RADIOMETER BASEL AG

RADIOMETER

TOSCA *500*
Operating Manual

for USA

Software Version MAIN: 1.33 and upwards

TOSCA *500*
Operating Manual

CAUTION:
FEDERAL LAW (USA) RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Publ. No: 520.81.009/9
Issued: July 2010

Part No.: 520 0918

The TOSCA 500 Operating Manual is intended to provide the necessary information for proper operation of the TOSCA 500 system. General knowledge of transcutaneous measurement and pulse oximetry and an understanding of the features and functions of the TOSCA 500 system are a prerequisite for proper use.

Do not operate the TOSCA 500 system without completely reading and understanding these instructions.

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The equipment has been designed and manufactured to meet the requirements of the following safety standards:

IEC 60601-1 (1988 +A1:1991 +A2:1995); IEC 60601-1-2 (2001 +A1:2004); IEC 60601-1-4 (1996 +A1:1999); IEC 60601-1-6 (2006); IEC 60601-1-8 (2003 +A1:2006); IEC 60601-2-23 (1999); IEC 60601-2-49 (2001); ISO 9919 (2005); IEC 60601-3-1 (1996); CSA C22.2 No 601.1-M90 and UL 60601-1 (2003).

CE 0123	This equipment is fully in conformance with the requirements of the Council Directive 93/42 EEC of June 14, 1993 concerning Medical Devices.

Masimo patents of the integrated Masimo SET technology

This device is covered under one or more of the following U.S.A. patents: 5.758.644, 5.823.950, 6.011.986, 6.157.850, 6.263.222, 6.501.975 and other applicable patents listed at: www.masimo.com/patents.htm.

No implied license

Purchase or possession of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

QUALITY, RELIABILITY AND SAFETY

This equipment is designed with an emphasis on QUALITY, RELIABILITY AND SAFETY, but Radiometer Basel AG will accept responsibility for these aspects only when the following conditions are met:

- Electrical installations of the room or building in which the equipment is to be used must comply with regulations specified by the country in which the equipment is to be used.
- The equipment is used in accordance with the instructions for use provided by Radiometer Basel.
- All modifications and repairs to the equipment must be carried out by Radiometer Basel or by authorized service technicians.
- Modifications must not be carried out unless they conform with approved Engineering Service Information issued according to the appropriate Radiometer Basel procedure.
- Equipment installation must be carried out in accordance with local requirements regarding responsibility and warranty.
- Only original sensors and accessories of Radiometer Basel must be used. Other sensors and accessories may cause improper monitor performance.

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1 SAFETY INFORMATION

The instructions regarding precautionary measures given in this operating manual must be followed carefully. It is mandatory that these instructions are read prior to installation of the monitor.

Definition

- A "**WARNING !"** indicates that there is a risk of injury to the patient or user.
- A "***CAUTION*** " refers to a condition that may lead to damage or malfunction of the equipment.
- A ***"Note"*** provides additional information.

WARNING !

The TOSCA 500 system is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.

Explosion and flammability hazards: Do not use the monitor in the presence of flammable anesthetics or other flammable substance in any combination with air, oxygen-enriched environments, or nitrous oxide.

Do not use the equipment in a hyperbaric environment.

Do not use TOSCA 500 monitor and sensor on patients undergoing magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The TOSCA 500 monitor may affect the MRI image, and the MRI unit may affect the accuracy of the measurement.

Electrical shock hazard. Do not remove the monitor cover. Only a qualified operator may perform maintenance procedures specially described in this manual.

Failure of operation: If TOSCA 500 monitor fails any part of the setup procedures, remove the monitor from the operation until qualified service personnel have corrected the situation.

Patient safety: If a sensor is damaged in any way, discontinue use immediately.

As with all medical equipment, carefully rout patient cabling to reduce the possibility of patient entanglement or strangulation.

The TOSCA 500 $tcPCO_2$ monitoring is not a device for blood gas analysis. It is recommended that, prior to any decisive therapeutic measures, an accurate arterial blood gas analysis is carried out. The use of the TOSCA 500 monitoring system cannot replace a permanent supervision of the patient by medical personnel.

The TOSCA 500 pulse oximetry should NOT be used as an apnea monitor. The pulse oximetry should be considered an early warning device. As a trend towards patients deoxygenation is indicated by pulse oximetry, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

Interfering substances to SpO_2 measurement: Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Do not reuse any sensor fixation accessories to prevent contamination and cross-infections and because the adhesive will not correctly adhere to the skin resulting in incorrect measurements.

Do not reprocess any sensor fixation accessories by exchanging the adhesive part as it may result in incorrect measurements and biocompatibility inconvenience.

Do not reuse or reprocess any membraning kits as it may result in incorrect measurements.

Do not refill any cal gas cylinders because of the risk of explosion related to the refilling process and for preventing inaccurate gas concentration resulting in incorrect measurements.

Do not use calibration gas cylinder other than the original Radiometer calibration gas and do not use the calibration gas with an expired "use before date" as it will result in incorrect measurement.

CAUTIONS

Certain types of mobile telecommunication equipment could potentially interfere with equipment operation. Mobile telecommunication equipment should not be used within five meters of the monitoring equipment.

This unit needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the section 13 of this document.

The equipment can be used during defibrillation, but the readings may be inaccurate during defibrillation, but will rapidly recover.

When this equipment is used with a defibrillator, the user must precisely follow the instructions given in the defibrillator operating manual.

To ensure protection of patient, operator and equipment from the effects of defibrillation and diathermy / electro surgery, cables manufactured by Radiometer Basel must be used.

The equipment is protected against electrostatic discharge. The tcPCO_2 display may be temporarily affected during discharge to chassis ground but will rapidly recover.

For use during electro surgery the monitor, sensor and their cables must be physically separated from the electrosurgical equipment. The sensor must not be placed in the electrical pathway between cutting and counter electrode. Electro surgery will produce, at most, a minimal transient disturbance in the reading and will not affect the system calibration.

If any function fails to operate correctly, consult an authorized service technician.

When the equipment has been wetted accidentally it must be wiped dry externally and allowed to dry thoroughly before further use.

2 INTRODUCTION

2.1 Intended use

The TOSCA 500 system is used for noninvasive monitoring of transcutaneous PCO_2 ($tcPCO_2$), functional oxygen saturation SpO_2 and pulse rate, using a single sensor. It is indicated for use on adult and pediatric patients.

Environment of use

In hospital / clinical environment.

Operator profile

Only licensed health care professionals are permitted to use the monitor.

2.2 TOSCA 500 monitor

The Radiometer TOSCA 500 system combines the best technologies of Radiometer transcutaneous PCO_2 with the Masimo SET® for SpO_2 and pulse rate. The integrated calibration unit allows a fully automatic calibration and provides also a storage facility for the sensor. These features ensure that the sensor is always READY TO USE.

High quality standard

TOSCA 500 is a compact and portable unit which operates by AC power and, for transport inside a healthcare facility. The monitor is microprocessor based and incorporates most advanced circuit design and user friendly software. The monitor is equipped with an extensive built-in self-check program ensuring a reliable and safe system performance.

Easy operation

All settings and adjustments are made with a few function and control keys which are arranged in a straightforward and easily understandable manner.

Display

The values of the three parameters $tcPCO_2$, SpO_2 and PR (pulse rate) are displayed on three clearly visible, bright LED windows. Additionally the trend can be displayed on the middle screen during patient monitoring. Together with the pulse rate value, a bar graph indicates the pulse waveform. In the center, a wide backlit LCD window serves to guide the user through the selection of parameters and to show text messages during alarm and fault situations. Four different display modes are available during operation: "Status", "Trend", "Plethysmogram" and "Heating power".

Patient safety

The monitor fulfills the requirements of the Medical Device Directive 93/42/EEC. The inputs are fully isolated and filtered so that the monitor can be used with defibrillators and diathermy apparatus. Particular emphasis has been placed on the reliability of the sensor heating circuitry, which incorporates full temperature control redundancy based on the proven dual thermistor approach. In order to prevent excessively long exposure of the sensor to the skin, a built-in site timer alerts the user when the preset application time has elapsed.

Storage of patient results

The TOSCA 500 monitor incorporates a memory to store automatically all measured patient results for the last 72 hours using the FIFO (First In First Out) principle. Data are stored whenever values are displayed e.g. during patient monitoring. The memory will indicate blank spaces for those time intervals in which no values are displayed e.g. while the sensor is placed in the calibration/storage chamber or while the monitor is turned off. The results can be downloaded to a printer or to a personal computer (PC).

Communication interface

The TOSCA 500 monitor is equipped with a "Parallel Interface" and a "Systems Connector". The "Parallel Interface" is used for connecting a printer. The "Systems Connector" allows the connection to any patient monitoring system or to a computer. The protocol is selectable through the menu of the system parameters.

2.3 TOSCA sensor 92

The TOSCA sensor 92 employs the most advanced technology for combining two measurement methods. It determines transcutaneous PCO_2, oxygen saturation and pulse rate at the ear lobe. The sensor is heated to a constant temperature to achieve local arterialization of the skin, which is required for the transcutaneous measurement. The increased perfusion of the ear lobe produced in this way serves also to augment the pulse oximetric signal strength.

Sensor memory

The TOSCA sensor contains an electronic memory to store PCO_2 calibration values and other relevant sensor data (such as date of last sensor preparation or light intensities of LEDs). By evaluating these data on the monitor, an irregularity of the sensor characteristics or the need for a new sensor preparation is detected. In addition, the memory feature allows the operator to change the sensor from one monitor to another without the need for a new preparation.

Easy remembraning

For fast and easy new preparation ("remembraning") of the sensor, a convenient "fit & click" preparator is provided which allows a reproducible sensor preparation within seconds. A message is displayed when the sensor needs to be remembraned. This is required once every 14 days.

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 a high reliability of the measurement.

2.4 Concept of operation

2.4.1 Transcutaneous PCO_2

Principle of measurement

Transcutaneous measurement of PCO_2 makes use of the fact that carbon dioxide gas is 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 PCO_2 value ($tcPCO_2$) has to be interpreted primarily as the PCO_2 partial pressure prevailing at the level of the arterialized skin tissue. In general, this value correlates well with the corresponding arterial PCO_2 partial pressure.

The PCO_2 part of the TOSCA sensor consists of a Stow-Severinghaus type electrode. PCO_2 is measured by determining the pH of an electrolyte solution. A change in pH is proportional to the logarithm of the PCO_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 PCO_2) is preset in the sensor memory.

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.

PCO_2 Temperature corrections

In general, a high correlation between transcutaneous PCO_2 ($tcPCO_2$) and arterial PCO_2 ($PaCO_2$) is found in patients of all ages. However, due to the elevated temperature of the sensor, the transcutaneous PCO_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 close as possible to arterial PCO_2.

The shift of $tcPCO_2$ towards higher values is attributed to two main factors. First, the elevated temperature raises local blood and tissue PCO_2 by approx. 4.5% /°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 PCO_2 by approx. 5 mmHg.

Taking into account both effects, the relationship between $tcPCO_2$ and $PaCO_2$ can be expressed by the following equation:

$$tcPCO_2 = 10\exp [0.019\ (T-37)] \cdot PaCO_2 + 5mmHg$$

or

$$tcPCO_2 = F_T \cdot PaCO_2 + C_M$$

whereby:

F_T = temperature correction factor

C_M = metabolic constant

The theoretical basis of this algorithm is described by J. W. Severinghaus in his paper "Transcutaneous blood gas analysis", Respiratory Care 1982, 27(2): 152-159.

The correction of $tcPCO_2$ is combined with the sensor calibration, i.e. the sensor is calibrated to a value which is adjusted to compensate for both effects. The correction parameters F_T and C_M can be selected by the operator as described in section 7.2.3.

In the AUTO mode, F_T is automatically adjusted to the sensor temperature according to the above equation. In this case, it is recommended to use C_M = 5 mmHg.

Alternatively, specific values for both correction parameters may be used (for example F_T = 1.5 and C_M = 0 at a sensor temperature of 42°C). In this case, F_T is not automatically adjusted to the sensor temperature. When selecting F_T = 1 and C_M = 0, no correction is applied.

For calculating the PCO_2 calibration values, the barometric pressure is taken into account in both cases.

PCO_2 "In vivo" correction

In addition to the temperature correction, the $tcPCO_2$ value can be adjusted based on the result of an arterial blood gas analysis. This possibility is provided for special applications or when a systematic difference between $tcPCO_2$ and $PaCO_2$ is clearly established by several arterial blood gas measurements. When this correction is made, it must be checked periodically and adapted in cases of changes.

2.4.2 Oxygen saturation SpO_2

General description

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by attaching the sensor at the ear lobe of the patient. The sensor collects signal data from the patient and sends it to the monitor. The monitor displays the calculated data in three ways:

- as a percent value for arterial oxygen saturation (SpO_2
- as a pulse rate (PR) and
- as a plethysmographic waveform

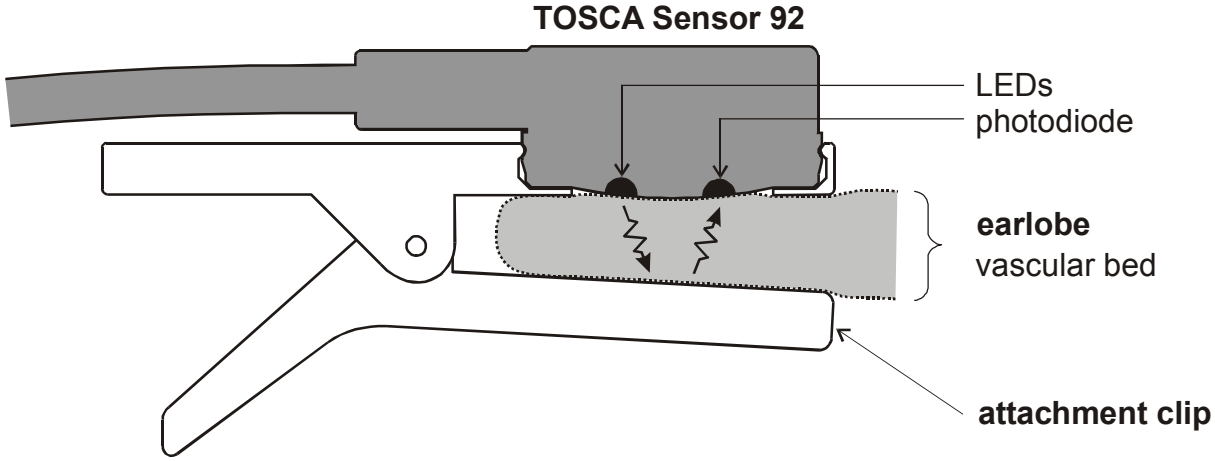
Principle of measurement

Pulse oximetry is governed by the following principles:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
- The amount of arterial blood in tissue changes with the pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The TOSCA 500 uses a two-wavelength pulsatile system to distinguish between oxygenated and deoxygenated blood. Signal data is obtained by passing red (658 nm wavelength) and infrared (880 nm wavelength) light through a capillary bed and measuring changes in light absorption during the pulsatile cycle. The TOSCA sensor 92 utilizes red and infrared light-emitting diodes (LEDs) that pass light through the site to a photodiode (photodetector). The

photodetector receives the light, converts it into an electronic signal and sends it to the TOSCA 500 monitor for calculation.



Once the TOSCA monitor receives the signal from the sensor, it utilizes Masimo SET signal extraction technology for calculation of the patient's functional oxygen saturation and pulse rate.

Functional vs. fractional saturation

The TOSCA 500 measures and displays functional saturation: the amount of oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. The TOSCA does not measure fractional saturation: oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin. To convert fractional saturation to functional saturation, the fractional saturation measurements must be converted according to:

$$\text{Functional saturation} = \frac{\text{Fractional saturation}}{100 - (\%\ \text{carboxyhemoglobin} + \%\ \text{methemoglobin})} \text{ x } 100$$

Masimo SET®

The TOSCA 500 system incorporates the Masimo Signal Extraction Technology for SpO_2 measurement. The Masimo SET'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 Masimo SET 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, TOSCA 500 with Masimo SET 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.

3 CLINICAL APPLICATION

3.1 Indications

The need to monitor simultaneously carbon dioxide tension and arterial oxygen saturation exists in various fields of medicine, such as:

- anesthesia / preoperative monitoring
- intensive / critical care
- diagnostic procedures such as bronchoscopy
- sleep studies and apnea testing
- exercise testing
- pulmonary stress testing
- respiratory research

Monitoring of transcutaneous PCO_2 and SpO_2 with TOSCA 500 is of particular value in following up the immediate effect of any therapeutic measures which have a direct or indirect influence on the patient's degree of oxygenation and ventilatory efficiency. The information on trends provided by TOSCA 500 permits an instantaneous qualitative assessment of the effect of the therapy.

Monitoring with TOSCA 500 allows, in general, a more rapid detection of hypoxemic events and of critically high or low levels of carbon dioxide tension, as compared to conventional arterial blood gas analysis. Also, it can be of assistance in deciding the timing of arterial blood gas sampling, and may therefore considerably reduce the frequency of sampling.

Measuring sites

The TOSCA sensor is applied to the ear lobe using the Attachment Clip (Ref. 560 1300). It can also be applied to the forehead or to the cheek using the TOSCA Fixation Ring (Ref. 560 1500), or to other measuring sites for tcPCO2 only measurement , refer to section 5.5.

3.2 Points to be regarded during monitoring

3.2.1 General

Monitoring during surgery

For use during electro surgery the monitor, sensor and their cables are to be physically separated from the electrosurgical equipment. The sensor must not be placed in the electrical pathway between cutting and counter electrode. Electro surgery will produce, at most, a minimal transient disturbance in the reading but it will not affect the system calibration.

3.2.2 Transcutaneous PCO_2 measurement

Recommended sensor temperature and application time

The quality of the correlation between arterial and transcutaneous PCO_2 has been found to be similar at sensor temperatures between 41°C and 44°C. With decreasing sensor temperature, however, the in vivo response time to rapid arterial PCO_2 changes increases.

It is recommended to use a sensor temperature of 42°C, which has been found to be tolerated by the skin for up to twelve hours. When higher sensor temperature is used, the exposure time should be shorter (see specification, section 12.2).

Note

The sensitivity of the skin to heat may not only be different from patient to patient, but may also vary in an individual patient. In particular, any clinical situation resulting in reduced skin blood flow will increase the sensitivity to heat and the risk of skin burn. Also, excessive mechanical pressure against the sensor will provoke such a condition.

$tcPCO_2$ in anesthesia

There is no measurable interferences in nitrous oxide, halothane, isoflurane and enflurane with the transcutaneous PCO_2 measurement (see section 12.3)

3.2.3 SpO_2 measurement

At high saturation, the oxyhemoglobin dissociation curve becomes almost flat, so that small changes in the measured SpO_2 represent large changes in PO_2. Pulse oximetry is therefore of limited use to quantify the degree of hyperoxemia.

The shape of the oxyhemoglobin dissociation curve can differ from patient to patient. Therefore, the SpO_2 alarm limits should be selected specifically for each patient after comparing SpO_2 readings with arterial PO_2 data obtained by laboratory analysis.

The stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each. The stability of the readings over time is affected by the averaging mode being used. The longer the averaging time, the more stable the readings tend to be become. This is due to a dampened response as the signal is averaged over a longer period of time than shorter average times. However, longer average times delay the response of the oximeter and reduce the measured variations of SpO_2 and PR.

Pulse rate values

The pulse rate display on TOSCA 500 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 TOSCA 500.

