not visibly blinking or no SpO₂/PR readings can be obtained, an authorized service personnel should check the sensor.

Note: The tc Sensor 92 is not supported in the NICU user mode.

Note: This test can be carried out on a daily basis by healthcare professionals to check the functionality of the system.

Remembraning the sensor

You must remembrane the sensor after 28 days (default value) or as defined in the **Service** menu. You will receive a reminder if you do not remembrane the sensor after 28 days.

A request to remembrane the sensor can appear before 28 days, see *Chapter 6, Specifications*. You can help to extend the lifetime of the membrane by activating **Automatic Standby** setting.

Note: After remembranring, the stabilization of the sensor can take up to 4 hours.

To remembrane the sensor

Required item(s)

			
Tissue	Remembraning tool	Electrolyte	Distilled water

Note: Each sensor type has a specific color code for the remembraning tool and electrolyte.

- tc Sensor 54 - green
- tc Sensor 84 - yellow
- tc Sensor 92 - blue

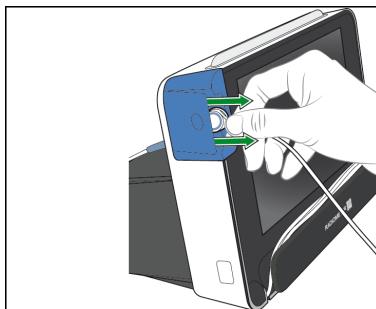
 **WARNING – Risk of infection and inaccurate results**

Reuse of single-use devices may lead to infection of patients and inaccurate results.

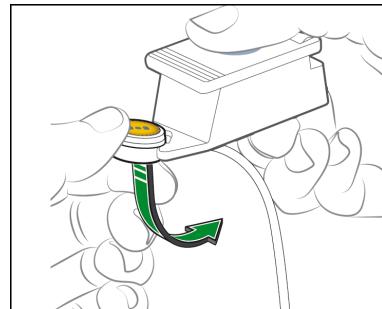
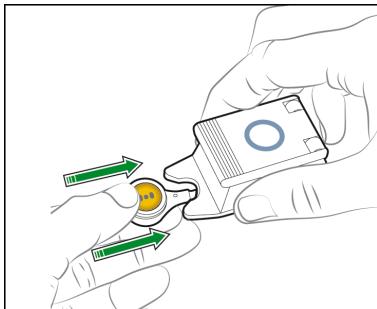
 **WARNING – Risk of incorrect measurements**

Use a lint-free cloth to remove electrolyte from the sensor before you put it in the calibration chamber. The electrolyte can result in incorrect calibration values, which can cause incorrect measurements.

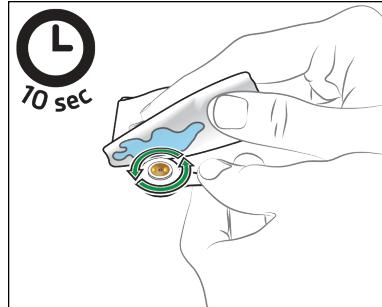
1. Switch on the monitor.
2. Tap **Menu > Tutorial > Remembrane**.
3. Tap the **Start** button.
4. Follow the instructions on the screen.
Tap the **Next** button to see the next screen.
5. Remove the sensor from the calibration chamber.



6. Use the V-shaped notch of the remembranring tool to remove the membrane retainer ring.

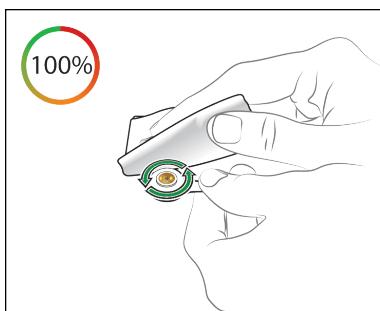


7. Use a lint-free cloth soaked in distilled water to remove the used membrane and to clean the sensor surface.

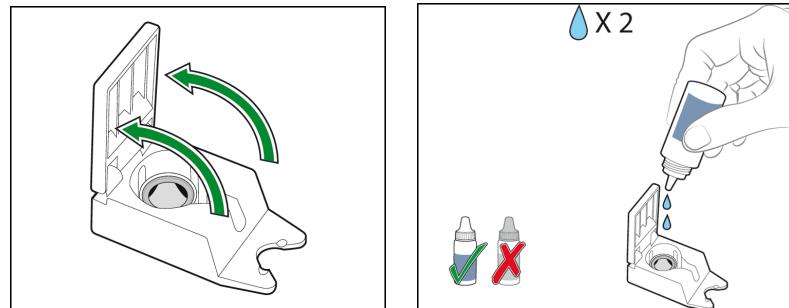


8. Dry the sensor surface until the 100 % limit on the screen is reached.

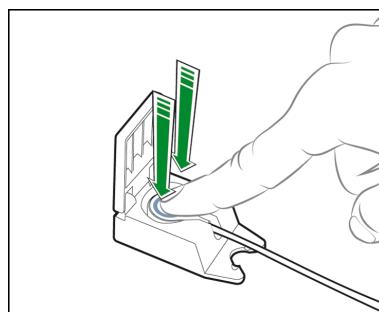
Note: Use a paper tissue.



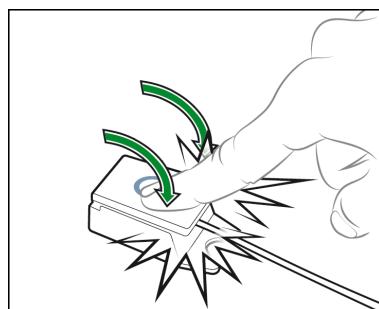
9. Open the remembranring tool and apply 2 drops of electrolyte into the retainer ring.



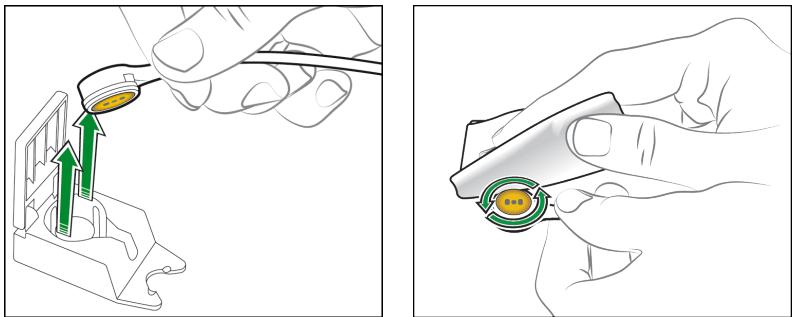
10. Put the sensor (surface pointing downwards) into the remembranring tool and press gently until it is locked.



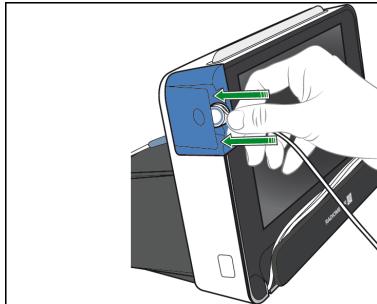
11. Close the remembranring tool and press until you hear the retainer ring click into position.



12. Remove the sensor and clean remaining electrolyte from the surface.



13. Put the sensor in the calibration chamber.



To set the remembrancing frequency

Prerequisite(s)

- You must have a password for the **Service** menu
1. Enter your password for the **Service** menu.
 2. Tap the **Done** button.
 3. Tap **Settings > Usage > Membrane duration**.
 4. Select the duration.
 5. Tap the **Apply** button.

To clean and disinfect the sensor

This procedure should be performed before using the sensor on a new patient.

Required item(s)

	
Lint-free cloth	Cleaning or disinfection solution (e.g. 70 % ethanol)



WARNING – Risk of incorrect measurements

Make sure to follow the sensor cleaning instructions before storing the sensor in the calibration chamber.



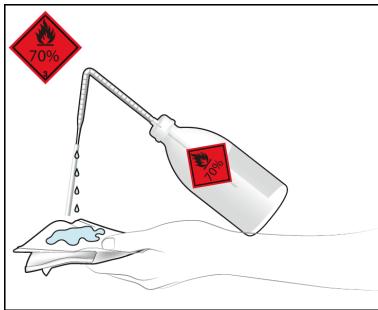
WARNING – Risk of incorrect measurements

Do not immerse the sensor in disinfection solution. Immersing the sensor in disinfection solution will cause the sensor to fail.

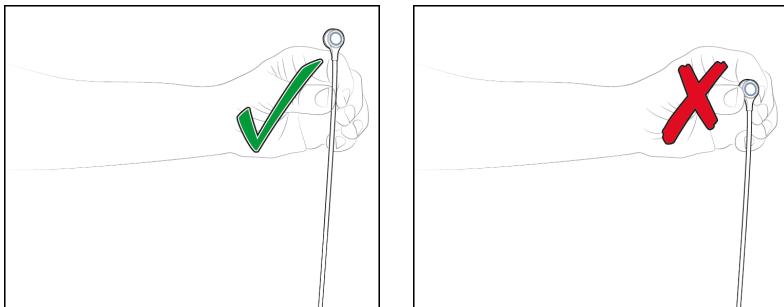
⚠️ WARNING – Risk of incorrect measurements

Do not sterilize the sensors by any methods, including irradiation, steam autoclave, soaking, or immersing in a liquid solution. This will cause the sensors to fail.

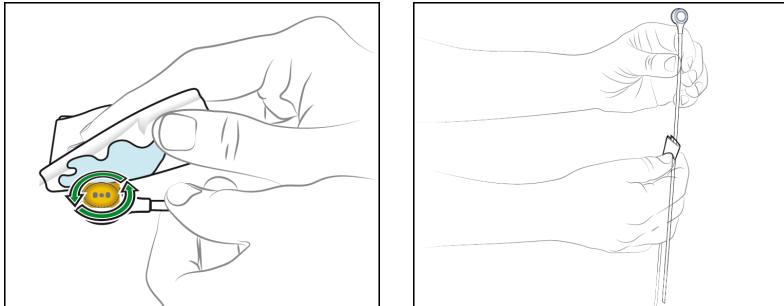
1. Lightly dampen a lint-free cloth with a cleaning or disinfection solution.



2. Hold the sensor by the cable.



3. Gently wipe the sensor head and the sensor cable.



Routine maintenance of the monitor

Routine maintenance should be performed regularly.

Monitor self-test

During startup, the monitor does a self-test. When you perform a self-test of the TCM5 monitor, verify that the startup video and audio is played, the alarm light bar is flashing and that there are no monitor errors displayed.

Note: The self-test can be carried out on a daily basis by healthcare professionals to check the functionality of the system.

To perform a monitor self-test

1. Make sure the monitor is switched off.
2. Press the **Standby** button.
The monitor will perform the self-test automatically.

Alarm test

During patient monitoring, the alarm functions may be tested by temporarily changing the alarm limits so that the current parameter reading is outside the alarm limit range.

Note: This test can be performed on a daily basis by healthcare professionals to check the functionality of the system.

