Integra®

Licox® PtO_2 Monitor

USER'S MANUAL

Oxygen Partial Pressure and Temperature Monitor for Neurosurgical Applications

REF LCX02

INTEGRA®

Caution

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

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Integra® Licox® PtO2 Monitor User's Manual for Neurosurgical Applications

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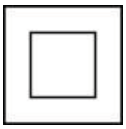
LIST OF SYMBOLS AND ABBREVIATIONS

Packaging and Label Symbols

Symbol	Definition	Symbol	Definition
	Follow instructions for use		Defibrillation-proof type CF applied part
	Caution		Direct current
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.		Class II equipment
SN	Serial number		Waste Electronics and Electrical Equipment
LOT	Batch code		USB connection
	Manufacturer		Safety information for transporting lithium ion batteries.
	Date of manufacture		Due date for annual maintenance
REF	Catalogue number		

Software Symbols

Symbol	Description		Symbol	Definition
	Active alarm			AC power not being used/available
	Audio paused			Battery charge indicator
	Inactive alarm			No battery connected or faulty battery
	Low PtO2 alarm limit			Battery being charged
	AC power being used			System information panel
	On/Off power			

List of Abbreviations

Abbreviation	Definition
µl	Microliters
ABP	Arterial Blood Pressure
AC	Alternating Current
ºC	Degrees Celsius
CPP	Cerebral Perfusion Pressure
CSV	Comma-separated values
CT	Computer tomography
dB	Decibels
DC	Direct Current
DMM	Digital Multimeter
EtO	Ethylene oxide
ºF	Degrees Fahrenheit
hPa	Hectopascal pressure unit
IFU	Instructions for use
IPA	Isopropyl alcohol
I.V.	Intravenous
LED	Light Emmitting Diode
mm	Millimeters
mmHg	Millimeters of mercury
MR	Magnetic resonance
OR	Operating Room
PMIO	Patient Monitor Input Output
PtO_2	Partial pressure of oxygen in tissue
TBI	Traumatic Brain Injury
USB	Universal Serial Bus
V	Volt
W	Watt

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CHAPTER 1 SYSTEM OVERVIEW

Indications for Use / Intended Use

The Integra® Licox® PtO2 Monitor measures oxygen partial pressure (PtO2) and temperature in brain tissue and these parameters are used together as an aid in the determination of the perfusion status of cerebral tissue local to sensor placement. Monitor values are relative within an individual, and should not be used as the sole basis for determining a diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

Contraindications

The Integra Licox PtO2 Monitor and its accessories are contraindicated for use in a Magnetic Resonance (MR) environment.

Intended User

The Integra Licox PtO2 Monitor is intended to be used by the following qualified medical and biomedical professionals:

- A qualified neurosurgeon should perform the placement and handling of the probes.
- Designated qualified hospital staff (i.e. neurosurgeon, nurse, intensivist, trauma physician, or physician's assistant) should perform the operation of the monitor.

Chapter 10 provides instructions for testing and maintaining the monitor. The procedures in Chapter 10 are intended to be performed by the hospital's biomedical engineering staff.

Intended Patient Population

Patients undergoing treatment with this monitor under the cranial applications are expected to have had a traumatic brain injury, undergone a major neurosurgical procedure, or some other traumatic, ischemic or hemorrhagic incident requiring controlled monitoring of PtO2.

Description of the Integra Licox PtO2 Monitor

The Integra Licox PtO2 Monitor provides functionality for continuously monitoring oxygen partial pressure (PtO2) in brain tissue. Tissue temperature compensation, which is required for the calculation of PtO2 measurements, may also be continuously measured with an accuracy of ± 1°C. To measure PtO2 and temperature tissue compensation continuously, the Integra Licox PtO2 Monitor supports a series of minimally invasive probes that are inserted directly into the patient:

- The PtO2 probe uses an electrochemical (polarographic) micro-cell for oxygen measurements.
- The temperature probe uses a thermocouple (type K) for temperature measurements.

In place of a temperature probe, the monitor also provides an option for entering tissue temperature compensation values manually for the calculation of PtO2 measurements.

PtO2 Probe's Calibration Data Stored on Smart Card

Each Integra PtO2 probe includes a designated Smart Card that contains calibration data.

Warning

Only use the designated Smart Card supplied with the PtO2 probe. Using the wrong Smart Card will produce incorrect PtO2 measurements.

Key Functions of Monitor

During clinical use, the Integra Licox PtO2 Monitor provides several key functions to facilitate the process for monitoring and analyzing patient data:

- Touch screen interface for evaluating patient data and setting patient parameters (see page 53)
- Physiological alarm that activates if the patient's PtO2 value falls below a user-specified limit for more than 5 seconds (see page 55)
- Rechargeable lithium ion battery that supplies power to monitor during patient transport (see page 29)
- Storage of patient's trend data for up to 5 days (see page 58)
- Outputs for transferring patient data to a patient bedside monitor (see page 48)

- Outputs for extracting patient data to remote media types via USB drive or digital streaming (see page 75).

For instructions on using the Integra probes that work with the Integra Licox PtO2 Monitor, see the instructions for use supplied with each respective probe.

Reviewing the User's Manual

Integra recommends that all physicians, nurses, and technicians who will be using, operating, and maintaining the Integra Licox PtO2 Monitor review this user's manual prior to using the system. If there are additional questions after reading this manual, contact Integra.

List of Warnings for Using the Monitor

Failure to observe one or more of the following warnings could compromise patient safety or result in measurement errors.

Warnings

- Use of the Integra Licox PtO2 Monitor is restricted to one patient at a time.
- The Integra Licox PtO2 Monitor and its accessories are contraindicated for use in a Magnetic Resonance (MR) environment.
- This equipment is not a bloodgas device.
- Always verify the low PtO2 alarm limit is set appropriately for each patient prior to treatment.
- Selecting the **Alarm Off** feature on the **Alarm** panel will disable the low PtO2 alarm limit indefinitely. Use caution if this feature is selected. To re-enable this alarm, select the **Alarm On** and **Accept** buttons.
- No modification of the Integra Licox PtO2 Monitor is allowed.
- Only use the designated Smart Card supplied with the PtO2 probe. Using the wrong Smart Card will produce incorrect PtO2 measurements.
- The Integra Licox PtO2 Monitor is a sensitive electronic device. When using the monitor, always handle with care. If damage is suspected, contact Integra.
- The calculations for PtO2 measurements require tissue temperature compensation. If you are not measuring the tissue temperature with a probe, the temperature has to be entered manually. Make sure to measure the patient's tissue temperature either hourly or prior to recording the PtO2 values for intervention. If any changes in temperature occur, use the **Manual Temperature Input** arrows to specify the new temperature value accordingly.
- Read the user's manual from the patient bedside monitor's manufacturer before connecting the Integra Licox PtO2 Monitor to a patient bedside monitor.
- To prevent injury to the patient, user, or other persons, or to prevent damage to the monitor, always verify that the monitor is clamped securely to the equipment pole.

Warnings

- To prevent injury to the patient, user, or other persons, or to prevent damage to the monitor, make sure to position the cables so that they are free from all foot traffic.
- To reduce the risk of electric shock, do not disassemble the Integra Licox PtO2 Monitor. Refer all servicing to qualified service personnel at Integra.
- To prevent electrical shock, only use the AC power adapter supplied by Integra (REF # MONPWR). Using a different AC power adapter may not provide protection against electric shock.
- Danger - Possible explosion hazard if used in the presence of flammable anaesthetics.
- Halothane interferes with polarographic PtO2 probe measurements. It causes an overestimation, which is usually reversible within 20 minutes after discontinuation. Other commonly used anesthetic gases (e.g. N2O, Enflurane or Isoflurane) are not known to interfere with polarographic PtO2 probe measurements.
- Temperature measurements may be inaccurate if the connector of the temperature sensing probe is subjected to considerable changes in ambient temperature or if the ambient temperature of the Integra Licox PtO2 Monitor lies outside the defined range of 15°C to 30°C.
- If an alarm is triggered for an overheating monitor while a Licox temperature probe is being used, the excessive heat from inside the monitor may affect the monitor's temperature measurements. If this condition occurs, the calculations for the PtO2 measurements - which require temperature compensation values - may be unreliable until the overheating monitor condition has been resolved.
- Only use Integra supplied accessories on the Integra Licox PtO2 Monitor. This applies in particular to probes, probe cables, battery, AC power adapter, and USB-to-RS232 adapter cable.
- If the Integra Licox PtO2 Monitor loses power and shuts down while it is connected to a patient bedside monitor, do not use the PtO2 values on the patient bedside monitor for patient measurements; the PtO2 values on the patient bedside monitor will be invalid.
- Connect the monitor to an AC power supply immediately if the low battery alarm is activated.
- When using the battery:
  - Do not heat above 80°C.
  - Do not open battery.
  - Do not dispose of in fire.
  - Do not short circuit as battery may ignite, explode, leak, or get hot causing personal injury.
  - Replace battery with same part number only (REF # BAT1001).
  - Use of another battery may present a risk of fire or explosion.
- To prevent injury to the patient, user, or other persons, make sure that the battery cover is closed securely during monitor use.

Warnings

- The Integra Licox PtO2 Monitor will only store the PtO2 data from the most recent 5 days. All stored trend data older than 5 days will be lost. If monitoring is continued for more than 5 days, placement of a new PtO2 probe and Smart Card under sterile conditions is recommended. Note that replacing a probe and Smart Card with a new probe and Smart Card will reset the trend data. Please extract any data that you wish to retain prior to replacing the probe and Smart Card.
- Do not autoclave or immerse the Integra Licox PtO2 Monitor in liquid as damage may occur. If the monitor is exposed to liquids, turn off the unit, remove the AC power adapter, remove the battery, dry the unit thoroughly, and send to biomed staff for evaluation before reapplying power.
- Only use the cleaning agents listed in Chapter 8 for cleaning and disinfecting the Integra Licox PtO2 Monitor system. Using solvents or cleaning agents not listed in Chapter 8 may damage the plastic exterior of the Integra Licox PtO2 Monitor.

Risks to Patients

General Risks to Patients

Integra Licox products are intended for use by qualified physicians or surgeons only. They must ensure sterile technique and general surgical precautions when penetrating human tissue. Contraindications for needle insertion into the body also apply, e.g. coagulopathy and/or susceptibility to infections or infected tissue. A platelet count of less than 50,000 per µL is considered a contraindication. This value may differ according to different hospital protocols.

Special Coagulation Problems

To avoid hemorrhage-related complications, blood coagulation must be carefully monitored when measuring in the tissue during hypothermia. This also applies to patients in hepatic coma or other conditions which could impair coagulation or those patients who receive any substances that interfere with blood hemostasis.

Risk of Invasive Monitoring

There is a general risk of infection with the use of introducer systems and probes. The risk for infection increases after a certain period of time, depending on the application. Please refer to the corresponding probe's Instructions for Use (IFU).

Risks of Artifacts

Note the following warnings:

Halothane

Warning

Halothane interferes with polarographic PtO2 probe measurements. It causes an overestimation, which is usually reversible within 20 minutes after discontinuation. Other commonly used anesthetic gases (e.g. N2O, Enflurane, or Isoflurane) are not known to interfere with polarographic PtO2 probe measurements.

Temperature Gradient

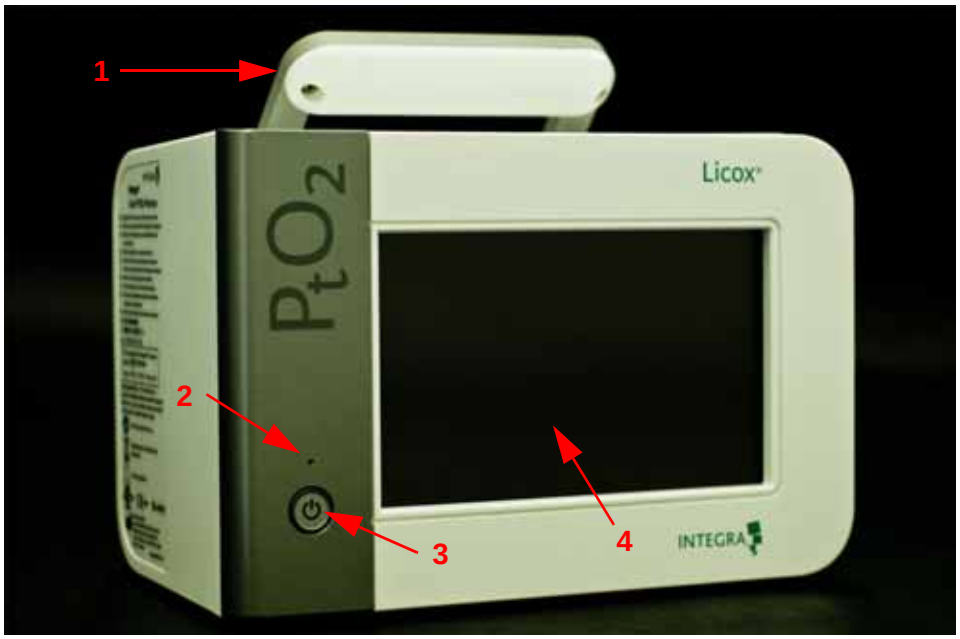
Warning

Temperature measurements may be inaccurate if the connector of the temperature sensing probe is subjected to considerable changes in ambient temperature or if the ambient temperature of the Integra Licox PtO2 Monitor lies outside the defined range of 15°C to 30°C.

Parts of the Monitor

The Integra Licox PtO2 Monitor contains hardware, software, and electrical components that support specific Integra probes for monitoring the patient's PtO2 and temperature values. The following section provides information on the different parts of the monitor.

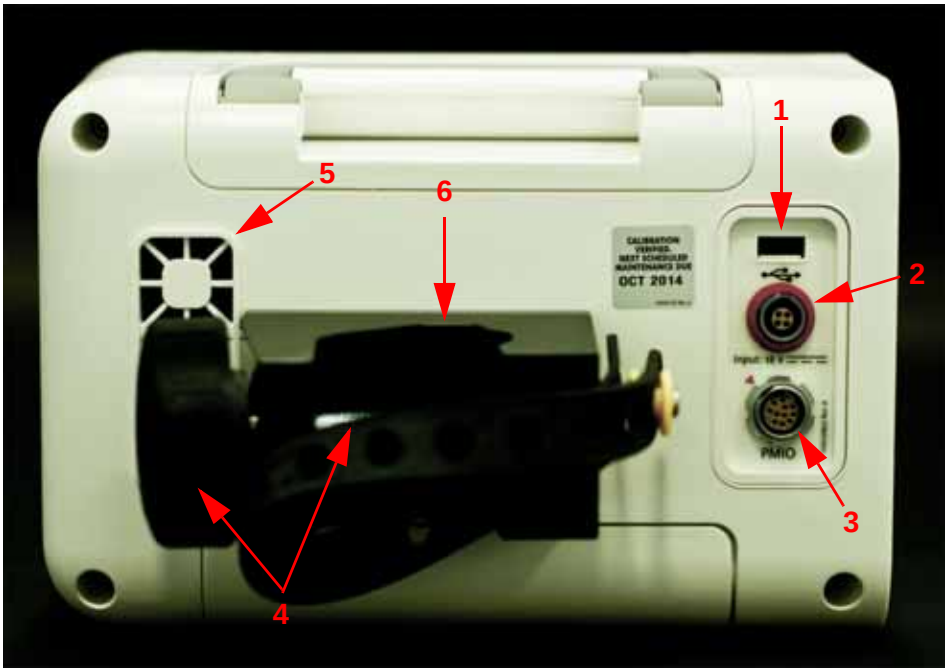
About the Front Panel



The front panel contains:

Number	Item	Description
1	Handle	Handle used for carrying the monitor.
2	AC Power Indicator	Green LED that indicates the monitor is being powered by the AC power adapter. Note that this button does not illuminate if the monitor is being powered by the battery.
3	Power Button	Turns the monitor on and off. Note that this button will illuminate if the monitor is turned on.
4	Touch Screen	Provides software tools for viewing data and controlling parameters for monitoring the patient's PtO2 and tissue temperature levels.

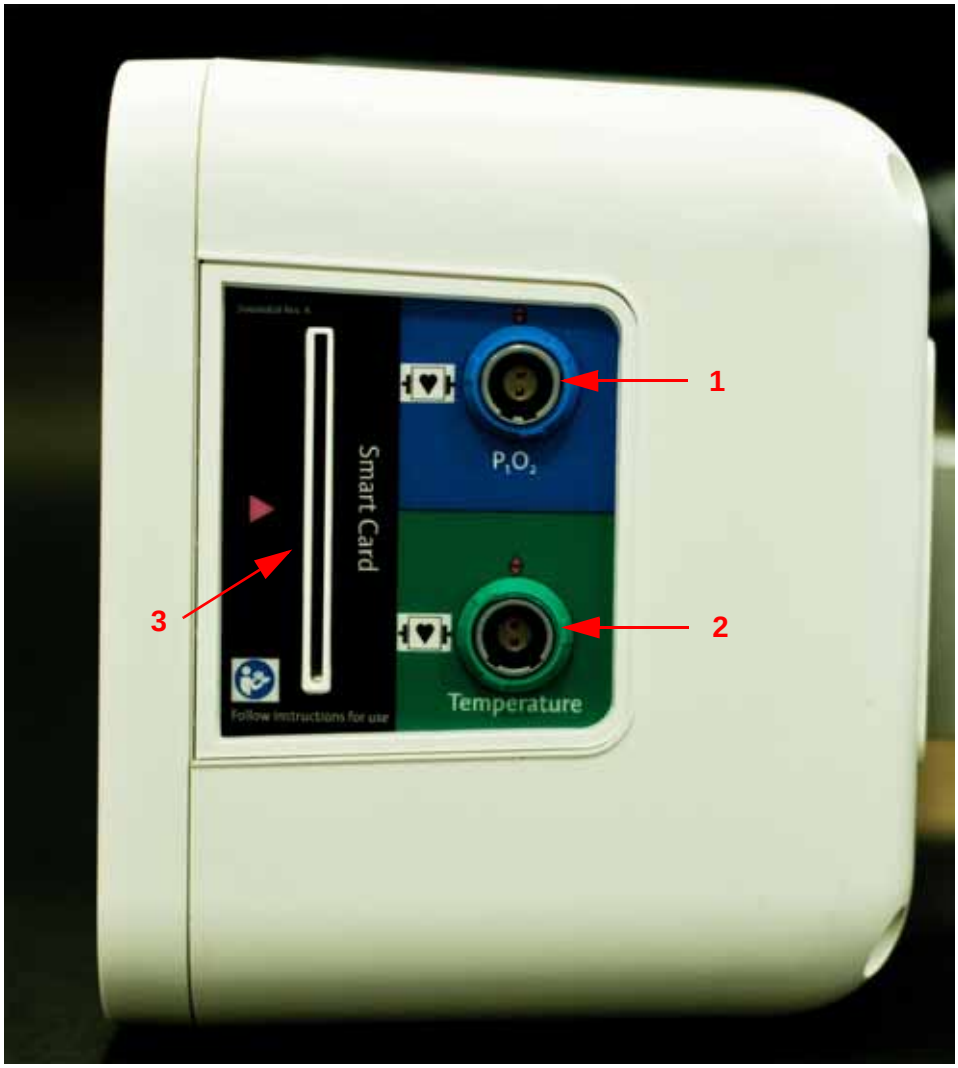
About the Rear Panel



The rear panel contains:

Number	Item	Description
1	USB Port	Connection port for extracting trend data via USB transfer or digital streaming.
2	AC Power Adapter Port	Connection port for the AC power cord.
3	PMIO Port	Connection port for PMIO cable. This cable is used to connect the Integra Licox PtO2 Monitor to a patient monitor.
4	Pole Clamp	Clamping system for securing monitor to an equipment pole.
5	Air Vent	Grated opening that allows air being circulated by the internal cooling fan to leave the monitor.
6	Cable Strap	Rubber strap used to secure AC power adapter and other cables during transport.

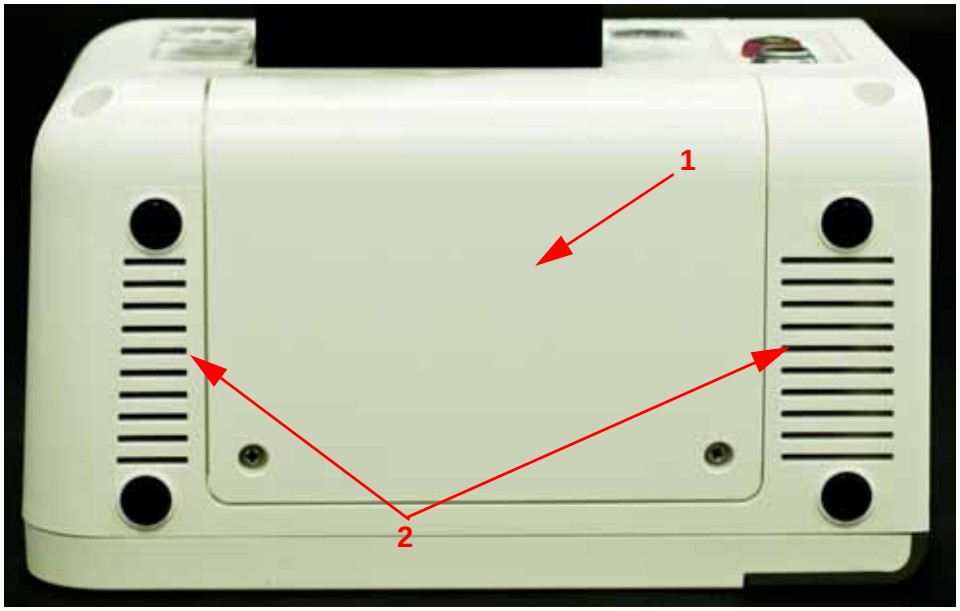
About the Right Panel



The right panel contains:

Number	Item	Description
1	PtO2 Port	Connection port for the PtO2 probe.
2	Temperature Port	Connection port for the temperature probe.
3	Smart Card Slot	Slot for inserting the designated Smart Card for the PtO2 probe.