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 TOSCA 500. The signal IQ is a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO_2 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 TOSCA 500 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 SpO_2 measurement may be comprised, and a "Low Signal IQ" 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 IQ" 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 TOSCA 500 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 Index" is displayed when there are very low amplitude arterial pulsation.

CAUTION:

If the message "Low Perfusion Index" 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.

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. FastSat feature is automatically enables when an averaging of 2 or 4 seconds is selected, see section 7.2.4 for parameter definition.

Sensitivity

The sensitivity level enables the clinician to tailor the response of the TOSCA 500 to the needs of the particular patient situation. The sensitivity level can be selected in the parameter menu of TOSCA 500 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 TOSCA 500:

- 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 TOSCA 500 monitor from readings, switch from APOD to Normal or Max sensitivity, see section 7.2.4 for parameter settings.

3.3 Limitations

3.3.1 Transcutaneous PCO_2 measurement

Under the following clinical situations there is, according to current knowledge, limited or no correlation between transcutaneous and arterial PCO_2:

- profound peripheral vasoconstriction
- circulatory centralization (shock)
- hypothermia during surgery
- use of vasoactive drugs

The Perfusion Index "PI” value may be used to qualify the above listed situations. (Reference: "Use of a peripheral perfusion index derived from the pulse oximetry signal as a non invasive indicator of perfusion", Critical Care Medicine 2002, Vol. 30, No 6, 1210-1213).

- skin anomalies
- skin edema

It should be regarded that transient skin edema at the ear lobe may occur during the early recovery phase after anesthesia, or when a patient is in the Trendelenburg position.

3.3.2 SpO_2 measurement

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, SpO_2 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 oximetric measurement may not be valid under the following conditions:

- excessive ambient light
- severe electrical interference
- excessive patient movement (such as shivering)
- significant levels of dysfunctional hemoglobin (e.g. COHb and metHb)
- presence of intravascular dyes
- skin pigmentation
- very low hemoglobin levels
- venous pulsation at the frequency of the patient's arterial pulse
- venous return when the sensor is applied to the forehead or cheek on a patient in Trendelenburg position (head lower than the heart).

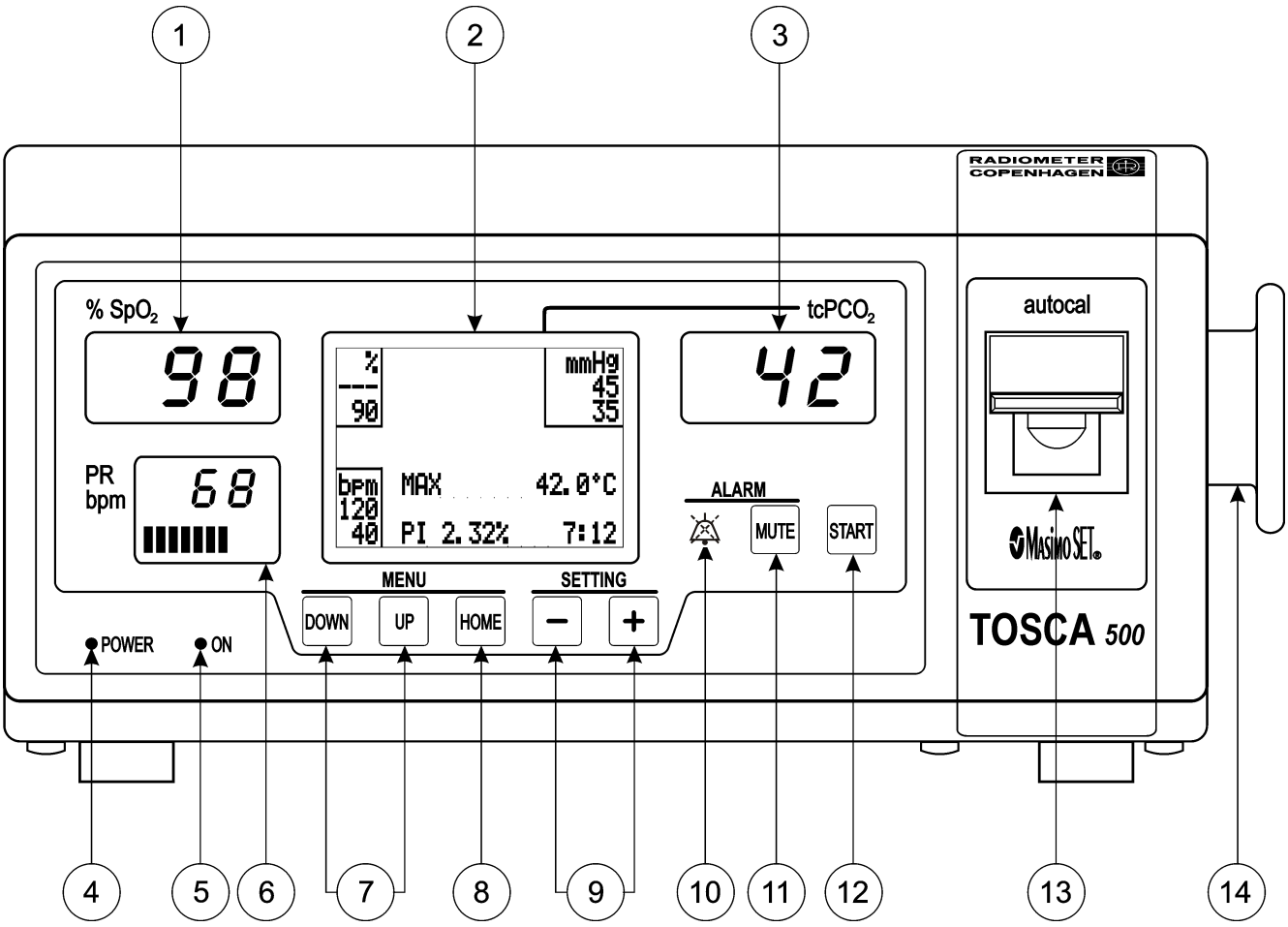
WARNING !

The TOSCA 500 monitoring system is not a device for blood gas analysis. It is recommended that, prior to any decisive therapeutic measures, an accurate arterial blood gas analysis is carried out. The use of the TOSCA 500 monitoring system cannot replace a permanent supervision of the patient by medical personnel.

4 DESCRIPTION OF THE MONITOR

4.1 Overview

4.1.1 Front panel



1	LED display indicating the oxygen saturation (% SpO2) between 0 and 100% or "---" if no value is available or if SPO2/PR is disabled (see section 7.2.4). The value is updated once per second. This display is switched off when the sensor is in the calibration / storage chamber.
2	Illuminated LCD display which serves to guide the user through the programming of the system and to show text messages. During operation, one of the four display modes can be selected: "Status", "Trend", "Plethysmogram" and "Heating power". The tcPCO2 unit (mmHg or kPa) is indicated at the upper right corner.
3	LED display indicating the tcPCO2 value between 0 and 200 mmHg (0.0 and 25.0 kPa) or "---" if no value is available or "EEE" if PCO_2 value is higher than 200 mmHg (25.0 kPa). The value is updated once per second. While the sensor is in the calibration / storage chamber, this display is switched off as long as no key is pressed.
4	"Line connected" indicator lamp

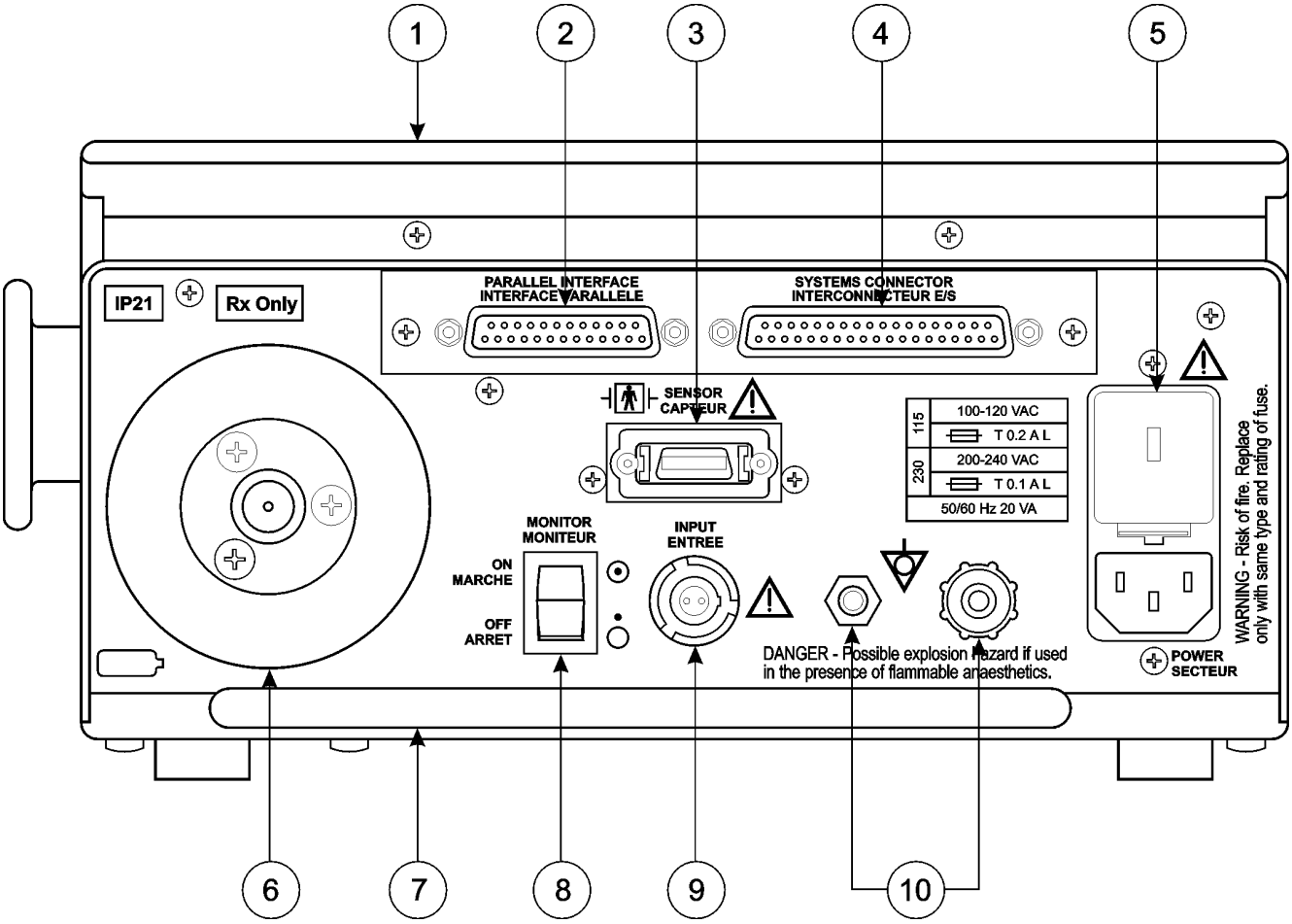
5	"Monitor ON" indicator lamp (ON/OFF switch on rear panel)
6	LED display indicating the pulse rate (PR) in beats per minute (bpm) between 25 and 250 bpm or "---" if no value is available or if SPO2/PR is disabled (see section 7.2.4). The value is updated once per second. The LED bar graph display (10 segments) indicating the pulse waveform. For a Perfusion Index (PI) value of less than 1%, the amplitude of the bar graph is proportional to this value (the Perfusion Index value is defined in section 3.2.3). For example, an amplitude of 7 segments represents a PI value of 0.7%. At values above 1%, the waveform is displayed over the full range of the bar graph and is therefore not proportional to the Perfusion Index. This display is switched off when the sensor is in the calibration / storage chamber.
7	Keys to enter the parameter setting menu and to select the adjustable parameters.
8	Key to return to the last chosen display mode during a parameter setting procedure, or to select one of the display modes "Status", "Trend", "Plethysmogram" and "Heating power" during monitoring. By pressing this key for one second, one may return directly to the last chosen display mode during a parameter setting procedure, or to the "message display", if a message is displayed.
9	Keys to decrease / increase the value of a selected parameter. If no parameter setting is in progress, pressing + or - for more than 2 seconds will start or stop the printer. See section 7.2.7 for details.
10	"Alarm suspended" indicator lamp to indicate that the auditory alarm is suspended (flashing). See section 8.1 for details.
11	"Auditory alarm mute" key to mute or suspend the auditory alarm. See section 8.1 for details.
12	Key to start monitoring of a patient. The parameter alarm detection is enabled (except for PCO2 which is enabled only after five minutes) and the site time clock is started. See section 8.3 for details. By pressing this key for four seconds, a calibration can be activated when the sensor is within the calibration chamber. During this calibration, the PCO2 value is displayed.
13	Calibration and storage chamber for the TOSCA sensor 92. An automatic calibration of the sensor is executed when the sensor is placed into the chamber.
14	Spool for sensor cable

4.1.2 Underside

Adjustable feet

Labels indicating:
- Warning statements
- Device type (CE mark)
- Serial number
- Service status of instrument (ESI)
- Software revision status
- Masimo patents

4.1.3 Rear panel



IP21 Degree of protection against ingress to solids and water provided by the enclosure.

Rx Only CAUTION FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

1	Handle of the monitor.
2	Connector for printer interface (see section 15 - External Connections).
3	Sensor input socket. ⊣⍾⊢ Type BF applied part, defibrillator proof. ⚠ Attention: Physiological effects (sensor connection). Note that the sensor has a heated surface. Operate strictly in accordance with section 3.2 of this manual.
4	Connector for system interface, including RS 423, analog output for monitored parameter and nurse call relay (see section 15 - External Connections).
5	AC power compartment, containing line cord plug, fuses and voltage selector. ⚠ Attention: Read the instructions before using the connector adjacent to this symbol.
6	Container with screw connector for Radiometer Basel CAL-Gas cylinder.
7	Protective bar
8	Monitor On/Off switch. ⊙ = On ○ = Off

9	Connector for external 12 - 24 V battery (see section 15.9).
10	Connectors for equipotential ground. ⏚ Equipotential ground connector adjacent to this symbol. Equipotential earthing in treatment areas used for cardiac procedures is intended to minimize any voltage differences between earthed parts of the equipment and any other exposed metals in the room. ⚠ Attention: Read the instructions before using the connector adjacent to this symbol.

5 OPERATION

5.1 Initial setup of the system

The TOSCA 500 system is delivered with following items:

- 1 TOSCA 500 monitor
- 1 Power Cord
- 2 Mains Fuses
- 1 TOSCA Sensor 92
- 1 Starter Kit, including:
  - 2 Sensor Preparators
  - 1 TOSCA Sensor Electrolyte (10 ml)
  - 1 Contact Gel (10 ml)
  - 20 Attachment Clips
- 1 CAL-Gas cylinder
- 1 Operating Manual, English
- 1 Sensor application and preparation card

Unpacking

Unpack the TOSCA 500 monitor, the TOSCA sensor 92 and the accessories.

Inspect the monitor and sensor for visual damage and clean if necessary.

Follow local regulations regarding disposal of packaging waste.

Location

The monitor should be located so that the sensor cable is close enough to the patient and will not be unduly stretched by movements of the patient. The alarms produced by the monitor should be clearly audible from the operator's position. Lighting on and around the monitor should be such that the displays and indicator lamps are clearly legible and visible.

Operating environmental conditions

Temperature: +10°C to +40°C (+ 50°F to +104°F) *

Humidity: <90%

Ambient pressure: 525 to 800 mmHg (700 to 1060hPa)

* The ambient temperature must be at least 3°C lower than the set sensor temperature.

5.2 Precautions

The instructions regarding precautionary measures given below must be read prior to the installation of TOSCA 500.

For electromagnetic compatibility see section 13.

WARNING !

The TOSCA 500 system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the TOSCA system should be observed to verify normal operation in the configuration in which it will be used.

When operated by AC power, the monitor must only be connected to a three-wire, grounded, hospital-grade receptacle. The three-conductor plug must be inserted into a properly wired three-wire receptacle; if this is not available, a qualified electrician must install one in accordance with the governing electrical code. Do not under any circumstances remove the grounding conductor from the power plug.

Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.

If there is any doubt about the integrity of the protective earth conductor arrangement, operate the monitor on internal battery power until the AC power supply protective conductor is fully functional.

The correct type and rating of live and neutral fuses must always be used.

The monitor has no mains switch. Disconnect the mains plug to isolate the monitor from the supply mains.

Note: Do not connect to an electrical outlet controlled by a wall switch or dimmer.

When connecting other equipment to TOSCA 500, the manufacturer of the equipment or a qualified engineer must be consulted to ensure that the safety of the patient, the operator or the environment will not be impaired. The resulting combined system must comply with EN 60601-1-1.

When the monitor is operated by an external battery which is connected to a battery recharging device, this device must be medical grade (double isolation).

To ensure patient electrical isolation, connect only to other equipment with electronically isolated circuits.

As with all medical equipment, carefully rout patient cabling to reduce the possibility of patient entanglement or strangulation.

Do not place the monitor in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or sensor cable, use the handle of the monitor

CAUTION

Do not expose the monitor to high humidity or heat (for details see specifications in section 12.3)

5.3 Setup for operation

Main steps to setup

In the following, the main steps and processes required to setup the system are summarized. The details of each step are described below.

- Check the monitor for the correct mains voltage setting (rear panel). The monitor can be operated at 100-120V or 200-240V (50/60 Hz).
- Connect the monitor to the mains
- In rooms classified as 'cardiac protected' electrical areas, connect the equipotential ground of the monitor to the equipotential earthing system
- Install the CAL-Gas cylinder
- Switch on the monitor at the rear
- Connect the TOSCA sensor 92
- Prepare the sensor
- Allow the sensor to stabilize for at least 4 hours prior to use
- Check the parameter settings

CAL-Gas installation

Install the CAL-Gas cylinder in the appropriate position at the rear of the monitor by turning it in a clockwise direction. Tighten it firmly, but do not over screw.

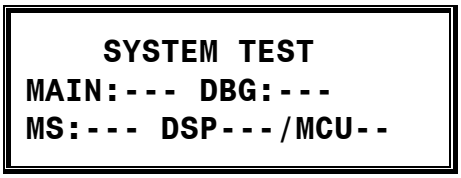
Power connection

Connect the power cable to the power source and switch monitor on (switch at the rear panel). Check that the "Line connected" and "Monitor on" indicator lamps (at the front panel) are illuminated.

Self-check

The monitor performs an extensive self-check after it has been switched on. The relevant functions of the microcomputer system are checked, the display segments are illuminated and the alarm tone sounds. If any fault is detected in the course of this self-check program, a message is displayed (see sections 8.2.2 and 9 for details).

After completion of the self-check the message



appears, followed by:

along with an audible alarm

Display contrast

Before continuing, set the optimal contrast for your viewing angle by pressing [+] or [–] while holding [HOME] pressed (see also section 7.2.5).

Sensor

Connect the sensor to the input socket at the rear of the monitor. The label of the sensor plug must face upwards. If the sensor was remembraned within the previous 14 days, the message

CALIBRATE SENSOR

appears (in this case skip the next step and proceed with calibration).

If the sensor is new or if the date of the last sensor preparation is older than 14 days, the following message is displayed:

SENSOR
REMEMBRANED ?
+ YES +
- NO -

Remembrane the sensor as described in section 5.4. Keep the sensor connected to the monitor during preparation with the monitor turned on. When finished, press [+] to confirm the new preparation and to store the date in the sensor memory.

If the sensor is not remembraned at this time, press the [–] key. If the date of the last sensor preparation is older than 14 days, the message

REMEMBRANE SENSOR

will immediately appear when trying to start a calibration.