Barometric air pressure test

The TCM5 monitoring system measures the barometric air pressure to calibrate the sensors. This measurement can be checked against a calibrated local reference (e.g. local airport).

To check the barometric air pressure

Prerequisite(s)

- You must have a password for the **Service** menu
1. Tap **Menu > Service**.
 2. Enter the password for the **Service** menu.
 3. Tap **System > Information > TC core / Masimo**.
 4. Read the barometric air pressure value (TC Core Barometric pressure) and compare it to the calibrated reference.

Note: The acceptable deviation is: ± 20 mmHg (± 27 hPa).

Check for damages

In case of damage to the monitor housing, sensor assembly, interface cables, or power supply cords, contact a Radiometer service representative. Do not attempt to repair.

Safety check

Safety checks should be performed at regular intervals.

Where local and governmental regulations apply, the safety check should be performed at regular intervals in accordance to these regulations.

Where no local and governmental regulations apply, it is recommended to perform the safety checks every 2 years. The safety check must be done by a trained and authorized service technician only.

With normal use of the TCM5 monitor, there is no internal adjustment or new calibration required.

Cleaning and disinfection of outer surfaces

Cleaning and disinfection of the monitor exterior and touch screen may be performed when appropriate. The disinfection frequency depends on local requirements and the use of the monitor.

Note: Follow legal requirements and local rules for safe work practices with chemicals.

These cleaning and disinfection agents, dissolved in water, may be used to clean or disinfect the monitor exterior and touch screen:

- Distilled water
- Mild soapy solution (0.1 % Hospec liquid detergent in warm tap water at 40-50 °C)
- Ethanol (max. 96 %)
- Isopropyl alcohol (Propan-2-ol) 80 %
- SurfaSafe (Didecyldimethylammoniumchloride 1.4 mg/g, Polyhexamethylenbiguanid 0.96 mg/g)
- Bacillol AF (Propan-1-ol 450 mg/g, Propan-2-ol 250 mg/g, Ethanol 47 mg/g)
- Bacillol 30 (Propan-1-ol 60 mg/g, Propan-2-ol 100 mg/g, Ethanol 140 mg/g, N-Alkylaminopropylglycin 5 mg/g)
- Meliseptol (Propan-1-ol 500 mg/g, Glyoxal 80 mg/g)
- Hydrogen peroxide (10 %)

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

Note: Do not use abrasive cleansers or pads; the finish may become damaged.

Note: Do not use aggressive detergents. Extensive use may cause the plastic to become brittle and cracks may occur.

To clean and disinfect the calibration chamber

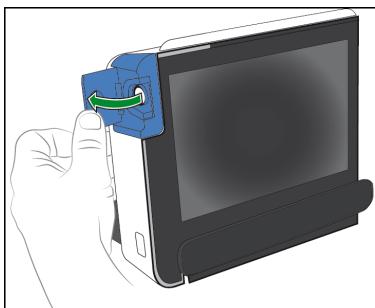
Required item(s)

	
Lint-free cloth	Cleaning or disinfection solution (e.g. 70 % ethanol)

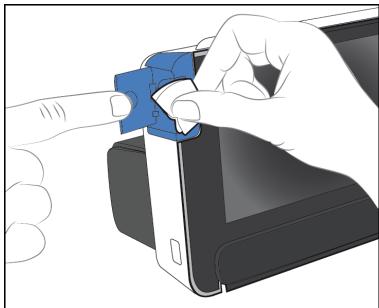
1. Lightly dampen a lint-free cloth with a cleaning or disinfection solution.



2. Open the calibration chamber.



3. Gently wipe inside the calibration chamber and allow to dry.



To clean and disinfect the outer surfaces of the monitor

Required item(s)

	
Lint-free cloth	Cleaning or disinfection solution (e.g. 70 % ethanol)

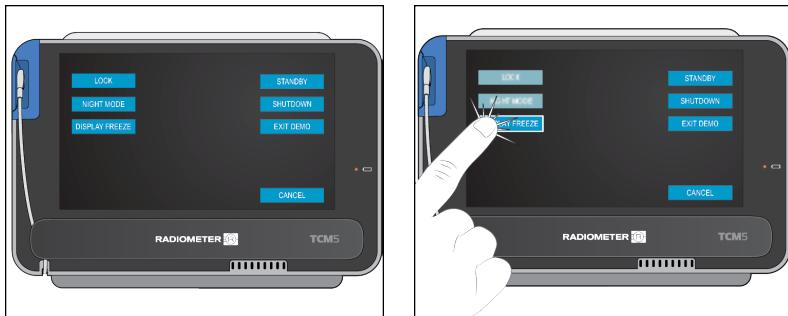
1. Lightly dampen a lint-free cloth with cleaning or disinfection solution.



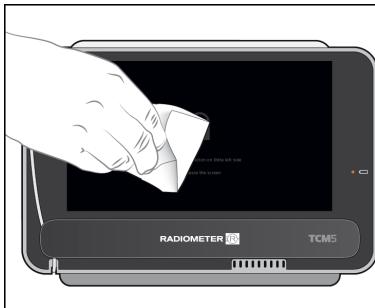
2. Press and hold the **Standby** button.



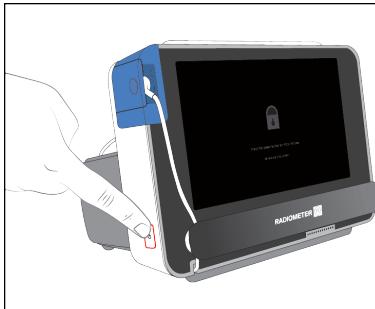
3. Tap **Display freeze.**



4. Gently wipe the outer surface of the monitor and allow to dry.



5. Press and hold the **Standby button to unfreeze the display.**



Cleaning the touch screen

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

To replace a fuse

Required item(s)



A screwdriver



WARNING – Risk of fire

Replace fuse only as recommended by Radiometer. Otherwise you risk that the monitor catches fire.

1. Use the screwdriver to unscrew the fuse holder.
2. Replace the fuse.
3. Use the screwdriver to put the fuse holder back in place.

Note: The fuse should only be replaced by qualified service personnel.

To install the battery

Required item(s)



A torque screwdriver

1. Open the battery cover on the bottom of the monitor.
2. Put the battery in.
3. Close the battery cover.
4. Connect the TCM5 monitor to mains to activate the battery.

Note: New batteries are delivered in a deactivated state. Batteries are activated by connecting the monitor to the mains.

Note: The battery should only be replaced by qualified service personnel.

Battery replacement

Only use a Li-Ion Battery, type RRC2040.

You can use the monitor for up to 4 hours on battery supply. If the battery level is low, an alert sounds and the battery level indicator flashes. If the battery level is very low, an alert message is shown.

Note: Do not let the battery discharge fully. Recharge the battery every 6 months. Under these conditions, the battery lifetime is 2-3 years.



WARNING – Risk that the patient is not monitored

To prevent a complete discharge of the battery, connect the monitor to the mains as soon as possible to recharge the battery. Recharging the battery takes approximately 2 hours.



WARNING – Risk that the patient is not monitored

Replace battery only with the type recommended by Radiometer.



WARNING – Risk that the patient is not monitored

A battery must always be connected to the system.



CAUTION – Environmentally hazardous waste

Dispose of the battery according to local procedures.



CAUTION – Risk that the patient is not being monitored

Do not let the battery power reach a critically low level.

To check the battery charge status

1. Tap **Menu > Overview**.
You can see the status under **Battery**.

To check the battery life status

1. Tap **Menu > Overview**.
You can see the status under **Battery life**.

Routine maintenance of consumables

Check expiration date of all consumables and replace if necessary.

Disposal of sensor and consumables

Dispose of the sensor and the consumables according to local procedures.

To see the status of consumables

1. Tap **Menu > Overview**.

Note: Before monitoring, check the status of all consumables.

Storage



WARNING – Risk of incorrect measurement

Use an alcohol swab to remove contact gel from the sensor before you put it in the calibration chamber. The contact gel can result in incorrect calibration values, which can cause incorrect measurements.

If the system is not used for 2 weeks or more, remove the membrane from the sensor and put the sensor in a safe place.

Before you start a new monitoring session, remembrane the sensor and keep it in the calibration chamber for at least 4 hours to stabilize.

Note: Make sure the cable is wrapped around the cable-wrap bar when the monitor is being transported or stored.

Troubleshooting

Messages

Note: If the monitor is not functioning properly, a blue screen with an error message appears.

Medium-priority alarms

Message	Cause	Recommended action(s)
tcpCO ₂ High	The measured pCO ₂ value is above the alarm limits	Take clinical action
tcpCO ₂ Low	The measured pCO ₂ value is below the alarm limits	Take clinical action
tcpO ₂ High	The measured pO ₂ value is above the alarm limits	Take clinical action
tcpO ₂ Low	The measured pO ₂ value is below the alarm limits	Take clinical action
SpO ₂ High	The measured SpO ₂ value is above the alarm limits	Take clinical action
SpO ₂ Low	The measured SpO ₂ value is below the alarm limits	Take clinical action
PR High	The measured pulse rate is above the alarm limits	Take clinical action

Message	Cause	Recommended action(s)
PR Low	The measured pulse rate is below the alarm limits	Take clinical action
PI Low	The measured perfusion index is below the alarm limits	Take clinical action

Note: Available with FLEX configuration only.

Low-priority alarms

Message	Cause	Recommended action(s)
Battery very low	Battery level very low	Connect to mains immediately
Battery error	Battery is damaged	Replace battery Connect to mains (to complete the measurement) Contact authorized service personnel
No battery	No battery is placed in the monitor	Install battery
Sensor off patient	Sensor is not correctly attached on the patient's skin or placed correctly in the calibration chamber	Attach the sensor correctly to the skin or Place sensor in calibration chamber
Site time elapsed	The measuring site time has elapsed	Change measuring site or calibrate sensor
Interference	An electromagnetic interference with another instrument avoids correct measuring	Reduce interference or Move the monitor
Excessive light	Surrounding light is interfering with the sensor	Reduce ambient light

Message	Cause	Recommended action(s)
Connect sensor	Sensor is not correctly connected to monitor	Connect the sensor properly
Communication error	Monitor is not connected properly to another device	Connect according to this instruction for use Contact authorized service personnel
Sensor error (xxxxxxxx)	Sensor is damaged or not accepted by the monitor	Generate report (by pressing Report button) Contact authorized service personnel
Monitor error (xxxxxxxx)	Monitor is damaged	Generate report (by pressing Report button) Contact authorized service personnel
No pulse signal	Incorrect application site used or Low perfusion of underlying tissue	Place sensor on another application site
Low perfusion signal	Incorrect application site used or Low perfusion of underlying tissue	Place sensor on another application site (e.g. earlobe) Assess patient
Low signal quality	Incorrect application site used or Low perfusion of underlying tissue	Place sensor on another application site (e.g. earlobe) Assess patient

Notifications

Notifications	Cause	Recommended action(s)
Disabled alarms	Alarm settings are edited such that no alarms are activated	Check alarm settings