About the Bottom Panel

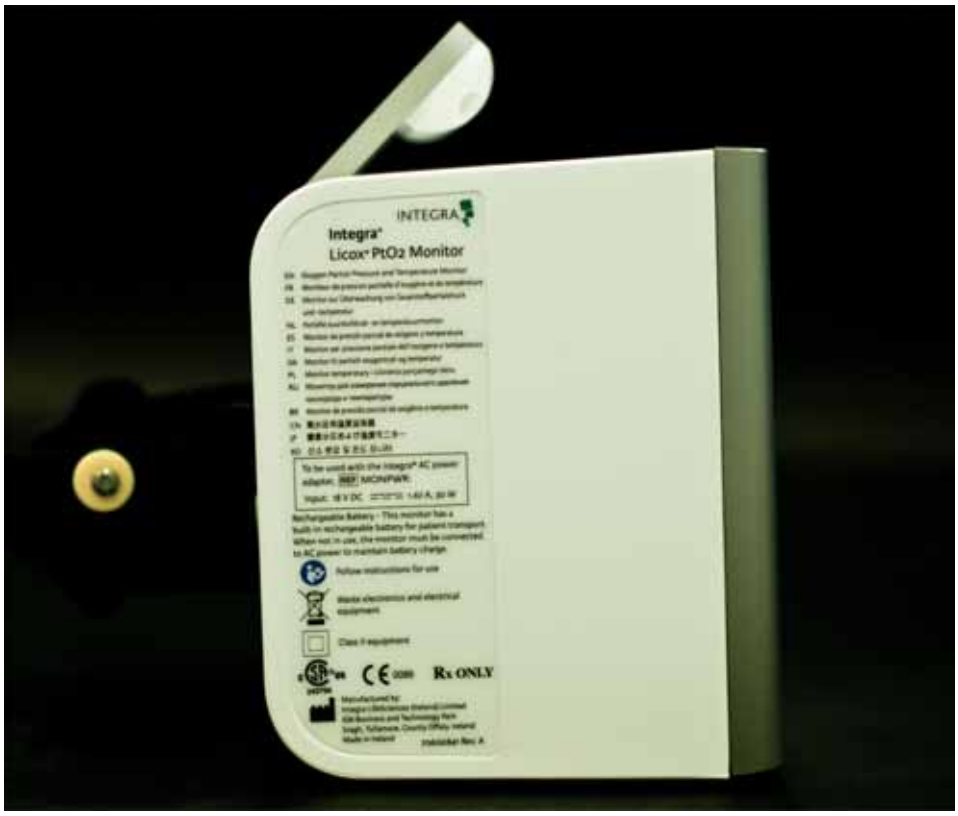


The bottom panel contains:

Number	Item	Description
1	Battery Cover	Removable cover for accessing/replacing the 14.4 V lithium battery.
2	Air Vent	Grated opening that allows air intake for internal cooling fan.

About the Left Panel

The left panel does not contain any usable connector ports or buttons.



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CHAPTER 2 SETTING UP SYSTEM FOR THE FIRST TIME

Procedures for Initial Setup

Step 1: Unpack the System (REF # LCX02)

Remove the contents from the Integra® Licox® PtO2 Monitor shipping box and verify the following items are included:

Warning

Only use Integra supplied accessories on the Integra Licox PtO2 Monitor. This applies in particular to probes, probe cables, battery, AC power adapter, and USB-to-RS232 adapter cable.

Content	Description
	• Integra Licox PtO2 Monitor • Quantity = 1
	• AC power adapter (18 V DC ⎓, 1.67 A, 30 W) • REF # MONPWR • Quantity = 1
	• 14.4 V lithium ion battery • REF # BAT1001 • Quantity = 1

Content	Description
	• Integra® PMIO patient bedside monitor cable • REF # PMIOMPM • Quantity = 1
	• USB-to-RS232 adapter cable • REF # EXPORTCAB • Quantity = 1
	• Test Set (test Smart Card, test probe) • REF # BC10R • Quantity = 1
• User manual • REF # UM-LCX02*XX* (where *XX* refers to the country's language code) • Quantity = 1	

List of Probe Cables

The kit also includes the following probe cables included in the Probe Cable Kit (BC10).

Measurements	Content	Item
PtO2 Only		• Blue PtO2 probe cable; length 2.3 m • REF # BC10PA • Quantity = 1 • For use with single PtO2 probes.
		• Blue PtO2 probe extension cable; length 1.6 m • REF # BC10PV • Quantity = 1 • For use with single PtO2 probes.
Temperature Only		• Green temperature probe cable; length 2.3 m • REF # BC10TA • Quantity = 1 • For use with single temperature probes.
		• Green temperature probe extension cable ; length 1.6 m • REF # BC10TV • Quantity = 1 • For use with single temperature probes.

Measurements	Content	Item
Combined PtO2 and Temperature		• Blue combined PtO2/temperature probe cable, length 2.2 m • REF # PMOCAB • Quantity = 1 • For use with combined PtO2/temperature probes.
		• Y-adapter cable for blue combined PtO2/temperature probe cable; length 0.3 m • REF # BC10PMO • Quantity = 1 • For use with combined PtO2 temperature probes.

After unpacking the contents, inspect the shipment for any signs of damage or loss. If any damages are discovered, notify the carrier, the supplier, and retain all shipping cartons for examination.

Step 2: Install the Battery

Perform the following steps with a Phillips screwdriver and the Integra-supplied 14.4 V lithium ion battery.

1. Make sure the monitor is unplugged and turned off.
2. Turn the monitor upside down so the handle is facing downward.
3. Remove the two screws to take off the battery cover.

4. Verify the Integra logo on the battery is facing up and insert the battery:

   A. Align the battery's connector on the front of the battery to the connector slots on the monitor.

   B. Slide the battery's connector into the monitor's connector slots until the battery is fully inserted into place.

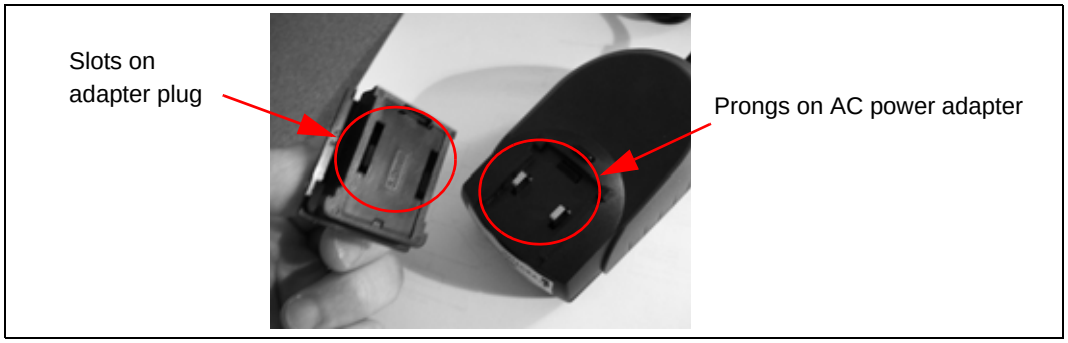
5. Secure the battery cover to the monitor by re-inserting the two small screws.

Step 3: Prepare the AC Power Adapter with Region-Specific Plug

1. Remove the AC power adapter from the package and attach the region-specific adapter plug to the backside of the AC power adapter.

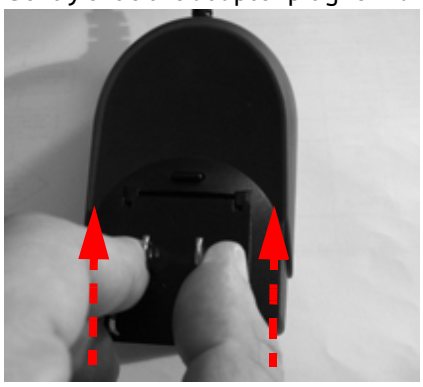
Backside of AC power adapter

A. Align the two slots on the adapter plug over the two prongs on the AC power adapter.

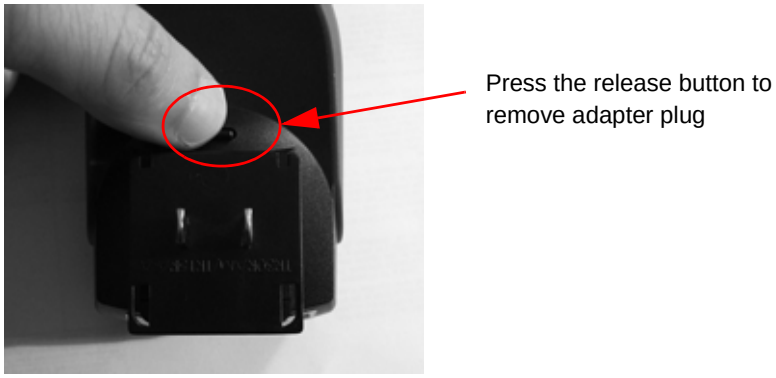


B. Push the adapter plug down over the two prongs until the entire base of the plug sits flush against the AC power adapter.

C. Gently slide the adapter plug forward until it snaps into place.



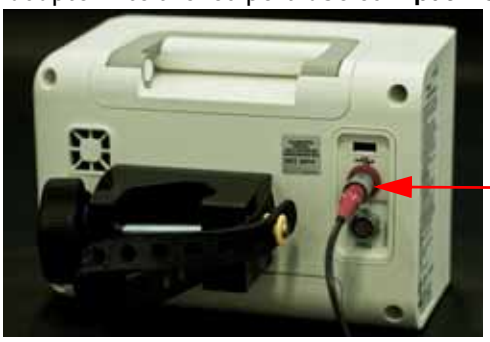
2. To remove the adapter plug, press the release button on the AC power adapter and pull the plug away from the adapter.



Step 4: Plug the Monitor to AC Power

Perform the following steps with the Integra-supplied AC power adapter:

1. Place the monitor on a flat surface.
2. Connect the AC power adapter to the Integra Licox PtO2 Monitor:
   A. On the back of the monitor, attach the red connector end of the AC power adapter into the red port labeled **Input: 18 V** ⎓ .



   B. Insert the plug end of the AC power adapter into an AC wall outlet.
3. Turn on the monitor. On the front of the monitor, press the power button; the Integra Licox PtO2 Monitor will display the Integra logo before initiating the monitor startup process.
4. After the initial setup process completes, the Integra Licox PtO2 Monitor sounds a one-second startup tone and displays the **Main** panel on the touch screen.

Caution

The purpose of the startup tone verifies that the audio alarms are functioning correctly. If this tone does not sound during the startup process, contact Integra for service.

Step 5: Set the Time and Date

The Integra Licox PtO2 Monitor provides tools for setting the current time and date that appears on the touch screen.

To set this information:

1. On the touch screen, press the **Settings** tab.

2. Press the **Set Time and Date** button.
3. On the displayed panel, press the desired field (hour, minutes, date, month, or year) and use the arrows to specify the appropriate setting. Note that you may adjust each of these settings prior to accepting them in the following step.
4. Press **Accept**; the Integra Licox PtO2 Monitor will display the selected time/date on the touch screen.

Step 6: Specify the Language

1. On the touch screen, press the **Settings** tab (fourth tab from the left)

2. Press **Set Language**.

3. In the displayed **Language:** menu, use the arrows to select the desired language.

4. Press **Accept**; the Integra Licox PtO2 Monitor will display all of the text that appears on the touch screen in the selected language.

Step 7: Use AC Power to Charge the Battery to Full Capacity

1. Turn off the monitor. On the front of the monitor, press the power button.
2. Keep the Integra Licox PtO2 Monitor on AC power with the monitor turned off for 5 hours. This will re-charge the battery to full capacity.
3. After 5 hours, turn on the monitor by pressing the power button.
4. On the touch screen, view the battery power symbol on the status bar to verify the symbol displays four green bars; this indicates the battery has full charge.

CHAPTER 3 ABOUT THE PTO2 MEASUREMENTS

Relationship Between Oxygen Pressure and Oxygen Content

Gases which are in contact with the surface of a liquid become physically dissolved in the liquid. If the pressure, the composition, and the temperature of the gas atmosphere over the liquid remain constant over time, a stable equilibrium of diffusion is established between the gas and the liquid. Ultimately, the pressure of the gas dissolved in the liquid reaches the pressure of the gas above the liquid. As partial pressure increases, the amount of gas that is dissolved in a particular volume of liquid also increases. The higher the partial pressure of a gas in solution, the higher the concentration.

PtO2 - A Measure of Cellular Oxygen Availability

The partial pressure of the oxygen physically dissolved in brain tissue corresponds to the availability of oxygen at the cellular level since the cell membranes do not represent a functionally variable O2 diffusion barrier and because the diffusion distance between the interstitial space and the mitochondria is short. As a result, the PtO2 value reflects the balance between O2 supply and O2 demand of the oxidative energy metabolism directly at the target of the complex oxygen transport. An increase in the PtO2 balance might be due to an increase in the oxygen transport rate to tissue or to a decrease of the tissue oxygen consumption.

Temperature Effect

The signal of a polarographic PtO2 probe (the probe current) changes depending on the temperature, even if the PtO2 value in the environment remains constant. The change in probe PtO2 sensitivity with change in temperature is approximately 4% per degree centigrade. The probe's zero signal (current without oxygen) does not depend on temperature. The temperature sensitivity of the probe signal is compensated for when the Integra® Licox® PtO2 Monitor calculates the PtO2 value. Therefore, the temperature of the PtO2 probe must be supplied to the Licox PtO2 monitor by either of the following methods:

- Using an Integra temperature probe to measure the tissue temperature continuously to an accuracy of ± 1°C (recommended when the tissue temperature is variable or unknown); or
- Using the **Manual Temperature Input** controls on the monitor's touch screen to specify the tissue temperature manually.

Note that the second bullet point above may be preferred when the patient's core temperature is continuously monitored by other means, for example with a foley catheter thermistor.

Microtrauma Caused from Probe Insertion

During the start of patient treatment, a local microtrauma results from the insertion of the PtO2 probe. When this occurs, tissue is affected in a layer concentrically surrounding the probe.

Effects of Microtrauma on PtO2 Measurements

The measured PtO2 value corresponds to the mean value of the local PtO2 levels at the interface between the damaged tissue around the probe and the surrounding undamaged tissue. Tissue without oxidative metabolism is transparent to PtO2 measurements. Immediately after inserting the PtO2 probe, the PtO2 readings are influenced by the evolving microtrauma. This normally applies to the first 20 minutes to 2 hours after insertion. During this phase, the PtO2 values do not provide reliable information about tissue oxygenation.

After the initial phase is over, the PtO2 measurements will reflect undamaged tissue.

Allowing Stabilization Time for Microtrauma

After probe insertion, allow stabilization time to ensure the PtO2 values represent the oxygen partial pressure of the surrounding tissue accurately. Note that this stabilization time may take between 20 minutes and 2 hours. To determine if the microtrauma values have stabilized, perform an oxygen challenge on the patient per the hospital's recommended procedure.

Optimal Clinical Readings When Using Temperature Probes

Warm-up Time

Integra recommends turning on the monitor as soon as it is determined that PtO2 readings will be required for a patient. Once the power is turned on, the Integra Licox PtO2 Monitor requires a maximum 3-hour warm-up time if temperature compensation will be measured with a Licox temperature probe. Monitoring may begin anytime during device warm-up. Before the 3-hour warm-up time is complete, the monitor may read up to 16% higher than the actual PtO2 due to the

effects of monitor warm-up. The majority of this error will be observed during the first hour, and the remaining error will continue to resolve until the 3-hour monitor warm-up time is complete.

The following table lists example patient PtO2 values and readings that may be displayed in the first 3 hours due to this error:

Actual Patient PtO2 Value (mmHg)	Maximum PtO2 Value Displayed as Result of Warm-Up (mmHg)
5	6
10	12
15	17
20	23

To avoid the need to repeat the warm-up procedure, Integra recommends leaving the monitor on for the duration of a patient's observation, including those times when a patient may be disconnected from the monitor.

Notice

The recommended warm-up time for optimal clinical readings is independent of stabilization time required for reducing the effects of tissue microtrauma following probe insertion.

Temperature Effect on PtO2 Readings

Once the warm-up time is complete, there is potential for a ± 1°C measurement variation when using temperature probes. The effect of this variation equates to a PtO2 error of approximately 4%. The following table lists example patient PtO2 values and readings that may be displayed as a result of a temperature accuracy of ± 1°C:

Actual Patient PtO2 Value (mmHg)	PtO2 Values Displayed with a ± 1°C Temperature Variation (mmHg)
5	5
10	10
15	14 to 16
20	19 to 21

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CHAPTER 4 SETTING UP SYSTEM FOR CLINICAL USE

Setting Up System for Clinical Use

The following section provides instructions for positioning the monitor, powering the monitor, and connecting probes to the monitor prior to clinical use.

Warning

The Integra® Licox® PtO2 Monitor is a sensitive electronic device. When using the monitor, always handle with care. If damage is suspected, contact Integra.

Positioning the Monitor

The Integra Licox PtO2 Monitor is intended to be positioned on a hard flat surface or securely clamped to an equipment pole or bed support next to the patient. The distance between the patient and the monitor is restricted by the length of the Integra probe cable. It is not permitted to extend the Integra probe cable with non-Integra extension cables:

Caution

To prevent the Integra Licox PtO2 Monitor from overheating:

- Do not block the air vents on the rear and bottom of the unit.
- Do not place the monitor on a soft or uneven surface, which may result in blockage of the monitor's air vents. For example, do not place the monitor on the bed during patient transport.

Notice

If you are using probes to measure temperature, the Integra Licox PtO2 Monitor contains sensitive electrical components that are susceptible to ambient temperature changes. To ensure optimal performance for measuring tissue temperature compensation:

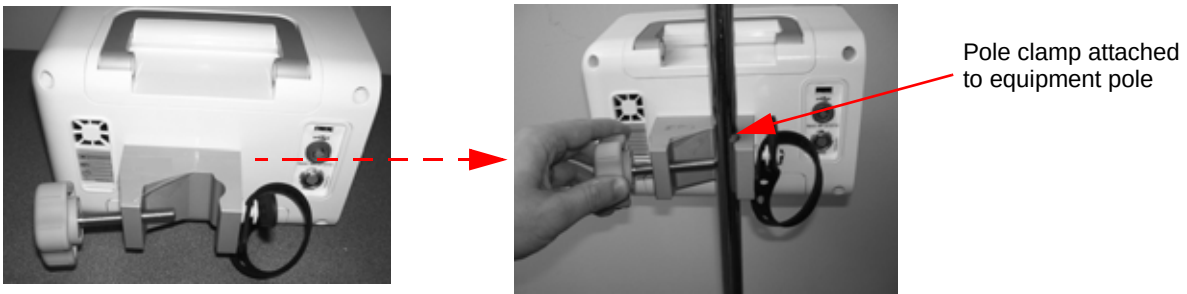
- Do not position the monitor near equipment that generates air turbulence (e.g. fans, heaters, air conditioners, etc).
- Do not position the monitor near equipment or in a location that generates heat (e.g. laptop or direct sunlight).

Do not position in an environment that exceeds the monitor's operation limits for temperature (between 15°C and 30° C).

Attaching to Equipment Pole (if applicable)

The Integra Licox PtO2 Monitor includes a pole clamp for attaching the monitor to an equipment pole. To attach:

1. On the rear of the monitor, fit the pole clamp around the equipment pole.
2. Tighten the knob on the pole clamp to secure the monitor to the equipment pole.



Pole Clamp

Note that the pole clamp supports equipment poles between 0.5 and 1.2 inches (12.7 and 30.5 mm) in diameter.

Warning

To prevent injury to the patient, user, or other persons, or to prevent damage to the monitor, always verify that the monitor is clamped securely to the equipment pole.

Caution

To prevent liquid from dripping inside the monitor and damaging the internal components, do not mount the monitor underneath an I.V. bag or tube feed. If liquid does drip onto the monitor, dry the monitor immediately.

