The LICOX® System

Brain Tissue Oxygen Monitoring System

INTEGRA
LIMIT UNCERTAINTY

Overview

- General presentation
- Product description
- Troubleshootings & Maintenance
- Reminder
- Literature

INTEGRA
LIMIT UNCERTAINTY

The LICOX® System

General Presentation

INTEGRA
LIMIT UNCERTAINTY

What is the LICOX® system ?

- Measures interstitial brain tissue oxygenation pressure *($P_{bt}O_2$ in mmHg)* and brain tissue temperature *(°C).*
- Oxygen probe inserted approximately 35mm below the dura into the white matter of the brain.
- $P_{bt}O_2$ used in conjunction with current ICP/CPP monitoring methods.

INTEGRA
LIMIT UNCERTAINTY

Who needs the LICOX® system ?

- Patients at risk for developing cerebral hypoxia or ischemia such as:
  - Head trauma patients
  - Aneurysm patients
  - Subarachnoid hemorrhage *(SAH)*
  - Stroke patients

INTEGRA
LIMIT UNCERTAINTY

When is the LICOX® system placed?

- Within the first 24-48 hours of injury
  - The sooner cerebral hypoxia is detected, the better secondary injury can be prevented
- Generally, when an ICP catheter is required, a LICOX® probe should be considered

INTEGRA
LIMIT UNCERTAINTY

Where is the LICOX® system placed?

- Placement is up to physician discretion.
- The idea is to prevent secondary injury by ensuring living tissue is receiving adequate amount of oxygen.
- LICOX® probe can be placed in either the injured side or non-injured side of brain
- Should not be placed directly into a lesion

INTEGRA
LIMIT UNCERTAINTY

How to interpret the data?

- Normal: 25-35mmHg
- Risk of bad clinical outcome*:
  - $P_{bt}O_2$ < 15mmHg for 30 minutes
  - $P_{bt}O_2$ < 10mmHg for 10 minutes
- $P_{bt}O_2$ < 5mmHg - High mortality*
- $P_{bt}O_2$ < 2mmHg - Neuronal death*

* Bardt T, Unterberg A, et al. Monitoring of brain tissue PO2 in traumatic brain injury: effect of cerebral hypoxia on outcome. *Acta Neurochirurgica.1998;71(Suppl):153-156.*

INTEGRA LIMIT UNCERTAINTY

How is patient outcome affected?

- It has been found that:
  - Head injured patients who undergo aggressive therapy to maintain ICP/CPP at normal levels still experience periods of severe brain hypoxia*
  - Interventions previously thought to improve tissue oxygenation may improve ICP and CPP but actually decrease $P_{bt}O_2$**

* Bardt T, Unterberg A, et al. Monitoring of brain tissue PO2 in traumatic brain injury: effect of cerebral hypoxia on outcome. *Acta Neurochirurgica.1998;71(Suppl):153-156.*

** Zauner A, Doppenberg E, et al. Extended neuromonitoring: new therapeutic opportunities? *Neurological Research. 1998;20(Suppl 1):85-90.*

INTEGRA
LIMIT UNCERTAINTY

How is patient outcome affected?

- The $P_{bt}O_2$ number can provide:
  - Notification of hypoxic episodes
  - Independent predictors of unfavorable outcome and death*
    - Treatments to maintain $P_{bt}O_2$ correspond to more favorable patient outcomes**

* Zauner A, Doppenberg E, et al. Extended neuromonitoring: new therapeutic opportunities? *Neurological Research. 1998;20(Suppl 1):85-90.*

** Valadka A, Gopinath S, et al. Relationship of brain tissue PO2 to outcome after severe head injury. *Critical Care Medicine. 1998;26(9):1576-1581.*