Notifications	Cause	Recommended action(s)
Battery operation	Monitor runs on battery operation	Connect to mains
Battery low	Battery level low	Connect to mains
Battery life low	Battery life is low	Battery has to be exchanged Contact authorized service personnel
Severinghaus correction disabled	The warning icon was tapped (Explanation of the warning icon)	None or Activate the Severinghaus correction
Atmospheric pressure set manually	The warning icon was tapped (Explanation of the warning icon)	None or Set Atmospheric pressure to automatic
Communication	tcpCO ₂ , tcpO ₂ or SpO ₂ not supported by connected monitor	None
Incompatible sensor	Sensor is not supported by the monitor or Incompatible sensor is connected	Update software or Use correct sensor
Gas bottle empty	Gas bottle is empty	Change gas bottle
Gas contents low	Gas bottle is nearly empty	Prepare gas bottle change
Membrane expiring	Membrane will expire within 24 hours	Remembrane sensor within the next 24 hours
Membrane expired	The sensor membrane lifetime has expired	The sensor has to be remembraned
Incomplete remembraning	Remembraning is not complete	Finish remembraning and place sensor in calibration chamber

Notifications	Cause	Recommended action(s)
Remembranring	Ongoing and not finished remembranring	Complete remembranring and place sensor in calibration chamber
Sensor remembraned?	The system wants to have the remembranring confirmed	Confirm remembranring or Refuse remembranring
Wet cleaning confirmed	The wet cleaning step during the remembranring has been completed	Continue with remembranring
Dry cleaning confirmed	The dry cleaning step during the remembranring has been completed	Continue with remembranring
Calibration error	Insufficient sensor membrane quality	Remembrane sensor
Stabilization error	Insufficient sensor membrane quality	Remembrane sensor
Calibrate sensor	Calibration of sensor required	Place sensor in calibration chamber
Invalid operation	Incorrect action during measurement	Do not repeat action, or place sensor in calibration chamber
Incorrect password	Entered password wrong	Retype correct password
USB storage full	Memory of USB storage is full	Use another USB storage
USB storage error	USB storage corrupt	Use another USB storage
Connect USB storage	No USB storage is connected to monitor and data cannot be exported	Connect USB storage to monitor
No profile on USB storage	No configuration file found on USB storage	Connect USB storage with profile file
Data export error	USB storage removed before completion	Repeat data transfer

Notifications	Cause	Recommended action(s)
Imported data corrupted	Imported data integrity check failed	Import correct profile file
Profile incompatible	Configuration file revision not supported by monitor software revision	Update software
$p\text{CO}_2$ out of range	The measured $p\text{CO}_2$ value is out of the measuring range	Adapt measurement scale to measurement range
$p\text{O}_2$ out of range	The measured $p\text{O}_2$ value is out of the measuring range	Adapt measurement scale to measurement range
Invalid Data	Entered data are not valid or System date and/or time is incorrect	Enter correct data Check correct date and hour of monitor
Patient ID reuse	The same patient ID has already been entered for another patient	Enter correct patient ID
Patient name reuse	The same patient name has already been entered for another patient	Enter correct patient name
No patient information	System requires patient information	Enter patient information
LAN disconnected	LAN connection lost	Check LAN connection
Arterialization	The measurement is in the arterialization phase	tcpCO_2 and tcpO_2 alarms suppressed. Values do not correspond to correct tc values
Incorrect sensor placement	Sensor has not been placed correctly in calibration chamber	Place sensor correctly in calibration chamber
Software update	Monitor on battery operation and battery charge below 50 %. Software update failed (but rollback successful)	Connect to mains Repeat software update

Notifications	Cause	Recommended action(s)
Auto-deletion of oldest record	Storage of monitor full	Delete unimportant patient data Contact authorized service personnel
Low storage capacity	Storage of monitor full	Delete unimportant patient data Contact authorized service personnel
Place sensor in chamber	Sensor is not placed in calibration chamber	Place sensor in calibration chamber
Contact provider	Sensor is damaged and has to be refurbished	Contact authorized service personnel
No TCM5 FLEX license	No license to run the monitor with TCM5 FLEX configuration has been bought	Contact authorized service personnel
Product version	Product configuration BASIC is active – no alarms can be set	Contact authorized service personnel
FLEX trial	FLEX configuration trial expires within the mentioned days/hours	Contact authorized service personnel
FLEX trial expired	FLEX configuration trial has expired	Contact authorized service personnel

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*.

WARNING – Risk of incorrect measurements

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING – Risk of incorrect measurements

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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 electric shock

Do not position the device so that it is difficult to disconnect the power supply cord from the device.

WARNING – Risk of fire

Do not cover the ventilator as this may cause the monitor to heat up.

WARNING – Risk of electrical shock

Do not use the monitor if it is damaged as this may result in electrical shock.

WARNING – Risk of fire

Replace fuse only as recommended by Radiometer. Otherwise you risk that the monitor catches fire.

WARNING – Risk of personal injury

Do not touch the monitor rear connectors while third-party equipment is connected.

Ventilation requirements

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

Operating conditions

Environmental requirements

The TCM5 monitor is for use in a hospital, clinic or transport within a clinical environment. The TCM5 monitor is not for use in or near areas of high EM disturbance, such as near active HF surgical equipment or the RF shielded room of an ME System for magnetic resonance imaging.

These environmental requirements must be met during operation of the TCM5 monitor:

- Ambient temperature: 5 - 40 °C (41 - 107 °F)
- Relative humidity 15 %-90 % non-condensing
- Atmospheric pressure: 525 - 800 mmHg (700 - 1060 hPa)

Note: Operating the monitor outside these limits may affect the precision of the monitor.

Note: More restrictive conditions may apply for sensors. See the *Instructions for use* accompanying the sensor.

Note: The ambient temperature must always be at least 3 °C lower than the set sensor temperature during the application. When the sensor is placed in the calibration chamber, the ambient temperature must always be at least 4 °C lower than the set sensor temperature.

To set up the monitor

1. Connect the power cord to the rear of the monitor and to a power supply.
2. Connect the system to external equipment, if required.



WARNING – Risk of electric shock

Only connect the monitor to a supply mains with protective earth to avoid electric shock.



WARNING – Risk of personal injury

Before connecting other equipment to the TCM5monitor, 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 IEC 60601-1.

If connecting to an IT network, ensure that all interconnected third party equipment are IEC 60601-1-certified or IEC 60950-certified, or connect via an IEC 60601-1-certified or IEC 60950-certified external LAN insulator.



CAUTION – Risk of equipment damage

Do not connect the monitor to unsecured or unprotected networks (e.g. direct connection to the Internet).

Note: Make sure all passwords are changed during installation.

Note: Place the monitor such that the power cord can be easily disconnected from the monitor.

Adapter plate

You can attach the monitor to a GCX plate. There are 3 threaded inserts on the bottom of the monitor. These are used to secure the monitor to an adapter plate.

To connect a sensor to the monitor

1. Connect the sensor to the sensor socket at the rear of the monitor.

Passwords

Setting	Password
Service menu	TCM5PW1
Encryption	TCM5PW2

To change the password

Prerequisite(s)

- You must have a password for the **Service** menu
1. Tap **Menu > Service**.
 2. Enter your password for the **Service** menu.
 3. Tap the **Done** button.
 4. Tap **Settings > Security**.
 5. Choose a password type.
 6. Enter new password.
 7. Confirm new password.
 8. Tap the **Apply** button.

To change from FLEX to BASIC configuration

Prerequisite(s)

- You must have a password for the **Service** menu
1. Tap **Menu > Service**.
 2. Enter your password for the **Service** menu.
 3. Tap the **Done** button.
 4. Tap **Settings > System > License**.
 5. Select **TCM5 BASIC**.
 6. Tap the **Apply** button.

To change from BASIC to FLEX configuration

Prerequisite(s)

- You must have a password for the **Service** menu
 - You must have a **TCM5 FLEX** license key
1. Tap **Menu > Service**.
 2. Enter your password for the **Service** menu.
 3. Tap the **Done** button.
 4. Tap **Settings > System > License**.
 5. Select **TCM5 FLEX**.
 6. Enter the **TCM5 FLEX** license key in the **New key** field.
 7. Tap the **Apply** button.

Note: If Russian is selected as the user interface language, you must change to another language before changing the configuration.

Use mode – default settings

When the use mode is changed, the following settings change automatically:

Default settings

Setting	NICU	Adult	Sleep
Sensor set temperature	42.0 °C	42.0 °C	42.0 °C
Site time	4 hours	4 hours	8 hours
Smart heat on/off	OFF	ON	ON
Audio pause	ON	ON	ON
tcpCO ₂ alarm low limit	30 mmHg/4.0 kPa For FLEX configuration only	30 mmHg/4.0 kPa For FLEX configuration only	30 mmHg/4.0 kPa For FLEX configuration only
tcpCO ₂ alarm high limit	50 mmHg/6.7 kPa For FLEX configuration only	50 mmHg/6.7 kPa For FLEX configuration only	50 mmHg/6.7 kPa For FLEX configuration only
tcpCO ₂ alarm setting (on/off)	ON	ON	ON
tcpCO ₂ scale low point	10 mmHg/1.3 kPa	10 mmHg/1.3 kPa	10 mmHg/1.3 kPa
tcpCO ₂ scale high point	High = 70 mmHg/9.3 kPa	High = 70 mmHg/9.3 kPa	High = 70 mmHg/9.3 kPa
tcpO ₂ alarm low limit	60 mmHg/8.0 kPa For FLEX configuration only	60 mmHg/8.0 kPa For FLEX configuration only	60 mmHg/8.0 kPa For FLEX configuration only
tcpO ₂ alarm high limit	95 mmHg/12.7 kPa For FLEX configuration only	95 mmHg/12.7 kPa For FLEX configuration only	95 mmHg/12.7 kPa For FLEX configuration only
tcpO ₂ alarm setting (on/off)	ON	ON	ON
tcpO ₂ scale low point	40 mmHg/5.5 kPa	40 mmHg/5.5 kPa	40 mmHg/5.5 kPa
tcpO ₂ scale high point	150 mmHg/20.0 kPa	150 mmHg/20.0 kPa	150 mmHg/20.0 kPa

Setting	NICU	Adult	Sleep
SpO ₂ alarm low limit	N/A	85 %	85 %
SpO ₂ alarm high limit	N/A	OFF	OFF
SpO ₂ alarm setting (on/off)	N/A	ON	ON
SpO ₂ scale low point	N/A	65 %	65 %
SpO ₂ scale high point	N/A	100 %	100 %
PR alarm low limit	N/A	40 bpm For FLEX configuration only	40 bpm For FLEX configuration only
PR alarm high limit	N/A	170 bpm For FLEX configuration only	170 bpm For FLEX configuration only
PR alarm setting (on/off)	N/A	ON For FLEX configuration only	ON For FLEX configuration only
PR scale low point	N/A	20 bpm	20 bpm
PR scale high point	N/A	190 bpm	190 bpm
PI alarm low limit	N/A	0.5 %	0.5 %
PI alarm setting (on/off)	N/A	OFF	OFF
Alarm volume	5	5 For FLEX configuration only	5 For FLEX configuration only
t _c pCO ₂ Metabolic correction value	8 mmHg	7 mmHg	7 mmHg
Automatic standby	ON	ON	ON

Setting	NICU	Adult	Sleep
Automatic Night mode	N/A	N/A	0:30 h
Barometric air pressure	Automatic	Automatic	Automatic
tcpCO ₂ Heating power mode	Absolute	Absolute	Absolute
tcpCO ₂ Severinghaus correction on/off	ON	ON	ON
tcpO ₂ Parameter on/off	ON	ON	N/A
Pulseoximetry Averaging time	N/A	8 seconds	8 seconds
Pulseoximetry Pleth duration time	N/A	5 seconds	5 seconds
Pulseoximetry Sensitivity mode	N/A	Normal	Normal
Pulseoximetry Pulse audio on/off	N/A	ON	OFF
Pulseoximetry FastSat on/off	N/A	OFF	OFF
Pulseoximetry Parameter on/off	N/A	ON	ON

To select the time to activate automatic night mode

1. Tap **Menu > Settings > Display & Audio**.
2. Tap the **Display** button.
3. Select a time for the **Automatic night mode**.
4. Tap the **Apply** button.