Powering the System On and Off

Turning On the System

Warning

To prevent electrical shock, only use the AC power adapter supplied by Integra (REF # MONPWR). Using a different AC power adapter may not provide protection against electric shock.

1. Plug the monitor to an AC power outlet:
   A. On the back of the monitor, attach the red connector end of the AC power cord into the red port labeled **Input: 18 V** ⎓ .

AC power adapter

   B. Insert the plug end of the AC power adapter into an AC wall outlet.
2. Turn on the monitor:
   A. On the front of the monitor, press the power button.
   B. Once the button illuminates, the Integra logo will appear on the touch screen for a few seconds before initiating the setup process.

Power Button

3. After the setup process completes:
   A. Listen for a a one-second startup tone that verifies the audio alarms are functioning correctly.

Caution

If the one-second startup tone does not sound during the startup process, contact Integra for service

Notice

There is a short beep when the monitor is first turned on; this is not the one-second startup tone.

B. Verify the monitor's screen displays the **Main** panel.

Caution

The purpose of the startup tone is to verify that the audio alarms are functioning correctly. If this tone does not sound during the startup process, contact Integra for service.

Warning

To prevent injury to the patient, user, or other persons, or to prevent damage to the monitor, make sure to position the cables so that they are free from all foot traffic.

Turning Off the System

On the front of the monitor, press the power button. If the monitor ever freezes and does not turn off, press and hold the power button for several seconds to perform a forced shutdown of the system.

Optimal Clinical Readings When Using Temperature Probes

Warm-Up Time

Integra recommends turning on the monitor as soon as it is determined that PtO2 readings will be required for a patient. Once the power is turned on, the Integra Licox PtO2 Monitor requires a maximum 3-hour warm-up time if temperature compensation will be measured with a Licox temperature probe. Monitoring may begin anytime during device warm-up. Before the 3-hour warm-up time is complete, the monitor may read up to 16% higher than the actual PtO2 due to the effects of monitor warm-up. The majority of this error will be observed during the first hour, and the remaining error will continue to resolve until the 3-hour monitor warm-up time is complete.

The following table lists example patient PtO2 values and readings that may be displayed in the first 3 hours due to this error:

Actual Patient PtO2 Value (mmHg)	Maximum PtO2 Value Displayed as Result of Warm-Up (mmHg)
5	6
10	12
15	17
20	23

To avoid the need to repeat the warm-up procedure, Integra recommends leaving the monitor on for the duration of a patient's observation, including those times when a patient may be disconnected from the monitor.

Notice

The recommended warm-up time for optimal clinical readings is independent of stabilization time required for reducing the effects of tissue microtrauma following probe insertion.

Temperature Effect on PtO2 Readings

Once the warm-up time is complete, there is potential for a ± 1°C measurement variation when using temperature probes. The effect of this variation equates to a PtO2 error of approximately 4%. The following table lists example patient PtO2 values and readings that may be displayed as a result of a temperature accuracy of ± 1°C:

Actual Patient PtO2 Value (mmHg)	PtO2 Values Displayed with a ± 1°C Temperature Variation (mmHg)
5	5
10	10
15	14 to 16
20	19 to 21

Effects of Tissue Microtrauma on PtO2 Measurements

Immediately after inserting the PtO2 probe, the PtO2 readings are influenced by evolving microtrauma. When this occurs, tissue is affected in a region concentrically surrounding the probe. This normally applies to the first 20 minutes to 2 hours after insertion. During this phase, the PtO2 values may not display optimal information about tissue oxygenation.

Using the Battery for Power

The Integra Licox PtO2 Monitor includes a rechargeable 14.4 V lithium ion battery that supplies power to the monitor for at least 1.5 hours when the battery is fully charged; the battery is only intended for use during patient transport.

- To charge the battery to full capacity, turn off the monitor and plug it into an AC outlet for at least 5 hours prior to use.
- To ensure the battery maintains charge during patient use, always plug the monitor to an AC outlet whenever possible.

If the battery exhibits problems powering the monitor for 1.5 hours, perform the "Battery Charge" test on page 101 to ensure the battery is functioning properly.

Battery Power Indicator

On the touch screen, a battery power indicator appears in the status bar that displays the amount of battery charge available (see page 55).

- If the battery charge level drops to 15 minutes or less, the monitor will activate visual warnings.
- If the battery charge level drops to 5 minutes or less, the monitor will sound an alarm.

For more information on responding to low battery alarms, see page 72. For specific information on testing/replacing the battery, see page 100.

Warning

When using the battery:

- Do not heat above 80°C.
- Do not open battery.
- Do not dispose of in fire.
- Do not short circuit as battery may ignite, explode, leak, or get hot causing personal injury.
- Replace battery with same part number only (REF # BAT1001).
- Use of a battery not supplied by Integra may present a risk of fire or explosion.

Warning

To prevent injury to the patient, user, or other persons, make sure that the battery cover is closed securely during monitor use.

Caution

To ensure appropriate battery power with use of the Integra Licox PtO2 Monitor, only use batteries supplied by Integra (REF # BAT1001). To order replacement batteries, contact Integra.

Notice

The Integra Licox PtO2 Monitor has been designed to operate during use while a battery is installed in the unit (even if the battery is not being used for power). As a result, always use the monitor with a battery installed.

Storing the Battery

If the Integra Licox PtO2 Monitor will not be used for several months or longer, remove the battery from the monitor prior to storing the monitor. Ensure the battery is stored in a cool, dry, and well-ventilated area.

Notice

If the Integra Licox PtO2 Monitor is not used for a long duration of time, the battery will lose charge. Always make sure the battery is charged to full capacity prior to use. The Integra Licox PtO2 Monitor will charge the battery while the monitor is plugged into AC power.

About the Integra Probes

The Integra Licox PtO2 Monitor supports three types of disposable Integra probes for measuring PtO2, temperature, or both PtO2 and temperature.

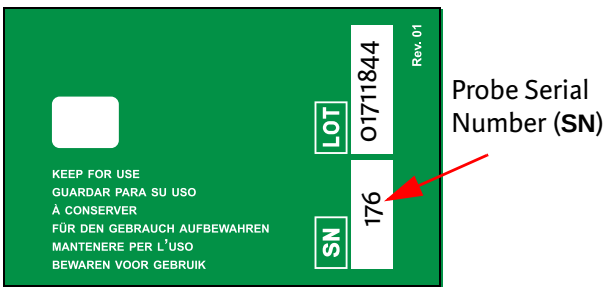
Integra® Licox® Probe Types	Description	Supported Probes
Single PtO2 (with Smart Card)	Measures PtO2 only	• CC1.SB (PtO2 probe, 0.8 mm diameter, 150 mm length)
Single Temperature	Measures tissue temperature only	• C8.B (temperature probe, 0.8 mm diameter, 126 mm length)
Combined PtO2 and Temperature (with Smart Card)	Measures both PtO2 and tissue temperature	• CC1.P1 (combined PtO2/temperature probe)

For complete instructions on using the probes, see the instructions for use supplied by Integra with each respective probe.

About the Integra PtO2 Probes and Smart Cards

Each PtO2 probe is filled with an electrolyte solution that requires refrigeration between 2°C and 10°C. Each probe also includes a Smart Card that stores calibration data for that specific probe.

Smart Card (Front)



Smart Card (Back)

Warning

Only use the designated Smart Card supplied with the PtO2 probe. Using the wrong Smart Card will produce incorrect PtO2 measurements.

When using the Smart Card, note the following guidelines:

- Do not discard PtO2 probe packaging before removing the Smart Card. Each Smart Card contains calibration data specific to that probe.
- Inserting a new Smart Card during the recording of trend data will reset the trend data.
- Only use the Smart Card supplied with the PtO2 probe. For verification, cross-check the probe serial number (**SN**) that appears on the following items to ensure they match:
  - Probe's packaging;
  - Probe's label;
  - Back of Smart Card; and the
  - **Probe #:** field that appears on the touch screen after the Smart Card in inserted into the monitor.

The Integra Licox PtO2 Monitor also includes a test Smart Card and test probe for use when testing the calibration of system. For instructions, see page 94.

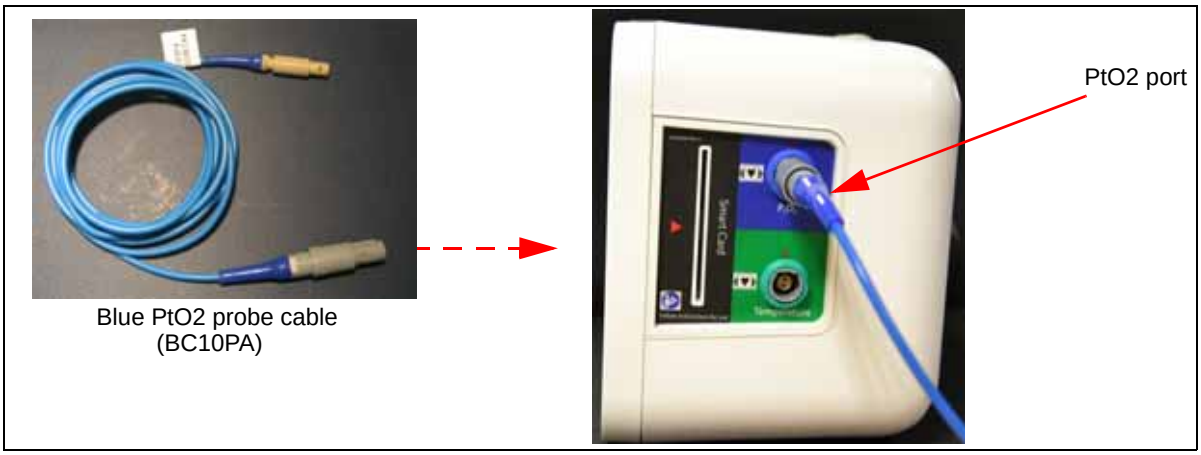
Connecting a Single PtO2 Probe

Connecting a single PtO2 probe to the Integra Licox PtO2 Monitor requires the following components:

Measurements	Components
PtO2	• Single PtO2 probe and Smart Card (CC1.SB) • Blue PtO2 probe cable (BC10PA) • Blue PtO2 extension cable (if necessary, BC10PV)

Step 1: Connect the PtO2 Probe Cable (BC10PA) to the Monitor

1. On the monitor's right side, connect the larger plug of the blue PtO2 probe cable into the blue port labeled **PtO2**.



2. When connecting, verify the probe cable snaps into place.
3. If additional cable length is required, attach the blue PtO2 extension cable (BC10PV) to the blue PtO2 probe cable.

Step 2: Insert the PtO2 Probe's Smart Card into the Monitor

1. Remove the single PtO2 probe and designated Smart Card from its packaging.

2. On the monitor's right side, insert the Smart Card into the **Smart Card** slot by aligning the arrow on the card with the arrow on the label.

Smart Card

Smart Card inserted into slot

3. When inserting the Smart Card, verify the card is positioned securely in its slot and the following message appears:

4. Press **Accept**.

Notice

After pressing **Accept**, the monitor will trigger an alarm that indicates the Smart Card is measuring a PtO2 value of zero, which is lower than the PtO2 Alarm Limit value specified on the **Alarm** tab. This alarm will be silenced in the following step.

5. Silence the alarm by pressing the flashing alarm symbol.

Step 3: Insert the PtO2 Probe into Patient and Connect the Probe to the Monitor

Depending on hospital protocol, you may either insert the PtO2 probe into the patient before (see **Option 1**) or after (see **Option 2**) connecting the PtO2 probe to the monitor:

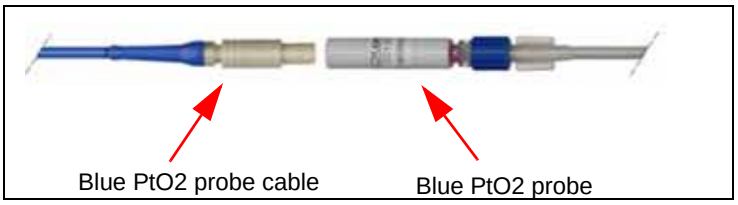
Options	Procedure
1	A. Insert the PtO2 probe into the patient. For instructions, see the instructions for use supplied with the probe. B. Connect the blue PtO2 probe to the blue PtO2 probe cable (see Figure 4-1); verify that they are connected securely. - OR -
2	A. Connect the blue PtO2 probe to the blue PtO2 probe cable (see Figure 4-1); verify that they are connected securely. B. Insert the PtO2 probe into the patient. For instructions, see the instructions for use supplied with the probe.

Notice

The purpose of connecting the PtO2 probe to the monitor prior to implantation is to verify the functionality of the probe before clinical use; it is not a requirement for calibration, as each PtO2 probe includes a designated Smart Card. When connecting the probe to the monitor prior to implantation, ensure that sterility is maintained. For sterilization instructions, see page 81.

Figure 4-1.

Connecting the PtO2 Probe to the PtO2 Probe Cable



Step 4: Allow Stabilization Time for Microtrauma

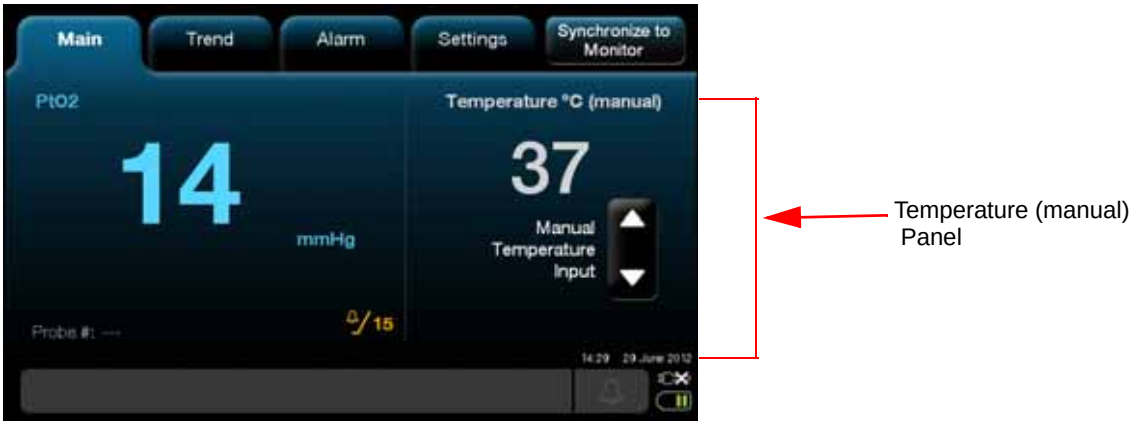
After probe insertion, allow stabilization time to address microtrauma (normally between 20 minutes and 2 hours); this will ensure the PtO2 values reported by the monitor are accurate. For details, see page 22.

Step 5: Enter Tissue Temperature Compensation Value Manually

1. Enter the tissue temperature compensation that will be used during PtO2 measurements:

   A. On the touch screen, press **Main**.

B. On the **Temperature (manual)** panel, adjust the **Manual Temperature Input** arrows to the desired temperature to the nearest whole number:



C. Note that the accepted range is between 30°C and 42°C; the monitor's default value is 37 °C.

2. Press **Accept.**

Warning

The calculations for PtO2 measurements require tissue temperature compensation. If you are not measuring the tissue temperature with a probe, the temperature has to be entered manually. Make sure to check the patient's tissue temperature either hourly or prior to recording the PtO2 values for intervention. If any changes in temperature occur, use the **Manual Temperature Input** arrows to specify the new temperature value accordingly.

Connecting a Single PtO2 Probe with a Single Temperature Probe

Connecting separate probes for measuring PtO2 and temperature require the following components:

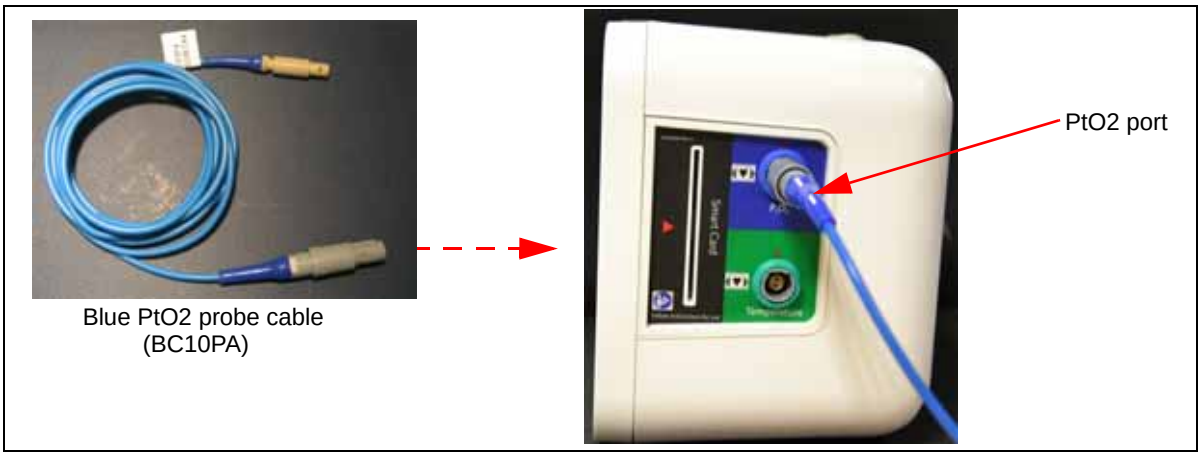
Measurements	Components
PtO2	• Single PtO2 probe and Smart Card (CC1.SB) • Blue PtO2 probe cable (BC10PA) • Blue PtO2 probe extension cable (if necessary, BC10PV)
Temperature	• Single temperature probe (C8.B) • Green temperature probe cable (BC10TA) • Green temperature probe extension cable (if necessary, BC10TV))

Notice

If you are measuring temperature compensation with a probe, do not touch the connector on the probe cable for a prolonged period of time before connecting it to the **Temperature** port on the Integra Licox PtO2 Monitor. Touching this connector may affect the initial temperature compensation readings. If this temperature fluctuation occurs, the PtO2 measurements will be unreliable.

Step 1: Connect PtO2 Probe Cable (BC10PA) to the Monitor

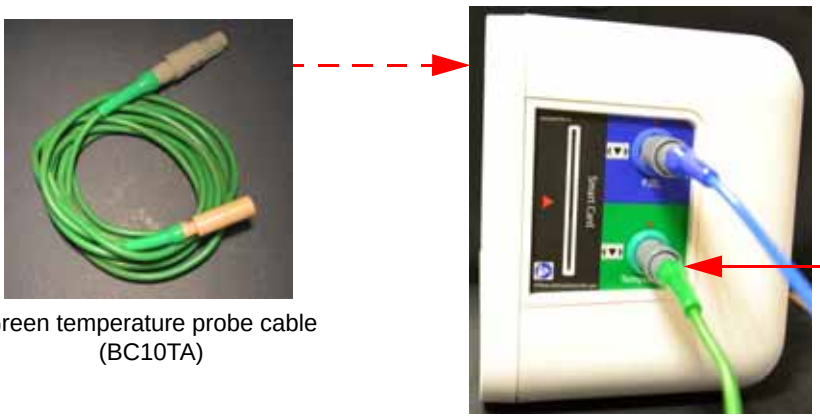
1. On the monitor's right side, connect the large plug of the blue PtO2 probe cable into the blue port labeled **PtO2**.



2. When connecting, verify the probe cable snaps into place.
3. If additional cable length is required, attach the blue PtO2 extension cable (BC10PV) to the blue PtO2 probe cable.

Step 2: Connect the Temperature Probe Cable (BC10TA) to the Monitor

1. On the monitor's right side, connect the green temperature probe cable into the green port labeled **Temperature**.



Green temperature probe cable (BC10TA)

2. When connecting, verify the probe cable snaps into place. If additional cable length is required, attach the green temperature probe extension cable (BC1oTV).

Step 3: Insert the PtO2 Probe's Smart Card into the Monitor

1. Remove the single PtO2 probe and accompanying Smart Card from its packaging.
2. On the monitor's right side, insert the Smart Card into the **Smart Card** slot by aligning the arrow on the card with the arrow on the label.

Smart Card

Smart Card inserted into slot

3. When inserting the Smart Card, verify the card is positioned securely into its slot. This will activate a temporary alarm and display the following message:

4. Press **Accept**.

Notice

After pressing **Accept**, the monitor will trigger an alarm that indicates the Smart Card is measuring a PtO2 value of zero, which is lower than the PtO2 Alarm Limit value specified on the **Alarm** tab. This alarm will be silenced in the following step.