INTEGRA
LIMIT UNCERTAINTY

LICOX® System: Product description

The LICOX® CMP Monitor

INTEGRA
LIMIT UNCERTAINTY

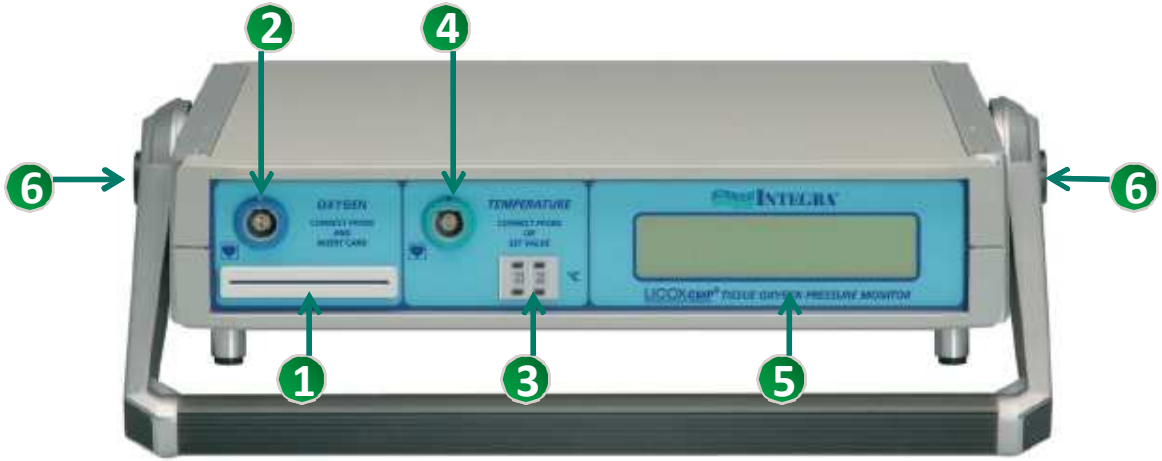
LICOX Monitor Features

- The CMP monitor displays a digital oxygen and temperature reading
- The Licox CMP monitor has no alarm system, therefore the low $P_{bt}O_2$ alarm is managed through a connection to the bedside monitor
- The LICOX® CMP Monitor can be:
  - used as a stand alone monitor with : $P_{bt}O_2$ & Temperature displays

  OR
  - connected to bedside monitors with: $P_{bt}O_2$ display only *(via LICOX Monitor Link LML1)*

INTEGRA
LIMIT UNCERTAINTY

LICOX® CMP monitor: Front Panel



1. Smart card slot
2. $P_{bt}O_2$ probe port
3. Temperature dial
4. Temperature probe port
5. Screen *(oxygen & temperature reading)*
6. Handle release bolt

INTEGRA
LIMIT UNCERTAINTY

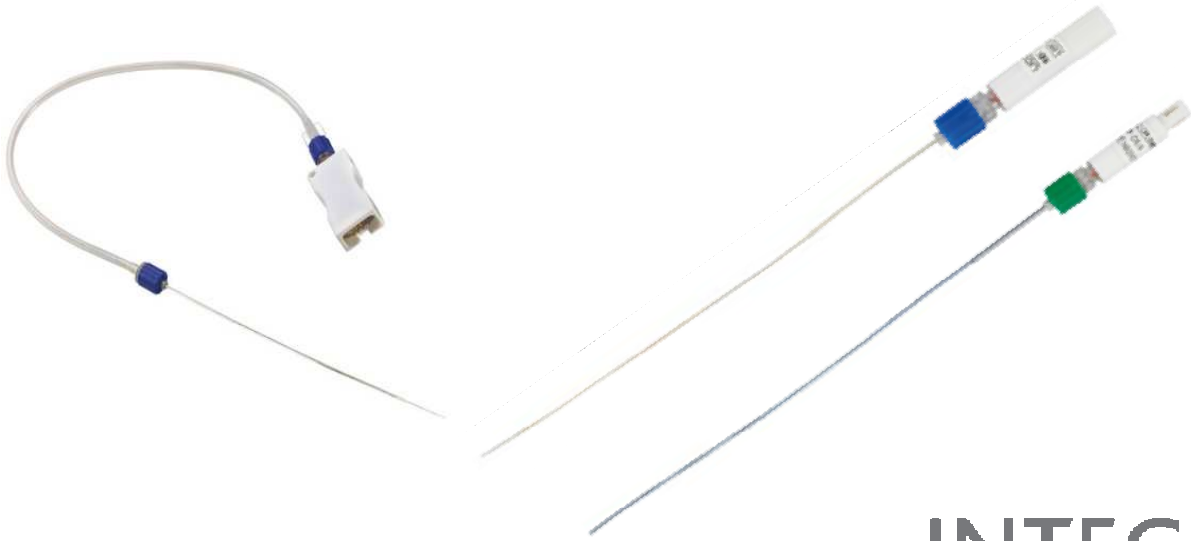
LICOX® CMP monitor: Rear Panel

1. On/Off switch
2. Power connector
3. Oxygen analog output
4. Temperature analog output
5. RS232 Data port
6. Fuse housing
7. Ground switch