Note: Available in **Sleep** mode only.

To set the alarm volume

1. Tap **Menu > Settings > Display & Audio.**
2. Tap **Audio.**
3. Select a volume.

Note: You can set the volume to **Off** in **Sleep** mode.

Note: Available with FLEX configuration only.

Alarm audio pressure

The volume can be set between 1 and 10.

Volume set	Medium-Priority Alarm (dB)	Low-Priority Alarm (dB)
1	30.7-33.8	29.4-33.5
10	60.4-71.1	61.8-69.5

Connectivity to polysomnography and patient monitoring systems

To connect to a polysomnography system

The monitor can be connected to various polysomnography (PSG) systems. For the correct adapter cables, see *Adapter cables for polysomnographs* in Chapter 7 *Ordering information*.

Prerequisite(s)

- You must have a password for the **Service** menu



WARNING – Risk that patient is not being monitored

Do not use the two communication channels Serial Port (RS232) and USB Device Connector at the same time. USB Device connection overrules the Serial Port connection resulting in a communication loss on the equipment connected to the Serial Port.

1. Connect the PSG interface cable to the TCM5 monitor.
2. Use the interface cable recommended by the PSG manufacturer.
If you are using the Open Interface Cable, connect the wires as following:

Analog output	Wire color	Range
tcpO ₂	Red	5 mV/mmHg @ 0-200 mmHg, ± 10 mV (± 2 mmHg) 4 mV/0.1kPa @ 0.0-25.0 kPa ± 10 mV (± 0.25 kPa) 1 mV/mmHg @ 0-800 mmHg ± 10 mV (± 10 mmHg) 1 mV/0.1kPa @ 0.0 100.0 kPa ± 10 mV (± 1.0 kPa)
SpO ₂	Green	10 mV/% SpO ₂ @ 0-100 % ± 10 mV (± 1 % SpO ₂)
tcpCO ₂	Yellow	10 mV/mmHg @ 0-100 mmHg ± 10 mV (± 1 mmHg) 8 mV/0.1kPa @ 0.0-12.5 kPa ± 10 mV (± 0.13 kPa) 8mV/mmHg @ 0-125 mmHg ± 10mV (± 1.25 mmHg) 5.9mV/0.1kPa @ 0-17.0 kPa ± 10mV (± 0.17 kPa) 5 mV/mmHg @ 0-200 mmHg ± 10 mV (± 2 mmHg) 4 mV/0.1kPa @ 0.0-25.0 kPa ± 10 mV (± 0.25 kPa)
Alarm status	Violet	Activated: 1000 mV ± 10 mV Not activated: 0 mV ± 10 mV

Analog output	Wire color	Range
PI	Blue	100 mV/% PI @ 0-10 % \pm 10 mV (\pm 0.1 %) 50 mV/% PI @ 0-20 % \pm 10 mV (\pm 0.2 %)
Heating power	Gray	1 mV/mW @ 10-1000 mW \pm 10 mV (\pm 10 mW) <10 mW \approx 0 mV
PR	Pink	4 mV/bpm @ 20-250 bpm \pm 10 mV (\pm 3 bpm)
Sensor temperature	Brown	20 mV/°C @ 10-50 °C, \pm 10 mV (\pm 0.50 °C)
Ground	Black	N/A

3. Tap **Menu > Service**.
 4. Enter your password for the **Service** menu.
 5. Tap the **Done** button.
 6. Tap **Connectivity > Analog**.
 7. Select the $p\text{CO}_2$ analog range: 0-100 mmHg/12.5 kPa, 0-125 mmHg/0-17.0 kPa or 0-200 mmHg/0-25.0 kPa range.
 8. Select the $p\text{O}_2$ analog range (if parameter available): 0-200 mmHg/0-25.0 kPa range or 0-800 mmHg/0-100.0 kPa range.
 9. Select the PI analog range (if parameter available): 0-10 % or 0-20 % range.
 10. Tap the  button.
This action will enable the output.
 11. Tap the **Apply** button.
- Note:** It is highly recommended to calibrate the analog output. When the calibration is completed, the analog output will correspond to the readouts on the screen. Calibration is only possible if the analog output is enabled and no measurement is on-going.
12. Set the calibration level to 0 % on the TCM5 monitor.
 13. Make sure that the PSG system is showing a calibration level of 0 volt on all signals.
- Note:** The calibration level on a PSG may be represented according to the parameter range definition and the selected unit.
14. Set the calibration level to 100 %.
 15. Make sure that the PSG system is showing a calibration level of 1 volt on all signals.

MonLink

MonLink is used to interconnect the TCM5 monitor with external Patient Monitoring Systems (PMS) or other external devices - e.g. Electronic Medical Records Systems (EMR). The TCM5 monitor can be connected to various PMS (e.g. Philips, GE Health-

care, Dräger, Mindray, Spacelabs, Nihon Kohden, Fukuda Denshi) and EMR (e.g. Capsule).

Contact the external device manufacturer for requirements needed to connect, e.g. supported devices, required device software revision, accessories, adapter cables and interfaces.

Each MonLink protocol revision provides a specific set of features, e.g. parameters provided, alarm status information and device information.

The parameter values are updated every second.

For information on alarm delay and source/identification on external equipment, please refer to the user instructions for the relevant external equipment.

To connect using MonLink

Prerequisite(s)

- You must have a password for the **Service** menu.
- Serial DB9 cable

1. Tap **Menu > Service**.
 2. Enter your password for the **Service** menu.
 3. Tap the **Done** button.
 4. Tap **Connectivity > Serial**.
 5. Select the applicable MonLink Protocol:
 - a) MonLink 2.0 (most recent protocol revision in this listing)
 - b) MonLink for TCM4 Series
 - c) MonLink for TOSCA 500
 - d) MonLink for Microgas 7650
- Refer to instructions provided by the external device manufacturer to select the appropriate MonLink protocol revision or contact your local Radiometer representative.
6. Tap the **Apply** button.
 7. Connect the serial DB9 cable to the TCM5 monitor's serial port (RS232).
 8. Follow the instructions provided by the external device manufacturer to complete the connection.

Connection to a Philips patient monitor

IntelliBridge is used to interconnect your TCM5 monitor with a Philips patient monitoring system (PMS) that supports the IntelliBridge and VueLink Open Interface (IVOI). The TCM5 can be connected to various Philips PMS, for example, CMS, IntelliVue MP40/50/60/70/80/90/MX 600/MX700/MX800, Agilent V24/V26.

Note: Default color definition is only valid for IntelliBridge.

Note: Semantic: Parameter: label (range), type, color.

Parameters

Parameters	IntelliBridge user interface	Range	Numeric/Graph	Graph color
tcpCO ₂	tcpCO ₂	0-200 mmHg or 0-26.6 kPa	Numeric/Graph	Blue
tcpO ₂	tcpO ₂	0-800 mmHg or 0-102.3 kPa	Numeric/Graph	Red
SpO ₂	SpO ₂	0-100 %	Numeric/Graph	Magenta
Pulse rate	PULSE	0-300 bpm	Wave form	Cyan
Perfusion index	PERF	0-20 %	Numeric	
Plethysmograph	PLETH	-128-127	Graph	White
Heating power	HEAT	0-999 mW	Numeric/Graph	White
Site time setting	Timer	0-12 hours	Numeric	
Site time remaining	LeftTi	12-0 hours	Numeric	
Sensor temperature	Tsens	37-44	Numeric	

Alarms

Philips PMS		TCM5 FLEX/BASIC equivalent	
Message/INOPs	Color	Description	Equivalent message
!! TC ALARM	Yellow	Medium priority alarm (Parameter alarm)	E.g. tcpCO ₂ High
! TC BAT CRIT	Yellow	Low priority alarm	Battery very low
! TC ALARM	Yellow	Low priority alarm (tc measurement relevant)	E.g. Site time elapsed
SEE TC MONITOR	Cyan	Notification (TCM5 monitor relevant)	E.g. Gas bottle empty

Philips PMS		TCM5 FLEX/BASIC equivalent	
Message/INOPs	Color	Description	Equivalent message
TC BAT LOW	Cyan	Notification (TCM5 monitor relevant)	Battery status low

Depending on the technical alarm message (INOPs), parameter values may be displayed in the following way:

Philips PMS	Description (TCM5 FLEX/BASIC equivalent example)
? LABEL 12.3	Data may be wrong (e.g. Low perfusion)
LABEL -?-	Provided data is wrong (e.g. Out of range)
LABEL	No data provided and no INOP

Note: The Philips IntelliBridge protocol is backwards compatible to the VueLink interface module. The TCM5 FLEX/BASIC monitor may be interconnected with a Philips VueLink interface module type B (M1032A #A05). Please contact your Philips representative to receive information about the required accessories.

Note: The Philips IntelliBridge EC5 Open Interface module shall be connected to the TCM5 monitor's serial DB9 connector. Do not connect the standard Ethernet cable coming from the Philips EC10 with the TCM5 monitor's Ethernet connector.

Note: Contact your Philips representative to receive information about the requirements needed (e.g. supported PMS, required PMS software revision, accessories, adapter cables, interfaces, etc.).

Note: Transmission of data from the TCM5 monitor to the Philips PMS may be delayed with up to 4 seconds. The maximum delay depends on the Philips PMS requesting and processing data from the TCM5 monitor.

Note: Philips IntelliBridge defines 2 types of alarms: red and yellow; but the FLEX/BASIC monitor only provides yellow alarms.

Note: With Philips IntelliBridge parameter values and attached alarm limit values can be transported from a TCM5 FLEX/BASIC monitor to a Philips PMS. The presentation of the data corresponds to normal view.