5. Silence the alarm by pressing the flashing alarm symbol.

Step 4: Insert the PtO2 and Temperature Probes into Patient and Connect the Probes to Monitor

Depending on hospital protocol, you may either insert the PtO2 probe and temperature probe into the patient before (see **Option 1**) or after (see **Option 2**) connecting the two probes to the monitor:

Options	Procedure
1	A. Insert the PtO2 probe and temperature probes into the patient. For instructions, see the instructions for use supplied with each probe. B. Connect the blue PtO2 probe to the blue PtO2 probe cable (see Figure 4-2); verify that they are connected securely. C. Connect the green temperature probe to the green temperature probe cable (see Figure 4-2); verify that they are connected securely. - OR -

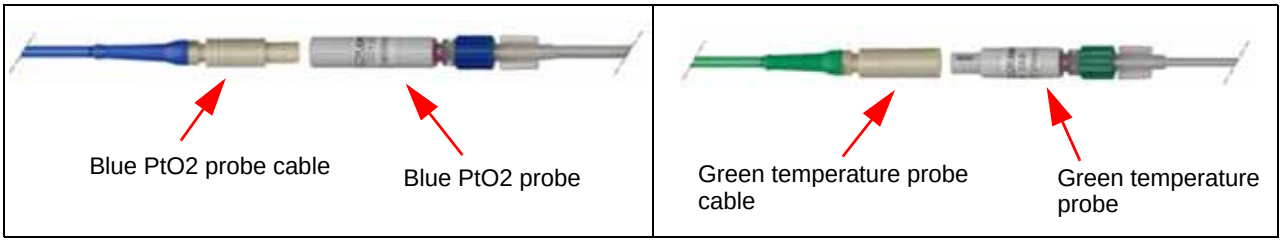
Options	Procedure
2	A. Connect the blue PtO2 probe to the blue PtO2 probe cable (see Figure 4-2); verify that they are connected securely. B. Connect the green temperature probe to the green temperature probe cable (see Figure 4-2); verify that they are connected securely. C. Note that the when the temperature probe is first connected to the monitor and in open air (room temperature), the monitor: • Sounds an alarm; and • Displays "**Temperature out of accuracy range**" on the status bar. To silence the alarm temporarily (3 minutes) while the temperature probe is still in the air, press the yellow alarm button.  D. Insert the PtO2 probe and temperature probe into the patient. For instructions, see the instructions for use supplied with each probe.

Notice

The purpose of connecting the probes to the monitor prior to implantation is to verify the functionality of the probes before clinical use; it is not a requirement for calibration, as each PtO2 probe includes a designated Smart Card. When connecting the probes to the monitor prior to implantation, ensure that sterility is maintained. For sterilization instructions, see page 81.

Figure 4-2.

Connecting the PtO2 Probe and Temperature Probe to Their Probe Cables



Step 5: Allow Stabilization Time for Microtrauma

After probe insertion, allow stabilization time to address microtrauma (normally between 20 minutes and 2 hours); this will ensure the PtO2 values reported by the monitor for tissue are accurate. For details, see page 22.

Step 6: Check PtO2 and Temperature Values

On the touch screen, press the **Main** tab and view the **PtO2** and **Temperature** values.

Note that when using a temperature probe, the temperature measurement being continuously reported by the monitor (with an accuracy of ± 1°C) will be applied to the calculation for PtO2 measurements.

Connecting the Combined PtO2/Temperature Probe

Connecting the combined PtO2/temperature probe requires the following components:

Measurements	Components	REF
PtO2 and Temperature	• Combined PtO2/temperature probe and Smart Card	CC1P1
	• Y-adapter cable for combined PtO2/temperature probe cable	BC10PMO
	• Blue PtO2/temperature probe cable	PMOCAB

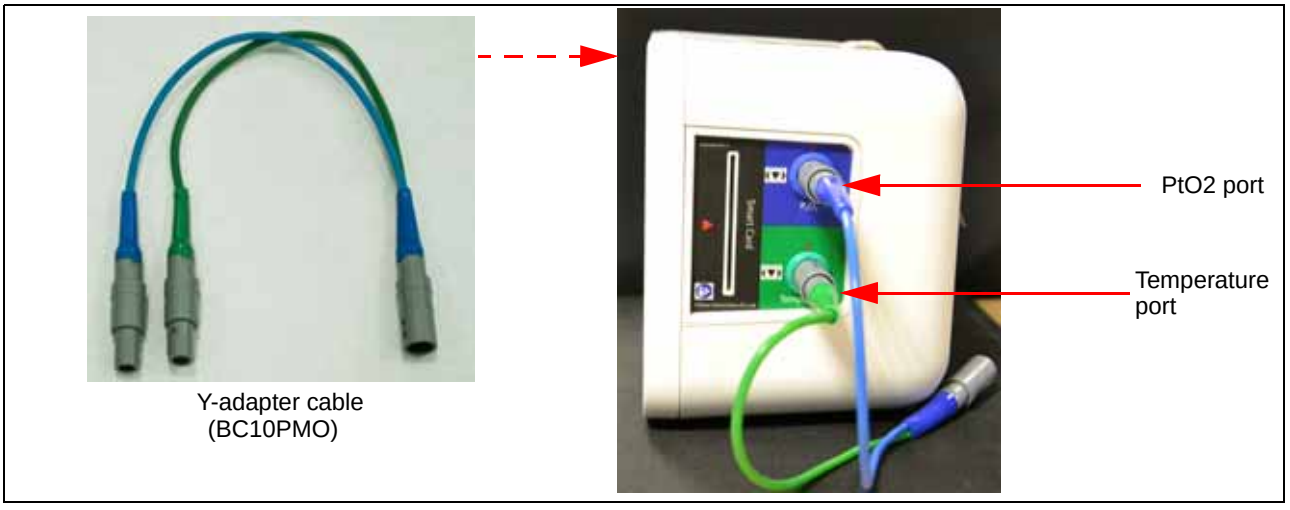
When using both probes, the Integra Licox PtO2 Monitor measures the tissue temperature compensation for the PtO2 calculations automatically.

Notice

If you are measuring temperature compensation with a probe, do not touch the connector on the probe cable for a prolonged period of time prior to connecting it to the **Temperature** port on the Integra Licox PtO2 Monitor. Touching this connector may affect the initial temperature compensation readings. If this temperature fluctuation occurs, the PtO2 measurements will be unreliable.

Step 1: Connect the Y-Adapter Cable (BC10PMO) to the Monitor

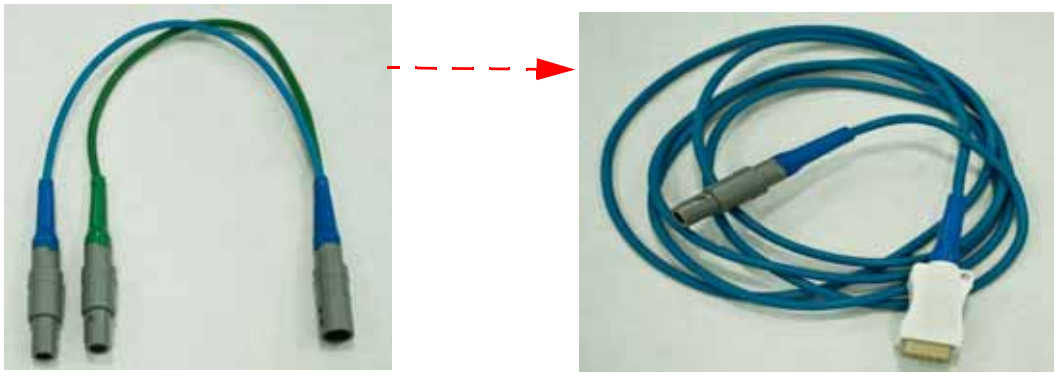
1. On the monitor's right side, connect the blue and green ends of Y-adapter cable into the following ports:
   - Connect the blue end into the blue port labeled **PtO2**
   - Connect the green end into the green port labeled **Temperature**



2. When connecting, verify each probe cable snaps into place.

Step 2: Connect the Y-Adapter Cable (BC10PMO) to the Combined PtO2/Temperature Probe Cable (PMOCAB)

1. Connect the blue, single-end of the Y-adapter cable to the blue combined PtO2/temperature probe cable.
2. When connecting, verify the single-end of the Y-adapter cable snap into place.



Y-adapter cable (BC10PMO)

Combined PtO2/Temperature probe cable (PMOCAB)

Step 3: Insert the PtO2 Probe's Smart Card into the Monitor

1. Remove the single PtO2 probe and accompanying Smart Card from its packaging.
2. On the monitor's right side, insert the Smart Card into the **Smart Card** slot by aligning the arrow on the card with the arrow on the label.

Smart Card

Smart Card inserted into slot

3. When inserting the Smart Card, verify the card is positioned securely into its slot. This will activate a temporary alarm and display the following message:

4. Press **Accept**.

Notice

After pressing **Accept**, the monitor will trigger an alarm that indicates the Smart Card is measuring a PtO2 value of zero, which is lower than the PtO2 Alarm Limit value specified on the **Alarm** tab. This alarm will be silenced in the following step.

5. Silence the alarm by pressing the flashing alarm symbol.

Step 4: Connect the PtO2/Temperature Probe to the PtO2 /Temperature Probe Cable

Depending on hospital protocol, you may either insert the combined PtO2/ temperature probe into the patient before (see **Option 1**) or after (see **Option 2**) connecting it to the monitor:

Options	Procedure
1	A. Insert the combined PtO2/temperature probe into the patient. For instructions, see the instructions for use supplied with the probe. B. Connect the white end of the combined PtO2/temperature probe to the white end of the combined PtO2/temperature probe cable (see Figure 4-3); verify that they snap into place. C. Note that the when the combined PtO2/temperature probe is first connected to the cable and in open air (room temperature), the monitor: • Sounds an alarm; and • Displays "**Temperature out of accuracy range**" on the status bar. To silence the alarm temporarily (3 minutes) while the temperature probe is still in the air, press the yellow alarm button.  - OR -

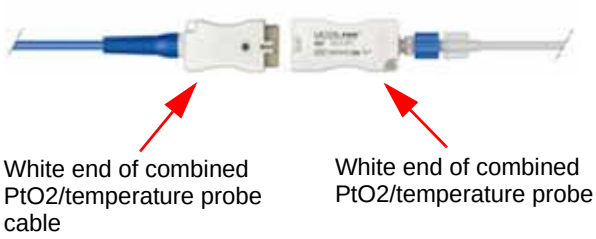
Options	Procedure
2	A. Connect the white end of the combined PtO2/temperature probe to the white end of the combined PtO2/temperature probe cable (see Figure 4-3); verify that they snap into place. B. Note that the when the temperature probe is first connected to the cable and in open air (room temperature), the monitor: • Sounds an alarm; and • Displays "**Temperature out of accuracy range**" on the status bar. To silence the alarm temporarily (3 minutes) while the temperature probe is still in the air, press the yellow alarm button.  C. Insert the combined PtO2/temperature probe into the patient. For instructions, see the instructions for use supplied with the probe.

Notice

The purpose of connecting the combined PtO2/temperature probe to the monitor prior to implantation is to verify the functionality of the probe before clinical use; it is not a requirement for calibration, as each combinPtO2 probe includes a designated Smart Card. When connecting the probe to the monitor prior to implantation, ensure that sterility is maintained. For sterilization instructions, see page 81.

Figure 4-3.

Connecting the Combined PtO2/temperature Probe to the Combined PtO2/ Temperature Probe Cable



Step 5: Allow Stabilization Time for Microtrauma

After probe insertion, allow stabilization time to address microtrauma (normally between 20 minutes and 2 hours); this will ensure the PtO2 values reported by the monitor are accurate. For details, see page 22.

Step 6: Check PtO2 and Temperature Values

On the touch screen, press the **Main** tab and view the **PtO2** and **Temperature** values.

Note that when using a temperature probe, the temperature measurement being continuously reported by the monitor (with an accuracy of ± 1°C) will be applied to the calculation for PtO2 measurements.

Verifying the PtO2 Probe Functionality

Notice

The functionality of the PtO2 probe may be verified before and after monitoring by allowing the probe to measure the PtO2 value of ambient air. When performing this check after monitoring, make sure to remove blood and tissue remains from the PtO2 probe with a gauze pad soaked in water.

This check requires either of the following probes:

- PtO2 probe and temperature probe

  or

- Combined PtO2/temperature probe

Note that this check is only intended to verify that the PtO2 probe is functioning correctly; it does not test the accuracy of the PtO2 probe.

1. Leaving the probes in their protector tubes, place the probes into the sterile field to allow them to reach ambient temperature.
2. Connect the probes to the Integra Licox PtO2 Monitor.
3. Prior to implanting the probes into the patient, remove the PtO2 probe from its protector tube and expose it to ambient air for at least one minute.
4. Using the following table, compare the PtO2 values reported by the monitor with those listed in the table:

Barometric Pressure Ranges (mmHg)	PtO2 (mmHg) at 22°C
740 to 780	150 to 159
700 to 740	142 to 150
660 to 700	134 to 142

5. Evaluate the results:
   - If the PtO2 values on the monitor are close (or trending close) to the PtO2 values listed in the table, the PtO2 probe is functioning correctly.
   - If the PtO2 values on the monitor are significantly different from the PtO2 values listed in the table, the PtO2 probe is not functioning correctly.

   If the check results in failure, replace the PtO2 probe and re-do steps 1 through 5 in this section.

Connecting to a Patient Bedside Monitor (if applicable)

The Integra Licox PtO2 Monitor provides outputs for connecting to a patient bedside monitor. This connection requires two Integra cables:

Cables	REF #	Description
PMIO	PMIOMPM	Main cable for connecting Integra monitor to patient monitor.
Monitor Adapter Cable	ICP-XX and ICT-XX	Adapter cables that fit between the PMIO cable and the vendor-specific patient bedside monitor. Note that XX refers to the vendor-specific patient bedside monitor code.

To determine which monitor adapter cables are required for your particular patient monitor, contact Integra.

Warning

Read the user's manual from the patient bedside monitor's manufacturer before connecting the Integra Licox PtO2 Monitor to a patient bedside monitor.

Procedures for Synchronizing the Two Monitors

Perform the following steps to verify that both the Integra Licox PtO2 Monitor and the patient bedside monitor report the same PtO2 values within ±1 mmHg for PtO2 values between 0 and 100 mmHg, or ±2 mmHg for PtO2 values over 100 mmHg).[1]

Note that these steps should be performed in each of the following situations:

- When first connecting the Integra Licox PtO2 Monitor to a patient bedside monitor.
- If the Integra Licox PtO2 Monitor becomes disconnected from a patient bedside monitor (e.g. due to patient transport to CT or OR), and then needs to be re-connected.
- If, during use, the reported PtO2 values between the Integra Licox PtO2 Monitor and the patient bedside monitor exceeds the stated accuracy range.[1,]

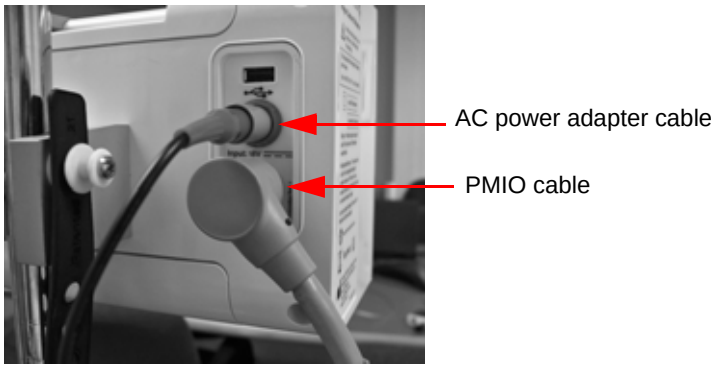
1. The accuracy range stated in this description does not include the accuracy of the patient bedside monitor, which may vary between manufacturers. If drift occurs persistently between the two monitors that exceeds the stated accuracy range, contact the biomed department to determine the cause of drift.

Step 1: Connect the Two Monitors

Notice

To cancel the synchronization process during any of the following steps, press **Done**.

1. Connect the Integra Licox PtO2 Monitor to the patient bedside monitor:
   A. On the rear panel of the Integra monitor, attach the connector end of the PMIO cable to the port labeled **PMIO.**
      - Align the red dot on the PMIO cable connector with the red triangle on the monitor's port and push firmly.
      - Verify the cable is completely connected to the monitor before proceeding.



   B. On the other end of the PMIO cable, attach the monitor adapter cable for pressure (and temperature if applicable).
   C. Attach the PMIO cable and adapter cable to the temperature/pressure modules on the patient bedside monitor.

Notice

The Integra Licox PtO2 Monitor does not measure Cerebral Perfusion Pressure (CPP). As a result, the ABP connector on the PMIO cable will not be used.

Step 2: Press the "Synchronize to Monitor" Button

1. On the Integra Licox PtO2 Monitor's touch screen, press the **Synchronize to Monitor** button.

2. Note the following actions:
   - The Integra monitor will transmit an PtO2 value of 0 mmHg for up to one minute.
   - A countdown will appear to display the amount of time left to zero the patient bedside monitor.

Step 3: Zero the Patient Bedside Monitor to the Integra Monitor

On the patient bedside monitor, follow the manufacturer's instructions to zero the monitor.

Step 4: Check Additional Values to Confirm Synchronization

Notice

The following synchronization checks at 25 mmHg, 50 mmHg, and 100 mmHg are not required, but are recommended by Integra.

On the Integra Licox PtO2 Monitor's touch screen, press the **Check Additional Values** button to transmit additional PtO2 values to the patient bedside monitor for scaling verification:

- 25 mmHg
- 50 mmHg
- 100 mmHg

Note that pressing **Check Additional Values** each time advances to the next PtO2 value. If you are not checking additional values, proceed to the final step, "Complete the Synchronization Process" on page 51.

1. Press the **Check Additional Values** button to transmit an PtO2 value at 25 mmHg for up to one minute to the patient bedside monitor.

   A countdown will appear to display the amount time left to confirm that the value is also displayed on the patient bedside monitor.

2. Once the PtO2 value on the patient bedside monitor stabilizes, verify that the patient bedside monitor reads the same value as the Integra Licox PtO2 Monitor:

   25 mmHg, ± 1 mmHg

3. Repeat steps 1 to 2 in this section for each additional value that you want to check.

Step 5: Complete the Synchronization Process

After completing the synchronization process, press **Done**. Once the PtO2 value on the patient bedside monitor stabilizes, verify that the patient bedside monitor reads the same PtO2 value as the Integra Licox PtO2 Monitor within ±1 mmHg for PtO2 values between 0 and 100 mmHg, or ±2 mmHg for PtO2 values over 100 mmHg).[2]

During patient treatment, Integra recommends comparing the PtO2 values between the two monitors per the guidance of the hospital's unit policy, or while the clinical staff is recording PtO2 or treating PtO2.

Warning

If the Integra Licox PtO2 Monitor loses power and shuts down while it is connected to a patient bedside monitor, do not use the PtO2 values on the patient bedside monitor for patient measurements; the PtO2 values on the patient bedside monitor will be invalid.

Notice

After completing the synchronization process, always use the Integra Licox PtO2 Monitor's measurements over the patient bedside monitor's measurements. If drift occurs between the two monitors, use the Integra Licox PtO2 Monitor's PtO2 values for the patient's measurements and repeat the procedures for synchronizing the two monitors (see page 48).

About PtO2 and Temperature Measurements on the Patient Bedside Monitor

The Integra Licox PtO2 Monitor is designed to measure PtO2 between the range of 0 mmHg and 150 mmHg, and tissue temperature (with an accuracy of ± 1°C) between the range of 30 °C and 42 °C. If the PtO2 or temperature value is outside these specific ranges on the Integra Licox PtO2 Monitor while it is connected to the patient bedside monitor, the Integra monitor will activate a low priority alarm for either the PtO2 or temperature accuracy range alarm condition (see page 73). Depending on the type of alarm condition, the Integra monitor will also transmit either a PtO2 value of -15 mmHg or a temperature value of 15°C to the patient bedside monitor to indicate that the Integra monitor is unable to make accurate measurements.

2. The accuracy range stated in this description does not include the accuracy of the patient bedside monitor, which may vary between manufacturers. If drift occurs persistently between the two monitors that exceeds the stated accuracy range, contact the biomed department to determine the cause of drift.

Storing the System

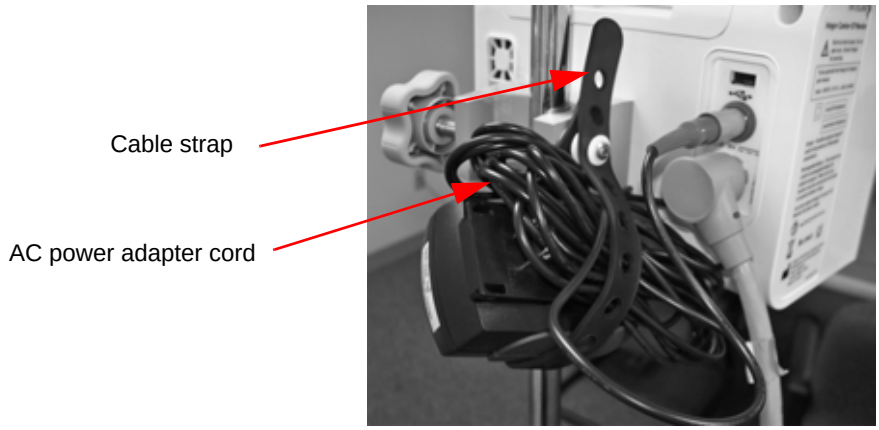
If the Integra Licox PtO2 Monitor will not be used for several months or longer, remove the battery from the monitor prior to storing the monitor. During storage, keep the monitor in a dry location that meets the following environmental conditions:

- Temperature: -20°C to 50°C
- Humidity: 25% to 80% RH, non-condensing

Also ensure the storage location is safe from any liquids that may drip inside the monitor and damage its internal components.