INTEGRA
LIMIT UNCERTAINTY

LICOX® System: Product description

The LICOX® Probes & Kits



INTEGRA
LIMIT UNCERTAINTY

LICOX® Probes

IMC Probes

Separate O2 & T° probes

Oxygen Probe ***(CC1.SB)***

Oxygen Probe ***(CC1.G2)***

Temperature Probe ***(C8.B)***

PMO Probe

Combined O2 & T° probe

Oxygen + Temperature Probe ***(CC1.P1)***

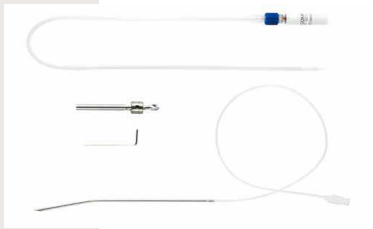
INTEGRA

LIMIT UNCERTAINTY

Introducer & Tunneling Kits Configurations

(separate probes)

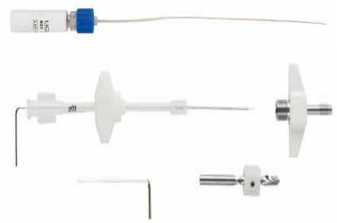
IT1



CC1.G2 + VK5.1

- Oxygen probe
- Parenteral probe guide for tunneling

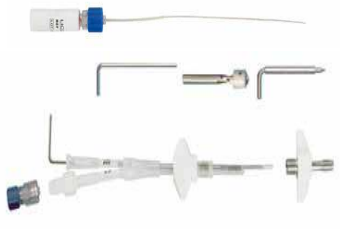
IM1.S



CC1.SB + IM1

- Oxygen probe
- 1 Lumen introducer

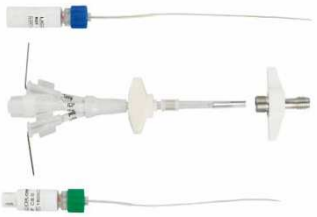
IM2.S_EU



CC1.SB + IM2

- Oxygen probe
- 2 Lumen introducer

IM3.ST_EU*



CC1.SB + C8.B + IM3_EU

- Oxygen Probe
- Temperature probe
- 3 Lumen introducer

*IM3.S_EU: without C8.B

INTEGRA
LIMIT UNCERTAINTY

Introducer & Tunneling Kits Configurations

(combined probes)

IP1.P

CC1P1 + IP1

- Combined oxygen & temperature probe
- Single lumen introducer

IP2.P

CC1P1 + IP2

- Combined oxygen & temperature probe
- Double lumen introducer

IT2_EU

CC1P1 + VK5.2

- Combined oxygen & temperature probe
- Tunneling probe guide

INTEGRA
LIMIT UNCERTAINTY

Features of the probes

- Accuracy
  - Oxygen measurement accuracy at 37°C:
    - $P_{bt}O_2$ *0-20 mmHg* accuracy is ± 2mmHg
    - $P_{bt}O_2$ *21-50 mmHg* accuracy is ± 10%
    - $P_{bt}O_2$ *51-150 mmHg* accuracy is ± 13%
  - Temperature measurement accuracy at 37°C: ± 0.2°C