To connect to a Philips monitor

Prerequisite(s)

- TCM5 FLEX or BASIC configuration
- Philips Patient Monitor supporting IVOI (SW Rev. H.15 or higher)
- Philips IntelliBridge EC5 Open Interface module (865114 #102)
- Philips IntelliBridge EC10 plug-in module (865115 #A01 with Firmware Rev. 1130 / 1310 or higher [for new EC10 modules] and IntelliBridge driver Rev. ED101 A.4 or higher)
- Standard Ethernet min. Cat. 5e cable with max. length of 10 m
- You must have a password for the **Service** menu

1. Tap **Menu > Service**.
2. Enter your password.
3. Tap the **Done** button.
4. Tap **Connectivity > Serial**.
5. Select the applicable protocol: **Philips IntelliBridge**.
6. Tap the **Apply** button.
7. Connect the Philips IntelliBridge EC5 Open Interface module to the TCM5 monitor's serial DB9 connector.
8. Connect the EC5 module with the EC10 plug-in module by using the standard Ethernet cable.
9. Plug-in the EC10 module to your Philips PMS.
10. Follow the instructions provided by Philips or your Radiometer representative to complete the connection.

Network connectivity

The Ethernet interface is intended to download CSV data from the TCM5 monitor to an external device or software tool. Follow the instructions provided by the external device or software manufacturer or contact your Radiometer representative to complete the connection.

WARNING – Risk of data loss

Make sure the network connection is safe. Failure to do so can result in unauthorized data access, (e.g. selection of IP address).

CAUTION – Unsecure IT networks

Failure of the IT network to provide the specified characteristics can result in the following hazardous situations:

- unauthorized access to patient data or device
- loss of data
- installation of malware on the monitor

Purpose of the TCM5 connection to IT networks:

- transfer of patient data
- transfer of patient information
- device information for post-processing

Required characteristics of an IT network:

- Transmission control protocol (TCP) and Internet protocol (IP) over ethernet
- Network safety according best practices

Required configuration of an IT network:

- Standard ethernet

Intended information flow between the TCM5 and an IT network:

- Patient data, patient information and device information for post-processing must be transferred over secure protocols (HTTPS) only
- No routing restrictions apply

Accessibility of TCM5 monitor through IT network is secured by enabled firewall.

Note: It is the responsibility of the network provider to identify, analyze, evaluate and control these risks.

Note: Disabling ethernet or unplugging the ethernet cable has no impact on safety, performance or monitor function – all TCM5 monitor functions will remain active, but data transfer to external devices over ethernet is interrupted.

Note: Changes to an IT network might introduce new risks that require additional analysis.

Changes to the IT network include:

- changes in network configuration
- connection of additional items
- disconnection of items
- update of equipment
- upgrade of equipment

To automatically connect to an Ethernet network

Prerequisite(s)

- You must have a password for the **Service** menu

Note: The TCM5 monitor supports IPv4 only (IPv6 is generally not supported).

Note: To avoid configuration failure or interference from other network devices, check with the local IT service provider before you manually configure the Ethernet interface.

1. Tap **Menu > Service**.
2. Enter your password for the **Service** menu.
3. Tap the **Done** button.
4. Tap **Connectivity > Ethernet**.
5. Enable Ethernet (if disabled).

6. Enable DHCP (Dynamic Host Configuration Protocol) (if disabled).

7. Tap the **Apply** button.

Note: The TCM5 monitor is using the monitor serial number as host name (RXXXXNXXX). You may change the host name to a value according to RFC 1123.

To manually connect to an Ethernet network

Prerequisite(s)

- You must have a password for the **Service** menu

Note: The TCM5 monitor supports IPv4 only (IPv6 is generally not supported).

Note: To avoid configuration failure or interference from other network devices, check with the local IT service provider before you manually configure the Ethernet interface.

1. Tap **Menu > Service**.

2. Enter your password for the **Service** menu.

3. Tap the **Done** button.

4. Tap **Connectivity > Ethernet**.

5. Enable Ethernet (if disabled).

6. Disable DHCP (Dynamic Host Configuration Protocol) (if enabled).

7. Tap the **Apply** button.

Note: The TCM5 monitor is using the monitor serial number as host name (RXXXXNXXX). You may change the host name to a value according to RFC 1123.

8. Enter a valid **IP address**.

9. Enter a valid **Network mask**.

10. Optionally, enter the **IP address** of the default gateway.

11. Optionally, enter DNS (Domain Name System) server information. You may provide 2 DNS server IP addresses for **DNS1** and **DNS2**.

12. Tap the **Apply** button.

Monitor settings

To set the language

1. Tap **Menu > Settings > Time & language & location**.

2. Select a language.

3. Tap the **Apply** button.

To set the date

1. Tap **Menu > Settings > Time & language & location.**
2. Tap **Date format** and select the format.
3. Tap **Date** and set the date.
4. Tap the **Apply** button.

To set the time

1. Tap **Menu > Settings > Time & language & location.**
2. Tap **Time format** and select the format.
3. Tap **Time** and set the time.
4. Tap the **Apply** button.

WARNING – Risk of data loss

If the date or time settings are changed backward in time, only the measurements that have been performed prior to the new date or time will be kept in the memory. Other data will be deleted.

To select a color for a parameter

You can select a different color for each parameter to make it easy to see values on a graph.

1. Tap **Menu > Settings > Display & audio > TC colors or Pulseoximetry colors.**
2. Select a color for each parameter.
3. Tap the **Apply** button.

To select metabolic correction settings

1. Tap **Menu > Settings > Parameters.**
2. Select the settings of the metabolic constant.
3. Tap the **Apply** button.

To set the averaging time of the SpO₂ measurement and the pulse rate

The longer the averaging time, the slower the response to changes in SpO₂ and pulse rate.

1. Tap **Menu > Settings > Parameters.**
2. Select **Pulseoximetry.**
3. Select the averaging time.
4. Tap the **Apply** button.

To set the plethysmograph duration of the SpO₂ measurement

1. Tap **Menu > Settings > Parameters**.
2. Select **Pulseoximetry**.
3. Select the **Pleth duration** time.
4. Tap the **Apply** button.

To set the sensitivity of the SpO₂ measurement

1. Tap **Menu > Settings > Parameters**.
2. Select **Pulseoximetry**.
3. Select **APOD** or **Maximum** or **Normal**.
4. Tap the **Apply** button.

To turn on the Pulse audio of the SpO₂ measurement

1. Tap **Menu > Settings > Display & audio**.
2. Select **Audio**.
3. Tap the  button.
4. Tap the **Apply** button.

To set the sensor heating power

1. Tap **Menu > Settings > Parameters**.
2. Select **Absolute** or **Relative**.
3. Tap the  button.

To set the barometric pressure

Prerequisite(s)

- You must have a password for the **Service** menu



WARNING – Risk of incorrect measurements

Selection of inappropriate manual air pressure setting can result in missing alarms. Check barometric air pressure setting mode selection before each application.

1. Tap **Menu > Service**.
2. Enter your password for the **Service** menu.
3. Tap **Settings > Usage**.
4. Select the air pressure.
5. Tap the **Apply** button.

To deactivate the Severinghaus correction



WARNING – Risk of incorrect measurement

The deactivation of the Severinghaus correction can result in alarms being missed. Check the Severinghaus setting before each application.

1. Tap **Menu > Settings > Parameters**.
2. Tap the button next to **Severinghaus correction**.

6

Specifications

Specifications

The table below lists the specifications for the TCM5 monitor:

Hardware

Item	Description
Dimensions	Width: 270 mm Depth: 152 mm Height: 188 mm Weight: 2.5 kg, 2.3 kg (without battery)
Display	Screen: 9" color, capacitive, multi-touch TFT, 800 x 480 pixels, 16:9 ratio Display options: numeric view, trend view, detail view Screen update rates: Numeric data values (SpO_2 , pulse rate, tcpCO_2 , tcpO_2 , heating power): 1/second Trend data range (depends on time axis scale): 1 pixel/2 second to 1 pixel/96 seconds Viewing angle adjustment: $-6^\circ/0^\circ/+10^\circ$
Computer specifications	CPU: Texas Instruments, AM3358 ARM Cortex A8, 1 GHz RAM 2 GB Data memory: 16 GB Software platform: Microsoft Windows® Start-up time: $<= 80$ seconds
Operating conditions	Ambient temperature: 5-40 °C (41-107 °F) Relative humidity: 15 % to 90 %, non-condensing Atmospheric pressure: 525 - 800 mmHg (700 - 1060 hPa)

Item	Description
Transport and storage conditions	<p>Ambient temperature: -20-50 °C (-4 -122 ° F)</p> <p>Relative humidity: 15 % to 90 %, non-condensing at 5-35 °C (41 -95 ° F)</p> <p>and up to 50 hPa water vapour pressure at 35-50 °C (95 -158 ° F)</p> <p>Atmospheric pressure: 375 - 800 mmHg (500 - 1060 hPa)</p> <p>Note: More restrictive conditions may apply for sensors.</p>
LED characteristics	<p>LED wave lengths: red 658 nm (+/- 1 nm) / infrared (880 nm)</p> <p>LED energy: 50 mW</p> <p>Note: Information about the range of wavelength can be useful specially to clinicians.</p>
Built-in barometer	<p>Range: 375-825 mmHg or 50-110 kPa</p> <p>Accuracy: ± 5 mmHg or 0.67 kPa</p>
Power supply	<p>100-240 V, 50-60 Hz, 55-85 VA (max.) (maximum cable length 2.5 m)</p> <p>Rechargeable Li-Ion battery, Type RRC2040</p> <p>High breaking capacity (ceramic tube) fuse: 1.25 A (250 V)</p> <p>Typical operating time: 4 hours per charge at 25 °C</p>
IP protection	<p>IP32</p> <p>Level of protection against the ingress of solid parts and the access to hazardous parts: 3</p> <p>Level of protection that the enclosure provides against harmful ingress of water: 2</p>

Item	Description
Connectivity	<p>Network connection: Ethernet 10/100 Base-T full duplex (maximum cable length 3 m)</p> <p>Personal security (TKIP or AES)</p> <p>USB: 3x USB 2.0 (1x side, 2x rear), Type-A (USB 1.1 compatible) (maximum cable length 2 m)</p> <p>Isolated serial output: USB 2.0, Type-B (USB 1.1 compatible) & RS232 (maximum cable length 2 m)</p> <p>The RS232 output from the monitor is transmitted continuously every 2 seconds</p> <p>Isolated Nurse call output: relay contact normally open (calling closed, not calling, opened), 60 V, 2.5A</p> <p>Isolated analog output: 0-1000 mV (maximum cable length 2 m)</p> <p>Data protocol: MonLink (2.0, TCM4 Series, TOSCA 500, MicroGas 7650)</p>
Interface with third-party products	<p>Polysomnographs: Alice 5/6, Embla, Embletta Gold and other</p> <p>Patient monitoring systems: Philips, General Electric (GE),</p> <p>Mindray vital sign monitors; (for TCM5 equipped with tc Sensor 84)</p> <p>Mounting system: compatible to GCX mounting system</p> <p>USB storage: Data export</p>
Expected monitor lifetime:	10 years