Using the Cable Strap to Wrap the AC Power Adapter

The Integra Licox PtO2 Monitor also includes an adjustable strap for securing the AC power adapter cord and other cables during patient transport or storage. To use this cable strap, wrap the rubber strap around the bundled adapter cord and secure it by inserting the round plastic fastener through the desired hole.



CHAPTER 5 MONITORING THE PATIENT'S PTO2 AND TEMPERATURE

About the Touch Screen

The Integra® Licox® PtO2 Monitor includes a touch screen for evaluating and controlling parameters for monitoring the patient's PtO2. The touch screen provides the following tabs for accessing and activating different parameters:

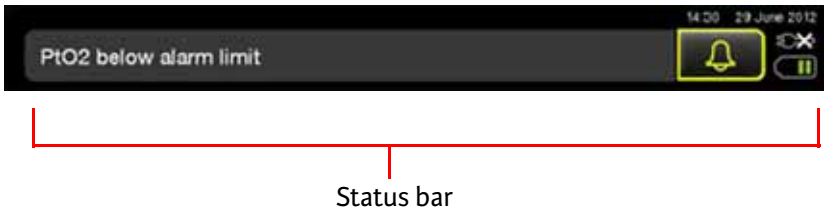
Tab	Description
Main	Provides tools for evaluating the patient's PtO2 (mmHg). For details, see page 55.
Trend	Provides tools for monitoring a 5-day history of the patient's PtO2 values. For details, see page 58.
Alarm	Provides tools for specifying low PtO2 limits the monitor will tolerate before sounding an alarm. For details, see page 55.
Settings	Provides tools for specifying languages, date and time. For details, see page 64.

About the Synchronize to Monitor Button

If you are planning to display patient data from the Integra Licox PtO2 Monitor to a patient bedside monitor, press the **Synchronize to Monitor** button to initiate the process of synchronizing the two monitors with each other. This process ensures that both monitors are displaying the same PtO2 values for the patient within ±1 mmHg for PtO2 values between 0 and 100 mmHg, or ±2 mmHg for PtO2 values over 100 mmHg).[1] For instructions on synchronizing the monitors, see page 48.

Reviewing the Status Bar

When using the Integra Licox PtO2 Monitor, the status bar on the bottom of the touch screen will display messages to indicate the current states of alarms, probes, Smart Cards, and AC/battery power.



Verifying Status of Battery and AC Power

The Integra Licox PtO2 Monitor may be powered by either AC power or battery charge. To determine the status of power for the monitor, view the battery and plug symbols that appear on the bottom right of the touch screen:

Symbol	Status
	Indicates AC power is in use.
	Indicates AC power is not in use/available.
	Indicates battery power is being used to power the monitor. Each green bar represents the level of remaining battery charge (see following section).
	Indicates AC power is being used to charge the battery.
	Indicates that either a battery is not connected or a battery is not functioning properly.

For instructions on powering the monitor, see page 27.

1. The accuracy range stated in this description does not include the accuracy of the patient bedside monitor, which may vary between manufacturers. If drift occurs persistently between the two monitors that exceeds the stated accuracy range, contact the biomed department to determine the cause of drift.

Verifying Amount of Battery Charge Available

The Integra Licox PtO2 Monitor displays the following symbols on the status bar to indicate battery charge levels:

Symbol	Color	Available Charge
	Green	75% to 100%
	Green	50% to 75%
	Green	25% to 50%
	Green	Less than 25%
	Flashing Yellow	Less than 5 minutes

If the level of battery charge falls to 15 minutes or less, the monitor will display an error message on the status bar. If the level of battery charge falls to 5 minutes or less, the monitor will activate a technical alarm. For more information, see page 72.

About the Alarms

The Integra Licox PtO2 Monitor activates one physiological alarm for falling under the low PtO2 alarm limit and several technical alarms for indicating equipment-related problems. For instructions on setting the low PtO2 alarm limit, see page 61. For detailed information on responding to each of these alarm types, see Chapter 6.

Monitoring the Patient's PtO2

Press the **Main** tab to view the patient's current PtO2 and temperature values.

The information on this screen includes:

Parameter	Description
1	Displays current PtO2 value in mmHg.
2	Identifies the current PtO2 probe number that appears on the probe's designated Smart Card and packaging. Users must confirm that the probe number that appears on the screen, the Smart Card, and the packaging all match (see page 31).
3	Displays the low PtO2 limit for the patient. If the patient's PtO2 falls below this limit for more than 5 seconds, an alarm will sound. To specify this limit, see page 62.
4	Displays the current tissue temperature in degrees Celsius (°C) with an accuracy of ± 1°C when a temperature probe is connected to the monitor. This value, which represents tissue temperature compensation, will be applied to the calculation of PtO2 measurements (see page 56).
5	Provides controls for specifying the tissue temperature manually if no temperature probe is connected to the monitor (see page 35).

This value will be applied to the calculation of PtO2 measurements.

How the Monitor Reports PtO2 Values

The patient's continuously measured PtO2 value that is displayed on the touch screen is rounded to the nearest 1 mmHg. If the patient's rounded PtO2 value falls below the user-specified low PtO2 alarm limit for more than 5 seconds, the monitor will trigger an alarm. For example, if the low PtO2 alarm limit is set to 18 mmHg, the alarm will trigger when the PtO2 value is less than 17.5 mmHg for more than 5 seconds.

How the Monitor Applies Tissue Temperature Compensation

The Integra Licox PtO2 Monitor provides two options for applying the tissue temperature compensation value that is required for the calculation of PtO2 measurements:

- Use of temperature probes to measure temperature continuously with an accuracy of ± 1°C
- Use of touch screen controls for specifying temperature values manually

Depending on which option is being used, the monitor's touch screen will display the temperature value as either continuous measurements (**Temperature (± 1 °C)**) or user-specified measurements (**Temperature °C (manual)**).

Display of Continuous Temperature Measurements with Temperature Probes

If a single Licox temperature probe or combined PtO2/temperature probe is connected to the **Temperature** connector, the Integra Licox PtO2 Monitor will measure the patient's tissue temperature continuously with an accuracy of ± 1°C , display the temperature value on the touch screen, and apply this value to the calculation for PtO2 measurements:

Reporting of continuous temperature measurements from use of temperature probe

For instructions on connecting these probes, see page 37 and page 42.

Display of Manual Temperature Measurements

If a single PtO2 probe is connected to the monitor without a separate temperature probe, the Integra Licox PtO2 Monitor activates the **Manual Temperature Input** control for specifying tissue temperature values between 30°C and 42°C. The specified value will be applied as temperature compensation to the calculation for PtO2 measurements:

By default, this value is set to 37°C. For instructions on setting the temperature manually, see page 35.

Monitoring Trend Data

Press the **Trend** tab to view a graph of recorded PtO2 trend data in mmHg at one-minute intervals. The Integra Licox PtO2 Monitor stores up to five days of trend data that may be viewed in specific ranges of time. This data may also be extracted from the monitor to other media types by either USB transfer or by digital streaming. For instructions on extracting data, see Chapter 7.

The information on this panel includes:

Items	Description
1	**Extract Data** Copies the patient's trend data to a USB drive that has been connected to the USB port on the rear of the monitor (see page 75).
2	**Data Streaming Enabled** Indicates that the feature for streaming patient trend data digitally to another media type has been activated. This feature requires the use of the USB-to-RS232 adapter cable (see page 77).
3	**PtO2 Scale** Specifies the range of the PtO2 values displayed on the **Trend** graph (see page 60).
4	**Time Scale** Specifies the range of time displayed on the **Trend** graph (page 60).
5	Displays graph of PtO2 versus time.
6	Displays the low PtO2 limit. If the patient's PtO2 falls below this limit for more than 5 seconds, an alarm will sound. To specify this limit, see page 62.
7	Displays the current PtO2 in mmHg.
8	Displays the current tissue temperature in degrees Celsius (°C) with an accuracy of ± 1°C when a temperature probe is connected to the monitor. If no temperature probe is connected, this value represents the tissue temperature specified manually by the user (see page 58).

Scaling Time Ranges for Trend Data

On the **Trend** panel, press the **Time Scale** button to view the history of PtO2 trend data in different ranges of time: 3 hours, 12 hours, 24 hours, 48 hours, and 120 hours. Note that pressing the **Time Scale** button each time will change the display of PtO2 trend data in the graph to the next time range selection. The current time range that is specified by the **PtO2 Scale** button is listed under the PtO2 graph.

Scaling the PtO2 Ranges for Trend Data

If the PtO2 graph on the **Trend** panel requires resizing for optimal viewing, press the **PtO2 Scale** button to change the range of PtO2 measurements that is displayed along the Y-axis of the graph. The ranges that can be displayed on the graph include the following:

Ranges (mmHg)	Increments (mmHg)
0 to 30	5
0 to 50	5
0 to 100	10
0 to 150	25

Note that pressing the **PtO2 Scale** button each time will advance the graph to the next range of PtO2 measurements.

Conditions that Reset Trend Data

Some conditions may result in the loss of trend data during the recording process. For details, see page 77.

Setting the Low PtO2 Alarm Limit

Press the **Alarm** tab to specify settings for controlling the physiological alarm. This panel includes controls for specifying the low PtO2 limit value, turning the alarm on and off, and restoring low PtO2 limit from a customized setting to the original default setting (15 mmHg).

The information on this panel includes:

Item	Description
1	**Alarm On** Activates the physiological alarm settings. If this option is selected, the monitor will sound an alarm if the patient's PtO2 value falls below the specified low PtO2 limit value for more than 5 seconds. By default, this option is selected and set to 15 mmHg (see page 62).
2	**Alarm Off** Deactivates the physiological alarm settings. If this option is selected, the monitor will disable the current low PtO2 limit value and prevent a low PtO2 alarm from sounding. In this mode, the monitor will display **PtO2 Alarm Off** in the status bar. Note that technical alarms cannot be disabled with this option (see page 63).
3	**Low PtO2 Alarm Limit** Specifies the minimum PtO2 value for the patient that the monitor will tolerate before activating the physiological alarm. To specify this limit, press the arrows to set a value between +1 mmHg and +150 mmHg in 1 mmHg increments (see page 62).

Item	Description
4	**Restore Defaults** Restores customized settings for the low PtO2 alarm limit to the original factory default settings (15 mmHg). Pressing this button also activates the **Alarm On** button (see page 64).
5	**PtO2** Displays PtO2 in mmHg.
6	**Temperature** Displays the current tissue temperature in degrees Celsius (°C) with an accuray of ± 1°C when a temperature probe is connected to the monitor. If no temperature probe is connected, this value represents the tissue temperature specified manually by the user (see page 58).

About the Low PtO2 Alarm Limit Calculation

The Integra Licox PtO2 Monitor bases the low alarm limit on the patient's PtO2 value, which is represented by the numerical PtO2 value that appears on the touch screen (see page 53). The low PtO2 alarm is triggered if the patient's displayed PtO2 value continuously remains below the low PtO2 alarm limit for a period of at least 5 seconds.

Specifying the Low PtO2 Limit Value

Warning

Always verify the low PtO2 alarm limit is set appropriately for each patient prior to treatment.

Notice

The default setting for the **Low PtO2 Alarm Limit** is15 mmHg. If a new low PtO2 limit is specified, the **Restore Default** button, which appears on the **Alarm** panel, can be used to restore the low PtO2 limit back to 15 mmHg.

1. On the touch screen, press the **Alarm** tab.
2. Press the **Alarm On** button; this will activate the alarm settings.

3. In the **Low PtO2 Alarm Limit** field, use the arrows to specify the low PtO2 limit value for the patient. Note that the range limits are +1 mmHg and +150 mmHg.

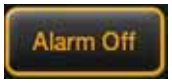
4. Press **Accept**. If the patient's PtO2 value falls below this specified limit for more than 5 seconds, the monitor will activate the physiological alarm. To respond to this alarm, see page 71.

Touch Screen Labels Indicating Low PtO2 Limit

Note that the PtO2 value specified in the above step 3 appears in the **Main** and **Trend** screens as the following indicator labels:

- A horizontal line in the graph corresponding to the specified low PtO2 limit value
- A number value next to the active alarm symbol.

Disabling the Low PtO2 Alarm



To turn off the low PtO2 limit and prevent the Integra Licox PtO2 Monitor from sounding a physiological alarm, press the **Alarm** tab and select **Alarm Off**. If this option is selected, the monitor will display **PtO2 Alarm Off** in the status bar. The monitor will also remove the corresponding low PtO2 alarm limit indicator labels from the **Main** and **Trend** screens. To turn on the low PtO2 alarm limit, press **Alarm On** and then **Accept**.

Warning

Selecting the **Alarm Off** feature on the **Alarm** panel will disable the physiological alarm indefinitely. Use caution if this feature is selected.

Silencing the Low PtO2 Alarm Temporarily

To silence the physiological alarm temporarily, press the active alarm symbol on the status bar. This will silence the alarm for either 3 minutes or until the patient's PtO2 value falls within the specified limit. In this silenced state, the status bar will display **Audio Paused**, the alarm symbol will change from active to inactive (see page 68), and the PtO2 value

- if still lower than the user-specified low PtO2 Alarm limit - will continue to flash yellow. If the patient's PtO2 value does not rise above the specified low PtO2 alarm limit, the alarm tone will resume.

Restoring Default Low PtO2 Alarm Limit Values

After specifying the low PtO2 alarm limit value on the **Alarm** tab, the Integra Licox PtO2 Monitor saves this current value into memory . If the monitor is turned off for any duration of time and then turned back on, the last saved low PtO2 alarm limit value will be restored. To restore the low PtO2 alarm limit from a customized setting to the factory default setting (15 mmHg), press **Restore Defaults** and then **Accept**. Note that pressing **Restore Defaults** button will also activate the **Alarm On** mode automatically.

Customizing the User Settings

Press the **Settings** tab to control the appearance of specific graphical and textual information that appears on the touch screen. This panel also includes a button for determining system information regarding software and firmware.

The information on this panel includes:

Item	Description
1	**Set Time and Date** Specifies the time and date that is displayed on the monitor. The purpose of the time/date display is for the **Extract Data** feature (see page 65).
2	**Set Language** Specifies the language that is displayed on the software interface (see page 65).

Item	Description
3	**System Information** Displays information regarding the system's software and firmware (see page 66). **Service Mode** Provides diagnostic information for errors. This mode appears on the **System Information** panel. This mode is password protected and is only accessible by Integra staff (see page 66).

Specifying Time and Date

The Integra Licox PtO2 Monitor provides tools for setting the current time and date that appears on the touch screen.

To set this information:

1. On the touch screen, press the **Settings** tab.
2. Press the **Set Time and Date** button.
3. On the displayed panel, press the desired field (hour, minutes, date, month, or year) and use the arrows to specify the appropriate setting. Note that you may adjust each of these settings prior to accepting them in the following step.
4. Press **Accept**; the Integra Licox PtO2 Monitor will display the selected time/date on the touch screen.

Specifying Languages

The Integra Licox PtO2 Monitor provides options for displaying onscreen text in different languages:

The list of supported languages include:

- English
- German
- Danish
- Japanese
- Portuguese (Brazilian)
- French
- Spanish
- Polish
- Korean
- Italian
- Dutch
- Russian
- Chinese (Simplified)

To change languages from any screen:

1. On the touch screen, press the **Settings** tab.
2. On the left side of the panel, press **Set Language**.
3. In the displayed **Language:** menu, use the arrows to select the desired language.
4. Press **Accept**; the Integra Licox PtO2 Monitor will display all onscreen text to the selected language.

Determining System Information

If you experience technical problems with your Integra Licox PtO2 Monitor, you may need to provide Integra with information regarding the system's software and firmware versions. To determine this information, press the information symbol.

About Extract Log and Service Mode Buttons

The **Extract Log** button only appears on the **System Information** panel if a USB drive is connected to the Integra Licox PtO2 Monitor. Note that when attaching a USB drive, this button may take several seconds to appear. Pressing the **Extract Log** button will copy system log information from the monitor to the USB drive. During a troubleshooting session, the Integra technical staff may request this log file.

The **Service Mode** button provides diagnostic information for Integra staff to troubleshooting errors. This button is only intended for Integra staff.

CHAPTER 6 RESPONDING TO PHYSIOLOGICAL AND TECHNICAL ALARMS

About the Two Alarm Types

The Integra® Licox® PtO2 Monitor activates two types of audio/visual alarms to indicate problems that require immediate attention:

Alarm Type	Description
Physiological	Alerts the nurse/physician that the patient's PtO2 value being monitored has fallen under the specified limit continuously for more than 5 seconds.
Technical	Alerts the nurse/physician that there is a problem with the monitor's battery, electrical components, software version, or probe connections. These technical alarms include: • Irreversible System Failures • Low battery level (5 minutes or less) • Monitor overheating • Cooling fan failure • PtO2 is out of accuracy range • Temperature is out of accuracy range • Battery failure

Warning

Do not block the alarm speaker with any materials that might muffle the alarm sound.

About the Technical Messages

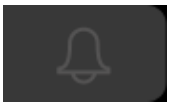
In addition to the technical alarms, the Integra Licox PtO2 Monitor also displays technical messages on the status bar to indicate problems with:

- Low battery level (15 minutes or less)
- Insert Smart Card for probe
- Calibration test failure
- Smart Card failure
- Probe initialization failure
- Cannot write to log file

For information on responding to these messages, see page 83.

Understanding the Alarm Symbols

On the status bar, the Integra Licox PtO2 Monitor displays different variations of the alarm bell symbol to indicate three different alarm states: Active, Audio Paused, and Inactive:

Symbol	State	Description
 (yellow borders)	Active	Indicates an active physiological or technical alarm. In this state, the status bar displays the description of the error that activated the alarm.
 (crossed-out yellow borders)	Audio Paused	Indicates an active physiological or technical alarm that has been paused temporarily by pressing the active alarm symbol. In this state, the status bar displays **Audio Paused**. After 3 minutes of silence, the **Audio Paused** message disappears and the alarm will re-activate automatically.
 (greyed out)	Inactive	Indicates no physiological or technical alarms are active.

How the Monitor Prioritizes the Alarms

The Integra Licox PtO2 Monitor assigns each error condition that may activate a physiological or technical alarm type with a range of clinical priorities between medium and low. These priorities are determined by two factors:

- The potential harm that may occur to the patient
- How quickly the onset of potential harm may occur if the user fails to respond to the cause of the alarm.

Clinical Priority	Potential Harm If Alarm Is Ignored	Timeframe for Potential Harm to Occur
Medium	Reversible injury	Prompt
Low	Reversible injury	Delayed

Audio and Visual Indicators for Medium and Low Priority Alarms

Depending on the clinical priority of the error condition that is causing the alarm, the Integra Licox PtO2 Monitor activates audio and visual indicators to alert the user of the condition:

Clinical Priority	Audio Indicators	Visual Indicators
Medium	• Sounds an alarm containing a burst of three pulses, with a pulse separation of 180 milliseconds and a burst separation of 3 seconds. • The volume of each alarm pulse measures a sound pressure of 70 dB.	• A message will appear on the status bar that identifies the error • If a system failure occurs, a standalone message window will appear that identifies an error code and description of the failure • The borders surrounding specific symbols (e.g, alarm, battery) on the touch screen will flash yellow • For some error conditions, the patient values will flash yellow
Low	• Sounds an alarm containing a single pulse, with a burst separation of 16 seconds. • The volume of the single alarm pulse measures a sound pressure of 69 dB.	• A message will appear on the status bar that identifies the error. • The patient values will appear yellow (not flashing) • For battery-related errors, the battery symbol indicates the battery has no remaining charge.

For specific information on which audio/visual indicators occur for each medium priority and low priority alarm type, see "Responding to the Physiological Alarm (PtO2 below alarm limit)" on page 71, and "Responding to Technical Alarms" on page 71.

Priorities of Physiological and Technical Alarms

The Integra Licox PtO2 Monitor includes one medium priority physiological alarm that gets activated if a patient's low PtO2 value falls below the user specified limit for more than 5 seconds; there are no other physiological alarms. If two or more error conditions occur simultaneously that can activate a physiological alarm and a technical alarm, the physiological alarm will always take precedence (unless the technical alarm is caused by an irreversible system failure, which results in the monitor being unusable; see page 71 for details). The remaining technical alarms will only become announced after the physiological alarm is resolved.

How the Monitor Prioritizes Between Two Technical Alarms

If two or more error conditions of the same clinical priority occur simultaneously that can activate different technical alarms, the Integra Licox PtO2 Monitor prioritizes which alarm it activates based on how the alarm condition affects the safety of the patient or stability of the equipment. Note that a technical alarm with a higher priority will always be activated over a technical alarm with a lower priority; a lower priority alarm will not be announced until the higher priority alarm is resolved.