Calibration

When confirmed with [+], the message

CALIBRATE SENSOR

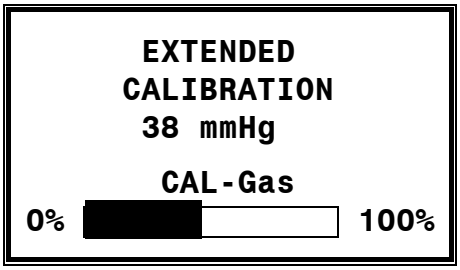
appears.

Place the sensor into the calibration chamber. The calibration is now automatically initiated, and the display shows

CALIBRATING
SENSOR
38 mmHg
CAL-Gas
0% 100%

The figure identifies the PCO_2 calibration value in mmHg or kPa (see section 7.2.3). The bar indicates the remaining gas level in the CAL-Gas bottle.

If the calibration cannot be completed within ten minutes, the message



appears and the calibration continues. If the calibration is not possible, this will be indicated by the message

In the case of a new sensor or an unprepared sensor stored in air before remembraning, ignore this message and leave the sensor in the calibration / storage chamber for at least four hours, preferably overnight. This time is required for stabilization of the PCO_2 part of the sensor. Thereafter, initiate a new calibration by pressing START for four seconds.

Ready to use

When the calibration is successfully completed, the message

(with date and time) appears. The sensor is now ready to be used for patient monitoring.

Parameter settings

The TOSCA 500 monitor is delivered with default parameter settings. Check the settings as described in section 7 and change them as required. At least check and define following parameters:

- Arterialization mode (see section 3.2.2 and 7.2.2)
- Sensitivity (see section 3.2.3 and 7.2.4)
- Sensor temperature (42°C recommended) (see section 3.2.2)
- Site time (see section 3.2.2)
- Alarm limits (see section 7.2.1)

Note

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

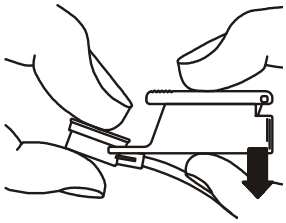
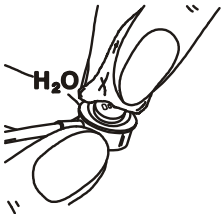
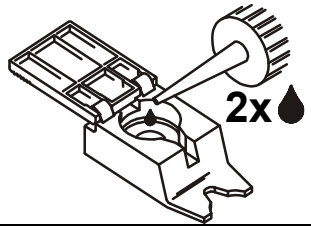
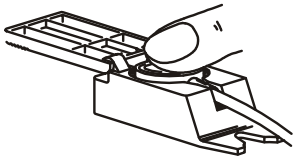
Sensor application

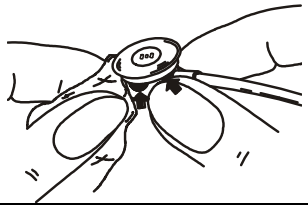
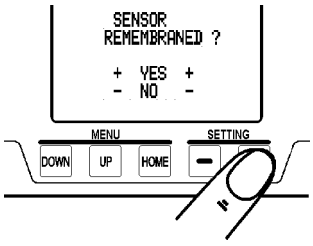
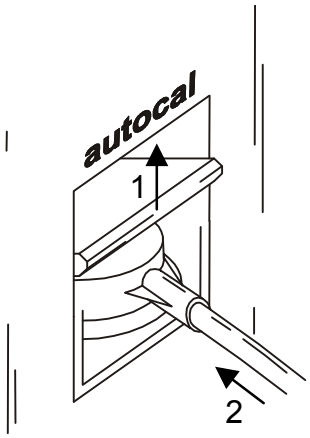
Proceed to section 5.5 for sensor application.

Stand-by conditions

The monitor must always be turned on and the sensor must be stored in the calibration chamber even when the system is not in use. The system automatically performs a calibration every 4 hours while the sensor is in the chamber. This ensures that the sensor is always in good operating condition and READY TO USE.

5.4 Sensor preparation

1. 	Ensure that the sensor is connected to the monitor, which must be turned on. Remove the membrane retainer ring assembly using the V-shaped notch of the preparator base. Discard the old retainer ring assembly. ***Note*** *A new sensor is delivered without membrane. In this case start with step 2.*
2. 	Clean the sensor surface with a tissue soaked in clean water. This will also remove the spacer. Dry the sensor surface and make sure that no fibers remain from the tissue. ***Note*** *Do not leave unprepared sensor in air. Proceed immediately with the next steps.*
3. **SENSOR REMEMBRANED ?** **+ YES +** **- NO -**	This message appears. Leave unanswered until step 8.
4. 	Lift up the cover of the preparator and place two drops of TOSCA sensor electrolyte into the center of the retainer ring assembly.
5. 	Insert the sensor (with its surface pointing downwards) into the preparator base until it is slightly locked. Do not apply pressure.
6. 	Close the cover of the preparator and press it down until the new retainer ring clicks into place. Open the cover, remove sensor and discard preparator.

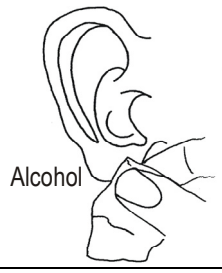
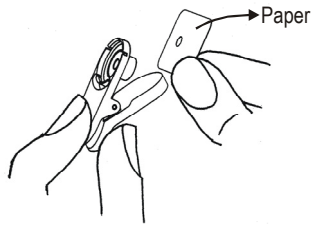
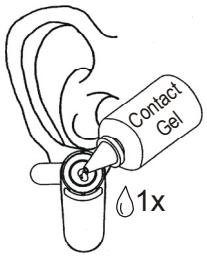
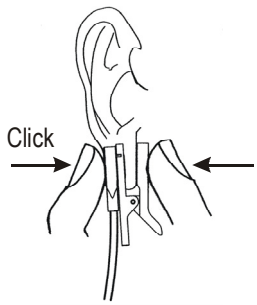
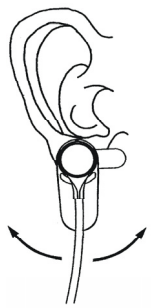
7. 	Clean excess electrolyte from the side of the sensor.
8. 	Press [+] to confirm the new sensor remembraning. The date is stored in the sensor memory.
9. 	Lift up the lever of the calibration chamber and insert the sensor with its surface pointing downwards as far as it will go. Release the lever. The message **CALIBRATING SENSOR 38 mmHg** **CAL-Gas** **0%** **100%** appears When the calibration is completed the message **READY TO USE** (with date and time) appears. The sensor is now ready to be applied to a patient.

5.5 Sensor application

The Clinical Application in section 3 should be carefully read before starting monitoring. The recommendations on sensor temperature and application time is given in section 3.2.2.

The sensor is applied to the ear lobe by using the Attachment Clip Ref. 5601300 (see section 5.5.1) or to alternative measuring sites using the TOSCA Fixation Rings Ref. 560 1500 (refer to section 5.5.2).

5.5.1 Application at the ear lobe with the Attachment Clip

1. 	Clean the ear lobe with an alcohol swab.
2. 	Take a TOSCA Attachment Clip out of the package, open the clip jaws and remove the white cover.
3. 	Attach the clip - with the retainer ring pointing outwards - to the fleshy part of the ear lobe. Squeeze gently to ensure that the adhesive area sticks firmly to the ear lobe. Make sure that no air is under the adhesive area.
4. 	Apply a small drop of Contact Gel to the visible skin area in the center of the retainer ring, just enough to slightly wet it.
5. 	Remove the sensor from the calibration chamber and insert it into the retainer ring of the clip. Press slightly until it snaps in.
6. 	Twist the sensor into the best position. Make sure that the sensor cable is loose and will not be stretched during monitoring. Route the sensor cable properly to avoid strangulation.

7.	Attach the sensor cable with the black cable clip on an appropriate site of the patient clothing.

After the sensor has been applied, the following message is displayed for up to five minutes:

```
PRESS
START KEY
TO START MONITORING
```

alternating with

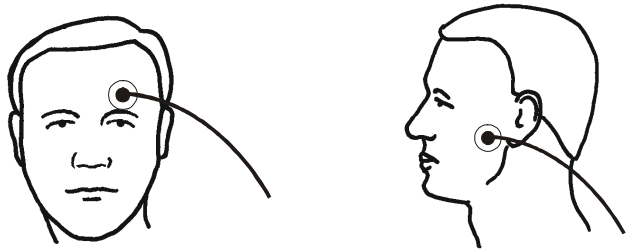
```
PCO2/SPO2/PR
ALARMS ARE DISABLED
UNTIL MONITORING IS
STARTED
```

and alternating with the selected display mode.

5.5.2 Application with the TOSCA Fixation Ring

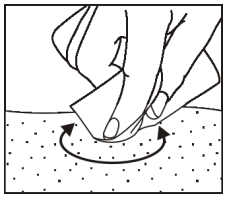
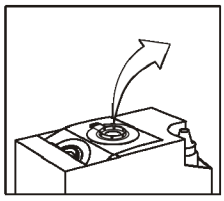
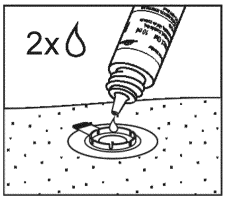
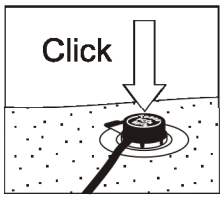
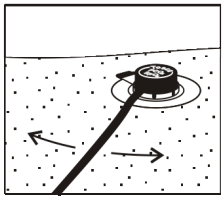
Measuring sites

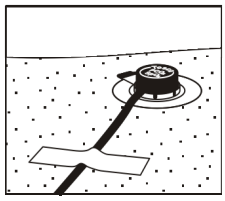
The choice of the measuring site depends on the parameter to be measured.

Parameters	Measuring sites
SpO_2, PR and $tcPCO_2$ simultaneously	Forehead Cheek  **Contraindications** The use of those measuring sites are contraindicated for patients who exhibit allergic reactions to adhesive tapes.

tcPCO2 only	– Thorax, left and right side, below the clavicles – Abdomen – Upper arm – Thigh **WARNING !** **The measurement of SpO_2 and PR are not reliable on these sites. In order to avoid erroneous readings and false alarms of SpO_2 and PR, these parameters must be turned off in the "SPO2/PR Parameter" menu of the monitor.**

Sensor application

1		Clean the skin at the monitoring site with an alcohol swab and dry it.
2		Pull out one TOSCA Fixation Ring and remove it from the paper strip.
3		Attach the Ring to the measuring site and press gently onto the Ring. Then run a finger around the rim circumference to ensure a good seal. Apply two drops of Contact Gel to the skin area in the center of the ring.
4		Remove the sensor from the calibration chamber and insert it into the TOSCA Fixation Ring. Press the sensor gently against skin until it snaps in.
5		Twist the sensor into the best position.

6 

Secure the sensor cable with an adhesive tape.

WARNING !

Do not use the TOSCA Fixation Ring at the ear lobe. This would lead to unreliable readings.

After the sensor has been applied, the following message is displayed for up to five minutes:

```
PRESS
START KEY
TO START MONITORING
```

alternating with:

```
PCO2/SPO2/PR
ALARMS ARE DISABLED
UNTIL MONITORING IS
STARTED
```

and alternating with the selected display mode.

5.6 Patient monitoring

The application site (ear lobe) should be checked periodically during the monitoring. It is important to check that the sensor does not become detached from the ear lobe and that the patient does not lie on the sensor.

Monitoring start

Press START to start monitoring and site time clock. The message

```
MONITORING STARTED
PCO2 ALARM SUSPENDED
UNTIL ARTERIALIZATION
IS COMPLETED
```

appears alternating with the selected display mode.

If the START key is not pressed within five minutes, monitoring is started automatically.

The SpO_2 and PR values are displayed immediately after the application. The SpO_2 and PR alarms are activated when the monitoring is started.

Arterialization

During the first five minutes after the start of monitoring the PCO_2 alarm detection is suspended to allow sufficient time for arterialization. Thereafter, the alarm is automatically activated. The display mode can be changed at any time by pressing HOME, see section 6.1.

Pulse tone

During monitoring, a short tone sounds synchronous with the pulse if a pulse rate value is available (for setting loudness level see section 7.2.4). The frequency of the tone changes with the SpO_2 value. A high frequency represents a high SpO_2 value (e.g. 900Hz ≈ 100%) and a decreased frequency indicates a low SpO_2 (e.g. 570Hz ≈ 70%). The tone is suppressed while any parameter is changed.

CAUTION

To ensure accuracy, check for adequate signal strength and repeatable pulse waves on the bar-graph display.

Inaccurate measurement may be caused by:

- incorrect sensor application or use
- significant levels of the dysfunctional hemoglobin (e.g., carboxyhemoglobin or methemoglobin)
- intravascular dyes such as indocyanine green or methylene blue
- expose to excessive illumination, such as surgical lamps (especially ones with xenon light source), bilirubin lamps, fluorescent lights, infrared lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material)
- excessive patient movement
- venous pulsations

Loss of pulse signal can occur in any of the following situations:

- there is too much pressure on the sensor (e.g. the patient lies on the sensor)
- there is excessive illumination from light source such as a surgical lamp, a bilirubin lamp, or sunlight
- the patient has hypotension, severe anemia, or hypothermia
- there is arterial occlusion proximal to the sensor
- the patient is in cardiac arrest or is in shock

WARNINGS !

Effect of temperature on skin

Effect of temperature on skin prolonged exposure to the heated sensor may cause a skin burn. The recommendations on sensor temperature and exposure time given in section 3.2.2 should be read carefully before using the instrument on a patient.

Failure of operation

If the monitor fails to operate as described, do not use it until the problem has been corrected by an authorized service technician.

Failure of sensor function

In spite of the extensive measures for automatic error recognition, certain sensor failures may not always be detected by the device (e.g. deactivation of the surface). It is therefore referred to the possibility of performing a simplified function test of the sensor (see section 10.2).

Application failure

The recommendations given in this manual concerning the selection of the measuring site and the application of the sensor should be read carefully. An incorrect application or handling of the sensor can entail false measured values.

Monitoring end

Before the preset site time of a monitoring session is elapsed the message:

```
SITE TIME
REMAINING
 xx MIN
```

indicating the remaining time (10% of the preset site time) appears. When the monitoring time (site time) is elapsed the message:

```
SITE TIME ELAPSED
```

appears along with an audible alarm.

- Remove the sensor from the clip (see section 5.7).
- Clean the sensor surface with alcohol
- Place it into the calibration chamber.

When the calibration is completed, reapply the sensor to the other ear lob of the patient if requested, proceed as described in section 5.5 step 1 when a new clip is used or section 5.5 step 4 when the clip is at the ear.

5.7 Removal of the sensor

The sensor must be removed from the ear lobe when the site time of the patient monitoring period is elapsed.

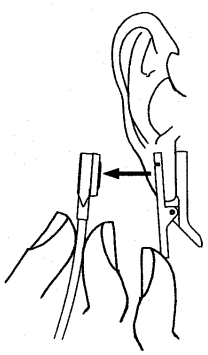
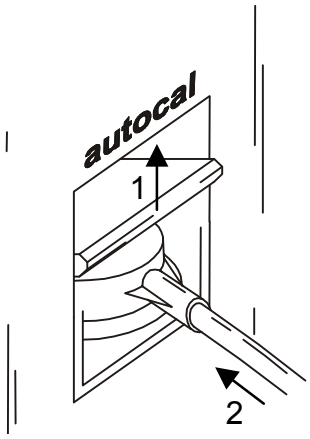
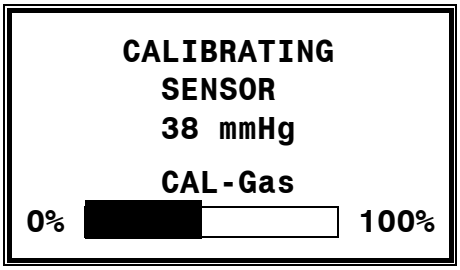
Long term monitoring

For continuous and long time monitoring of a patient the sensor can be moved from one ear to the other. An application (site) time of 8 hours, at a sensor temperature of 42°C, is recommended. The clip may remain on the ear lobe and re-used for a further sensor application. However, it is recommended to remove and discard the clip every 24 hours so that the ear lobe is free of the adhesive for one monitoring period (e.g. 8 hours), proceed as described in section 5.7.1.

Short term monitoring or spot check

When the patient monitoring is completed and the sensor should be removed with the clip, proceed as described in section 5.7.2.

5.7.1 Removal of the sensor from the clip

1. 	Grip the sensor at the cable neck and detach it from the clip while retaining the clip with a finger.
2. 	Clean the sensor surface carefully with an alcohol swab.
3. 	Lift up the lever of the calibration chamber and insert the sensor with its surface pointing downwards as far as it will go. Release the lever. The message  appears .

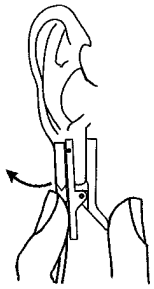
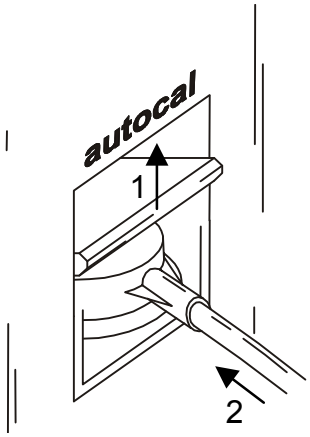
When the calibration is completed the message

```
READY TO USE
```

(with date and time) appears. The sensor is now ready to be applied to a patient.

Apply the sensor to the other ear lobe as described in section 5.5 Sensor application.

5.7.2 Removal of the sensor and the clip from the ear

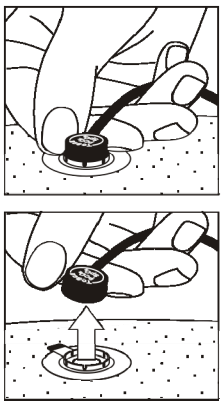
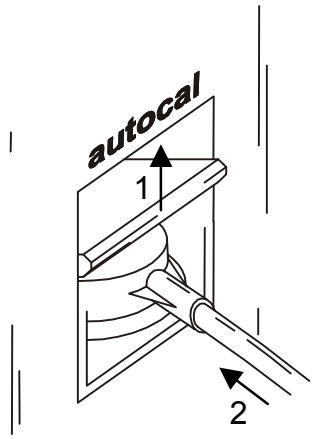
1. 	Open the sensor clip and remove it from the ear lobe by turning it sidewise.
2.	Remove the sensor from the clip and discard the clip.
3. 	Clean sensor surface carefully with an alcohol swab.
4. 	Lift up the lever of the calibration chamber and insert the sensor with its surface pointing downwards as far as it will go. Release the lever. The message **CALIBRATING SENSOR 38 mmHg CAL-Gas 0% 100%** appears.

When the calibration is completed the message

```
READY TO USE
```

(with date and time) appears. The sensor is now ready to be applied to a patient.

5.7.3 Removal of the sensor from the TOSCA Fixation Ring

1. 	Hold the outer part of the adhesive ring while removing the sensor head from the ring.
Note *The TOSCA Fixation Ring may remain on the skin and a second Fixation Ring may be attached in order to alternate the sensor application site.*	
2. 	Clean sensor surface carefully with an alcohol swab.
3. 	Lift up the lever of the calibration chamber and insert the sensor with its surface pointing downwards as far as it will go. Release the lever. The message **CALIBRATING SENSOR 38 mmHg** **CAL-Gas** **0%** **100%** appears.

When the calibration is completed the message

READY TO USE

(with date and time) appears. The sensor is now ready to be applied to a patient.