Software

Item	Description
Measuring range	<p>Transcutaneous carbon dioxide tension/tcpCO₂: 5-200 mmHg or 0.7-26.7 kPa</p> <p>Transcutaneous oxygen tension/tcpO₂: 0-800 mmHg or 0.0-99.9 kPa</p> <p>Oxygen saturation/SpO₂: 0-100 % (70-100 % with ±3 digits)</p> <p>Pulse rate: 25-240 bpm</p>

Item	Description
Calibration	<p>Automatic calibration</p> <p>Calibration gas: CO₂: 7.5 %, O₂: 12.0 %, N: 80.5 %</p> <p>Integrated calibration chamber</p> <p>Maximum interval between 2 calibrations is set to 12 hours.</p>
Patient data storage	<p>Up to 1 year of measuring data in 1-second data intervals</p> <p>Reviewing trends on screen</p> <p>Download of stored patient data to computer or USB storage</p>
Site timer	<p>Indication of remaining measuring time</p> <p>Measuring time elapsed: clock triggers an alarm (and sensor temperature is off after 15 minutes)</p>
Languages	Chinese, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Hungarian, Italian, Japanese, Lithuanian, Norwegian, Polish, Portuguese, Romanian, Russian, Slovak, Spanish, Swedish, Turkish

Alarm system

Item	Description
Alarm level	OFF, 1-10 (1 is minimum); OFF: only available in Sleep mode
Alarm delays	The alarm delay is the sum of the alarm condition delay (time from occurrence of the alarm triggering event to when the alarm system determines that an alarm condition exists) and the alarm signal generation delay (time from the onset of the alarm condition to the generation of its alarm signal).

Item	Description
Alarm condition delay	<p>The alarm condition delay is specified as the following:</p> <p>tcpCO_2 low/high alarm: the alarm condition delay depends mainly on the response time (see sensor specification). Typical value ≤ 60 seconds.</p> <p>tcpO_2 low/high alarm: the alarm condition delay depends mainly on the response time (see sensor specification). Typical value ≤ 25 seconds.</p> <p>SpO_2/PR low/high alarm and PI low alarm: the alarm condition delay depends mainly on the averaging time selected (see sensor specification, the maximum value is 16 seconds). Typical value ≤ 16 seconds.</p> <p>Technical alarm: alarm condition delay is typically ≤ 1 second.</p>
Alarm signal generation delay	Alarm signal generation delay is typically ≤ 5 seconds.
Alarm light bar	<p>Medium-priority alarms: flashing frequency 0.6 Hz; duty cycle 60 % on/40 % off</p> <p>Low-priority alarms: constantly on</p>
Audible alarm signal	Generation of the alarm signal melodies for medium-priority and low-priority alarms according to IEC 60601-1-8

Sensor specifications

Item	Description
Measuring principle	<p>tc Sensor 92: Stow-Severinghaus-type $p\text{CO}_2$ combined with: Masimo SET® SpO_2 pulseoximetry</p> <p>tc Sensor 84: Stow-Severinghaus-type $p\text{CO}_2$ combined with Clark-type $p\text{O}_2$ sensor</p> <p>tc Sensor 54: Stow-Severinghaus-type $p\text{CO}_2$ sensor</p>

Item	Description
Sensor temperature	Selectable between 37.0-44.0 °C in steps of 0.5 °C Reliable safe control by 2 independent circuits Accuracy: ±0.2 °C Automatic temperature off 15 minutes after site time is elapsed The temperature measured at the sensor surface never exceeds the maximum set temperature (44 °C) using the test method described in IEC 60601-2-23.
Heating power	Sensor heating power: 0-999 mW
Sensor remembranring requirements	Membrane duration up to 28 days (28 days default) Built-in alert when sensor needs remembranring Protected membrane (golden plate)
Sensor dimensions	Diameter: 15 mm or 0.6 in Height: 8 mm or 0.3 in Weight: 3 g or 0.1 oz Sensor cable length: 3 m or 9.8 ft, shielded, flexible, polyurethane coated
Biocompatibility	The sensors meet the requirements of ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" for surface devices contacting intact human skin. The evaluations include cell cytotoxicity, skin irritation and sensitization potential.

Sensor performance

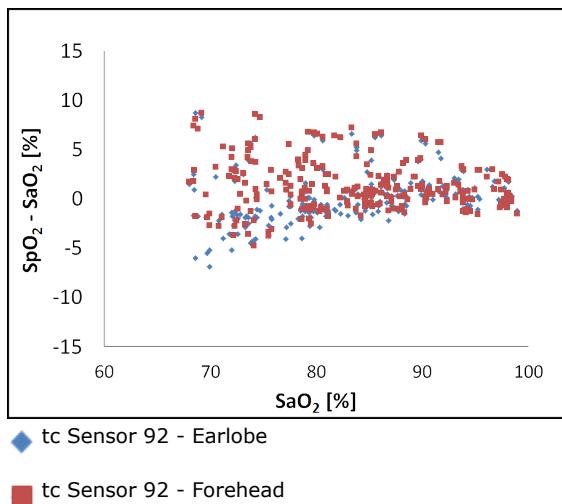
Item	Description
tc Sensor 54	<p>Conditions: sensor temperature of 43 °C</p> <p>Calibration interval: 12 hours</p> <p>tcpCO₂:</p> <p>Accuracy (5-200 mmHg): ± 5 mmHg</p> <p>Response time (0-90 %): ≤70 seconds</p> <p>Response time (10-90 %): ≤60 seconds</p> <p>Drift (at 42 °C): ≤0.5 %/hour</p> <p>Combined effects of linearity and hysteresis:</p> <ul style="list-style-type: none">• at 1 and 10 % CO₂: better than 1 mmHg or 0.13 kPa• at 33 % CO₂: better than 3 mmHg or 0.40 kPa

Item	Description
tc Sensor 84	<p>Conditions: sensor temperature of 43 °C</p> <p>Calibration interval: 12 hours</p> <p>tcpCO₂:</p> <p>Accuracy (5-200 mmHg): ± 5 mmHg</p> <p>Response time (0-90 %): ≤70 seconds</p> <p>Response time (10-90 %): ≤60 seconds</p> <p>Drift: ≤1 %/hour</p> <p>Combined effects of linearity and hysteresis:</p> <ul style="list-style-type: none">• at 1 and 10 % CO₂: better than 1 mmHg or 0.13 kPa• at 33 % CO₂: better than 5 mmHg or 0.67 kPa <p>tcpO₂:</p> <p>Accuracy (0-20.9 % O₂): ± 5 mmHg, (20.9-100 % O₂): ± 10 %</p> <p>Response time (0-90 %): ≤25 seconds</p> <p>Drift: ≤1 %/hour</p> <p>Combined effects of linearity and hysteresis:</p> <ul style="list-style-type: none">• at 0 % O₂: better than 1 mmHg or 0.13 kPa• at 20.9 % O₂: better than 3 mmHg or 0.4 kPa• at 50 % O₂: better than 5 mmHg or 0.67 kPa• at 90 % O₂: better than 25 mmHg or 3.33 kPa

Item	Description
tc Sensor 92	<p>Conditions: sensor temperature of 43 °C</p> <p>Calibration interval: 12 hours</p> <p>tcpCO₂:</p> <ul style="list-style-type: none"> Accuracy (5-200 mmHg): ± 5 mmHg Response time (0-90 %): ≤70 seconds Response time (10-90 %): ≤60 seconds Drift (at 42 °C): ≤0.5 %/hour <p>Combined effects of linearity and hysteresis:</p> <ul style="list-style-type: none"> at 1 and 10 % CO₂: better than 1 mmHg or 0.13 kPa at 33 % CO₂: better than 5 mmHg or 0.67 kPa <p>SpO₂ and Pulse rate:</p> <ul style="list-style-type: none"> Accuracy (70-100 %): ± 3 digits^(a) Pulse oximeter equipment is calibrated according to ISO 80601-2-61 to display functional oxygen saturation Accuracy (25-240 bpm): ± 3 bpm^(b) SpO₂ and pulse rate: signal averaging 2, 4, 8, 10, 12, 14 and 16 seconds Data update rate: 1 per second

(a) The SpO₂ accuracy is expressed as plus or minus "3" digits (oxygen saturation percentage points) between saturation of 70 % and 100 %. This variation equals ± one standard deviation 1SD, which encompasses 68 % of the population. The accuracy specification is based on tests performed with a TOSCA 500 monitor compared with arterial blood sample and the reference is measured with a CO-oximeter as reference on healthy adult volunteers in induced hypoxia studies across the specified range. The tests were performed on the earlobe using an ear clip and on the forehead with a fixation ring respectively.

(b) The pulse rate accuracy has been validated in bench testing against a Bio-Tek Index 2 SpO₂ Simulator with a signal strength set to 1.



Application site	Hemoximeter Range [%]						
	60-80	80-100	60-100	70-100	70-80	80-90	90-100
Arms Earlobe	3.16	2.04	2.52	2.32	2.76	2.31	1.56
Arms Forehead	2.61	1.96	2.24	2.14	2.44	2.01	1.87

Note: Since pulse oximeter measurements are statistically distributed, it can be expected that only about two thirds of the measurements fall within the specified accuracy compared to CO-oximeter measurements.

Note: Functional tester cannot be used to assess the SpO₂ accuracy.

The analysis includes data from 12 healthy volunteers (6 females / 6 males). The subjects were 21 - 41 years of age and were from three different ethnicities (9 Caucasian, 2 African-American, 1 Asian).