List of Priorities for Each Alarm

Notice

If any of the software, firmware, or electrical components inside the monitor suffers a serious malfunction during a physiological alarm, the Integra Licox PtO2 Monitor will activate a technical alarm that will override the physiological alarm and indicate a system failure. If this irreversible technical alarm is activated, the monitor will no longer report patient values and the user will need to contact Integra for service. For more information on this error condition, see page 71.

The following table lists the priorities of each alarm condition:

Alarm Priority	Type of Error Condition	Type of Clinical Priority
1	System Failures (see page 71)	Medium
2	PtO2 below alarm limit (see page 71)	Medium
3	Low battery level (5 minutes or less) (see page 72)	Medium
4	Monitor overheating (see page 72)	Medium
5	Cooling fan failure (see page 73)	Low
6	PtO2 is out of accuracy range (see page 73)	Low
7	Temperature is out of accuracy range (see page 73)	Low
8	Battery failure (see page 74)	Low
9	Low Battery level (15 minutes or less)	N/A
10	Smart card failure	N/A
11	Insert smart card for probe	N/A
12	Calibration test failure	N/A
13	Cannot write to log file	N/A

Responding to the Physiological Alarm (PtO2 below alarm limit)

If the patient's low PtO2 value falls below the specified limit continuously for more than 5 seconds, the Integra Licox PtO2 Monitor will activate a medium priority clinical alarm that will:

- Sound an alarm containing a burst of three pulses
- Display the following error message on status bar: **"PtO2 below alarm limit"**
- Flash the alarm symbol on status bar
- Flash the current PtO2 value in yellow on the **Main**, **Trend**, and **Alarm** screens

To silence the alarm temporarily, press the flashing alarm symbol on the touch screen. This will silence the alarm for either 3 minutes or until the patient's PtO2 value rises above the low PtO2 alarm limit for at least one measurement. After 3 minutes, the alarm will reactivate. To turn off the alarm completely, press the **Alarm** tab and select **Alarm Off** and **Accept**. For instructions on specifying the low PtO2 alarm limit, see page 61.

Warning

Selecting the **Alarm Off** feature will disable the low PtO2 alarm limit indefinitely. Use caution if this feature is selected.

Responding to Technical Alarms

Use the following guidelines to respond to each technical alarm.

Responding to System Failure Alarms

If any of the software, firmware, or electrical components inside the monitor suffers a serious malfunction during use, the Integra Licox PtO2 Monitor will stop reporting measurement values on the touch screen and activate a medium priority technical alarm. During this alarm mode, the monitor will:

- Sound an alarm containing a burst of three pulses
- Display a standalone message window that specifies an error code and a description of the applicable system failure, which include the following:
  - Sensor board failure
  - Power board failure
  - General software programming error
  - Incompatible firmware error
  - Sensor board calibration self-test failure

For a complete list of error codes, see page 90. If any of these alarms occur, turn off the monitor and then turn back on. If the error alarm persists, tend to the patient's need, note the specific error code, and contact Integra for service.

Responding to Low Battery Alarm

The Integra Licox PtO2 Monitor includes a replaceable 14.4 V lithium ion battery that supplies power to the monitor for at least 1.5 hours. The battery is intended to power the monitor during patient transport only; use AC power whenever possible.

15 Minutes or Less of Remaining Power

If the battery power level drops to 15 minutes or less of remaining charge, the Integra Licox PtO2 Monitor will display the following message on status bar: **"Battery is low"** If this occurs, plug in the monitor to an AC power outlet. This warning message will not disappear until the monitor is connected to AC power.

5 Minutes or Less of Remaining Power

If the battery power level drops to 5 minutes or less of remaining charge, the Integra Licox PtO2 Monitor will activate a medium priority alarm that will:

- Sound an alarm containing a burst of three pulses
- Display the following message on the status bar: **"Battery is low"**
- Flash the battery symbol in yellow on status bar

If this occurs, plug in the monitor to an AC power outlet immediately. This alarm will stop once the monitor is connected to AC power

Warning

Connect the monitor to an AC power supply immediately if the low battery alarm is activated.

Silencing the Low Battery Alarm Temporarily

Press the flashing alarm symbol on the touch screen. This will silence the alarm for 3 minutes while you plug the monitor into an AC power outlet to charge the battery. If the battery does not receive charge within 3 minutes, the alarm will reactivate.

The Integra Licox PtO2 Monitor battery may be replaced by the hospital's biomedical engineer. For instructions, see page 102.

Responding to Monitor Overheating Alarm

If the temperature inside the Integra Licox PtO2 Monitor exceeds 80°C, the monitor will activate a medium priority alarm that will:

- Sound an alarm containing a burst of three pulses
- Display the following error message on status bar: **"Monitor overheating, check vent"**

To resolve this problem, check the vents on the rear and bottom panels of monitor to ensure nothing is blocking them. If something is blocking them, remove it immediately. Once the temperature inside the monitor falls below 80°C, this alarm will stop and the message will disappear. If this problem continues to occur, turn off the monitor and contact Integra.

Warning

If an alarm is triggered for an overheating monitor while a Licox temperature probe is being used, the excessive heat from inside the monitor may affect the monitor's temperature measurements. If this condition occurs, the calculations for the PtO2 measurements - which require temperature compensation values - may be unreliable until the overheating monitor condition has been resolved.

Silencing the Monitor Overheating Alarm Temporarily

Press the flashing alarm symbol on the touch screen. This will silence the alarm for 3 minutes while you clean the vent from any obstructions. If the temperature inside the monitor does not fall below 80 °C within 3 minutes, the alarm will reactivate.

Responding to Cooling Fan Failure Alarm

The Integra Licox PtO2 Monitor contains an internal fan that circulates air to cool the internal electronic components. If the monitor detects the cooling fan has stopped running, the monitor will activate a low priority technical alarm that will:

- Sound an alarm containing a burst of one pulse every 16 seconds
- Display the following error message on status bar: **"Cooling fan failure"**

If this problem occurs, turn off the monitor to prevent possible overheating. After turning off the monitor, contact Integra for service.

Silencing the Cooling Fan Alarm Temporarily

Press the yellow alarm symbol on the touch screen. This will silence the alarm for 3 minutes while you turn off the monitor's power to prevent possible overheating. If the monitor remains on for 3 minutes while there is still a cooling fan error condition, the alarm will reactivate.

Responding to Accuracy Range Alarm

The Integra Licox PtO2 Monitor is designed to provide accurate measurements of PtO2 and tissue temperature between specific clinical ranges:

Measurements	Range
PtO2	Between 0 mmHg to 150 mmHg that include the following levels of accuracy: • 0 - 20 mmHg: ±2 mmHg • 21- 50 mmHg: ±10% • 51 - 150 mmHg: ±13%
Temperature	Between 30° C to 42° C (±1°C)

If the measured PtO2 or tissue temperature falls outside these ranges, the monitor will activate a low priority alarm that will:

- Sound an alarm containing a burst of one single pulse every 16 seconds
- Display one of the following messages on the status bar:

  "PtO2 is out of accuracy range" or **"Temperature is out of accuracy range"**

- Display the current PtO2 or temperature value in yellow on the **Main**, **Trend**, and **Alarm** screens

To resolve this problem, the PtO2 or tissue temperature must fall within the rated accuracy ranges listed in the above table.

Silencing the PtO2 and Temperature Accuracy Range Alarm Temporarily

Press the yellow alarm symbol on the touch screen. This will silence the alarm for 3 minutes while the PtO2 or temperature values fall back within the rated accuracy ranges displayed in the above table. If the PtO2 or temperature values remain outside the rated accuracy ranges for the 3 minutes, the alarm will reactivate.

Responding to Battery Failure Alarm

If the battery control system inside the Integra Licox PtO2 Monitor fails during the use of the monitor, the monitor will no longer be able to report the amount of remaining charge that battery has. If this problem occurs, the monitor will activate a low priority technical alarm that will:

- Sound an alarm containing a burst of one single pulse every 16 seconds
- Battery power symbol on the touch screen will appear crossed-out.
- Displays the following message on the status bar:

  "Battery Failure"

If this battery failure alarm activates, do not run the monitor on battery power. If necessary, plug the monitor into an AC outlet to maintain power. After patient treatment, try the following:

- Turn off the monitor and then turn it back on.
- Replace the battery.

If this alarm condition persists, contact Integra for service.

Silencing the Battery Failure Alarm Temporarily

Press the yellow alarm symbol on the touch screen. This will silence the alarm for 3 minutes. If the monitor remains on for 3 minutes while there is still a reported battery failure, the alarm will reactivate.

CHAPTER 7 EXTRACTING TREND DATA FOR REMOTE EVALUATION

About Data Extraction

The Integra® Licox® PtO2 Monitor provides two options for extracting PtO2 trend data for remote evaluation:

- External USB Drive
- Digital Streaming via USB-to-**RS232** Serial Cable

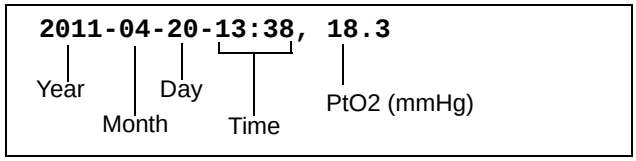
Both media types are connected to the monitor via a USB connection that is located on the rear panel.

Notice

The USB connector port on the Integra Licox PtO2 Monitor is only intended for connecting a USB drive and USB-to-RS232 adapter cable for extracting PtO2 trend data. The USB port is not intended to be connected to a network connection (e.g. USB bluetooth adapter, USB ethernet adapter, etc).

Extracting Data to USB Drive

Use the **Extract Data** feature to export up to 5 days worth of PtO2 trend data from the monitor to an external USB drive. When using this feature, the Integra Licox PtO2 Monitor exports the data to the USB drive as a comma separated value (**.csv**) file. This **.csv** file records the date, time, and PtO2 values in one-minute intervals and displays the information as ASCII text. The following text provides a sample **.csv** trend data entry:

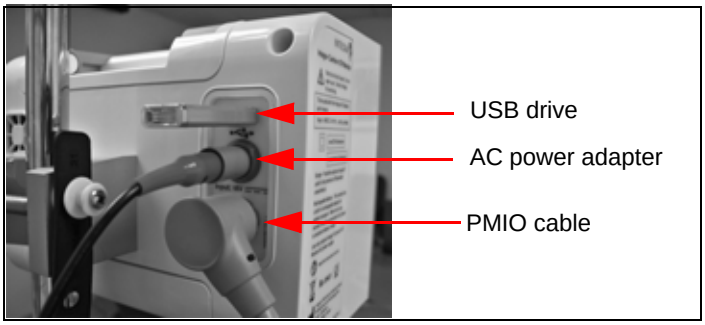


Notice

The external USB drive needs to be a FAT (FAT16 or FAT32) formatted drive. Other file system formats are not supported.

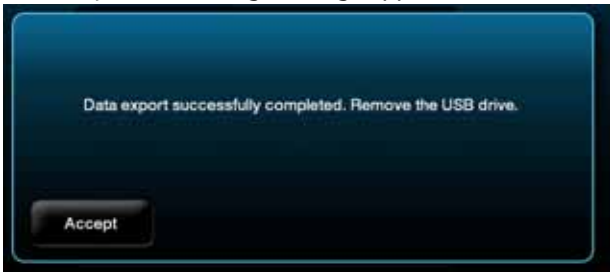
To extract the data to a USB drive:

1. On the rear panel, attach the USB drive to the USB connector.



2. On the touch screen, press **Trend** and select **Extract Data**.

3. Verify the following message appears:



4. Press **Accept**, remove the USB drive, and view the **.csv** file in the desired output device (e.g. laptop).

Notice

To ensure the complete transfer of trend data to the USB drive, do not remove the USB drive until the message specified in the above step 3 appears confirming the extraction.

Note

In the **.csv** file, the timestamp for the data extraction is based on the monitor's date/time settings that are specified on the **Settings** tab. In countries where daylight savings are observed, the time must be adjusted manually. For instructions, see page 65.

How the Monitor Stores Trend Data for Up to 5 Days

The Integra Licox PtO2 Monitor will only store the PtO2 data from the most recent 5 days. All stored trend data older than 5 days will be lost.

Warning

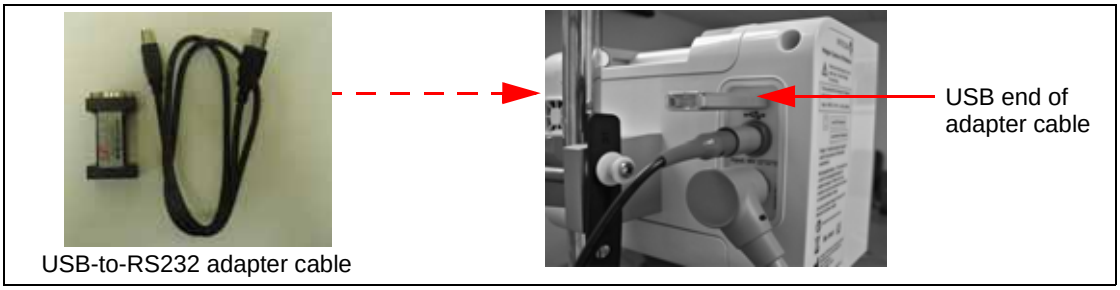
If monitoring is continued for more than 5 days, placement of a new probe under sterile conditions is recommended. Note that replacing an existing probe and Smart Card with a new probe and Smart card will reset the trend data. Please extract any data that you wish to retain prior to replacing the probe and Smart Card..

Extract Data via Digital Streaming

Use the streaming data feature to export PtO2 trend data digitally from the Integra Licox PtO2 Monitor to a remote device via a USB-to-RS232 adapter cable. Note that the Integra-supplied USB-to-RS232 adapter cable is required to use this feature. When streaming data, the monitor reports the PtO2 value in mmHg of the current PtO2 trend data in one-minute intervals. The USB-to-RS232 adapter cable delivers the information as 9600 baud, 8 data bits, 1 stop bit, even parity configurations.

To connect the USB-to-RS232 adapter cable to a computer, you need a female to female, null modem RS232 cable. To extract the data via digital streaming:

1. On the rear panel, attach the USB end of the USB-to-RS232 adapter cable to the **USB** connector.



2. On the touch screen, press **Trend** and verify the following message appears on screen: **"data streaming enabled"**
3. Connect the other end of the USB-to-RS232 adapter cable to the external monitoring device.

Condition That Resets Trend Data During Recording

Replacing a smart card with a different smart card will reset the trend data.

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CHAPTER 8 CLEANING AND STERILIZING THE SYSTEM

Cleaning the System and Components

Before cleaning the surface and touch screen of the Integra® Licox® PtO2 Monitor, note the following.

- Turn off the monitor before cleaning.
- To reduce the risk of shock, follow all safety notices and never open the monitor case.
- The monitor is designed for surface cleaning only - do NOT immerse.
- Never spray cleaning agents or other fluids directly onto the monitor.
- Use particular care when cleaning around the vents, connectors, Smart Card slot, and USB slot. Be sure to wipe any excess fluid that accumulates in these areas.
- When cleaning the touch screen, do not use cloth or sponges that could scratch the surface.

Cleaning Guidelines

Use the following guidelines when cleaning the Integra Licox PtO2 Monitor and each of its system components that are listed in the box below:

• External surface	• Blue PtO2 probe cable (BC10PA)	• Green temperature probe extension cable (BC10TV)
• Touch screen	• Blue PtO2 probe extension cable (BC10PV)	• Blue combined PtO2/temperature probe cable (PMOCAB)
• Cable strap	• Green temperature probe cable (BC10TA)	• Y-adapter cable for blue combined PtO2/ temperature probe cable (BC10PMO)

Note that each of these components should be cleaned immediately after contamination.

Warning

Only use the cleaning agents listed in this section for cleaning and disinfecting the Integra Licox PtO2 Monitor system. Using solvents or cleaning agents not listed in the cleaning guidelines may damage the plastic exterior of the Integra Licox PtO2 Monitor.

Caution

Do not clean the probe cables or probe extension cables in an automatic disinfector.

Item	Guideline
Preparation for Cleaning	Ensure that all the connections between the cables, probe, cable strap, AC power adapter, USB-to-RS232 serial adapter, Smart Card, and monitor have been removed before cleaning the Integra Licox PtO2 Monitor.
Limits on Reprocessing	• The probe cables and probe extension cables may be sterilized ten (10) times. Do not use the cables after reaching this reprocessing limit. For tracking purposes, use the Reprocessing Record Sheets supplied with your cables. • There are no limits on reprocessing the Integra Licox PtO2 Monitor and cable strap.
Recommended Manual Cleaning Methods	• Using either 70% IPA with a lint free wipe or a Super Sani-Cloth® (or equivalent solution), thoroughly wipe all surfaces at least three (3) times and then inspect the surfaces for visible residues. • If residues remain, use a new Super Sani-Cloth (or equivalent solution) or lint free wipe soaked with 70% IPA and continue wiping the surfaces until they are visibly free of residues.
Recommended Disinfection Methods	• Using either 70% IPA with a lint free wipe OR Super Sani-Cloth (or equivalent solution), thoroughly wipe all surfaces once. • Ensure that the surfaces remain visibly wet for a minimum of two (2) minutes and use additional wipe(s), if needed, to ensure continuous two (2) minute wet contact time. • Let the Integra Licox PtO2 Monitor and any of its system components air dry prior to reuse.
Inspection and Functional Testing	After each reprocessing event, visually inspect the Integra Licox PtO2 Monitor and any of its system components for any wear and tear.
Containment and Transportation	It is recommended that the Integra Licox PtO2 Monitor and any of its system components be cleaned and disinfected as soon as is reasonably practical after use.

Sterilizing the Probe Cables and Probe Extension Cables

The probe cables and probe extension cables are provided non-sterile:

Warning

Do not autoclave or immerse the Integra Licox PtO2 Monitor in liquid as damage may occur. If the monitor is exposed to liquids, turn off the unit, remove the AC power adapter, remove the battery, dry the unit thoroughly, and send to biomed staff for evaluation before reapplying power.

Notice

All probe cables must be sterilized whenever they are to be used in the sterile field. Prior to sterilization, clean the probe cables using the guidelines listed on page 79.

Limits on Sterilization

Each of the following probe cables and probe extension cables may be sterilized ten (10) times:

Notice

The Y-Adapter cable for the blue combined PtO2/temperature probe cable (BC10.PMO) cannot be sterilized.

- Blue PtO2 probe cable (BC10PA)
- Blue PtO2 probe extension cable (BC10PV)
- Blue combined PtO2/temperature probe cable (PMOCAB)
- Green temperature probe cable (BC10TA)
- Green temperature probe extension cable (BC10TV)

Do not use the cables after reaching these this reprocessing limit. For tracking purposes, use the Reprocessing Record Sheets supplied with your cables.

Sterilization Parameters

Each probe cable and probe extension cable supports steam sterilization only. Prior to sterilization, the cables should be packaged individually in a self-sealing pouch with dimensions 7.5" x 13" or larger.

Steam Pre-Vacuum Sterilization Parameters

Option 1 (US)	
Parameters	**Specifications**
Temperature	132°C (270°F)
Exposure Time	4 minutes
Dry Cycle Time	20 minutes

Option 2 (EU)	
Parameters	**Specifications**
Temperature	134°C to 137°C (273°F to 279°F)
Exposure Time	3 minutes
Dry Cycle Time	16 minutes

Option 3 (EU)	
Parameters	**Specifications**
Temperature	134°C (273°F)
Exposure Time	18 minutes
Dry Cycle Time	20 minutes

The Option 2 and Option 3 sterilization cycles are not considered by the United States Food and Drug Administration (US FDA) to be standard sterilization cycles. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

Following Sterilization of Probe Cables and Probe Extension Cables

Allow the cables to cool down to ambient temperature before starting the monitoring process. Before each use, visually inspect the sterilized cables for any possible defects and check the functionality of the cables by performing checks as described on page 94. Do not use defective cables.

About Single-Use Only Probes

Integra probes are intended for single use only. Reuse of the device can result in contamination and/or disease transmission. This product should not be resterilized. Resterilization may affect the performance characteristics and the safety of the device.

Disposal of the Monitor System and Components

Unless stipulated otherwise in the sales contract, the end-of-life Integra Licox PtO2 Monitor, cables and AC power adapter must be returned to Integra for disposal or disposed according to the hospital recommended procedure. The devices must be clean and free from blood or other biological contaminants when returned for disposal. Please contact Integra for further details.

CHAPTER 9 TROUBLESHOOTING THE SYSTEM

About the Troubleshooting Process

This chapter provides guidelines for responding to technical errors, system failures, and system messages that appear on the touch screen. For instructions on responding to alarms, see Chapter 6.

Responding to System Status Messages

The following table lists each error message alphabetically that appears on the touch screen:

System Message	Cause	Recommendation
Battery failure	Battery's control system has failed.	• Plug Integra® Licox® PtO2 Monitor into AC power outlet (see page 27). • After patient treatment, turn off Integra Licox PtO2 Monitor and then turn back on. • Replace the battery (see page 102). • If problem persists, contact Integra.
Battery is low	Battery has 15 minutes or less of charge.	Plug Integra Licox PtO2 Monitor into AC power outlet (see page 27).
	Battery has 5 minutes or less of charge (accompanied by alarm tone).	Plug Integra Licox PtO2 Monitor into AC power outlet (see page 27).
Calibration test failure	Test probe is not connected.	• Connect test probe to the blue probe cable. • If failure persists, contact Integra.