- The maximum duration of use of probes & introducers is 5 days

INTEGRA LIMIT UNCERTAINTY

Features of the probes

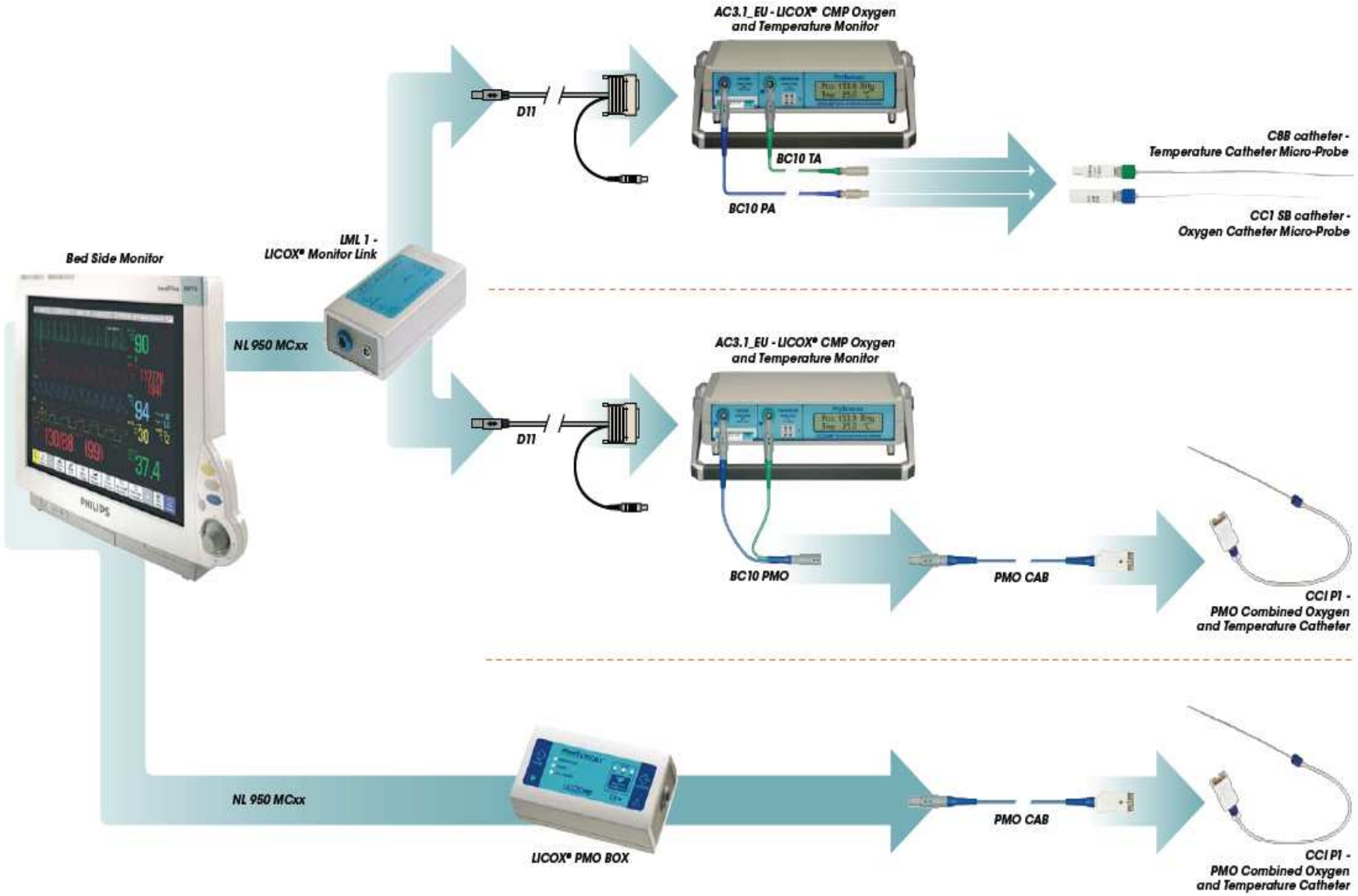
- The $P_{bt}O_2$ probe is delivered in a protection tube filled with electrolyte solution.
- The probe must be stored refrigerated at 2°-10°C in its packaging to avoid drying of the probe.
- Individual calibration data of LICOX probes is stored on a smart card delivered with the probe

INTEGRA
LIMIT UNCERTAINTY

LICOX® System: Product description

Connections

INTEGRA
LIMIT UNCERTAINTY


AC3.1_EU - LICOX® CMP Oxygen and Temperature Monitor
D11
BC10 TA
BC10 PA
C8B catheter - Temperature Catheter Micro-Probe
CC1 SB catheter - Oxygen Catheter Micro-Probe
Bed Side Monitor
LML 1 - LICOX® Monitor Link
NL 950 MCxx
AC3.1_EU - LICOX® CMP Oxygen and Temperature Monitor
D11
BC10 PMO
PMO CAB
CC1 P1 - PMO Combined Oxygen and Temperature Catheter
NL 950 MCxx
LICOX® PMO BOX
PMO CAB
CC1 P1 - PMO Combined Oxygen and Temperature Catheter

Bedside monitors connection: LML.1

- The LML.1 connects the LICOX® CMP monitor to a patient bedside monitor.
- Converts Digital signal from Licox® system to Analog signal for Bedside Monitor
- The LML.1 consists of Model D1 interface module and cable D11.