Essential performance

Item	Description
tc Sensor 54	<p>tcpCO₂:</p> <p>Accuracy (5-200 mmHg): ± 5 mmHg</p> <p>Combined effects of linearity and hysteresis:</p> <ul style="list-style-type: none"> • at 1 and 10 % CO₂: better than 1 mmHg or 0.13 kPa • at 33 % CO₂: better than 3 mmHg or 0.40 kPa
tc Sensor 84	<p>tcpCO₂:</p> <p>Accuracy (5-200 mmHg): ± 5 mmHg</p> <p>Combined effects of linearity and hysteresis:</p> <ul style="list-style-type: none"> • at 1 and 10 % CO₂: better than 1 mmHg or 0.13 kPa • at 33 % CO₂: better than 5 mmHg or 0.67 kPa <p>tcpO₂:</p> <p>Accuracy (0-20.9 % O₂): ± 5 mmHg</p> <p>Accuracy (20.9-100 % O₂): ± 10 %</p> <p>Combined effects of linearity and hysteresis:</p> <ul style="list-style-type: none"> • at 0 % O₂: better than 1 mmHg or 0.13 kPa • at 20.9 % O₂: better than 3 mmHg or 0.4 kPa • at 50 % O₂: better than 5 mmHg or 0.67 kPa • at 90 % O₂: better than 25 mmHg or 3.33 kPa
tc Sensor 92	<p>tcpCO₂:</p> <p>Accuracy (5-200 mmHg): ± 5 mmHg</p> <p>Combined effects of linearity and hysteresis:</p> <ul style="list-style-type: none"> • at 1 and 10 % CO₂: better than 1 mmHg or 0.13 kPa • at 33 % CO₂: better than 5 mmHg or 0.67 kPa <p>SpO₂ and pulse rate:</p> <p>Accuracy (70-100 %): ± 3 digits</p> <p>Accuracy (25-240 bpm): ± 3 bpm</p>

Item	Description
TCM5 monitor	<p>Alarm signal generation delay</p> <p>Alarm signal generation delay is typically \leq 5 seconds.</p> <p>Medium-priority alarms</p> <p>The TCM5 monitor features a medium-priority alarm system for the following parameter measurements:</p> <ul style="list-style-type: none"> • $t_{cp}CO_2$ high • $t_{cp}CO_2$ low • $t_{cp}O_2$ high • $t_{cp}O_2$ low • SpO_2 high • SpO_2 low • PR high • PR low • PI low

Accessory specification

Item	Description
Biocompatibility	<p>Fixation ring/adhesive ring</p> <p>The suitability of the adhesives for use on intact human skin is supported by a series of in vitro and in vivo evaluations.</p> <p>The adhesives meet the requirements of ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" for surface devices contacting intact human skin. The evaluations include cell cytotoxicity, skin irritation and sensitization potential.</p>

Known sources of interference**Interference by anesthetic – gases (in-vitro)**

Item	Description
tcpCO₂	75 % N ₂ O: negligible 2 % Halothane: negligible 2 % Enflurane: negligible 2 % Isoflurane: negligible 2 % Desflurane: negligible 2 % Sevoflurane: negligible
tcpO₂	75 % N ₂ O: < 10 mmHg (1.33 kPa) 2 % Halothane: approx. 200 mmHg (26.67 kPa) 2 % Enflurane: negligible 2 % Isoflurane: negligible 2 % Desflurane: negligible 2 % Sevoflurane: negligible

Possible SpO₂ interference

Item	Description
SpO₂	<p>Inaccurate measurements can be caused by:</p> <ul style="list-style-type: none"> • prolonged patient movement • venous pulsations • intravascular dyes such as indocyanine green or methylene blue • defibrillation • incorrect application of the sensor • placement of the sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line • excessive ambient light • severe electrical interference • elevated levels of bilirubin • extreme motion artifact • vasospastic disease, such as Raynaud's, and peripheral vascular disease • hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc. • hypocapnic or hypercapnic conditions • birthmark(s), tattoos, skin discolorations, moisture on skin • physical deformities • skin color disorders <p>Loss-of-pulse signal can occur for the following reasons:</p> <ul style="list-style-type: none"> • The sensor is applied too tightly • A blood pressure cuff is inflated on the same extremity as the one with the sensor attached • There is arterial occlusion proximal to the sensor

EMC approvals and compliance

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

Electromagnetic (EM) disturbances to the TCM5 monitoring system could result in inaccurate measurements (tcpCO₂/tcpO₂/SpO₂/PR) or system errors. If any inaccurate measurements occur, the system will recover without user interaction after

electromagnetic disturbances have ended. If system errors occur, user interaction is required.

Guidance and manufacturer's declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The TCM5 monitor uses RF energy only for its internal function. Therefore, its RF emission is very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A ^a	The TCM5 monitor is suitable for use in all establishments other than domestic establishments 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

^a **Note:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±(2,4,8,15) kV air	±8 kV contact ±(2,4,8,15) 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 %.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential 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	0 % U_T for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0 % U_T for 1 cycle and 70 % for 25/30 cycles single-phase at 0 degrees 0 % U_T for 250/300 cycles at 0 degrees	0 % U_T for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0 % U_T for 1 cycle and 70 % for 25/30 cycles single-phase at 0 degrees 0 % U_T for 250/300 cycles at 0 degrees	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TCM5 monitor requires continued operation during mains interruptions, it is recommended that the TCM5 monitor is powered from an uninterruptible power supply or a battery.
Power frequency (50-60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels of a typical location in a commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 V _{rms} outside ISM band 6 V _{rms} in ISM band 150 kHz to 80 MHz	3 V _{rms} outside ISM band 6 V _{rms} in ISM band 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the TCM5 monitor, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.
Note: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.			
Radiated RF IEC 61000-4-3	80 MHz to 2.7 GHz: 3 V/m 385 MHz: 27 V/m 450 MHz: 28 V/m 710 MHz, 745 MHz, 780 MHz: 9 V/m 810 MHz, 870 MHz, 930 MHz: 28 V/m 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m 2450 MHz: 28 V/m 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m	80 MHz to 2.7 GHz: 3 V/m 385 MHz: 27 V/m 450 MHz: 28 V/m 710 MHz, 745 MHz, 780 MHz: 9 V/m 810 MHz, 870 MHz, 930 MHz: 28 V/m 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m 2450 MHz: 28 V/m 5240 MHz, 5500 MHz, 5785 MHz: 9 V/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.

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

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

^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 TCM5 monitor is used exceeds the applicable RF compliance level above, the TCM5 monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TCM5 monitor.

Ordering information

Ordering information

Monitor and FLEX license

Item	Code numbers (REF)
TCM5 BASIC monitor	393-500
TCM5 FLEX license	933-340

Sensors

Accessory	Code numbers (REF)
tc Sensor 92	5621000
tc Sensor 84	945-737
tc Sensor 54	945-736

Miscellaneous

Accessory	Code numbers (REF)
TCM5 <i>Short-form instruction</i>	Contact your local Radiometer representative.
TCM5 <i>Service manual, (English)</i>	996-604
TCM Communication Protocol Specifications	994-038
TCM5 Battery	905-975
TCM5 Calibration Gas	962-209
Adhesive Rings N20 Kit	905-872
Sensor Attachment Clips (ear clip)	5601300

Accessory	Code numbers (REF)
Fixation Kit N20	905-873
Fixation Rings 32	5601500
Preparation Supplies (Membraning Kit 92)	5601100
Membraning Kit 84	905-871
Membraning Kit 54	905-868
Contact Gel (1 x 10 mL)	0603210
Electrolyte for tc Sensor 92 (1 x 10 mL)	5601110
Electrolyte for tc Sensor 84 (4 x 10 mL)	905-869
Electrolyte for tc Sensor 54 (4 x 10 mL)	905-866

Power cords

Accessory	Code numbers (REF)
Power cord 100 - 120 V, JPN	615-403
Power cord 230 V, UK	615-312
Power cord 230 V, ITA	615-313
Power cord 230 V, ISR	615-315
Power cord 230 V, CHE	615-316
Power cord 230 V, AUS and NZA	615-317
Power cord 230 V, ZAF and IND	615-318
Power cord 230 V, other 230 V countries	615-303

Adapter cables for polysomnographs

Accessory	Code numbers (REF)
TCM5 Embla Interface Cable	903-600
TCM5 Embletta Gold Interface Cable	903-599

Accessory	Code numbers (REF)
TCM5 Alice Int Interface Cable	903-598
TCM5 Embla MDrive Interface Cable	903-601
TCM5 Open Interface Cable	903-602

Modules for Philips IntelliBridge

Accessory	Code numbers (REF)
Philips IntelliBridge EC5 Open Interface module	865114 #102
Philips IntelliBridge EC10 plug-in module	865115 #A01

Note: Data subject to change without notice.

Functional description

Transcutaneous sensors

Transcutaneous measurement of $p\text{CO}_2$ and $p\text{O}_2$ makes use of the fact that carbon dioxide and oxygen gases are able to diffuse through body tissue and skin and can be detected by a sensor at the skin surface. By warming up the sensor, a local hyperemia is induced, which increases the supply of arterial blood to the dermal capillary bed below the sensor.

The transcutaneous blood gas values (tcpCO_2 and tcpO_2) have to be interpreted primarily as the blood gas partial pressures prevailing at the level of the arterialized skin tissue.

Reliable transcutaneous measurements require good gas diffusion through the body tissue and skin. This process of arterIALIZATION of the capillary blood flow is accelerated by increased temperature. The SmartHeat feature allows a stable value of $p\text{CO}_2$ and $p\text{O}_2$ very shortly after sensor application, even at a sensor temperature of 42 °C.

Sensor memory

The sensor contains an electronic memory to store $p\text{CO}_2$ and $p\text{O}_2$ calibration values and other relevant sensor data (such as the date of the last sensor remembranring or light intensities of LEDs). By evaluating this data on the monitor, an irregularity of the sensor characteristics or the need for a new sensor remembranring is detected.

Easy remembranring

For fast and easy sensor remembranring, a "fit & click" preparator is provided which allows a reproducible sensor remembranring within seconds. A message is displayed when the sensor needs to be remembraned. This is required once every 28 days (default value). The remembranring frequency can be changed to suit the user's needs.

A specially designed thin golden plate protects the sensor measurement surface from mechanical damage to the membrane. This enhances the function time of the sensor and ensures high reliability of the measurement.

tc Sensor 92

This sensor employs the most advanced technology for combining 2 measurement methods. It determines transcutaneous $p\text{CO}_2$, oxygen saturation, pulse rate and the perfusion index at the earlobe or other alternative measuring sites. The sensor is heated to a constant temperature to achieve local arterialisatIOn of the skin, which is required for the transcutaneous measurement. The increased perfusion of the

earlobe produced in this way serves also to augment the pulse oximetric signal strength.

tc Sensor 84

This sensor combines the basic elements of a Stow-Severinghaus-type $p\text{CO}_2$ electrode and a Clark-type $p\text{O}_2$ electrode. It determines simultaneously $p\text{CO}_2$ and $p\text{O}_2$ that pass through the cutaneous layer of the skin.

tc Sensor 54

This sensor employs the elements of a Stow-Severinghaus-type $p\text{CO}_2$ electrode. It determines transcutaneous $p\text{CO}_2$ at the earlobe (on pediatric and adult patients) or other alternative measuring sites. The sensor is heated to a constant temperature to achieve local arterialization of the skin, which is required for the transcutaneous measurement.

$p\text{CO}_2$ measurement

Measuring principles

The $p\text{CO}_2$ part of the tc Sensor 92 and the tc Sensor 84 consists of a Stow-Severinghaus type electrode. $p\text{CO}_2$ is measured by determining the pH of an electrolyte solution. A change in pH is proportional to the logarithm of the $p\text{CO}_2$ change. The pH is determined by measuring the potential between a miniature glass pH electrode and an Ag/AgCl reference electrode. The electrolyte is provided within a thin hydrophilic spacer, which is placed over the sensor surface and is coupled to the skin via a highly gas-permeable hydrophobic membrane. The membrane is protected with a thin golden plate to eliminate any mechanical damage. The sensor is calibrated in a gas of a known CO_2 concentration. The slope (change of potential with $p\text{CO}_2$) is preset in the sensor memory.