System Message	Cause	Recommendation
	Faulty test probe cable.	• Swap the blue probe cable that the test probe is connected to. • Connect the test probe into the new blue probe cable. • If failure persists, contact Integra.
Cannot write to log file	Cannot write data to log file that is used by Integra for servicing.	Not resolvable. Contact Integra.
Cooling fan failure	Cooling fan inside of Integra Licox PtO2 Monitor has stopped running.	Turn off the Integra Licox PtO2 Monitor to prevent overheating and contact Integra (see page 73).
Data export failed. Could not detect or write to a USB drive.	Problem with the connection or compatibility of USB drive.	See troubleshooting details on page 89: No transfer of trend data via USB connection.
Insert Smart Card for Probe	Smart Card not inserted into slot.	Firmly insert the PtO2 probe's designated Smart Card into slot (page 33).
Monitor overheating, check vent	Temperature inside Integra Licox PtO2 Monitor has exceeded 80 °C.	Check air vent on rear panel of Integra Licox PtO2 Monitor. If anything is blocking vent, remove it (see page 72).
No temperature probe detected. Use Manual Temperature Input.	A PtO2 probe and Smart Card is connected to the Integra Licox PtO2 Monitor without a temperature probe.	• Select **Accept** button and use the **Manual Temperature Input** arrows to specify the temperature (see page 58). • If temperature will be measured with a probe, attach a temperature probe to the **Temperature** port on the Integra Licox PtO2 Monitor.
PtO2 below alarm limit	Patient's PtO2 value has fallen below the user-specified low PtO2 alarm limit for more than 5 seconds.	Respond to patient's need immediately. Once the patient's PtO2 value moves within the alarm limit, the alarm will turn off (see page 71).
PtO2 is out of accuracy range	PtO2 value has exceeded the range that the Integra Licox PtO2 Monitor can measure accurately (between 0 mmHg and +150 mmHg).	Do not rely on PtO2 measurements until the PtO2 value is within the accuracy range (see page 73).

System Message	Cause	Recommendation
Smart Card Failure	Smart Card orientation is incorrect or Smart Card is not seated properly in the slot.	• Remove the Smart Card from the slot (see page 33). • Check orientation of the Smart Card by aligning the arrows on the card with the red arrow next to slot. • Firmly re-insert the Smart Card into the slot.
	Faulty Smart Card.	• If problem persists, attach a new PtO2 probe and designated Smart Card (see page 33). • If the problem does not resolve after attaching multiple Smart Cards, contact Integra.
Temperature is out of accuracy range	Temperature value is outside the range that the Integra Licox PtO2 Monitor can measure accurately (between 30° C and 42° C).	Do not rely on the PtO2 measurements until the temperature value is within the accuracy range (see page 73).
		• Enter temperature manually by unplugging temperature probe (see page 58). • On the touch screen, use the **Manual Temperature Input** arrows to specify the temperature.

Responding to Problems During Use

The following table provides guidelines for responding to technical problems that may occur with the Integra Licox PtO2 Monitor during use.

Problem	Cause	Recommendation
Integra Licox PtO2 Monitor does not operate with AC power.	AC power adapter not connected	Attach AC power adapter to Integra Licox PtO2 Monitor (see page 27).
	Faulty AC power adapter cord	• Attach AC adapter cord to Integra Licox PtO2 Monitor (page 27). • Perform AC power test to ensure AC power works (see page 100). • Contact Integra to order new AC power adapter cord.

Problem	Cause	Recommendation
Integra Licox PtO2 Monitor does not operate on battery power.	Battery not installed.	• Attach AC power adapter to Integra Licox PtO2 Monitor (see page 13). • On touch screen, check battery indicator on status bar to ensure the battery is installed (see page 30). • If not, install the battery (see page 102).
	Battery not charged	• Attach AC power adapter to Integra Licox PtO2 Monitor (see page 27). • On touch screen, check battery indicator on status bar to ensure the battery is being charged (see page 30).
	Faulty battery	• Attach AC adapter cord to Integra Licox PtO2 Monitor (page 27). • Perform battery charge test on page 101 to ensure battery holds charge properly. • Contact Integra to order new battery.
Touch screen freezes	System hardware error	• Press and hold the power button for several seconds to perform a forced shutdown of the system. • Press the power button to turn on the system.
Integra Licox PtO2 Monitor does not power on or off when power button is pressed.	Firmware error	• Disconnect AC adapter cord from Integra Licox PtO2 Monitor and remove battery (see page 102). • Re-insert the battery and then re-connect AC adapter cord to Integra Licox PtO2 Monitor. • Press the power button.
The **PtO2** value on the touch screen displays two dashes (**- -**).	No Smart Card is inserted into slot.	Firmly insert the designated Smart Card into the slot (page 33).
	Smart Card orientation is incorrect or Smart Card is not seated properly in the slot.	• Remove the Smart Card from the slot (see page 33). • Check orientation of the Smart Card by aligning the arrows on the card with the red arrow next to slot. • Firmly re-insert the Smart Card into the slot.

Problem	Cause	Recommendation
PtO_2 value on the touch screen displays zero (0) mmHg or less.	No PtO_2 probe is connected to the Integra Licox PtO_2 Monitor.	Connect a PtO_2 probe to the Integra Licox PtO_2 Monitor (see page 33).
	Poor connection between the PtO_2 probe cable and the Integra Licox PtO_2 Monitor.	Make sure the cable is properly connected to the Integra Licox PtO_2Monitor (see page 33).
	Poor connection between the PtO_2 probe cable and the PtO_2 probe.	Make sure the probe cable is properly connected to the probe (see page 33).
	Damaged PtO_2 probe cable.	Replace PtO_2 probe cable (see page 33).
	Faulty PtO_2 probe.	Replace the probe and Smart Card with a new probe and Smart Card (see the instructions for use supplied with the probe).
The **temperature** value on the touch screen displays two dashes (**- -**).	No Smart Card is inserted into the slot.	Firmly insert the designated Smart Card into the slot (page 33).
	Smart Card orientation is incorrect or Smart Card is not seated properly in the slot.	• Remove the Smart Card from the slot (see page 33). • Check orientation of the Smart Card by aligning the arrows on the card with the red arrow next to slot. • Firmly re-insert the Smart Card into the slot.
	Poor connection between the temperature probe cable and the Integra PtO_2 monitor.	• Make sure the cable is properly connected to the Integra Licox PtO_2 Monitor (see page 38).
	Poor connection between the temperature probe cable and the temperature probe.	• Replace the probe (see the instructions for use supplied with the probe).
	Damaged temperature probe cable	• Replace the probe cable.
	Faulty temperature probe	• Replace the probe (see the instructions for use supplied with the probe).
Time/date appears incorrectly.	Time and/or date is set incorrectly.	On touch screen, press the **Settings** tab and select **Set Time and Date** to specify current time and date (see page 65).

Problem	Cause	Recommendation
Incorrect language is displayed.	Choice of language is set incorrectly.	On touch screen, press the **Settings** tab and select **Set Language** to specify language (see page 65).
Discrepancy of **PtO2** measurements between the Integra Licox PtO2 Monitor and the patient bedside monitor.	Patient bedside monitor is not synchronized to the Integra Licox PtO2 Monitor correctly.	On the Integra Licox PtO2 Monitor, press **Synchronize to Monitor** to re-calibrate the two monitors (see page 48).
	Incorrect patient bedside monitor adapter cable is used.	Verify correct patient bedside monitor cable is being used (see page 48).
	PMIO cable or patient bedside monitor adapter cable is faulty.	Replace PMIO cable or patient bedside monitor adapter cable (see page 48).
	PMIO cable or patient bedside monitor adapter cable is loose.	Check cable connections between Integra Licox PtO2 Monitor and patient bedside monitor (see page 48).
	Patient bedside monitor has malfunctioned.	Refer to manufacturer's troubleshooting guide for the patient bedside monitor.
	Patient bedside monitor is not compatible with the Integra PtO2 monitor.	• See the patient bedside monitor specifications in Appendix A (see page 108). • See the manufacturer's troubleshooting guide for the patient bedside monitor.
Discrepancy of **temperature** measurements between the Integra Licox PtO2 Monitor and the patient bedside monitor.	Incorrect patient bedside monitor adapter cable is used.	Verify correct patient bedside monitor cable is being used (see page 48).
	PMIO cable or patient bedside monitor adapter cable is faulty.	Replace PMIO cable or patient bedside monitor adapter cable (see page 48).
	PMIO cable or patient bedside monitor adapter cable is loose.	Check cable connections between Integra Licox PtO2 Monitor and patient bedside monitor (see page 48).
	Patient bedside monitor has malfunctioned.	Refer to manufacturer's troubleshooting guide for the patient bedside monitor.

Problem	Cause	Recommendation
	Patient bedside monitor is not compatible with the Integra PtO2 monitor.	• See the patient bedside monitor specifications in Appendix A (see page 108). • See the manufacturer's troubleshooting guide for the patient bedside monitor.
No transfer of trend data via digital streaming with USB-to-RS232 adapter cable.	Loose USB-to-RS232 adapter cable.	• Reconnect USB-to-RS232 adapter cable (see page 77). • On touch screen, press **Trend** tab and verify **Data Streaming Enabled** message appears.
	Faulty USB-to-RS232 adapter cable.	• Replace USB-to-RS232 adapter cable (see page 77). • On touch screen, press **Trend** tab and verify **Data Streaming Enabled** message appears.
	External monitoring device is not configured correctly for digital streaming.	See digital streaming requirements on page 77.
No transfer of trend data via USB connection.	No USB drive is connected.	• Connect USB drive to rear panel (see page 75). • On touch screen, press **Trend** tab and select **Extract Data** button. • Verify confirmation message appears that indicates successful USB transfer (see page 76) .
	USB drive not seated properly in monitor.	• Check connection of USB drive on rear panel (see page 75). • On touch screen, press **Trend** tab and select **Extract Data** button. • Verify confirmation message appears that indicates successful USB transfer (see page 76).
	USB drive has been removed before completion of data transfer.	• Re-connect USB drive to rear panel (see page 75). • On touch screen, press **Trend** tab and select **Extract Data** button. • Verify confirmation message appears that indicates successful USB transfer (see page 76).

Problem	Cause	Recommendation
	USB drive is corrupted.	• Connect new USB drive to Integra Licox PtO2 Monitor (see page 75). • On touch screen, press **Trend** tab and select **Extract Data** button. • Verify confirmation message appears that indicates successful USB transfer (see page 76).
	Brand of USB drive is not recognized by Integra Licox PtO2 Monitor.	Insert different brand of USB drive into rear panel of Integra Licox PtO2 Monitor (see page 76).
	USB drive is not formatted with the FAT (FAT16 or FAT32) formatted drive.	Insert a USB drive with a FAT (FAT16 or FAT32) formatted file system.

Responding to System Failure Messages

If a system failure occurs, the Integra Licox PtO2 Monitor will display a message window that identifies an error code and description of the problem. The following table lists each error code associated with a system failure:

Error Codes	Cause	Recommendation
E0011, E3002, E3003, E3004, E3008, E3025, E3026, E3032, E3037, E3038, E3039, E3041, E3042, E3044, E3045, E3046, E3047, E3048, E3051, E3057, E3061, E3101, E3103, E3104, E3105	Sensor board failure.	• Turn off Integra Licox PtO2 Monitor and then turn back on. • If error persists, contact Integra.
E3051	Sensor board failure caused by USB drive that is connected to monitor during startup.	• Remove USB drive from monitor. • Turn off Integra Licox PtO2 Monitor and then turn back on. • After the monitor completes the startup process and displays the **Main** panel, re-connect USB drive to monitor (see page 75). • If error persists, contact Integra.

Error Codes	Cause	Recommendation
E0012, E1002, E1003, E1004, E1008, E1032, E1033, E1041, E1042, E1044, E1045, E1046, E1047, E1050, E1057, E1061, E1101, E1103, E1104, E1105	Power board failure.	• Turn off Integra Licox PtO2 Monitor and then turn back on. • If error persists, contact Integra.
E0013	General software error.	• Turn off Integra Licox PtO2 Monitor and then turn back on. • If error persists, contact Integra.
E0015	Incompatible firmware error.	• Turn off Integra Licox PtO2 Monitor and then turn back on. • If error persists, contact Integra
E0019	Calibration self test failure.	• Turn off Integra Licox PtO2 Monitor and then turn back on. • If error persists, contact Integra

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CHAPTER 10 TESTING AND PREVENTIVE MAINTENANCE

About These Procedures

Notice

The procedures in this chapter are intended for the hospital's biomedical staff.

Perform the following operational checks periodically to verify that the Integra® Licox® PtO2 Monitor is operating safely and effectively. Some checks may be helpful to diagnose problems that may occur with the system. None of these checks require disassembling the monitor.

Notice

The operational checks may be performed in any order.

Testing Pressure Input

Perform the following procedures to test the calibration accuracy of the PtO2 measurements.

Testing Accuracy of PtO2 Measurements

Note the following testing guidelines:

Guidelines	Requirements
Maintenance Interval	Once every three months is suggested
Equipment	• Test Set (BC10R) containing the test Smart Card and test probe • Blue PtO2 probe cable (BC10PA); or • Blue combined PtO2/temperature probe cable (PMOCAB) with the required Y-adapter cable (BC10PMO)

Notice

Before performing this test, verify that the Integra Licox PtO2 Monitor is turned off and not connected to any cables.

1. Plug the Integra Licox PtO2 Monitor to an AC wall outlet.
2. On the right side of the monitor, connect one of the following probe cables to the monitor:
   - The blue PtO2 probe cable (BC10PA) to the port labeled **PtO2.**;

   or

   - The blue combined PtO2/temperature probe cable (PMOCAB) with the required Y-adapter cable (BC10PMO) to the monitor. This requires the following steps:
     A. Connect the blue and green ends of the Y-adapter cable into the ports labeled **PtO2** (for blue end of cable) and **Temperature** (for green end of cable).
     B. Connect the blue PtO2 probe cable (PMOCAB) into the Y-adapter cable.
3. On the right side of the monitor, attach the following components that are supplied in the test set (BC10R):
   A. Connect the test probe to the blue probe cable that was used in step 2.
   B. Insert the test Smart Card into the slot and verify it is positioned securely (see page 33).
4. Turn on the monitor.

5. On the touch screen, press the **Main** tab and verify the **PtO2** value appears as:

   154.7 mmHg (± 0.4 mmHg)

6. If the touch screen displays the message "**Calibration Test Failure**" in the status bar:

   A. Make sure that the test probe is inserted firmly into the blue PtO2 probe cable. that was used in step 2.

   B. If the touch screen still displays the "**Calibration Test Failure**" message, contact Integra.

Testing Pressure Output

Note the following test guidelines:

Guidelines	Requirements
Maintenance Interval	Once every three months is suggested.
Equipment	• Digital Multimeter (DMM), 1 mV (resolution) • PMIO cable (part #PMIO-MPM) • DC bench power supply (10 V DC)

Notice

Before performing this test, verify that the Integra Licox PtO2 Monitor is turned off and not connected to any cables.

1. Plug the Integra Licox PtO2 Monitor to an AC wall outlet.
2. On the rear of the monitor, connect a PMIO cable to the PMIO connector, but not to an external patient bedside monitor.
3. Using the DC bench power supply and the Digital Multimeter (DMM), do the following:

   A. Set DC power supply to 10 ± 0.1 volts and connect "**+**" and "**-**" leads to pins "**1**" and"**4**" of the six pin cannon connector, respectively.

   B. Connect the "**+**" and "**-**" leads of the DMM to pins "**2**" and "**3**" of the six pin cannon connector, respectively.

4. Turn on the monitor. On the touch screen, press **Synchronize to Monitor** to test the following PtO2 values.

Simulated Pressure (mmHg)	Simulated Voltage (mVDC)
0	0.000 ± .25
25	1.250 ± .25
50	2.500 ± .25
100	5.000 ± .25

Note that pressing **Check Additional Values** each time will advance to the next fixed PtO2 value.

5. If any of the values exceed their tolerance criteria, contact Integra.
6. Turn off all test equipment, power down monitor, and then disconnect all test equipment.

Testing Temperature Input and Output

Note the following test guidelines:

Guidelines	Requirements
Maintenance Interval	Once every three months is suggested.
Required Equipment	• Digital Multimeter (DMM), 1 mV (minimum reading of 1 k and 2 k ohms having an accuracy of 1 ohm) • Water bath or beaker • Reference Thermometer (between 30 and 40°C) • 1 Smart Card (not the test Smart Card) • 1 Integra Licox temperature probe • Green temperature probe cable (BC10TA) • PMIO cable (PMIOMPM)

Notice

Before performing this test, verify that the Integra Licox PtO2 Monitor is turned off and not connected to any cables.

1. Plug the Integra Licox PtO2 Monitor to an AC wall outlet.
2. Turn on the monitor and allow the monitor to warm-up for 3 hours (see page 28 for details).
3. On the right side of the monitor:
   A. Connect the green temperature probe cable (BC10TA) to the port labeled **Temperature.**
   B. Connect the Licox temperature probe to the temperature probe cable (BC10TA).
   C. Insert the Smart Card into the **Smart Card** slot by aligning the arrow on the card with the arrow on the label. Verify that the card is positioned securely into the slot.
4. On the rear of the monitor, connect a PMIO cable (PMIOMPM) to the port labeled **PMIO**, but not to an external patient bedside monitor.
5. Fill a water bath or beaker with warm water at approximately **32°C** and do the following:
   A. Place the Licox temperature probe in the water.

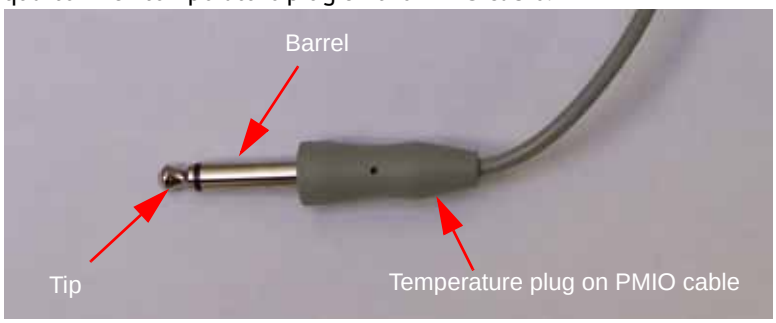
B. Place the reference thermometer in water.

C. Allow a run-in period of at least 15 minutes after the temperature reaches approximately 32°C.

D. On the touch screen, press the **Main** tab and verify the **Temperature** value matches the reference thermometer reading to an accuracy of ± 1°C .

E. If the measured temperature on the monitor and the reference thermometer differs more than ± 1°C, contact Integra.

6. Using the DMM, measure the resistance in Ohms between the tip and barrel on the quarter inch temperature plug on the PMIO cable:



7. Using the table that appears on page 98:

A. Verify that the measured resistance is between the low and high limits for the temperature value that is displayed on the monitor.

B. If any of the values exceed their tolerance criteria, contact Integra.

8. Fill a water bath or beaker with warm water at approximately **38**°C and do the following:

A. Place the Licox temperature probe in the water.

B. Place the reference thermometer in the water.

C. Allow a run-in period of at least 15 minutes after the temperature reaches approximately 38°C.

D. On the touch screen, press the **Main** tab and verify the **Temperature** value matches the reference thermometer reading to an accuracy of ± 1°C.

E. If the measured temperature on the monitor and the reference thermometer differs by more than ± 1°C, contact Integra.

9. Using the DMM, measure the resistance in Ohms between the tip and barrel on the quarter inch temperature plug on the PMIO cable.

10. Using the table that appears on page 98:

A. Verify that the measured resistance is between the low and high limits for the temperature value that is displayed on the monitor.

B. If any of the values exceed their tolerance criteria, contact Integra.

11. Disconnect DMM, and turn off monitor.

Temperature vs. Resistance Table

Output Temperature Range: 31 °C to 33 °C

Temperature (°C)	Low Ω	High Ω
31	1727	1751
31.1	1718	1751
31.2	1709	1742
31.3	1692	1742
31.4	1692	1733
31.5	1684	1716
31.6	1676	1708
31.7	1676	1700
31.8	1668	1700
31.9	1660	1692
32	1652	1684
32.1	1635	1684
32.2	1635	1676
32.3	1627	1659
32.4	1627	1651
32.5	1620	1651
32.6	1612	1644
32.7	1604	1636
32.8	1597	1628
32.9	1582	1628
33	1582	1621

Output Temperature Range: 37 °C to 39 °C

Temperature (°C)	Low Ω	High Ω
37	1337	1367
37.1	1335	1361
37.2	1330	1359
37.3	1325	1354
37.4	1320	1349
37.5	1310	1344
37.6	1305	1334
37.7	1300	1329
37.8	1295	1324
37.9	1290	1319
38	1285	1314
38.1	1280	1309
38.2	1275	1304
38.3	1270	1299
38.4	1266	1294
38.5	1261	1290
38.6	1256	1285
38.7	1251	1280
38.8	1242	1275
38.9	1238	1266
39	1233	1262

Testing Low PtO2 Alarm Limit

Note the following test guidelines:

Guidelines	Requirements
Maintenance Interval	Once every three months is suggested.
Equipment	1 Smart Card (not the test Smart Card)

Notice

Before performing this test, verify that the Integra Licox PtO2 Monitor is turned off and not connected to any cables. Also verify that no Smart Card is inserted into the monitor.