5.8 Operation with a printer

The TOSCA 500 monitor is equipped with a parallel interface to connect a printer with an IBM proprinter emulation mode.

Note
The monitor incorporates insulation to protect the patient against accidental exposure to high voltage from the printer. However, most printer types with IBM proprinter emulation are not designed for medical applications. Therefore, local regulations concerning the use of line operated printers in close proximity to patients must be considered.

CAUTION !

The resulting electrical medical system must comply with EN 60601-1-1.

Printing

- Connect printer to monitor
- Access the MENU, PRINT SETTINGS
- Select PARAMETER TO PRINT and define the requested parameter to be printed
- Select PRINT MODE and define the requested print mode
- Select START PRINTING and press [+] for two seconds to start the printer

When the recording is completed

- Select STOP PRINTING and press [−] to stop the printer

See section 7.2.7 for printer settings.

5.9 Power supply interruption

If the TOSCA 500 monitor is switched on and the energy supply of the monitor is no longer sufficient to guarantee safe functioning (i.e. internal battery is almost empty and the monitor is not connected to the mains supply), the power is automatically switched off and an alarm tone sounds (see section 8.1 for power failure alarm). In this case :

- switch off the TOSCA 500 monitor
- connect it to the mains supply and
- switch it on again.

The parameter settings and patient data are stored in memory as long as the internal battery is not completely empty, even if the TOSCA 500 monitor is switched off (internationally or automatically and disconnected from the mains supply. When the monitor is switched on again, the data and settings are available as previously stored.

See section 10.3 for battery refresh charge after long term power interruption.

6 DISPLAY MODES

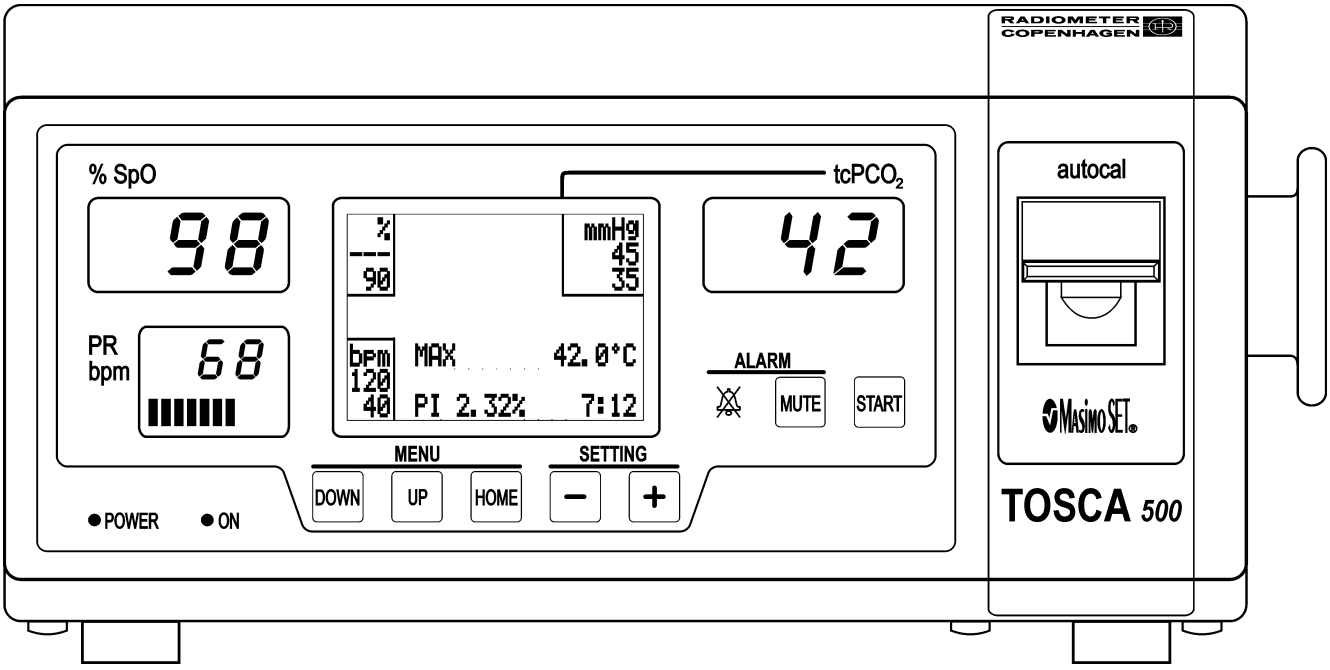
The TOSCA 500 system provides four display modes, two of them in different versions:

- STATUS
- TREND (4 versions)
- PLETHYSMOGRAM
- HEATING POWER (2 versions)

The heating power display mode must be enabled in the configuration menu (see section 7.2.5).

The display modes can be selected and changed at any time, also during monitoring, by pressing HOME. To select the TREND, PLETHYSMOGRAM or HEATING POWER display modes, see sections 6.2, 6.3 or 6.4.

6.1 STATUS display



6.1.1 Description

The values of the following parameters are displayed and can be changed in this mode:

- alarm limits for SpO_2 (%)
- alarm limits for pulse rate (bpm)
- alarm limits for $tcPCO_2$ (mmHg or kPa)
- (remaining) site time (hours : minutes)

The values of the following parameters are only displayed and cannot be changed in this mode:

- unit of $tcPCO_2$ (mmHg or kPa)
- sensitivity mode: MAX or APOD (NORMAL is not displayed)
- sensor temperature (°C)
- PI (Perfusion Index) in %

Note

When SPO2/PR are disabled, the alarm limits for SpO_2 and pulse rate are not available and displayed as "--". (see section 7.2.4)

6.1.2 Parameter settings

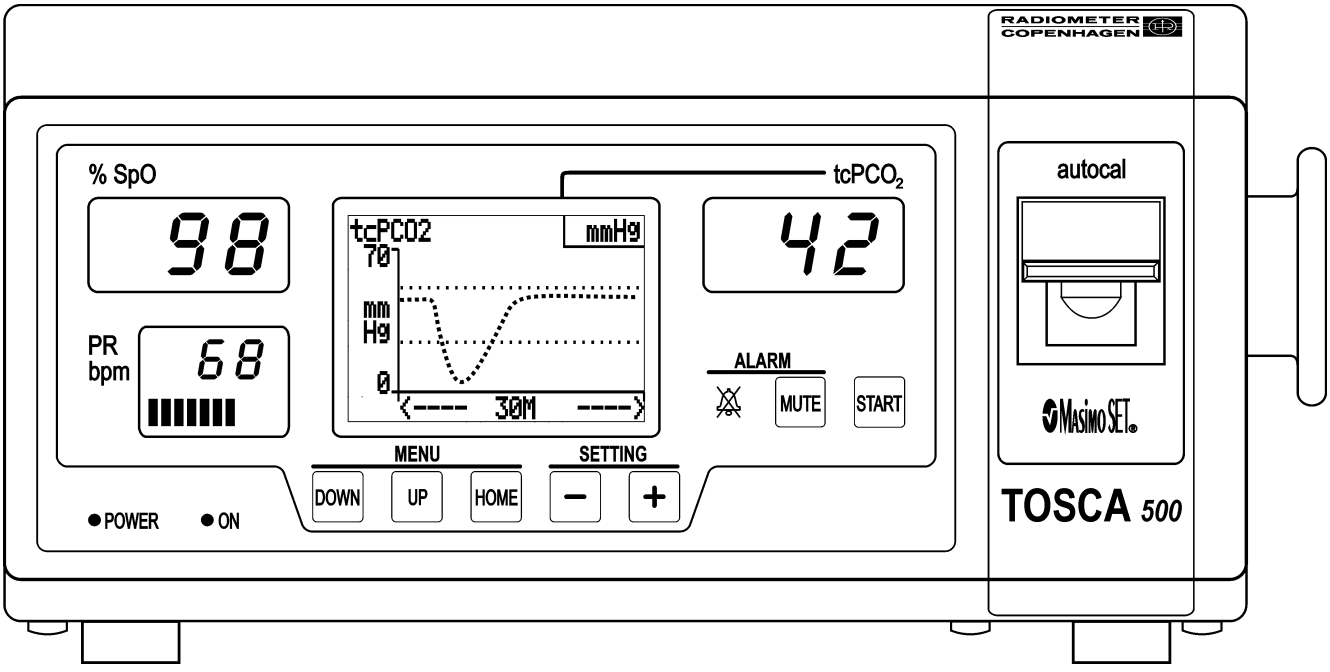
The displayed values of the alarm limits and site time can be directly changed at any time in this mode. These parameters may also be changed in the main menu. The alarm limits for SpO_2 and pulse rate are available when SPO2/PR is enabled. The sensor temperature, the PCO2 unit and the mode of arterialization can only be changed in the main menu. See section 7.2 for parameter description.

- Press [DOWN] to access the parameter setting mode
- (+MENU+ appears on the display).
- Press [DOWN] or [UP] to move to the requested value.
- Press [+] or [−] to change it.

Note

A change of the remaining site time will also change the setting of the total site time.

6.2 TREND display



6.2.1 Description

This mode allows the graphical presentation of the trend of one of the four parameters $tcPCO_2$, SpO_2, PR and PWR (heating power), if the Heating Power parameter is enabled in the CONFIGURATION menu.

Trend graphs

The trend of the selected parameter is displayed within a defined time window. It is possible to display the actual trend or the trend (of max. 12 hours) during selectable time periods within the previous 72 hours (patient data memory). Blank spaces indicate those time intervals in which no values are available (e.g. while the sensor is placed in the calibration/ storage chamber or while the monitor is turned off).

Alarm limits

The active low and high alarm limits are indicated as two dotted lines.

Heating power reference

The relative heating power reference value is indicated as a dotted line.

6.2.2 Parameter settings

- Press [HOME] to select the current TREND display mode .
- Press [DOWN] to access the parameter setting mode
- (+MENU+ appears on the display).
- Press [DOWN] or [UP] to move to the parameter which should be changed.
- Press [+] or [−] to change it.

Trend parameter selection: $tcPCO_2$, SpO_2, PR or PWR.

Default parameter: $tcPCO_2$

For the heating power trend (PWR), the heating power display must be enabled in the configuration menu (see section 7.2.5).

For SpO_2 and pulse rate (PR), the SPO2/PR parameter must be enabled in the SpO_2 menu (see section 7.2.4).

Parameter range values

The maximum and minimum values may be changed to the values as indicated in the below table. The difference between the maximum and minimum values is automatically adjusted so that it corresponds to at least three step values.

Range:

Parameter	Minimum	Maximum	Step
$tcPCO_2$	0 - 150 mmHg (0 - 20 kPa)	50 - 200 mmHg (5 - 25 kPa)	10 mmHg (1 kPa)
% SpO_2	0 - 90 %	50 - 100 %	5 %
PR	0 - 200 bpm	100 - 240 bpm	10 bpm
PWR	0 - 800 mW	250 - 999 mW	50 mW

Default values:

Parameter	Minimum	Maximum
$tcPCO_2$	0 mmHg (0 kPa)	80 mmHg (10 kPa)
% SpO_2	75 %	100 %
PR	50 bpm	150 bpm
PWR	0 mW	999 mW

Time window

The time window of the trend graph can be defined by selecting the time period and the end time. To display the actual trend, define the time period and select the actual time as end time. The start time is then automatically set and the selected time period is indicated between two arrows. To recall trend values from the past 72 hours, define the time period and the end time. The start time is then automatically set. A time period of up to 12 hours can be selected from the 72 hours memory.

Time period

The time period may be changed as follows:

Range: 5, 10, 30 minutes and 1, 2, 4, 8, 12 hours

Default value: 1 hour

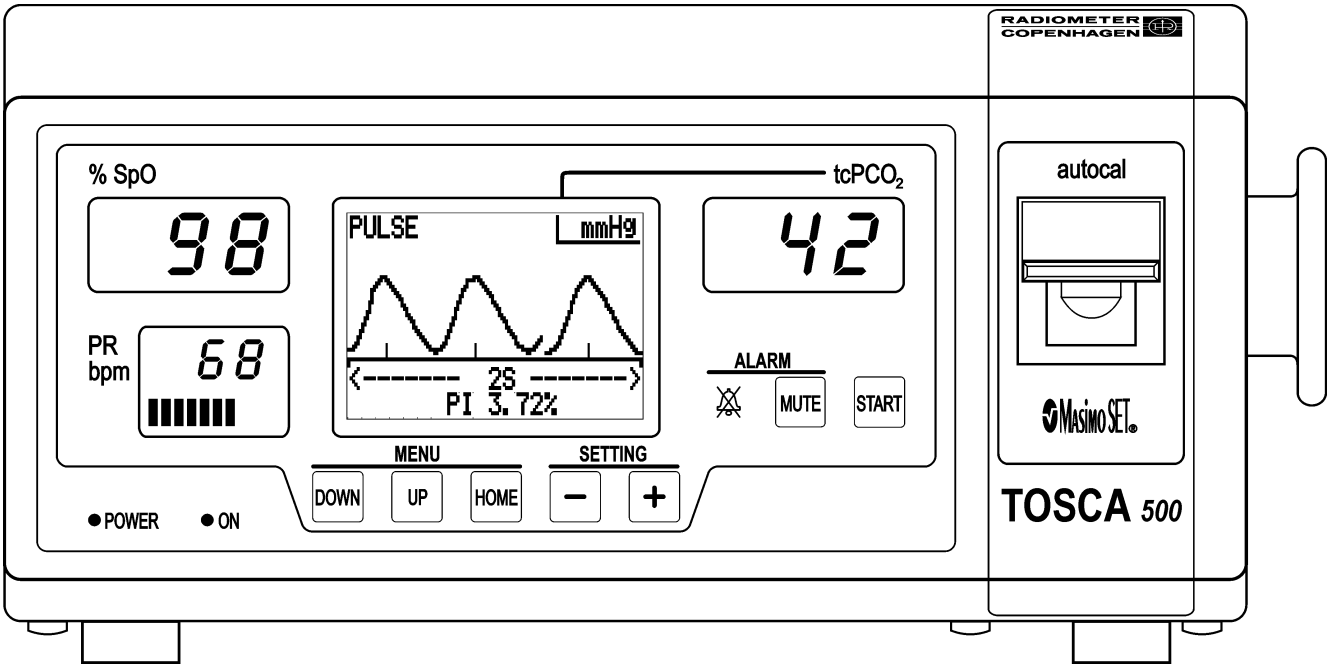
End time

The end time of the trend graph can be selected in steps, whereby the width of a step is identical with the selected time period. The start time is always automatically adjusted.

Range: up to 72 hours

Default value: actual time

6.3 PLETHYSMOGRAM display



6.3.1 Description

The PLETHYSMOGRAM display mode allows the presentation of the actual pulse waveform. The pulse wave is displayed over the full range and is therefore not proportional to the Perfusion Index (PI) value. The PI value is indicated at the bottom line (for definition of Perfusion Index value see section 3.2.3).

The signal IQ is showed as vertical line coinciding with the peak of the pulse wave (for definition, see section 3.2.3)

The Plethysmogram display mode and the PI value are not available when SPO2/PR is disabled in the SpO_2 menu.

6.3.2 Parameter settings

- Press [HOME] to select the current PLETHYSMOGRAM display mode .
- Press [DOWN] to access the parameter setting mode (+MENU+ appears on the display).
- Press [DOWN] or [UP] to move to the parameter which should be changed.
- Press [+] or [−] to change it.

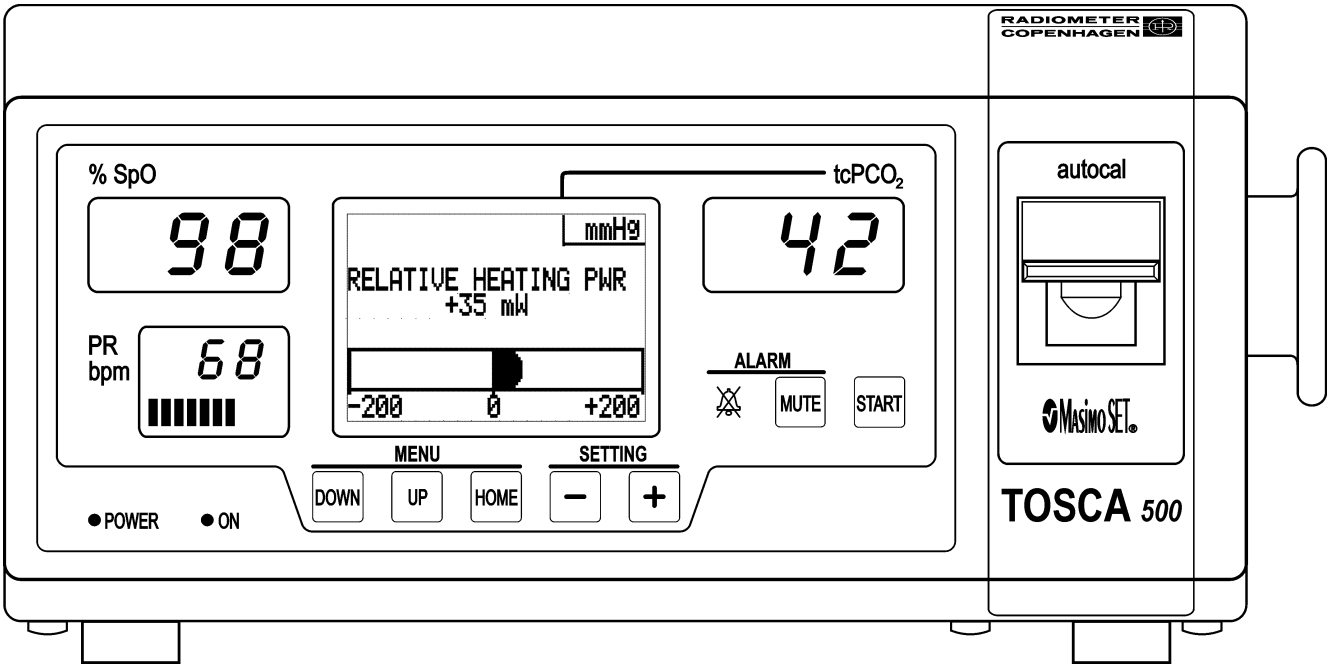
Time period

Selection of the time window of the plethysmogram display.

Range: 2, 4, 6, 8 seconds

Default value: 4 seconds

6.4 HEATING POWER display



6.4.1 Description

The HEATING POWER display mode is available only when it is enabled in the CONFIGURATION menu (see section 7.2.5). It includes two versions allowing the display of the value and the graphical presentation of the HEATING POWER and the RELATIVE HEATING POWER.

The HEATING POWER is the absolute value of the actual electrical power needed to heat the sensor.

The RELATIVE HEATING POWER is the difference between the actual heating power and a reference value which has been previously stored. It is necessary to reset this reference value to the actual heating power (i.e. after the sensor is warmed up at the patient) prior to displaying the RELATIVE HEATING POWER. For the interpretation of this parameter, see section 3.2.2.

No value is displayed and the bar indicates 0 while the sensor is within the calibration / storage chamber.

6.4.2 Parameter settings

- Press [HOME] to select the current HEATING POWER display mode .
- Press [DOWN] to access the parameter setting mode (+MENU+ appears on the display).
- Press [DOWN] or [UP] to move to the parameter which should be changed.
- Press [+] or [–] to change it.

Display version

Selection of one of the two versions of the heating power display.

Options HEATING POWER or RELATIVE HEATING POWER

Default: RELATIVE HEATING POWER

Reset of heating power reference value

- Press [DOWN] or [UP] to move to the message

```
RESET REL. HEATING
POWER REFERENCE
```

- Press [+] to reset.