Severinghaus temperature correction

In most clinical settings, transcutaneous $p\text{CO}_2$ monitoring is performed using the Severinghaus temperature correction factor.

In general, a high correlation between transcutaneous $p\text{CO}_2$ (tcpCO_2) and arterial $p\text{CO}_2$ ($p\text{CO}_2(\text{aB})$) is found in patients of all ages. However, due to the elevated temperature of the sensor, the transcutaneous $p\text{CO}_2$ is higher than the arterial value. It has therefore become a common practice to apply a correction to the transcutaneous value to provide a monitor readout which corresponds as closely as possible to arterial $p\text{CO}_2$.

The shift of tcpCO_2 towards higher values is attributed to 2 main factors. First, the elevated temperature raises local blood and tissue $p\text{CO}_2$ by approximately 4.5 %/ $^{\circ}\text{C}$ ("anaerobic" factor). Secondly, the living epidermal cells produce carbon dioxide, which contributes to the capillary CO_2 level by a constant amount (metabolic constant). This metabolic contribution may change with age, skin thickness and other variables. A generally accepted estimation is that skin metabolism raises the transcutaneous $p\text{CO}_2$ by approximately 6-7 mmHg.

This means that the tcpCO_2 readings are corrected to $37\text{ }^{\circ}\text{C}$ (normal body temperature), using the following formula:

$$\text{tcpCO}_2(T) = p\text{CO}_2(37\text{ }^\circ\text{C}) \times 10^{-0.019(T-37\text{ }^\circ\text{C})}$$

where T is the set sensor temperature ($^\circ\text{C}$).

pO₂ measurement

Measuring principle

Oxygen is measured amperometrically by reduction at a platinum microcathode which is negatively polarized with respect to an Ag/AgCl reference electrode. The current measured is proportional to the oxygen partial pressure. The tc Sensor 84 uses the same Ag/AgCl electrode for measuring both oxygen and carbon dioxide. The electrolyte is provided within a hydrophilic spacer, which is placed on top of the sensing area. The spacer is covered by a highly gas-permeable hydrophobic membrane, and the membrane is protected by a thin golden plate.

Heating power

The electrical power needed to heat the sensor to a constant temperature depends to a small fraction on the local tissue perfusion. At constant ambient temperature, deviations of the heating power from a stored reference value ("relative heating power") may indicate changes in perfusion.

SpO₂ and pulse rate

Measuring principles

The TCM5 monitoring system uses pulseoximetry to measure functional oxygen saturation in the blood. Pulseoximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector.

Bone, tissue, pigmentation and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO₂).

Because a measurement of SpO₂ is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, sensor application and patient conditions is contained throughout this manual.

The TCM5 monitoring system displays pulse rates between 25 and 240 beats per minute. Detected pulse rates outside the range of 25 to 240 beats per minute are displayed as the closest value within the range.

Pulseoximetry

Pulseoximetry is based on 2 principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO₂ by passing red and infrared light into an arteriolar bed and measuring changes in light

absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photodiode serves as the photodetector.

Note: Information about the range of wavelength can be useful to clinicians in particular.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase.

During diastole, blood volume and light absorption reach their lowest point. The TCM5 monitoring system bases its SpO₂ measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of non-pulsatile absorbers such as tissue, bone and venous blood.

MasimoSET®

The TCM5 monitoring system incorporates the Masimo Signal Extraction Technology for SpO₂ measurement. The MasimoSET's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the non-arterial blood also moves, which causes conventional pulse oximeters to read low values because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Masimo SET utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The MasimoSET signal processing algorithm, Discrete Saturation Transform (DST), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor. Although venous saturation is not displayed, the TCM5 monitoring system with MasimoSET measures and calculates the values of both the arterial and venous oxygen saturation. This is referred to as stereo saturation measurement, since it separates the arterial from the venous information instead of mixing them together as is done with conventional pulse oximeters.

The pulse oximetric signal strength (Perfusion Index "PI") is displayed on the status and plethysmogram screen. The Perfusion Index "PI" is a qualitative indicator of tissue perfusion and the value is defined as the ratio of the amplitudes of the pulsatile and the non-pulsatile infrared signals, expressed in percent.

Pulse rate

The pulse rate display on the TCM5 monitoring system may differ slightly from the heart rate displayed on the ECG monitor due to the differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor. The pulsation from intra aortic balloon support can be additive to the pulse rate displayed on the TCM5.

FastSat

The FastSat enables rapid tracking of arterial oxygen saturation changes. It is a special feature of the Masimo SET technology. Rapid changes in arterial oxygen saturation are typically smoothed out by pulse oximeter averaging algorithm, yielding blunted readings. FastSat captures and reports these rapid oxygen saturation changes. The FastSat feature is automatically enabled when an average of 2 or 4 seconds is selected. See *Chapter 5, Setup* for parameter definitions.

Sensitivity

The sensitivity level enables the clinician to tailor the response of the TCM5 monitoring system to the needs of the particular patient situation. The sensitivity level can be selected in the parameter menu of TCM5 monitoring system and includes the options of: APOD, Normal and Max. The APOD (Adaptive Probe Off Detection) technology is a special feature of the Masimo SET technology. It is a suite of complex and powerful signal processing algorithm that carefully analyze the incoming signal to determine if the TOSCA sensor is on or off the patient. The following sensitivity levels can be selected in the parameter settings of TCM5 monitoring system:

- APOD is the least sensitive in picking up on patients with low perfusion
- Normal sensitivity provides the best combination of sensitivity and sensor-off detection performance and is recommended for the majority of patients
- Max sensitivity is reserved for the sickest patients, where obtaining a reading is most difficult. Max sensitivity is designed to interpret and display data for even the weakest of signals, and is recommended during procedures and when clinician and patient contact is continuous.

If low perfusion combined with movement inhibits the TCM5 monitoring system from readings, switch from APOD to Normal or Max sensitivity. See *Chapter 5, Setup* for parameter settings.

Signal IQ

The Signal IQ is a Signal Identification and Quality indicator and a special feature of the Masimo SET technology and displayed on the plethysmogram display of the TCM5. The signal IQ is a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO₂ value is not based on adequate signal quality. The Signal IQ can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement. With motion, the plethysmographic waveform is often distorted and may be obscured by artifact. The Signal IQ, shown as a vertical line, coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the TCM5 monitoring system locates the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the Signal IQ.

The height of the vertical line of the signal IQ indicates the quality of the measured signal:

- High vertical bar indicates a good quality signal
- Low vertical bar indicates a low quality signal

When the signal quality is very low the accuracy of the SpO₂ measurement may be compromised, and a *Low signal quality* message is displayed. When this message appears proceed with caution and check the following:

- Assess the patient
- Check the sensor and ensure proper sensor application
- Determine if an extreme change in the patient's physiology and blood flow at the ear lobe occurred, (e.g. an inflated blood pressure cuff, severe hypotension, vasoconstriction in response to hypothermia, medication, or a spell of Rynaud's syndrome)

After performing the above and if the *Low signal quality* message is displayed frequently or continuously it may be considered to verify the oxygen saturation value by a co-oximetry analysis.

Low perfusion (PI)

The Perfusion Index (PI) is a relative assessment of the pulse strength at the monitoring site. The PI is defined as the ratio of the amplitudes of the pulsatile (AC) and the non-pulsatile (DC) infrared signals, expressed in percent. The TCM5 displays this value on the status display. The PI is a relative number and varies from patient to patient, as physiologic conditions vary. A low value indicates weak pulse strength and a high value a strong pulse strength. The message of *Low Perfusion signal* or *Low signal quality* is displayed when there are very low amplitude arterial pulsation.

Note: If the low priority error message *Low Perfusion signal* or *Low signal quality* is frequently displayed, assess the patient and, if indicated, verify oxygenation status through other means. If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and check the monitor for proper functioning.

Oxygen saturation vs oxyhemoglobin fraction

The monitor measures oxygen saturation, also called functional saturation (oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen). It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. To compare oxygen saturation measurements with those from an instrument that measures oxyhemoglobin fraction, also erroneously called fractional saturation (oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins), the oxyhemoglobin fraction must be converted as follows:

$$sO_2 = \frac{FO_2 Hb}{100 - (FCOHb + FMetHb)} \times 100$$

Glossary

Glossary

Abbreviation	Description
1SD	One standard deviation
AC	Alternating current
Ag	Silver
AgCl	Silver chloride
AIDS	Acquired immune deficiency syndrome
AM	Amplitude modulation
APOD	Adaptive Probe of Detection
COHb	Carboxy hemoglobin
CO-oximeter	Carboxy hemoglobin saturation monitor
CSV	Comma-separated values
DB9	9-pin connector with a D-shaped metal shield
DC	Direct current
DHCP	Dynamic host configuration protocol
DNS	Domain name system
ECG	Electrocardiography
EM	Electromagnetic
EMC	Electromagnetic compatibility
EMR	Electronic medical record
EU	European Union

Abbreviation	Description
FM	Frequency modulation
HF	High frequency
HIV	Human immunodeficiency virus
IEC	International electrotechnical commission
INOP	Technical alarm messages on Philips systems
IP	Ingress Protection
IPv4	Internet protocol version 4
IPv6	Internet protocol version 6
LAN	Local area network
LED	Light emitting diode
Li-Ion	Lithium ion
ME	Medical electrical
metHb	Methemoglobin
MRI	Magnetic resonance imaging
N/A	Not available
N ₂ O	Nitrous oxide
NICU	Neonatal intensive care unit
Patient ID	Patient identifier
PC	Personal computer
pCO ₂	Partial carbon dioxide pressure
PI	Perfusion index
Pleth	Plethysmograph
pO ₂	Partial oxygen pressure
PR	Pulse rate
PSG	Polysomnograph

Abbreviation	Description
RAM	Random-access memory
RF	Radio frequency
RS232	Serial communication transmission standard
SpO ₂	Oxygen saturation
SSID	Service set identifier
SW	Software
TC	Transcutaneous
tcpCO ₂	Transcutaneous partial carbon dioxide pressure
tcpO ₂	Transcutaneous partial oxygen pressure
TFT	Thin-film transistor
TV	Television
USB	Universal serial bus
WEEE	Waste electrical and electronic equipment directive

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Compliance

The TCM5 monitor complies with the following standards: IEC 60601-1 (general safety), IEC 60601-1-2 (EMC), IEC 60601-1-6 (usability), IEC 60601-1-8 (alarms), IEC 60601-2-23 (transcutaneous monitors), ISO 80601-2-61 (pulse oximeters), ISO 14971 (risk management), IEC 62366 (usability engineering), IEC 62304 (software in medical devices), ISO 10993-1 (biocompatibility), EN1041 (information supplied by manufacturers) and ISO 15223-1 (symbols).

This product complies with the requirements of the Medical Device Directive 93/42/EEC.



CAUTION – Risk of voidance of authorization

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Report to manufacturer

For EU: If, during the use of this device, or as a result of its use, a serious incident has occurred, please report it to the manufacturer.

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