1. Plug the Integra Licox PtO2 Monitor to an AC wall outlet.
2. Turn on the monitor.
3. On the **Alarm** tab:
   A. Press the **Alarm On** button.
   B. Note the current **Low PtO2 Alarm Limit** value specified by the clinician. After completing this test, you will reset the alarm limit to this value.
   C. In the **Low PtO2 Alarm Limit:** field, specify **15** mmHg.
   D. Press **Accept**.
4. On the right side of the monitor, insert the Smart Card into the slot; this will produce a PtO2 measurement of approximately 0 mmHg.
5. After approximately 5 seconds, verify the monitor:
   - Sounds an alarm containing a burst of three pulses
   - Displays the following error message on status bar: **"PtO2 below alarm limit"**
   - Flashes the alarm symbol on status bar
   - Flashes the PtO2 value in yellow on the **Main**, **Trend**, and **Alarm** screens
6. Silence the alarm temporarily. On the touch screen, press the flashing alarm symbol and verify the monitor:

   - Silences the audio alarm
   - Changes the active alarm symbol to the silenced alarm symbol
   - Displays **Audio Paused** on the status bar
7. Wait approximately 3 minutes and verify the monitor re-activates the alarms specified in step 5.
8. Reset the low PtO2 alarm limit back to the value specified by the clinician (see see Step 3B):
   A. In the **Low PtO2 Alarm Limit:** field, specify **15** mmHg.
   B. Press **Accept**.

Testing AC Power and Battery Charge

AC Power

Notice

Before performing these tests, verify that the Integra Licox PtO2 Monitor is turned off and not connected to any cables.

Integra recommends performing this test once every three months:

1. Plug the Integra Licox PtO2 Monitor to an AC power outlet.
2. Press the power button to turn on the monitor and verify the following:
   - On the front of the monitor, check that the LED AC power indicator that appears above the power button is illuminated.
   - On the touch screen, check that the plug icon appears in the status bar. 
3. On the rear of the monitor, disconnect the power cord and verify the following:
   - On the front of the monitor, check that the green LED AC power indicator turns off.

   - On the touch screen, verify the plug icon appears crossed-out in the status bar. 
4. If any of the AC power checks listed in steps 2 and 3 fail, contact Integra.

Low Battery Alarm

Notice

Before performing these tests, verify that the Integra Licox PtO2 Monitor is turned off and not connected to any cables.

Integra recommends performing this test once every three months:

1. Run the Integra Licox PtO2 Monitor on battery power until the following message appears: **"Battery is low",** indicating that the battery has 15 minutes or less of remaining charge before the monitor shuts off. Note a fully charged battery will take over an hour before falling to the charge level that displays the "**Battery is low**" message.
2. Keep running the monitor on battery power for another 10 minutes. After approximately 10 minutes, verify that the monitor:
   - Sounds an alarm containing a burst of three pulses
   - Continues to display the following alarm message on status bar: **"Battery is low"**
   - Flashes the battery symbol in yellow on the status bar

   These audible and visual alarms indicate that the battery has approximately 5 minutes or less of remaining charge before the monitor shuts off. If problems with the low battery alarm persist, contact Integra.

Battery Charge

1. Run the Integra Licox PtO2 Monitor on battery power until the remaining battery charge is depleted. Note the when the battery power falls to approximately 5 minutes or less of remaining charge, the monitor will activate an audible alarm. After the alarm sounds for approximately 5 minutes, the monitor will automatically shut down.
2. Plug the monitor into an AC adapter outlet to start re-charging the battery.
3. Press the power button to turn on the monitor. On the touch screen, verify that the battery power symbol that appears on the status bar displays the electrical charge symbol.

4. Press the power button again to turn off the monitor. Continue charging the battery to full capacity; The time for re-charging the battery while the monitor is turned off will take less than 5 hours.

Notice

If the battery takes more than 5 hours to charge to full capacity, try replacing the battery with a new one. To order a battery, contact Integra.

5. Once the battery reaches full charge, the battery power symbol will display four green bars.

6. Unplug the monitor and run it on battery power only and verify that the battery charge lasts a minimum of 1 hour and 30 minutes. If the battery charge does not last a minimum of 1 hour and 30 minutes, contact Integra to order a new battery.

Inserting A New Battery

The Integra Licox PtO2 Monitor requires the Integra-supplied 14.4 V lithium ion battery (REF # BAT1001) to provide battery power to the monitor during transport. To order a replacement battery, contact Integra.

To insert the battery:

1. Verify that the Integra Licox PtO2 Monitor is turned off and the AC power adapter is unplugged.
2. Turn the monitor upside down so the handle is facing downward.
3. Remove the 2 screws and take off the battery cover.
4. Remove the old battery by gently pulling the battery from the monitor's connector slots. Make sure to dispose of the old battery according to local regulations.
5. Insert the new battery:
   A. Verify the Integra logo on the battery label is facing up.
   B. Align the battery's connectors on the front of the battery to the connector slots on the monitor.
   C. Slide the battery's connector into the monitor's connector slots until the battery is fully inserted into place.

Notice

The battery for the Integra Licox PtO2 Monitor can only be inserted in one orientation.

6. Secure the battery cover to the monitor by re-inserting the two small screws.

Warning

To prevent injury to the patient, user, or other persons, make sure to close the battery cover securely. Note that the battery cover should remain closed at all times during use of the monitor.

Notice

If the monitor is not used, the battery will lose charge. Always make sure the battery is charged to full capacity prior to use. The Integra Licox PtO2 Monitor will charge the battery while the monitor is plugged into AC power.

Determining Software Version

On the touch screen, press the **Settings** tab and select the information symbol and verify the software version.

Testing Synchronizing to Patient Bedside Monitor

Perform the procedures for synchronizing the Integra Licox PtO2 Monitor to a patient bedside monitor on page 48.

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CHAPTER 11 CONTACTING INTEGRA FOR TECHNICAL SUPPORT AND ANNUAL MAINTENANCE

About Technical Support

If the Integra® Licox® PtO2 Monitor fails to perform as specified, and the cause cannot be determined, do not use or attempt to repair it. Instead, contact Integra for technical service:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA
Tel: 1-800-654-2873 (USA only)
1-(609) 275-0500
Fax: 1-609-275-5363

For service and repairs outside the United States, contact your local authorized Integra representative.

Warning

To reduce the risk of electric shock, do not disassemble the Integra Licox PtO2 Monitor. Refer all servicing to qualified service personnel at Integra.

Warning

No modification of the Integra Licox PtO2 Monitor is allowed.

About Annual Maintenance

The Integra Licox PtO2 Monitor requires annual maintenance to be performed by Integra at their service center to ensure proper function and calibration of the monitor. During this process, Integra will also replace the battery with a new one if necessary.

- To determine the next due date for annual maintenance, see the label that appears on the rear panel.
- To schedule the Integra Licox PtO2 Monitor for annual maintenance, contact Integra.

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APPENDIX A TECHNICAL SPECIFICATIONS

List of Technical Specifications

The following table lists the technical specifications for the Integra® Licox® PtO2 Monitor:

Item	Specification
Monitor Type	Integra Licox PtO2 Monitor
Dimensions	240 mm x 165 mm x 185 mm (Width x Height x Depth)
Weight	3.0 kg (6.7 lbs)
Display	• 7.0" WVGA color TFT LCD display • 800 x 480 pixel resolution • The numeric parameters displayed on the touch screen can be read from a distance of 10 feet, up to a 30° angle off center.
Power Supply	Use only Integra-supplied AC power adapter, REF # MONPWR, 18 V DC ⎓, 1.67 A, 30 W
Battery	Use only Integra-supplied 14.4 V lithium ion battery, REF # BAT1001. • Charge time = No more than 5 hours while the monitor is plugged into an AC power outlet and the monitor is turned off. • Operation time is at least 1.5 hours
Principle Technology	**PtO2 Measurement** • Polarographic electrochemical sensor **Temperature Measurement** • Type K thermocouple
Low PtO2 Alarm Limit	• 1 to 125 mmHg, 1 mm increments • Factory default set to 15 mmHg

Item	Specification
Pressure (PtO_2) Excitation Voltage from Patient Bedside Monitor	• DC: 2 to 10V (single-ended) • DC: ±2.5V differential • AC: 2 to 10V RMS up to 5000 Hz (sine wave)
Output to Patient Bedside Monitor	• PtO_2 Measurement = 5.0 µ V/V/mmHg • Temperature Measurement= Conforms to a standard YSI 400 thermistor interface. • PtO_2 = ±1 mmHg or 1% of monitor reading (whichever is greater)[1] • Temperature = ±0.2 ° C to YSI 400 standard
Data Extraction	• USB = USB 1.1 • RS232 = 9600 baud, 8 data bits, 1 stop bit, even parity configurations
Operating Pressure	700 to 1060 hPa
Shipping / Storage Pressure	500 to 1060 hPa
Operation Limits	• Temperature = 15°C to 30°C • Humidity = 30% to 75% relative humidity, non-condensing
Shipping / Storage Limits	• Temperature = -20°C to 50°C • Humidity = Relative humidity ranging from 25% to 80%
Accuracy in Long Term Operation	PtO_2 Probe • Range 0 - 20 mmHg: ±2 mmHg • Range 21 - 50 mmHg: ±10% • Range 51 - 150 mmHg: ±13% Temperature Probe • ±1 °C Test Probe • 154.7 ± 0.4 mmHg at 22°C
Rated PtO_2 Accuracy Range	0 to 150 mmHg.
Rated Temperature Accuracy Range	30 to 42°C
Factory Default Temperature for Manual Setting	Factory default is 37°C when setting the temperature manually.

Item	Specification
Protection Against Electric Shock	Class II, type CF, defibrillation proof applied parts: PtO2 probe, temperature probe.
Protection Against Harmful Ingress of Water	IPXO
Mode of Operation	Continuous
Fire Hazard	Not suitable for use in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.
Languages	English, Danish, Dutch, French, German, Italian, Polish, Spanish, Portuguese (Brazilian), Chinese (Simplified), Japanese, Korean, Russian

1. This accuracy range does not include the accuracy of the patient bedside monitor, which may vary between manufacturers. If drift occurs persistently between the two monitors that exceeds ±1 mmHg or 1% of the Integra monitor's reading, contact the biomed department to determine the cause of drift.

Classifications and Standards

The Integra Licox PtO2 Monitor has been designed for continuous operation. The Integra Licox PtO2 Monitor meets the safety and essential performance requirements for medical electrical equipment:

- 60601-1, 1-4, 1-8, 2-49 2nd edition

EMI / EMC

- EN60601-1-2 2nd edition (2001)
- EN60601-2-49 2nd edition (2001)

Safety and Essential Performance

- EN60601-1 1990 with A1: 1993 and A2: 1996
- UL-IEC 60601-1: 2003
- CSA 60601-1: 1990 with A1: 1994 and A2: 1998
- EN/UL-IEC/CSA 60601-1-4 1996 with A1: 1999
- EN60601-1-8 2004 with A1: 2006
- UL-IEC 60601-1-8 2003 with A1: 2006
- CSA 60601-1-8 2003
- EN/UL-IEC 60601-2-49 2001
- CSA 60601-2-49 2004

Manufacturer's Declaration Table

The information contained in this section (such as separation distances) is in general specifically written with regard to the Integra Licox PtO2 Monitor. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use this device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the equipment is used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Integra Licox PtO2 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Integra Licox PtO2 Monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Integra Licox PtO2 Monitor 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 A	The Integra Licox PtO2 Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Integra Licox PtO2 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Integra Licox PtO2 Monitor should assure that it is being 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 ±8 kV	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 ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV ±2 kV	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 for 0.5 cycle 40 % U_T for 5 cycles 70 % U_T for 25 cycles <5 % U_T for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Integra Licox PtO2 Monitor requires continued operation during power mains interruptions, it is recommended that the Integra Licox PtO2 Monitor 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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Integra Licox PtO2 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Integra Licox PtO2 Monitor should assure that it is being 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 Integra Licox PtO2 Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz		$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz
	80 MHz to 95 MHz, 110 MHz to 2.5 GHz 95 to 110 MHz	3 V/m 1.8 V/m	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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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.			
[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 Integra Licox PtO2 Monitor is used exceeds the applicable RF compliance level above, the Integra Licox PtO2 Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Integra Licox PtO2 Monitor. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Integra Licox PtO2 Monitor.

The Integra Licox PtO2 Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Integra Licox PtO2 Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Integra Licox PtO2 Monitor 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 m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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.

APPENDIX B INTEGRA WARRANTY

1. Warranty

Integra LifeSciences Corporation and its wholly owned subsidiaries (“Integra”) warrants to Integra authorized distributors and the original purchaser only that each new Integra product is free from manufacturing defects in material and workmanship under normal use and service for a period of one (1) year (except as otherwise provided as to accessory items) from the date of delivery by Integra (or its authorized distributor) to the original purchaser, but in no event beyond the expiration date stated on any product labeling. For purposes of products sold by Integra through an authorized distributor of Integra, "original purchaser" shall include the purchaser of Integra products to whom the distributor first sells the product.

- Surgical instruments are guaranteed to be free from defects in material and workmanship when maintained and cleaned properly and used normally for their intended purpose.
- Any covered product that is placed by Integra under a lease, rental or installment purchase agreement and that requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement.

If any covered defect occurs during the warranty period or term of such placement agreement, the purchaser or distributor should communicate directly with Integra. If purchaser or distributor seeks to invoke the terms of this warranty, the product must be returned to Integra. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to Integra shall be at sender’s risk. Integra sole responsibility under this warranty shall be repair or replacement, at the sole discretion and expense of Integra, subject to the terms of this warranty and applicable agreements.

IN NO EVENT SHALL INTEGRA BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA PRODUCT. Further, this warranty shall not apply to, and Integra shall not be responsible for, any loss arising in connection with the purchase or use of any Integra product that has been repaired by anyone other than an authorized Integra service representative or altered in any way so as, in Integra judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by Integra. THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON INTEGRA’S PART OR ON THE PART OF DISTRIBUTORS, AND INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY REPRESENTATIVE OR OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH INTEGRA PRODUCTS.

IN NO EVENT SHALL INTEGRA AUTHORIZED DISTRIBUTORS BE LIABLE TOWARDS THE ORIGINAL PURCHASER FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF

ANY INTEGRA PRODUCT. Further, this warranty shall not apply to, and INTEGRA authorized distributors shall not be responsible towards the original purchaser for, any loss, arising in connection with the purchase or use of any INTEGRA product that has been repaired by anyone other than an authorized INTEGRA service representative or altered in any way so as to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA. THIS INTEGRA DISTRIBUTOR LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES TOWARDS THE ORIGINAL PURCHASER, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES TOWARDS THE ORIGINAL PURCHASER ON INTEGRA AUTHORIZED DISTRIBUTOR'S PART.

INTEGRA AND ITS AUTHORIZED DISTRIBUTORS DISCLAIM ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE, AND ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, USAGE OR TRADE OR OTHERWISE, OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS. No warranty or guarantee may be created by any act or statement nor may this Standard Warranty be modified in any way, except as a result of a writing signed by an officer of INTEGRA. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

2. Service, Repairs and Replacement

2. 1 Service and Repairs. All service and repairs covered by this Warranty may be referred to hereinafter as “in-warranty repairs,” and all service and repairs not covered by this Warranty may be referred to as “out-of-warranty repairs.” Customer shall be responsible to pay Integra’s then-standard charges for any out-of-warranty repairs performed by Integra. Integra’s sole obligation for Equipment defects and failures of performance shall be to make all necessary adjustments and repairs in accordance with this Warranty.

2. 2 Equipment Replacement. The defective Equipment or part thereof that is replaced in accordance with the Warranty shall be the property of Integra. Integra reserves the right to fill spare parts requests using refurbished sub-assemblies provided that such sub-assemblies are functionally equivalent to new sub-assemblies and carry the same warranty as the replaced sub-assemblies.

2. 3 Notification. In order to avail itself of its rights under the Warranty, Customer must immediately notify Integra of any defects and provide Integra every opportunity to inspect and remedy defects.

3. Repair Parts and Services

3. 1 Included under the Warranty are the following services:

3. 1.1 Modifications to Covered Equipment. From time to time, at its sole discretion, Integra may propose modifications to the covered Equipment and to the specifications for the Equipment (“Specifications”). Subject to Customer’s approval and at its sole expense, the Customer may request

Integra to make such modifications to the covered Equipment and to the Specifications. Integra shall make such modifications for the Customer, which modifications may include the installation of new parts in the Equipment, at a price equal to the then-current list price for such modifications, as such list price is established by Integra in its sole discretion.

4. Quality Control

4. 1 Customer shall maintain reasonable standards of quality control, operations, procedures, safety testing and inspection of Equipment to ensure that unnecessary service or maintenance is not required hereunder.

4. 2 Customer shall provide a technical counterpart to Integra's Service Agent for assistance in Integra's telephonic diagnosis of the malfunction with the Equipment. Customer shall reasonably accept Integra's determination whether a repair or service is an in-warranty repair or an out-of-warranty repair.

5. Limitation of Liability

5. 1 THE WARRANTIES DESCRIBED IN SECTION 1 HEREOF ARE EXCLUSIVE AND ARE GIVEN AND ACCEPTED IN LIEU OF ALL OTHER WARRANTIES OF INTEGRA OR ITS SERVICE AGENTS WITH RESPECT TO THE QUALITY, PERFORMANCE AND OPERATION OF THE EQUIPMENT, WRITTEN OR ORAL, EXPRESSED OR IMPLIED, AND WHETHER OR NOT ATTRIBUTABLE TO SERVICE PERFORMED PURSUANT TO THE WARRANTY. ALL OTHER REPRESENTATIONS OR WARRANTIES OF INTEGRA OR ITS REPRESENTATIVES, EXPRESS OR IMPLIED, WITH RESPECT TO THE EQUIPMENT OR THE SERVICES, DIAGNOSES, ADVICE, ASSISTANCE OR PARTS TO BE TENDERED PURSUANT TO THE WARRANTY, INCLUDING, WITHOUT LIMITATION , THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY EXPRESSLY DISCLAIMED. IN NO EVENT SHALL INTEGRA, ITS AFFILIATES, ASSIGNEES OR SERVICE AGENTS BE LIABLE FOR LOSS OF USE, REVENUE OR PROFIT OR ANY OTHER DIRECT, INDIRECT, INCIDENTAL, EXEMPLARY, CON SEQUENTIAL, SPECIAL OR OTHER DAMAGES, WHETHER ARISING IN CONTRACTOR IN TORT, BY VIRTUE OF THE WARRANTY OR ANY PERFORMANCE OR BREACH BY INTEGRA, ITS AFFILIATES, ASSIGNEES OR SERVICE AGENTS HEREUND ER OR PURSUANT HERETO IN EXCESS OF THE AMOUNTS PAID BY CUSTOMER TO INTEGRA DURING THE WARRANTY PERIOD.

5. 2 Customer agrees that, notwithstanding the technical assistance provided pursuant to the Warranty by Integra or its representatives, Customer shall be fully responsible for all treatments performed or attempted with the Equipment. INTEGRA MAKES NO REPRESENTATION OR WARRANTY AS TO THE EFFICACY OF THE EQUIPMENT OR OF THE TECHNICAL ASSISTANCE TO BE RENDERED BY INTEGRA, ITS AFFILIATES, ASSIGNEES OR SERVICE AGENTS, FOR PURPOSES OF THE PARTICULAR TREATMENT THAT CUSTOMER UNDERTAKES TO PERFORM FOR THIRD PARTIES. Moreover, Customer shall not make any claim against Integra or any of its affiliates, assignees or representatives with respect to the efficacy of the Equipment or of said technical assistance or with respect to any claims by third parties related to any treatment undertaken by Customer.

5. 3 Force Majeure. Notwithstanding anything to the contrary herein contained, if the performance of the Warranty by Integra or Customer or any obligation of Integra or Customer hereunder is prevented, restricted or interfered with by

reason of fire, explosion, act of God, labor disputes or accidents affecting performance under the Warranty, or war, mobilization, civil commotions, blockade or embargo, or any future law, regulation, ordinance or requirement of any government or regulatory agency or any other act, whatsoever similar to those above enumerated, or any other circumstance being beyond the reasonable control of Integra or Customer, then and in that event Integra or Customer, as the case may be, shall promptly notify the other party hereto of the resulting difficulties therefrom, and any of the foregoing events shall excuse any performance required under the Warranty.

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