Display range

Selection of the RELATIVE HEATING POWER graphic display range

Range: ± 50, 100, 200, 500 mW

Default: ± 100 mW

7 SYSTEM PARAMETERS / MESSAGES

7.1 Parameter settings

The TOSCA 500 system is delivered with factory default parameter settings as listed in section 7.3. These parameters can be changed / modified / stored and restored at any time.

CAUTION

The auditory alarm signal and the SpO_2 pulse tone are automatically suspended during parameter setting.

Access to main menu: Starting from any display mode

- Press [DOWN] to access the parameter setting mode (+MENU+ appears on the display, inverted and the + sign flashing).
- Press [+] to enter the main menu.

Main menu

The main menu consists of six submenus (arranged in a loop) which can be selected with [DOWN] or [UP]. The selected submenu is inverted and the + sign flashes., Select CLOSE MENU and press [+] or [HOME] to exit the main menu

Example: ALARM PARAMETERS

```
ALARM PARAMETERS    +
PCO2 PARAMETERS     +
SPO2/PR PARAMETERS  +
CONFIGURATION       +
USER SETTINGS       +
PRINT SETTINGS      +
--------------------
CLOSE MENU          +
```

Submenus

- Press [+] to enter a selected submenu
- Press [DOWN] or [UP] to move to the requested parameter and
- Press [+] or [−] to change it.
- Select RETURN TO MAIN MENU and press [+] or [HOME], to return to the main menu.

```
ALARM
LOUDNESS LEVEL      3
--------------------
PCO2 MAXIMUM  50 mmHg
PCO2 MINIMUM  25 mmHg
--------------------
SPO2 MAXIMUM    100 %
SPO2 MINIMUM     90 %
```

The submenu PCO2 PARAMETER has one lower level menu, the SPECIAL PCO2 PARAMETERS. To select and change a parameter at this level, proceed in the same way as for a submenu.

Note

The display will automatically return to the last chosen display mode if no key is pressed for more than 15 seconds.

7.2 Description of parameters

Note

In the menu Alarm parameters (7.2.1), PCO_2 parameters (7.2.2) Special PCO_2 parameters (7.2.3), User settings (7.2.6) and Print settings (7.2.7) PCO2 stays for $tcPCO_2$

7.2.1 Alarm parameters

ALARM LOUDNESS LEVEL	Selection of the loudness level of the alarm tone. Range: 1 to 6, in steps of 1. Default value = 3
AUDITORY ALARM MODE	The auditory alarms suspension is set to: "suspension 2 min.". A change of this mode may be requested for special applications, e.g. in sleep centers. This mode can be changed only by an authorized Radiometer representative.
ALARM LIMITS	The alarm limits for SpO_2 and pulse rate are available when SPO2/PR is enabled in the SpO_2 menu. But, if SPO2/PR is disabled, the alarm limits are not selectable and displayed as "---".

Alarm limit ranges:

Parameter	Minimum	Maximum	Step[1]
PCO_2	0 - 99 mmHg (0 - 13.0 kPa)	5 - 200 mmHg (0.7 - 25.0 kPa)	1 mmHg (0.1 kPa)
% SpO_2	50 - 95 %	70 - 100 % / ---[2]	1 %
PR	25 - 150 bpm	50 - 240 bpm	1 bpm

Default values:

Parameter	Minimum	Maximum
PCO_2	25 mmHg (3.3 kPa)	50 mmHg (6.6 kPa)
% SpO_2	85 %	---
PR	50 bpm	150 bpm

[1] Note

The difference between the maximum and the minimum alarm limit is automatically adjusted so that it corresponds to at least 5 step values.

[2] Note

The maximum SpO_2 alarm limit can be made inactive by selecting one step above 100%. This will be indicated as "---".

7.2.2 PCO_2 parameters

IN VIVO PCO2 CORRECTION	This parameter is activated only if the IN VIVO PCO2 CORRECTION mode is enabled at the level of SPECIAL PCO2 PARAMETERS (section 7.2.3). This function provides the possibility of adjusting the $tcPCO_2$ value displayed by the TOSCA 500 monitor to the arterial PCO_2 value as determined by an arterial blood gas analysis (for details see section 2.4.1). The entered correction value is added or subtracted to the measured $tcPCO_2$ value during patient monitoring. A triangle ▲ will appear automatically next to the $tcPCO_2$ unit to indicate that a correction (≠0) is applied to this value. The automatic reset of the entered correction value can be turned ON or OFF, see section 7.2.3 "IN VIVO AUTOMATIC RESET". The in vivo PCO_2 correction is not active during calibration. Range: -7 to +7 mmHg (-1.0 to +1.0 kPa) in steps of 1 mmHg (0.1 kPa). Default value = 0. **WARNING !** **The function IN VIVO PCO2 CORRECTION may be used only if a systematic difference between the transcutaneous and arterial PCO_2 value is clearly established by several arterial blood gas analyses. The entered correction value must be checked periodically and adapted in case of changes. The transcutaneous PCO_2 value remains an estimate of arterial PCO_2 also after the in vivo correction.**
SENSOR TEMPERATURE	Selection of the sensor temperature. The recommended temperature is 42°C. Range: 37.0 to 44.0°C, in steps of 0.5°C Default value = 42°C. ***Note*** *When changing the sensor temperature, a change of the site time may become necessary. Be cautious when using a temperature above 42°C. Read recommendations given in section 3.2.2.*

SITE TIME	Selection of the duration of a monitoring period Range: 30 minutes to 24 hours in steps of 30 minutes and unlimited ("--H--"). Default value = 4H00. ***Note*** *When changing the site time, a change of the sensor temperature may become necessary. See section 3.2.2.*
AUTO BAROMETRIC PRESSURE	This parameter is activated when the BAROMETRIC PRESSURE mode is set to AUTO at the level of SPECIAL PCO2 PARAMETERS (section 7.2.3). The barometric pressure measured by the monitor is indicated in mmHg when this unit is selected for the $tcPCO_2$ value, and in hPa when kPa is selected for $tcPCO_2$.
MANUAL BAROMETRIC PRESSURE	This parameter is activated when the BAROMETRIC PRESSURE mode is set to MANUAL at the level of SPECIAL PCO2 PARAMETERS (section 7.2.3) The actual barometric pressure must be entered manually. The value of the barometric pressure is indicated in mmHg when this unit is selected for the $tcPCO_2$ value and in hPa when kPa is selected for $tcPCO_2$. Range: 450 to 800 mmHg (600 to 1067 hPa) in steps of 1 mmHg (1 hPa). Default value = 750 mmHg (1000 hPa).

7.2.3 Special PCO_2 parameters

While in the submenu PCO2 PARAMETERS, select the lower level menu SPECIAL PCO2 PARAMETERS.

PCO2 TEMP. CORRECTION FACTOR	Selection of the temperature correction factor for calculating the $tcPCO_2$ calibration value. This factor is used in combination with the $tcPCO_2$ metabolic constant (see section 2.4.1 for details). When AUTO is selected, the correction is automatically adjusted to the sensor temperature. When a specific value is selected, this adjustment is not made, and the sensor must be recalibrated after a change of the sensor temperature. Also, the correction parameters should then be adjusted if necessary. Range: AUTO; 1.00 to 2.00 in steps of 0.01 Default = AUTO
PCO2 METABOLIC CONSTANT	Selection of the metabolic constant for calculating the $tcPCO_2$ calibration value. This constant is used in combination with the $tcPCO_2$ temperature correction factor (see section 2.4.1 for details). Range: 0 to 8 mmHg (0.0 to 1.0 kPa) in steps of 1 mmHg (0.1 kPa) Default value = 5 mmHg (0.7 kPa). It is recommended to select the following settings: $tcPCO_2$ temperature correction factor = AUTO $tcPCO_2$ metabolic constant = 5 mmHg
IN VIVO PCO2 CORRECTION	Selection of the option to adjust the $tcPCO_2$ to the arterial blood gas value. Only when "ON" is selected, the IN VIVO PCO2 CORRECTION mode is activated at the level of PCO2 PARAMETERS, and the correction value can be entered there (see section 7.2.2). Selection: ON, OFF Default = OFF

IN VIVO AUTOMATIC RESET	This parameter is active only when the IN VIVO CORRECTION parameter is ON and allows to turn ON or OFF the automatic reset feature. ON: The entered "in vivo correction" value is automatically reset to zero after a sensor calibration. OFF: The entered "in vivo correction" value remains active even after a sensor calibration. ----: Four dashes are displayed when the IN VIVO CORRECTION is turned OFF (disabled) Selection: ON, OFF Default = ON
BAROMETRIC PRESSURE MODE	The barometric pressure is used to calculate the $tcPCO_2$ calibration value. Selection of the options AUTO or MANUAL. AUTO: the barometric pressure measured by the monitor is automatically set. MANUAL: the barometric pressure must be entered manually. Only when this mode is selected can the MANUAL BAROMETRIC PRESSURE be entered at the level of "$tcPCO_2$ Parameters" (see section 7.2.2). Selection: AUTO, MANUAL Default = AUTO
LAST SENSOR PREP. (with date)	The date of the last sensor preparation is displayed.
SENSOR REMEMBRANED ?	Option to set the preparation date of the sensor to the current date by pressing [+] (+YES+). This function can be used when the sensor has been remembraned on the same day without being connected to the monitor. The current date is stored in the memory as "last sensor preparation date".
PCO2 UNIT	Selection of the $tcPCO_2$ unit: mmHg or kPa. Default unit = mmHg
RETURN TO PCO2 PARAMETER	To return to the submenu PCO_2 PARAMETERS.
RETURN TO MAIN MENU	To return to the main menu.

7.2.4 SpO_2 / PR parameters

Sp02/PR	The SpO_2 and pulse rate parameters may be turned off. ON: the SpO_2 and pulse rate values and the corresponding alarm limits are available and displayed. The SpO_2 and PR trend can be selected in the TREND display mode and the PLETHYSMOGRAM display mode is selectable. OFF: the SpO_2, pulse rate values and the corresponding alarm limits are not available and displayed as "--". The Plethysmogram display is not selectable and the "Perfusion Index" value is not available. Therefore the SpO_2, pulse rate and perfusion values cannot be recalled or downloaded. Selection: ON, OFF Default = ON
PULSE AVERAGING TIME	Selection of the pulse averaging time. When 2 or 4 is selected the FastSat algorithm is automatically activated. This parameter is not selectable and is displayed as "--" when the SPO2/PR parameter is disabled. Range: 2, 4, 8, 10, 12 and 16 seconds Default value = 8 s ***Note*** *See section 3.2.3 for potential implications of a long averaging time.*
SENSITIVITY	Selection of the sensitivity mode of the pulse signal. NORMAL: sensitivity setting is for normal patient monitoring (this mode is not displayed). APOD: (Adaptive Probe Off Detection) setting should be selected when the sensor is in danger of detaching from the patient, due to wet skin, severe motion, or other circumstances. MAX: setting is for improved sensitivity performance on patients with extremely low perfusion. The sensitivity settings APOD and MAX is displayed on the status screen, if selected. The sensitivity mode is not stored in user settings and is automatically reset to NORMAL after monitor was turned off. Selection: NORMAL, APOD, MAX Default: NORMAL

FASTSAT	Selection of the FastSat algorithm. ON: the FastSat algorithm is activated. In the 2 and 4 seconds pulse average mode, the FastSat algorithm is automatically enabled. OFF: the FastSat algorithm is deactivated when 8, 10, 12, 14 or 16 seconds of pulse average time is selected. Selection: OFF, ON Default: OFF
AUDIO PULSE LOUDNESS LEVEL	Selection of the loudness level of the auditory pulse signal. The level cannot be set higher than the selected "alarm loudness" level. This parameter is not selectable and is displayed as "--" when the SpO_2/PR parameter is disabled. Range: OFF, 1 to 6 in steps of 1. Default value = 3
RETURN TO MAIN MENU	To return to the main menu.

7.2.5 Configuration

YEAR MONTH DAY	Setting of the current date.
HOUR:MINUTE	Setting of the current time.
DISPLAY CONTRAST	Selection of the optimal contrast of the LCD display for a given viewing angle. Range: 1 to 20 in steps of 1 Default value = 10 The display contrast can also be set at any time by pressing [−] and [+] while holding [HOME] pressed.

DISPLAY BACKLIGHT	Selection of the LCD display backlight mode. ON: the backlight is unconditionally switched on. AUTO: the display backlight is switched off if one of the following events persists for more than 5 seconds; otherwise it is switched on. – No message is displayed or the sensor is in the calibration / storage chamber – No parameter selection is in progress – No key is pressed – No alarm is active Default = ON
KEY FEEDBACK TONE	Selection of the key feedback tone mode. ON: a tone sounds each time a key is pressed. The volume of the key feedback tone is the same as that of the alarm tone. OFF: no feedback tone when any key is pressed. Selection: ON, OFF Default = ON
HEATING POWER DISPLAY	The heating power display mode can be turned on or off. ON (enabled), OFF (disabled). ON: the HEATING POWER display mode and the heating power TREND (PWR) mode are activated. OFF: these two modes are not available. Selection: ON, OFF Default = OFF (disabled)
COMMUNICATION	Selection of the communication protocol for the serial interface of the "Systems Connector". Selection: EASYLINK, VUELINK, MONLINK Default = EASYLINK For detailed description see Section 15

TEACHING MODE 1 HOUR	Selection of the "teaching mode". ON: During parameter setting, the selected display mode remains for up to one hour. The alarm functions of the monitor are turned off, but they are activated when no key is pressed for 15 seconds. This function can be used, e.g. during a demonstration of the system or for training purposes. OFF: The display returns automatically to the last chosen display mode when the parameter setting is completed and no key is pressed for 15 seconds. Selection: ON, OFF Default = OFF
MAIN: X.XX DBG: X.XX **MS11: DSPXXXX/MCUXXXX**	Display of the installed software revision levels.
ENGLISH	Selection of the display language. Selection: ENGLISH, DEUTSCH, FRANCAIS, ITALIANO, ESPANOL, SWEDISH Default = ENGLISH
RETURN TO MAIN MENU	To return to the main menu.

7.2.6 User settings

WARNING !

A potential hazard can exist if different alarm settings are used for several TOSCA 500 monitors and/or similar devices in a single area. It is recommended to check the alarm settings before starting monitoring. See parameter settings in section 5.3. Setup for operation.

ERASE PATIENT DATA	Option to erase the complete contents of the 72 hours patient data memory. Press [+] for two seconds to erase these data. The message: **PATIENT DATA ERASED** is displayed to confirm the action.

STORE USER SETTINGS	Option to store the current parameter settings as "user settings". This function can only be executed by an authorized person who is responsible for the operation of this equipment. Press [+] for two seconds, and the following message is displayed: **CONTACT A PERSON AUTHORIZED TO STORE THE USER SETTINGS** –
RESTORE USER SETTINGS	Option to restore the last defined "user settings" and those default factory parameter settings which are not available in the "user settings" memory. Press [+] for two seconds to restore the settings. The message: **USER SETTINGS RESTORED** is displayed to confirm the action.
RESTORE FACTORY SETTINGS	Option to restore the factory parameter settings. This function can only be executed by an authorized person who is responsible for the operation of this equipment. Press [+] for two seconds, only the following message is displayed: **CONTACT A PERSON AUTHORIZED TO RESTORE THE FACTORY SETTINGS**
RETURN TO MAIN MENU	To return to the main menu.

7.2.7 Print settings

These settings apply when a printer with an IBM proprinter emulation mode is connected (see section 5.7).

START PRINTING	Press [+] for two seconds to start printing. The message: **PRINTING STARTED** **PRESS - 2 SEC** **TO STOP PRINTING** is displayed to confirm the action.
STOP PRINTING	Press [−] for two seconds to stop printing. The message: **PRINTING STOPPED** **PRESS + 2 SEC** **TO RESTART PRINTING** is displayed to confirm the action.
PARAMETER TO PRINT	Selection of the trace to be printed. Options: PCO2 & SPO2, PR & SPO2, PULSE SIGNAL, SELECTED TREND. The SpO_2 and pulse rate parameters are not available when SPO2/PR is disabled.
PRINT MODE	Selection of the print mode. Appears only if the selected trace is PCO2, PCO2 & SPO2 or PR & SPO2. Options: ONLINE FAST, ONLINE SLOW, SELECTED TREND TIME with the time windows LAST 1H, LAST 12H, LAST 24H or LAST 72H. Default: LAST 24H Print resolution: – ONLINE FAST 20 dots/min. (34 cm/hour) – ONLINE SLOW 2 dots/min. (3.4 cm/hour) – LAST 1H 20 dots/min. (34 cm/hour) – LAST 12H / 24H / 72H 2 dots/min. (3.4 cm/hour) – SELECTED TREND TIME max. 500 dots (14 cm)
PRINT MODE IS **LAST 12 S**	Display of the print mode. Appears only if the trace to be printed is PULSE SIGNAL.

PRINT MODE IS SELECTED TREND TIME	Display of the print mode. Appears only if the trace to be printed is SELECTED TREND.
RETURN TO MAIN MENU	To return to the main menu.

7.2.8 Print messages

PRINTING STARTED PRESS - 2 SEC TO STOP PRINTING	Appears when printer is started with selected parameter(s) and print mode. Printing can be stopped by pressing [−] for two seconds.
PRINTING STOPPED PRESS + 2 SEC TO START PRINTING	Appears when printing is stopped. The printer can be restarted by pressing [+] for two seconds.
STOP PRINTING FIRST TO CHANGE ANY PRINTER SETTINGS	Appears when printing is in progress and the parameter PRINT MODE or SELECTED TREND is selected to change the print settings. Press [HOME] to return to the status display mode and press [−] for two seconds to stop printing.
PRESS - 2 SEC TO STOP CURRENT PRINTING FIRST	Appears when printing is in progress and when [+] is pressed for two seconds. Press [−] for two seconds to stop current printing before a parameter can be changed.
NO PRINTING IN PROGRESS	Appears when [−] is pressed for two seconds and the printer is not operating.
PRINTER FAULT	Appears when the printer is started but the printer is off line, no paper is available or no printer is connected. Turn printer on, insert a new paper roll or press [−] for two seconds (stop printing).

7.3 Default parameter settings

Note

In the settings PCO2 stays for $tcPCO_2$

The TOSCA 500 monitor is provided with default factory parameter settings. These settings can be restored if required in the submenu USER SETTINGS as described in section 7.2.6.

- ALARM LOUDNESS LEVEL = 3
- PCO2 MAXIMUM = 50 mmHg (6.6 kPa)
- PCO2 MINIMUM = 25 mmHg (3.3 kPa)
- SPO2 MAXIMUM = ---
- SPO2 MINIMUM = 85%
- PR MAXIMUM = 150 BPM
- PR MINIMUM = 50 BPM
- AUDITORY ALARM MODE = suspension 2 min.
- SENSOR TEMPERATURE = 42°C
- SITE TIME = 4H00
- MANUAL BAROMETRIC PRESSURE = 750 mmHg (1000 hPa), if selected
- PCO2 TEMP. CORRECTION FACTOR = AUTO
- PCO2 METABOLIC CONSTANT = 5 mmHg (0.7 kPa)
- IN VIVO PCO2 CORRECTION = OFF
- IN VIVO AUTOMATIC RESET = ON
- BAROMETRIC PRESSURE = AUTO
- PCO2 UNIT = mmHg
- SPO2/PR = ON
- PULSE AVERAGING TIME = 8 s
- SENSITIVITY = NORMAL
- FASTSAT = OFF
- AUDIO PULSE LOUDNESS LEVEL = 3
- DATE = 01.01.2001
- TIME = 12:00
- DISPLAY CONTRAST = 10
- DISPLAY BACKLIGHT = ON
- KEY FEEDBACK TONE = ON
- HEATING POWER DISPLAY = OFF
- COMMUNICATION = EASYLINK
- TEACHING MODE = OFF
- LANGUAGE = English
- PARAMETER TO PRINT = PCO2 & SPO2
- PRINT MODE = last 24H

8 ALARMS AND MESSAGES

8.1 Description of the alarm functions

The TOSCA 500 monitor is equipped with an alarm system which corresponds to international regulations.

The alarm system employs three levels:

- high priority physiological alarm,
- medium priority technical alarm,
- low priority operating alarm

They are defined as follows:

High priority alarm

Signal indicating that immediate operator response is required in the situation of:

- Physiological alarms

A physiological alarm is activated if a monitoring value equals or falls outside the set alarm limits.

The triggering delay of the high priority physiological alarm signal is one to five seconds (depending on monitor conditions).

Medium priority alarm

Signal indicating that prompt operator response is required for the following situations:

- Monitor fault and sensor fault
- Technical alarms which prevent measurement or accurate measurement of a physiological parameter (i.e. no sensor, no signal…)

Low priority alarm

Signal indicating that operator awareness is required for the following situations:

- Site time elapsed
- Other technical alarms (e.g. no gas flow, request to calibrate sensor …)

All alarm messages are indicated by an auditory and visual signal (flashing of the parameter or of the middle display, dependent on the alarm level). The alarm indications (auditory and visual) disappear automatically when the alarm condition is ceased. See section 8.2 for description of alarm messages.

Operator's position

In order to respond to alarm signals, the operator, should be in a position of being capable of:

- to hear the auditory alarm signals;
- to see which of the LED display and/or LCD displays is flashing during alarm manifestation.

The operator should be capable to read the alarm messages on the LCD display during manifestation of medium and low priority visual alarm, in order to determine the event of the alarm.

Visual alarm indication

For physiological alarms (see 7.2.1), the $tcPCO_2$, SpO_2 or Pulse Rate LED display is flashing and a corresponding alarm message is indicated on the middle LCD display.

For technical and operating alarms (see 7.2.2 and 7.2.3), a corresponding alarm message is indicated on the middle LCD display and the LCD display backlight is flashing.

For each alarm message on the middle LCD display, the first line of the display indicates the priority of the corresponding alarm as follows:

- high priority: ' ! ! ! '
- medium priority: ' ! ! '
- low priority: ' ! '

Example of high priority alarm message:

```
    ! ! !
SPO2 TOO LOW
 ALARM LIMIT
    xx%
```

The visual alarms are always active, they cannot be switched off. The visual alarm indications remains as long as the alarm conditions exists.

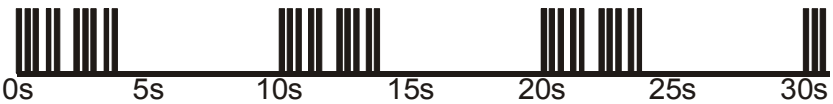
If more than one alarm is active, all corresponding alarm messages will be displayed alternating.

Auditory alarm tone

The type of alarm tone is different for each level:

The alarm tone of a HIGH PRIORITY ALARM consists of two bursts of five short pulses, which are repeated every 10 seconds. The melody generated represents the "Oxygen" cause of alarm, related to “Oxygen” as defined in the international standard IEC 60601-1-8.

Timing representation of a HIGH PRIORITY ALARM:



The alarm tone of a MEDIUM PRIORITY ALARM consists of 3 pulses, and is repeated every 25 seconds. The melody generated represents a "General" cause of alarm, as defined in the international standard IEC 60601-1-8.

Timing representation of a MEDIUM PRIORITY ALARM:

The alarm tone of a LOW PRIORITY ALARM consists of 2 pulses, and is repeated every 25 seconds. The melody generated represents "Any" cause of alarm, as defined in the international standard IEC 60601-1-8.

Timing representation of a LOW PRIORITY ALARM:

Monitoring message tone

Every monitoring message described in section 8.3 is announced once by an auditory signal as follows:

This signal is not generated if a parameter adjustment is in progress

Alarm muting

There are two possible situations:

Situation 1

The "MUTE" key is pressed when the auditory alarm is sounding during an alarm/fault condition:

The auditory alarm is muted.

The visual alarm (flashing parameter value and/or alarm/fault message) remains active.

The message

ALARM MUTED

appears below the alarm/fault message in the middle LCD display.

If more than one alarm is active, all of them are muted.

The auditory alarm remains muted until the alarm/fault condition is discontinued.

The auditory alarm will be reactivated by any new alarm/fault condition.

Each new alarm can be muted, the message "ALARM MUTED" appears below each corresponding alarm/fault message in the middle LCD display.

Situation 2

The "MUTE" key is pressed when no auditory alarm is sounding (no alarm condition or an auditory alarm has been muted:

The auditory alarm will be temporarily suspended for two minutes for all alarm/fault conditions.

The message

AUDITORY ALARMS SUSPENDED FOR 2 MINUTES

appears during two seconds and the "alarm suspended indicator lamp" flashes during two minutes.

If during these two minutes an alarm/fault condition occurs, only the visual alarm (flashing parameter value and/or alarm/fault message) will be displayed.

The auditory alarm suspension can be switched off within the 2 minutes by pressing the "MUTE" key a second time.

After the suspension period of 2 minutes, the "alarm suspended indicator lamp" is switched off, the auditory alarm is again active for all alarm/fault conditions except for those which are muted.

WARNING !

If an alarm condition occurs while the auditory alarm is suspended, the only alarm indication will be visual, no alarm tone will sound.

While the auditory alarm is muted or suspended, the remote alarm is deactivated.

Remote alarm

The alarm signals available at the nurse call and serial communication interface are activated during an alarm condition (which is not muted or suspended) with a delay of max. 0.3 seconds.

Automatic suspension of alarms

The auditory and / or visual alarm signals are automatically suspended in situations in which a particular alarm is not relevant. Those alarms which are automatically suspended are listed below along with the related situations.

Type of alarm suspended	Situation
1) All high priority auditory and visual alarm signals 2) Medium priority auditory and visual alarm signals related to SpO_2, e.g. TOO MUCH AMBIENT LIGHT	1) The sensor is in the calibration chamber 2) The sensor has been taken out of the calibration chamber but monitoring has not yet been started (e.g. during sensor application). When the START key is pressed, the alarms are automatically activated (except for tcPCO2, see below).
High priority visual and auditory alarm signals related to $tcPCO_2$	During the first five minutes after the start of monitoring (to allow sufficient time for arterialization). Thereafter, the alarms are activated automatically.
All visual alarm signals (except flashing of parameter display)	The "home" key has been pressed during the past 15 seconds
All visual and auditory alarm signals (except flashing of parameter display)	During adjustment/setting of any parameter

Power failure alarm

If the energy supplying the monitor is no longer sufficient to guarantee safe functioning (i.e. internal battery almost empty), the power is automatically switched off and an independent alarm tone sounds for at least two minutes.

8.2 Alarm messages

Note

In the alarm messages, PCO2 stays for tcPCO$_2$.

8.2.1 Physiological alarm messages – high priority

PCO2 TOO HIGH ALARM LIMIT xxx mmHg	The tcPCO$_2$ value is equal to or higher than the defined "maximum alarm limit".
PCO2 TOO LOW ALARM LIMIT xxx mmHg	The tcPCO$_2$ value is equal to or lower than the defined "minimum alarm limit".
SPO2 TOO HIGH ALARM LIMIT xx%	The SpO$_2$ value is equal to or higher than the defined "maximum alarm limit".
SPO2 TOO LOW ALARM LIMIT xx%	The SpO$_2$ value is equal to or lower than the defined "minimum alarm limit".
PULSE RATE TOO HIGH ALARM LIMIT xxx BPM	The pulse rate (PR) value is equal to or higher than the defined "maximum alarm limit".
PULSE RATE TOO LOW ALARM LIMIT xxx BPM	The pulse rate (PR) value is equal to or lower than the defined "minimum alarm limit".

8.2.2 Technical alarm messages – medium priority

MONITOR FAULT NUMBER xx	A faulty function of the monitor is detected. Switch the monitor off and on again to try to reset this message. If the message disappears and the monitor can be restarted, check all parameter settings and readjust if required. If this message appears alternating with a sensor fault message as described below, disconnect the sensor to check the cause of the fault. If the message cannot be reset, note the indicated number and consult your service technician.
SENSOR FAULT	A failure of the TOSCA sensor 92 is detected. Disconnect and reconnect the sensor. If the message cannot be reset, replace the defective sensor.
UNKNOWN SENSOR	The connected sensor is not the TOSCA sensor 92. Connect TOSCA sensor 92.
CONNECT SENSOR	No sensor is connected. The message is automatically reset when the TOSCA sensor 92 is connected.
BATTERY IS LOW	The internal battery is at a very low charge level and needs to be recharged. Connect the monitor to mains.
LOW SIGNAL IQ	Low signal quality is detected. Check the fixation of the sensor and reapply if needed, see section 5.5 for details.
SENSOR OFF PATIENT	The sensor is detached. Check the fixation of the sensor and reapply it, if requested.
TOO MUCH AMBIENT LIGHT	The measurement is affected by light. Make sure that the sensor is not exposed to bright light.
INTERFERENCE	Outside signal or energy preventing reading. Remove outside interference.

LOW PERFUSION INDEX	The signal is too low. Move the sensor to the other ear lobe, see section 5.5 for details.

8.2.3 Operating alarm messages – low priority

SITE TIME ELAPSED	The selected monitoring time period is elapsed. Remove the sensor from the patient, place it into the calibration / storage chamber and reapply the sensor at the other ear if required.
PLACE SENSOR IN CALIBRATION CHAMBER	The sensor has been exposed to air for more than three minutes. Place sensor into the calibration / storage chamber or reapply it to the patient if it was detached.
CALIBRATE SENSOR	The sensor needs to be calibrated. Place sensor into the calibration / storage chamber.
REMEMBRANE SENSOR	The date of the last sensor preparation is older than 14 days or the sensor characteristics are out of specifications. Remembrane sensor as described in section 5.4
NO GAS FLOW RENEW GAS BOTTLE	The installed CAL-Gas bottle is empty or no gas bottle is installed. Install a new bottle.

8.3 Monitoring messages

PRESS START KEY TO START MONITORING alternating with: **PCO2/SPO2/PR ALARMS ARE SUSPENDED UNTIL MONITORING IS STARTED**	The sensor has been removed from the calibration / storage chamber and applied to the patient. Press START to start monitoring and site time clock. The alarm functions for $tcPCO_2$, SpO_2 and PR are suspended until monitoring is started. These two messages appear periodically (alternating with the selected display mode) until monitoring is started. ***Note*** *Monitoring is automatically started after five minutes if the START key has not been pressed by the operator.*

MONITORING STARTED PCO2 ALARM SUSPENDED UNTIL ARTERIALIZATION IS COMPLETED	The $tcPCO_2$ alarm detection is disabled for five minutes after monitoring has been started. The alarm detection is automatically activated after that time. This message appears periodically during these five minutes.
SITE TIME REMAINING xx MIN	Indication of the remaining time of the selected monitoring time period. This message is displayed when the remaining monitoring time (site time) is 10% of the preset "site time".
SEARCHING PULSE SIGNAL	The sensor detects no pulse signal. The sensor may not be correctly applied to the patient. This message will not appear while the sensor is in the calibration/storage chamber.
ALARMS MUTED	MUTE is pressed when the auditory alarm is sounding during an alarm / fault condition. The auditory alarm is muted. See section 8.1
AUDITORY ALARMS SUSPENDED FOR 2 MINUTES	MUTE is pressed when no auditory alarm is sounding. The auditory alarm is suspended for two minutes even if an alarm condition should arise during this time. See section 8.1
READY TO USE (with date and time)	The TOSCA sensor 92 is ready for patient monitoring.
CALIBRATING SENSOR 38 mmHg CAL-Gas (with bar graph)	Calibration of the sensor is in progress. The calibration value is indicated. The calibration value depends on the sensor temperature and barometric pressure. The bar indicates the remaining gas level (100% = full gas bottle).
EXTENDED CALIBRATION	Calibration of the sensor could not be completed within ten minutes and is continuing.
WEAK OPTICAL TEST SIGNAL	While the sensor is in the calibration / storage chamber, a potential malfunction is detected. Clean sensor surface with an alcohol swab. If the message reappears, consult your service technician.
CONNECT UNIT TO MAINS POWER CHARGE BATTERY MINIMUM 12 HOURS	The TOSCA 500 monitor is not connected to mains and the battery runs low. Connect the monitor to mains to recharge the battery.

9 TROUBLESHOOTING

9.1 During Monitoring - Application

Problem	Cause	Remedy
After sensor application on the patient, it takes longer than specified to reach a stable value	physiological cause e.g. edema of the skin, arteriovenous shunts, etc.	evaluate the status of the patient
	too much Contact Gel	reapply sensor using only one little drop of Contact Gel
After sensor application the $tcPCO_2$ value does not increase within 5 minutes	no Contact Gel	remove sensor from clip and apply one small drop of Contact Gel
Sudden and unexpected decrease of $tcPCO_2$	sensor is loosely attached, air is between sensor and ear lobe	reattach sensor securely
the message "TOO MUCH AMBIENT LIGHT" is displayed and no SpO2&PR values are displayed	the measurement is affected by light	make sure that the sensor is not exposed to bright light

9.2 During Calibration

Problem	Cause	Remedy
"REMEMBRANE SENSOR" appears during calibration	sensor operating time has been exceeded (last remembraning > 14 days)	remembrane sensor
	sensor has been stored in air for a prolonged period of time	initiate a new calibration and allow few hours for sensor stabilization in the cal/storage chamber
	the sensor is new or has been stored unprepared for a prolonged period of time	allow at least 4 hours for sensor stabilization in the cal/storage chamber
	the sensor was just remembraned but this was not confirmed by pressing YES "SENSOR REMEMBRANED?"	confirm sensor remembraning by selecting the parameter "SENSOR REMEMBRANED? YES" and then press + YES

9.3 Monitor / Sensor

Problem	Cause	Remedy
"SENSOR FAULT" appears	the sensor is defective	replace sensor
"SENSOR FAULT" appears during selection of a lower sensor temperature	safety circuitry in monitor detects too high sensor temperature	switch off monitor, allow sensor to cool down and switch on monitor again.
Excessive gas consumption	gas cylinder is not screwed in tightly	tighten up cylinder
	system is leaking	consult technical service
"MONITOR FAULT" appears with an identification number	a faulty function of the monitor is detected	switch OFF/ON the monitor to reset the message. If the message disappears and the monitor can be restarted, check all parameter settings and readjust if required.
	a faulty function of the monitor is detected	If the message cannot be reset, note the indicated identification number and consult technical service.

10 MAINTENANCE

10.1 Routine maintenance

The routine maintenance should be performed monthly according to the following procedure:

Monitor

- Switch monitor off and disconnect it from AC power.
- Clean housing, front and rear panel with a soft cloth lightly moistened with warm soapy water. Use only mild soap or detergents. Allow to dry completely before use. See section 11. for Decontamination.
- Inspect power cord assembly for any signs of mechanical damage to cable or connector. If damaged, replace with a genuine Radiometer Basel replacement part. Do not attempt to repair.
- Connect monitor to AC power:
- Switch monitor off and on again.
- Verify that during the following self-check, all display segments and control lamps are illuminated, that all dots of the middle LCD are visible and that a tone sounds.
- Check parameter settings and readjust if required.

Sensor

- Check sensor and cable assembly for any signs of mechanical damage. In case of a damage, replace sensor. Do not attempt to repair.
- Clean the prepared sensor and the cable with a soft cloth moistened with alcohol (carefully avoid damaging the delicate sensor surface). Allow to dry completely before use.
- Remembrane sensor if required.

Consumables

Check expiration date of all consumables. Replace if necessary.

WARNINGS !

Electrical shock hazard

The monitor must be switched off and disconnected from the AC mains power supply before cleaning it.

The plugs and connectors must be kept meticulously clean and dry. No liquid should enter the equipment.

CAUTION

Follow the instructions given above to clean the monitor and sensor. Do not use any abrasive agent or any chemical that is not recommended in this manual.

10.2 Check of monitor and sensor functions

System check

The operator may perform the following check of some important monitor functions.

Press both [−] and [+] when no parameter setting is in progress. Verify that:

- the alarm tone sounds with the selected loudness level,
- the "alarm suspended" indicator lamp is lit,
- all segments of the LED displays are lit,
- all dots of the middle LCD display are visible.

Alarm check

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

Barometric pressure check

When the barometric pressure is set to AUTO the indicated value may be checked against the local reference barometric pressure.

- Select the menu PCO2 PARAMETERS
- Move to AUTO BAROMETRIC PRESSURE and compare the indicated value with the reference barometric pressure.

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

Safety check

At normal use of the monitor there is no internal adjustment or new calibration of the monitor required. It is recommended to perform a safety check at regular intervals or in accordance with local and governmental regulations (see Service Manual for details). The safety check must be done by a trained and authorized service technician only.

CAUTION

If one of the above tests should fail, call an authorized service technician.

Sensor

A simplified function test of the PCO_2 part of the sensor may be carried out as follows:

Following a calibration, expose the sensor for approximately one to two minutes to ambient air. The displayed $tcPCO_2$ value should drop to a value below 5 mmHg (0.7 kPa). If this value is not reached, remembrane the sensor and repeat the test. After a renewed missing of this value, consult an authorized service technician.

10.3 Battery Refresh Charge

The TOSCA 500 monitor incorporates a battery which is recharged automatically while the monitor is connected to mains. When the monitor is not in use and not connected to mains

for more than 3 months, the battery charge must be refreshed. This ensures the functional capability of the battery and prevents the loss of the parameter settings.

For a full charge connect the TOSCA 500 monitor to mains power for 24 hours.

CAUTION

If the monitor stays without any electrical energy (monitor disconnected from the mains supply and internal battery is empty), the patient data are cleared, and the current and user parameter settings are automatically reset to the factory default parameter settings.

10.4 Disposal of equipment

Dispose the TOSCA 500 monitor in accordance with your country's laws for disposal of equipment containing electrical and electronic parts. For disposal of accessories, follow local regulations regarding disposal of hospital waste.

CAUTION

The battery contains lead and acid in gel form. Dispose of safely according to the local waste regulations.

DO NOT INCINERATE EQUIPMENT / GAS CYLINDER

11 DECONTAMINATION

11.1 Requirements

Due to the nature and seriousness of infectious diseases such as AIDS and Hepatitis B, it is important that equipment and accessories which can come into contact with human or animal tissues or fluids (particularly blood) should always be regarded as contaminated and potentially hazardous.

Contaminated equipment and accessories must be decontaminated by the procedures described below.

Decontamination must be carried out by a properly trained person.

If you are in any doubt regarding contamination or decontamination, consult your local infection control authority.

11.2 Decontamination procedures

CAUTION

Do not autoclave, pressure sterilize, or sterilize this equipment by irradiation, steam or ethylene oxide.

Do not soak or immerse the monitor in any liquid.

Use the cleaning solution sparingly. Excessive solution can flow into the monitor and cause damage to internal components.

Do not touch, press or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough surface materials, or bring them into contact with any that could scratch the panel.

Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the monitor. These substances attack the device's materials and device failure can result.

Cleaning

Where an equipment has been used but is not visibly contaminated, first wipe its surface with cotton wool swabs soaked in isopropyl alcohol (70%), and then dry the surface with a disposable cloth.

Disinfecting

Where surfaces of an equipment or accessories are visibly contaminated, wipe the surfaces with cotton wool swabs soaked in a surface disinfection solution containing e.g. quaternary ammonium derivatives to remove all visible traces of soiling. Then apply the disinfection solution to the surfaces, keeping them wet according to the recommendation of the disinfecting solution manufacturer. Rinse the surfaces with water and then dry them using disposable cloths.

Take care that liquids do not enter the equipment or connectors.

Dispose of swabs in the receptacle for biological waste immediately after use.

11.3 Risks

All human or animal tissues or fluids in the hospital and laboratory environment are capable of transmitting infection. Therefore, special precautions must be taken in hospitals and laboratories that deal with patients who have highly infectious disease.

Disease can enter by the following routes:

- Through broken skin;
- Needle or other sharp object;
- Contamination of cuts, abrasions or burns;
- Ingestion (placing a contaminated object in or near the mouth, e.g. pen, finger);
- Direct contact with mucous membranes (e.g. eyes);
- Inhalation of contaminated dust or aerosols.

Experience has proven that when proper precautions are taken, the risk of infection is very small and certainly of a lower order of magnitude than other risks that are taken routinely in daily life.

11.4 DO's and DON'Ts

When working in a contaminated area, observe the following rules:

- DO avoid any contact with sharp-edged objects.
- DO wear a laboratory coat, apron and gloves.
- DO disinfect tools after use.
- DO wash your hands thoroughly before leaving the contaminated area.
- DO dispose of gloves and aprons immediately after use, or if damaged.
- DO treat any cut or abrasion immediately.
- DO keep cuts and abrasions covered with a waterproof dressing.
- DO encourage any cut to bleed and then wash it under running water.
- DON'T put hands near mouth, eyes, ears or nose.
- DON'T eat, drink or smoke in any contaminated area.
- DON'T blow surfaces to remove dust; use a vacuum cleaner.

11.5 Equipment requiring service

When equipment or accessories are to be returned to the supplier or factory for service / repair, the clinical user may be required to ensure that the device has been properly decontaminated. A certificate of decontamination may be completed by the person responsible for the device, and this certificate must accompany the device on its return for service or repair.

For full decontamination procedures, see Service Manual.

Where equipment is to be serviced on site, a certificate of decontamination may also be required by the service engineer.

12 SPECIFICATIONS

12.1 TOSCA 500 monitor

Display

Three times 3 digit LED displays for PCO_2, SpO_2 and pulse rate

10 segment LED bar graph for pulse wave.

Graphic LCD (128 x 64 dots with LED back-light and adjustable contrast) for selectable parameter visualization modes, messages and alarms.

User selectable display modes for status, trend, plethysmogram and heating power

Patient Data Memory

Automatic storage of measured patient data over the last 72 hours using to the FIFO (First In, First Out) principle. (see also section 2.2)

Sensor heating

Sensor core temperature selectable between 37°C and 44°C in steps of 0.5°C

Calibration

Fully automatic calibration

Typical calibration time in routine use: 2 min.

Integrated calibration chamber with one-gas calibrator

CAL-Gas cylinder

Composition: 12.0% O_2, 7.0% CO_2, balance N_2

Volume: nominal 0.5 liter

Filling pressure: 10.8 bar at 21°C

Typical function time: 2 months

Site timer

Clock triggers an alarm when the selected measuring duration has elapsed

Indication of remaining site time

Sensor fault

Automatic shut down of heating in case of sensor fault, triggered by one of the following conditions:

- actual temp. > set temp. +1°C for 4 sec.
- actual temp. < set temp. -1°C for t_{max} (maximum time). t_{max} is normally 30 sec., but 5 min. during warming up of the sensor.
- (actual temp. - set temp.) > 0.3°C for t_{max}
- difference between thermistors > 0.6°C for 4 sec.
- difference between thermistors > 0.3°C for t_{max}

Alarms

Adjustable low and high limits for PCO_2, SpO_2 and pulse rate (PR)

Audio and visual alarm indication

Audio alarm loudness adjustable from level 1 to 6, corresponding to the following sound pressure range:

- High priority: 52 to 72 dB(A) ±5 dB
- Medium priority: 46 to 66 dB(A) ±5 dB
- Low priority: 43 to 63 dB(A) ±5 dB

(Sound pressure level measured at 1m according to IEC 60601-1-8, clause 201.3.3.2)

Power supply

Either by AC line voltages of 200-240 V (±10%) and 100 to 120 V (±10%), 50/60 Hz, or by an external battery 12-24 V

20 VA max. consumption

Internal battery

Lead acid cell, 12 V / 1.8 Ah, rechargeable.

Typical operating time: 1 hour

Complete charging time if empty: 24 hours

Protection

Protection against electrical shock:

- Class I, when connected to AC line voltage 100-120 or 200-240 Vrms
- Internally Powered Equipment, when supplied by the internal battery

Applied part type BF, protected against the effects of defibrillation

Degree of protection against ingress of solids and water: IP21

Electromagnetic compatibility (EMC)

The equipment complies with IEC 60601-1-2 (2001) and the relevant particular standards for emission and immunity, see section 13, Electromagnetic Compatibility Declaration.

External connections

1 x 37 way connector with analog output, RS 423 communication and nurse call

1 x 25 way connector with Centronics parallel interface for printer with IBM Proprinter emulation.

1 x 2 way connector for connecting an external battery (see section A.9)

Equipotential ground

Physical Specifications

Height: 135 mm (5.3’’)

Width: 266 mm (10.5’’)

Depth: 300 mm (11.8'')

Weight: 5.28 kg (11.6 lbs) including gas cylinder

12.2 TOSCA sensor 92

Principle of measurement

Stow-Severinghaus type PCO_2 sensor combined with pulse oximeter sensor.

Application time

The application time of the sensor on the patient depends on sensor temperature. The recommended maximum application time along with the sensor temperature is indicated in the table below:

Age of patient	Sensor core temperature	Corresponding maximum sensor-skin interface temperature	Recommended maximum application time
up to 1 year	42°C	41°C	12 hours
older than 1 year	42°C	41°C	12 hours
	43°C	42°C	8 hours
	44°C	43°C	4 hours

WARNING !

Temperature settings greater than 42 °C (skin interface temperature greater than 41 °C) must not be used on patients less than one year of age.

Sensor temperature

Recommended temperature: 42°C

Selectable between 37°C and 44°C, in steps of 0.5°C

Reliable, safe control by two independent circuits.

Accuracy: ± 0.2°C

Sensor LED characteristics

LED wave lengths: red 658 nm / infrared 880 nm

Maximum LED energy: 50 mW

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

Sensor memory

Built-in memory for storage of: calibration, preparation and test data

Sensor preparation

Remembraning required after two weeks at normal use

Protection

Degree of protection against ingress of solids and water: IP64

Physical specifications

Dimensions: 15 mm (0.6 ") diameter, 8 mm (0.3") high

Cable: 3 m (10 ft) long, highly flexible, shielded and polyurethane coated, latex free

Biocompatibility

TOSCA sensor 92 and accessories are in compliance with the biocompatibility testing recommended in ISO 10993-1, Biological Evaluation of Medical Devices.

12.3 System Performance

$tcPCO_2$

Measurement range: 1 - 200 mmHg (0.1 – 25.0 kPa)

Resolution: 1mmHg (0.1kPa)

Response time (in vitro, 10 – 90 % at 42°C): ≤ 60 sec.

Drift (in vitro): ≤ 0.5 %/h

Linearity (in vitro):

- at 1 % CO_2: better than 1 mmHg
- at 10 % CO_2: better than 1 mmHg
- at 33 % CO_2: better than 3 mmHg
- Calibration interval: recommended: after each patient monitoring session or after max. 12 hours.

Interferences by anesthetic gases (in vitro):
- 75% N_2O: negligible
- 2% Halothane: negligible
- 2% Enflurane: negligible
- 2% Isoflurane: negligible

SpO_2

Measurement range: 0 - 100 %

Resolution: 1%

Accuracy (saturation range 70 – 100%): ± 3 digits

The SpO_2 accuracy is expressed as plus or minus "3" digits (oxygen saturation percentage points) between saturation of 70% and 100%. This variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population [1)]. The accuracy specification is based on tests performed with the TOSCA 500 monitor compared with arterial

blood sample and the reference is measured with a CO-oximeter [2)] on healthy adult volunteers in induced hypoxia studies across the specified range.

1) 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.

2) If there is independent demonstration that a particular calibration curve is accurate for the combination of a pulse oximeter monitor and a pulse oximeter probe, then a functional tester can measure the contribution of a monitor to the total error of a monitor/probe system. The functional tester can then measure how accurate a particular pulse oximeter monitor is reproducing that calibration curve.

Pulse Rate

Measurement range: 25 – 240 bpm

Resolution: 1 bpm

Accuracy: ± 3 bpm

The pulse rate accuracy has been validated in bench testing against a Bio-Tek Index 2 SpO_2 Simulator with a signal strength set to 1%.

SpO_2 and Pulse Rate

Signal averaging over 2, 4, 8, 10, 12, 14 and 16 sec.

Sensitivity: APOD, normal or maximum

Perfusion Index (PI)

Range: 0.02 – 9.99% and 10.0 - 20.0%

Low perfusion accuracy

In low perfusion situations, the SpO_2 and Pulse Rate accuracies mentioned above have been validated in bench testing against a Bio-Tek Index 2 SpO_2 Simulator with a signal strength set to 0.03%.

Heating Power

Resolution: 1mW

Range: 0 – 999 mW

12.4 Environmental conditions

Operating conditions:

Temperature: +10 to +40°C *

Relative humidity: < 90%

Ambient pressure: 525 to 800 mmHg (700 to 1060 hPa)

* The ambient temperature must be at least 3°C leaver than the set sensor temperature.

Transport and storage conditions (in original factory packaging):

REF	Designation	Temperature		Relative humidity	Ambient pressure
		Storage	Transport (2 weeks)	Storage + Transport	Storage + Transport
520 100X	TOSCA 500 Monitor	**- 10 to + 50°C**	**- 10 to + 50°C**	**10 to 95%**	**375 to 800 mmHg (500 to 1060 hPa)**
562 1000	TOSCA Sensor 92				
500 0101	TOSCA-PC Interface Cable				
500 0100	TOSCA-VueLink Adapter Cable				
500 0115	TOSCA-Open End Interface Cable 5V FS				
500 0116	TOSCA-Open End Interface Cable 1V FS				
500 0117	TOSCA-Open End Nurse Call Cable				
560 1010	Cable fixation clip (5 pcs.)				
520 200X	TOSCA 500 complete system	**+ 10 to + 30°C**			
560 1200	Starter Kit TOSCA Sensor				
0640210	CAL-Gas (pack of 6 cyl.)				
560 1100	TOSCA Sensor Preparator Supplies				
560 1300	Attachment Clips (40)				
560 1500	TOSCA Fixation Rings (60)				
560 1110	TOSCA Sensor Electrolyte (1 bottle of 10 ml)				
0603210	Contact Gel (1 bottle of 10 ml)				
0603210.10	Contact Gel (10 bottles of 10 ml)				

13 COMPATIBILITY DECLARATION

WARNING !

The use of accessories, sensors and cables other than those specified, with the exception of sensors and cables sold by the manufacturer of the TOSCA 500 system as replacement parts, may result in increased emissions or decreased immunity of the TOSCA 500 system.

13.1 Electromagnetic emissions

The TOSCA 500 system is intended for use in the electromagnetic environment specified below. The customer or the user of the TOSCA 500 system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The TOSCA 500 system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The TOSCA 500 system is suitable for use in all establishments, including 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	

13.2 Electromagnetic immunity

The TOSCA 500 system is intended for use in the electromagnetic environment specified below. The customer or the user of the TOSCA 500 system should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ± 2 kV common mode	±1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TOSCA 500 system requires continued operation during power mains interruptions, it is recommended that the TOSCA 500 system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note

U_T is the a.c. mains voltage prior to application of the test level.

13.3 Electromagnetic immunity, RF portable equipment

The TOSCA 500 system is intended for use in the electromagnetic environment specified below. The customer or the user of the TOSCA 500 system should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Portable and mobile RF communications equipment should be used no closer to any part of the TOSCA 500 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	**Recommended separation distance** $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 			

NOTE 1

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

NOTE 2

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 TOSCA 500 system is used exceeds the applicable RF compliance level above, the TOSCA 500 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TOSCA 500 system.*

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

13.4 Recommended separation distances

The TOSCA 500 system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the TOSCA 500 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TOSCA 500 system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12 m (0.39 ft)	0.12 m (0.39 ft)	0.23 m (0.75 ft)
0.1	0.38 m (1.25 ft)	0.38 m (1.25 ft)	0.73 m (2.40 ft)
1	1.2 m (3.94 ft)	1.2 m (3.94 ft)	2.3 m (7.55 ft)
10	3.8 m (12.46 ft)	3.8 m (12.46 ft)	7.3 m (23.95 ft)
100	12 m (39.36 ft)	12 m (39.36 ft)	23 m (75.46 ft)
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

NOTE 1

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2

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

13.5 Cables length

WARNINGS !

The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity of the TOSCA 500 monitor.

Cables and sensor	Maximum length	Complies with
TOSCA sensor 92 (part no 562 1000)	3 m (10 ft)	RF emissions, CISPR 11, Class B/Group 1 Harmonic emissions, IEC 61000-3-2 Voltage fluctuations/flicker emission, IEC 61000-3-3 Electrostatic discharge (ESD), IEC 61000-4-2 Electric fast transient/burst, IEC 61000-4-4 Surge, IEC 61000-4-5 Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 Conducted RF IEC 61000-4-6 Radiated RF, IEC 61000-4-3
TOSCA-PC Interface Cable (part no 500 0101)	2 m (6.6 ft)	
TOSCA-VueLink Adapter Cable (part no 500 0100)	0.5 m (1.6 ft)	
PHILIPS-VueLink Interface Cable (25 pin "D" to 10 pin Philips, shielded)	2 m (6.6 ft)	
Printer Cable (25 pin "D" to 36 pin Centronics, shielded)	2 m (6.6 ft)	
TOSCA Open end interface cable 5V FS (part no 500 0115)	2 m (6.6 ft)	
TOSCA Open end interface cable 1V FS (part no 500 0116)	2 m (6.6 ft)	
TOSCA Open end nurse call cable (part no 500 0117)	2 m (6.6 ft)	

14 ACCESSORIES AND ORDERING INFORMATION

Part No.	Description
562 1000	TOSCA Sensor 92
560 1100	TOSCA Preparation Supplies including: – 12 TOSCA Sensor Preparators – 1 TOSCA Sensor Electrolyte (10 ml)
560 1300	Attachment Clips including: – 40 Attachment Clips – 1 Contact Gel (10 ml)
560 1500	TOSCA Fixation Rings 32 mm including: – 1 Dispenser of 60 TOSCA Fixation Rings – 1 Contact Gel (10 ml)
560 1010	Cable fixation clip (pack of 5 pieces)
560 1110	TOSCA Sensor Electrolyte (10 ml)
060 3210	Contact Gel (10 ml)
060 3210.10	Contact Gel (10 x 10ml)
064 0210	CAL-Gas (pack of 6 cylinders)
500 0100	TOSCA-VueLink Adapter Cable
500 0101	TOSCA-PC Interface Cable
500 0115	TOSCA Open End Interface Cable 5V FS
500 0116	TOSCA Open End Interface Cable 1V FS
500 0117	TOSCA Open End Nurse Call Cable

WARNING !

The use of accessories, sensors and cables other than those specified above, with the exception of parts sold by the manufacturer of the TOSCA 500 system as replacement parts for internal components, may result in increased emissions or decreased immunity of the TOSCA 500 system

15 EXTERNAL CONNECTIONS

15.1 Overview

Patient data can be obtained mainly through the serial interface and analog outputs of the "Systems Connector” on the back of the TOSCA 500 monitor by connecting it to a Personal Computer (PC) or a Component Multiparameter System (CMS).

When connecting the TOSCA 500 monitor to a PC or CMS, verify proper operation before clinical use. Both the TOSCA 500 monitor and the PC or CMS must be connected to a grounded AC outlet. The communication protocol setting must be set as described in the section "System Parameter/Configuration”, paragraph "Communication Protocol” of the TOSCA 500 Operating Manual.

Any PC or non-medical device connected to the "Systems Connector” must be certified according to IEC/EN 60950 Standard. All combinations of equipment must be in compliance with IEC/EN 60601-1-1 Standard systems requirements. Anyone who connects a PC or a CMS to the TOSCA 500 "Systems Connector” configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC/EN 60601-1-1 and the electromagnetic compatibility system standard IEC/EN 60601-1-2.

15.2 Connecting to the Systems Connector

The TOSCA 500 "Systems Connector” may be connected to the PC or CMS by using a cable terminated with a shielded DB-37 connector. The cable should be no more than 3 meters in length.

The cable used must have a braided shield providing 100% coverage. The shield must have a 360-degree connection to the metal shell on the DB-37 connector and to the connector on the PC or CMS. Do not create sharp bends in the cable, as this may tear or break the shielding.

See section 15.4 EasyLink, section 15.5 VueLink and section 15.6 Monlink for details.

15.2.1 Systems Connector pinouts

Pin	Signal name	Level
1	Reserved	DO NOT CONNECT
20	GND	0 V
2	TXD Transmit data	Output RS423
21	GND	0 V
3	RXD Receive data	Input RS423
22	GND	0 V
4	RTS Request to send	Input RS423
23	GND	0 V
5	CTS Clear to send	Output RS423
24	GND	0 V
6	Status signal MONITOR ON	Output 5 V = ON, 0 V = OFF
25	GND	0 V
7	Reserved	DO NOT CONNECT
26	GND	0 V
8	Auxiliary supply output voltage	Output 10 to 26 V, max. 200 mA
27	GND	0 V
9	Reserved	DO NOT CONNECT
28	GND	0 V
10	tcPCO2 analog output	Output 0 - 5 V = 0 - 125 mmHg or 0 - 25 kPa
29	GND	0 V
11	SpO2 analog output	Output 0 - 5 V = 0 - 100%
30	GND	0 V
12	Pulse Rate analog output	Output 0 - 5 V = 0 - 250 BPM
31	GND	0 V
13	Pulse wave analog output	Output 0 - 5 V (auto scaled)
32	GND	0 V
14	Reserved	DO NOT CONNECT
33	GND	0 V
15	Reserved	DO NOT CONNECT
34	Reserved	DO NOT CONNECT
16	Reserved	DO NOT CONNECT
35	Not Connected	-
17	Not Connected	-
36	Not Connected	-
18	Nurse Call relay common	Common pin (max. 0.5 A, 30 VDC, 50 VAC)
37	Nurse Call relay normally closed	Shorted to Common if NOT calling
19	Nurse Call relay normally open	Shorted to Common if calling

15.3 Communication protocol

Through the menu Configuration – Communication (see section 7.2.5), the following communication protocols are available on the serial interface:

EASYLINK

Unconditionally real-time data transmission. Memory dump / download functions can be request from the host device (PC or CMS), see section 15.4 for details

VUELINK

Compatible with the Philips VueLink Open Interface, see section 15.5 for details.

MONLINK

Transmission of real-time data on host request see section 15.6 for details

Note

In the messages, Heading and Data lines PCO_2 stays for $tcPCO_2$

15.4 EasyLink

Easy operation

When the EASYLINK communication protocol is set, the TOSCA 500 monitor sends automatically real-time data. The data format used is ASCII CSV (Coma Separated Values) which simplify the treatment of data by the PC or CMS host device.

Easy connection

To connect the PC or CMS to the TOSCA 500 "Systems Connector", you need only a 3 wire shielded cable.

Example of connection to a PC serial COM port:

TOSCA 500 DB-37		PC DB-9
pin 2 (TxD)	----------	pin 2 (RXD)
pin 3 (RxD)	----------	pin 3 (TxD)
pin 20 (GND)	----------	pin 5 (GND)
pin 21 (GND)	--shielding--	pin 5 (GND)

Principle

Real-time data is continuously sent to the serial port. A new line of data is send every second. Column heading line will be send after every 60 data lines, or if one of the values in the column heading changes.

Serial port settings

Baud rate of 19200, 8 bit data, even parity, 1 stop bit, without handshaking.

Memory dump / download

The host device can request a memory dump / download of the last 72H patient data. Also, the results can be downloaded to a printer or to a personal computer (PC). The monitor automatically stores the measured patient data over the last 72 hours according to the FIFO (First In, First Out) principle. Data are stored whenever values are displayed e.g. during patient monitoring. The memory will indicate blank spaces for those time intervals in which no values are displayed e.g. while the sensor is placed in the calibration/ storage chamber or while the monitor is turned off.

Heading and data lines content

Column pos. 1: Date and time		
Heading line:	$<date>, $2006.30.07,	Date of the next data line, format "yyyy.mm.dd”
Data line:	<time>, 11:22:33,	Time of the actual data line, format "hh:mm:ss”
Column pos. 2: PCO2 value		
Heading line:	PCO2[<unit>]<limit>, PCO2[mmHg] 0012:0123, PCO2[kPa_]01.2:12.3,	Indication of the PCO2 unit in "mmHg” or "kPa_” and alarm limits "low:high” valid for the next data lines.
Data line:	<value>, 0123, ---- EEE, 23.4, --.-, EE.E	PCO2 value in "mmHg” out decimal point or in "kPa” with decimal point. Indication of "----" or ”--.-" if no value is available. Indication of “EEE” or “EE.E if the value is out of range.
Column pos. 3: PCO2 alarm status		
Heading line:	PCO2s,	No heading parameter
Data line:	<code>, N, A, S,	Possible codes are: "N” no alarm "A” alarm active "S” alarm muted, reset
Column pos. 4: SPO2 value		
Heading line:	SPO2[%]<limit>, SPO2[%]90:098, SPO2[%]90:---,	Indication of the SPO2 alarm limits "low:high” valid for the next data lines.
Data line:	<value>, 087, ---,	Indication of "---"if no value is available.
Column pos. 5: SPO2 alarm status		
Heading line:	SPO2s,	No heading parameter
Data line:	<code>, N, A, S,	Possible codes are: "N” no alarm "A” alarm active "S” alarm muted, reset

Column pos. 6: PR value		
Heading line:	PR[bpm]<limit>, PR[bpm]050:150,	Indication of the PR alarm limits "low:high” valid for the next data lines.
Data line:	<value>, 087, ---,	Indication of "---"if no value is available.
Column pos. 7: PR alarm status		
Heading line:	PRs,	No heading parameter
Data line:	<code>, N, A, S,	Possible codes are: "N” no alarm "A” alarm active "S” alarm muted, reset
Column pos. 8: HPWR value		
Heading line:	HPWR[mW]<HPWRref>, HPWR[mW]256,	Indication of the <HPWRref> (relative heating power reference) valid for the next data lines.
Data line:	<value>, 252, ---,	Indication of "---"if no value is available.
Column pos. 9: Perfusion Index (PI)		
Heading line:	Perf.Index[%],	No heading parameter
Data line:	<value>, 12.3,	Indication of "--.-"if no value is available.
Column pos. 10: Sensor temperature		
Heading line:	Temp[C]<set>, Temp[C]42.0,	Indication of the temperature set valid for the next data lines.
Data line:	<value>, 41.9,	Indication of "--.-"if no value is available.
Column pos. 11: Site timer		
Heading line:	Timer,	No heading parameter
Data line:	<timer>, 02:15,	Site time left of the actual data line, format "hh:mm”
Column pos. 12: Mode		
Heading line:	Mode,	No heading parameter
Data line:	<mode>, C, R, P, M,	Possible modes are: "C” calibrating "R” ready to use "P” pre-measurement "M” measurement "?” other (connect sensor, monitor fault etc.)

Column pos. 13: General status		
Heading line:	Status<CR><LF> Status	No heading parameter This is the last column of the heading line, ending with "CR LF” (0x0D 0x0A) bytes.
Data line:	<code><CR><LF> N A S U	Possible codes are: "N” no alarm "A” at least one alarm active "S” at least one alarm muted "U” alarm suspended or inhibit This is the last column of the data line, ending with "CR LF” (0x0D 0x0A) bytes.

Bytes per line: heading line = 133 bytes, data line = 53 bytes

Column heading line example:

"$2006.07.31,PCO2[kPa]_01.2:12.3,PCO2s,SPO2[%]88:100,SPO2s,PR[bpm]050:150,PRs, HPWR[mW]541,Perf.Index[%],Temp[°C]44.0,Timer,Mode,Status”

Data line example:

"11:22:33,12.3,N,100,N,245,N,999,12.3,44.3,12:34,M,A”

15.5 VueLink

As part of a Philips Patient Monitoring Systems (Philips V24/26, Philips CMS and Philips IntelliVue, here after called "Philips Monitor"), the TOSCA 500 monitor is compatible with the following VueLink Open Interface module:

Module type

Philips VueLink module M1032A #A05 #K6B (type B, Auxiliary-plus, with Open Interface cable).

Ordering information:

M1032A #A05 VueLink Open Interface Module (type B, auxiliary-plus)

M1032A #K6B VueLink Open Interface Cable, 2m, Standard 25 pin male connector

Connection

Connect the VueLink module to the TOSCA 500 Systems Connector with the VueLink Open Interface cable (available from Philips) and the TOSCA VueLink adapter cable (Linde part No 500 0100).

Operation

When the VueLink protocol is selected (see section 7.2.5), the VueLink module plugged in to the Philips Monitor Module device will automatically recognize the TOSCA 500 monitor and will appear as "TOSCA” on the VueLink module setup menu.

See section "VueLink” of the Philips Monitor documentation for setting and configuration of the VueLink module.

Available data

The following real-time data are available on the Philips Monitor through the VueLink Interface:

Numeric values and settings

Philips Monitor-label	Description
"tcpCO_2"	tcPCO_2 with alarm status
"SpO_2"	SpO_2 with alarm status
"PR"	PR with alarm status
"HPwr"	absolute HPWR
"PERF"	Perfusion Index (PI)
"sOxiIv"	Pulse averaging time (oximeter averaging interval)
"Temp"	Sensor temperature
"TemSet"	Sensor temperature set
"Timer"	Site time remaining (format "hh.mm")
"TimSet"	Site time set (format "hh.mm")
"Barom"	Barometric pressure
"Bmode"	Barometric pressure mode

Wave forms

Philips Monitor-label	aligned value	description
"tcpCO_2"	"tcpCO_2"	tcPCO_2 analog value
"SpO_2"	"SpO_2"	SpO_2 analog value
"PR"	"PR"	PR analog value
"PLETH"	"PERF"	Pulse wave analog value

15.5.1 Messages

Alarm messages

Philips Monitor alarm	corresponding text in section 8
"TOSCA SPO2 LOW"	"SpO_2 too low" (highest priority)
"TOSCA PCO2 HIGH"	"PCO_2 too high"
"TOSCA PCO2 LOW"	"PCO_2 too low"
"TOSCA SPO2 HIGH"	"SpO_2 too high"
"TOSCA PR HIGH"	"PR too high"
"TOSCA PR LOW"	"PR to low" (lowest priority)

Note

The following alarm philosophy is used on the Philips Monitor with the TOSCA 500 VueLink Module:

- *The alarm messages described above are "yellow" priority alarms.*
- *The alarm signals are indicated on the display of the Philips Monitor by an alarm message on the center of the upper line and by the blinking of the related measured value, if displayed.*
- *The alarm signals disappear on the Philips Monitor if the related auditory alarm signals on the TOSCA 500 monitor are muted.*
- *Only one of the alarm messages described above is displayed at time. If more than one alarm condition is present, only the alarm message with the highest priority is displayed.*

INOP messages

Philips Monitor INOP	corresponding text in 7
"TOSCA MONIT. FAULT"	"Monitor fault" (highest priority)
"TOSCA SENSOR FAULT"	"Sensor fault"
"CONNECT TOSCA SENS"	"Connect sensor" or "Unknown sensor" or "Update software"
"TOSCA SENSOR OFF"	"Sensor off patient"
"TOSCA AMBI. LIGHT"	"Too much ambient light"
"TOSCA INTERFERENCE"	"Interference"
"TOSCA PULSE SEARCH"	"Searching pulse signal"
"TOSCA TIME ELAPSED"	"Site time elapsed"
"TOSCA BATTERY LOW"	"Battery is low"
"CAL. TOSCA SENSOR"	"Calibrate sensor" or "Place sensor in cal. chamber"
"REMEMBRANE TOSCA S"	"Remembrane sensor"
"TOSCA NO CAL GAS"	"No gas flow, renew gas bottle" (lowest priority)

Note

The following INOP philosophy is used on the Philips Monitor with the VueLink Module:

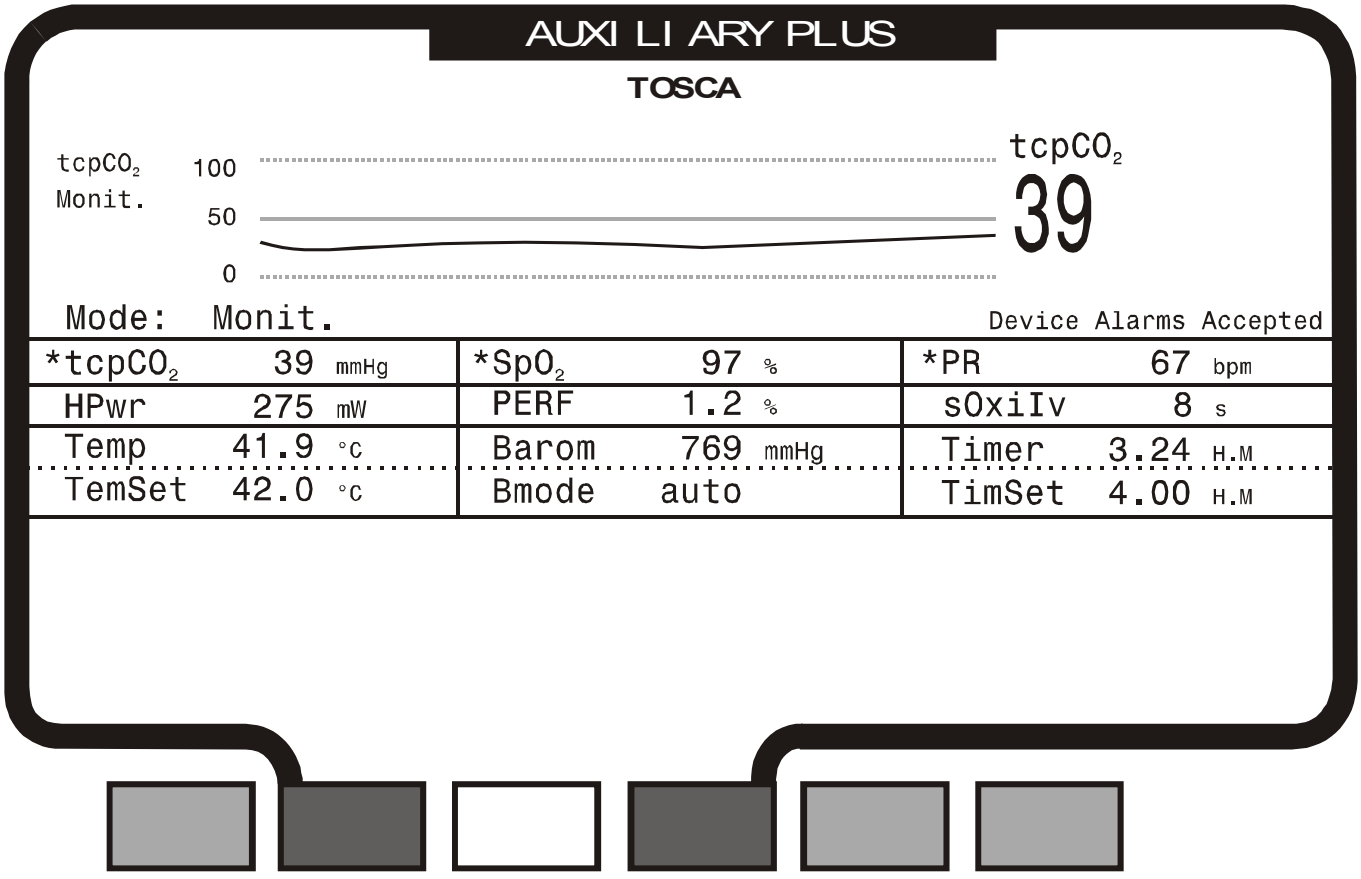
- *An INOP message is indicated on the left of the upper line on the Philips Monitor display as long as the related visual message is displayed on the TOSCA 500 monitor.*
- *Only one of the INOP messages described above is displayed at time. If more than one INOP condition is present, only the INOP message with the highest priority is displayed.*

Auditory alarms

The above described VueLink messages do not generate auditory signals on the Philips Monitor.

Philips Monitor mode	corresponding mode
"Calibr"	Calibrating sensor
"Ready"	Ready to use
"Applic"	Sensor application, monitoring not started
"Monit."	Monitoring in progress

15.5.2 VueLink Task Window example



15.6 MonLink

TOSCA 500 Transmission of real-time data on host request

15.6.1 Serial port configuration

Baud rate = 9,6 kBd, ASCII 7 bit, Parity even, 1 Stop bit, Pins 2, 3, 4, 5

15.6.2 Communication protocol

The monitor is always assumed to be "slave" in the sense that it cannot transmit information unless it has been requested to do so. The messages are always transmitted in "ASCII".

To initiate a communication the requesting device pulls RTS true and waits until the monitor replies with CTS true. Transmission can then proceed.

There are three different request codes possible which TOSCA 500 can understand. The format of these codes and the corresponding replies are described below.

Request code no. 1 status: "Monitor status record"

Request format:

```
CRLF01$
```

Reply format:

```
CRLFrrn1n2
          A C
          F U
CRLF[00_> N O _ND]
          S _
CRLF$
```

Example:

```
0000
[00 >N ND]
$
```

Request code no. 2 values: "Value and status record"

Request format:

```
CRLF02$
```

Reply format:

```
CRLFrrn1n2                      EE.EkPa
                          A     EEEmmHg
                          F     10.4kPa    A
CRLF00[PCO2(tc43.0)_>2    N _PCO2=078mmHg _> N ]
                          S                S
               A
               F                    A
CRLF00[SPO2_>3 N _SPO2=078PERCNT_> N ]
               S                    S
```

```
             A
             F                A
CRLF00[PR_>4 N _PR=088BPM_> N ]
             S                S
               A
               F
CRLF00[HPWR_>5 N _HPWR=0589mW_> N ]
               S                 S
CRLF$
```

Example:

```
0000
00[PCO2(tc43.0) >2N PCO2=048mmHg >N]
00[SPO2 >3N SPO2=076PERCNT >N]
00[PR >4A PR=128BPM >N]
00[HPWR >5N HPWR=1000mW >N]
$
```

Request code no. 3 limits: "Range and limits record"

Request format:

```
CRLF03$
```

Reply format:

```
CRLFrrn1n2
               A
               F           kPa         6.7:13.3kPa
CRLF00[PCO2_>2 N _(0:125 mmHg_5)_PCO2(50:100mmHg)]
               S
               A
               F
CRLF00[SPO2_>3 N_(0:100PERCNT_5)_SPO2(95:---PERCNT)]
               S
             A
             F
CRLF00[PR_>4 N_(0:250BMP_5)_PR(60:180BPM)]
             S
               A
               F
CRLF00[HPWR_>5 N_(0:1000mW_5)_REFHPWR(500mW)]
               S
CRLF$
```

Example:

```
0000
00[PCO2 >2N (0:125mmHg_5) PCO2(50:100mmHg)]
00[SPO2 >3N (0:100PERCNT_5) SPO2(95:---PERCNT)]
00[PR >4A (0:250BMP_5) PR(60:180BPM)]
00[HPWR >5N (0:1000mW_5) REFHPWR(500mW)]
$
```

15.6.3 Legend of codes

CR	Carriage Return code (0x0D)
LF	Line Feed code (0x0A)
_	Space code (0x20)
rr	00 = Request message ok 01 = Request code not recognized 02 = Invalid specifier in request message 03 = Request message corrupt
n1n2	configuration code number of monitor between 00 and 99
00	Slot number (always 0)
PO2	Parameter 1 name
PCO2	Parameter 2 name
SPO2	Parameter 3 name
PR	Parameter 4 name
HPWR	Parameter 5 name
REFHPWR	Reference value for relative HPWR
(tc44.0)	Sensor temperature set
1	PO2 is waveform 1
2	PCO2 is waveform 2
3	SPO2 is waveform 3
4	PR is waveform 4
5	HPWR is waveform 5
A	some parameter is in alarm / high priority alarm
C	parameter in alarm and silenced
O	auditory alarms have been switched off / inhibited
U	auditory alarms have been suspended
N	normal operation
S	Standby and Calibration
F	Fault / medium and low priority alarm
ND	Normal Direct (real time data)
PCO2=078 mmHg/kPa	PCO2 measurement value in mmHg or kPa
PCO2(50:100 mmHg/kPa)	PCO2 low and high alarm limits
(0:1000mW 5)	analog output range, 0 to 1000 mW = 0 to 5V
$	End of message

15.7 Analog outputs

PCO_2 analog output on pin 10:

0 to 5 V = 0 to 125 mmHg (40mV / mmHg) or 0 to 25 kPa (20 mV / 0.1 kPa)

SPO_2 analog output on pin 11:

0 to 5 V = 0 to 100% (50 mV / %SPO2)

Pulse Rate analog output on pin 12:

0 to 5 V = 0 to 250 BPM (20 mV / BPM)

Pulse Wave analog output on pin 13:

0 to 5 V auto scaled

15.7.1 Calibration of an analog recording system

The analog output signals can be used for the calibration of any analog recording system (e.g. polysomnograph in sleep labs).The analog outputs on the System Connector are set to full scale of 5V (+/- 15mV) during the system check.

To perform a system check: Press both [−] and [+] when no parameter setting is in progress (see section 10.2).

The analog outputs are set to “zero” when the connected sensor is placed into the calibration chamber (no PCO_2 value is displayed.)

15.8 Nurse call

The nurse call feature is activated if any of the following conditions are true:

- One or more alarms are active and not muted.
- The auditory alarm is not suspended.
- The auditory alarm is not inhibited.

Relais:

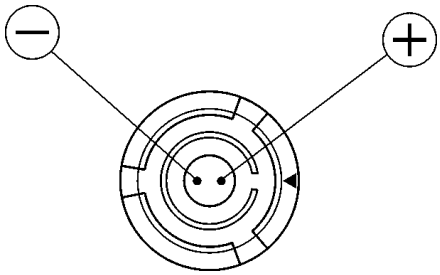
Shorts pin 19 to pin 18 (common) if calling

Shorts pin 37 to pin 18 if not calling

15.9 Connection to external battery

Connector type: Redel SA. Type PAG-M02 GLAC GSG

Polarity:



WARNING

If the external battery is connected to a battery recharging device, this device must be medical grade (double isolation).