INTEGRA
LIMIT UNCERTAINTY

Bedside monitors connection: **NL950MCXX**

- Connects LML1 to bedside monitors
- *XX* specific to bedside pressure port type

(See cable matrix on NeuroMonitoring catalogue)





INTEGRA
LIMIT UNCERTAINTY

Steps to connect a CMP Monitor to a Bedside monitor

Please carefully read the LICOX LML1 and CMP Monitor Operations Manuals before using these devices.

- Connect LML1 (D1 + D11) to rear panel of LICOX® monitor.
- Connect NL950MCXX cable to the D1 and the other end to the bedside monitor.
- Disconnect all probe cables from the front of LICOX® system
- Adjust the temperature on LICOX® monitor to read between 28-43°C
- …

INTEGRA
LIMIT UNCERTAINTY

Steps to connect a CMP Monitor to a Bedside monitor

Please carefully read the LICOX LML1 and CMP Monitor Operations Manuals before using these devices.

- …
- Wait one minute for reading on LICOX to stabilize then press “zero” on the bedside monitor
- Both monitors should now display 0 mmHg
- Re-connect the oxygen probe cable to monitor
- Both monitors should now read the same value

INTEGRA
LIMIT UNCERTAINTY

After probe connection, the probes can be disconnected and the measurement can be interrupted at any time and then restarted with the matching pair of the $P_{bt}O_2$ probe and smart card at the same Licox® CMP monitor or any other Licox® CMP monitor

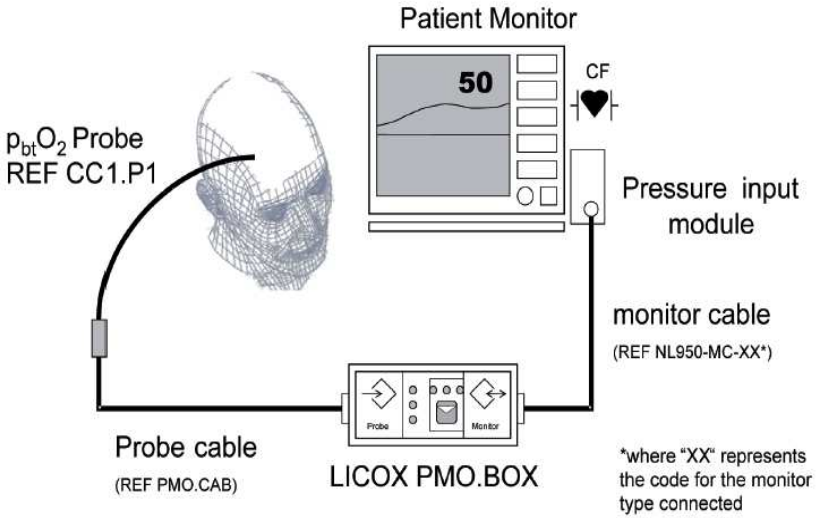
INTEGRA
LIMIT UNCERTAINTY

Steps to connect a PMO.Box to a Bedside monitor

For the complete process, please carefully read the LICOX PMO.Box Operations Manuals before using these devices.

- Connect the LICOX® PMO.BOX to the pressure input socket of the patient bedside monitor using the appropriate cable *(REF NL 950-MC-XX)*.
- Insert the probe cable connector into the socket of the LICOX® PMO.BOX.

As soon as the probe cable is connected with the LICOX® PMO.BOX, the device is automatically powered on and the ERROR LED will flash.



INTEGRA
LIMIT UNCERTAINTY

LICOX® System

Troubleshooting & Maintenance

INTEGRA
LIMIT UNCERTAINTY

Troubleshooting & Maintenance

Please carefully read the LICOX Complete Brain Probe Kits Directions for Use and the LICOX LML1 and CMP Monitor Operations Manuals before using these devices.

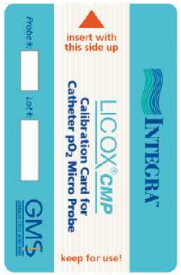
- Difficult placement of probes
  - Be sure the dura has been incised & burr hole has been cleaned of debris.
  - Do not tight compression cap prior to probe placement
- Low or zero $P_{bt}O_2$ reading
  - Verify the placement of catheter on CT, probe should not be located in infarcted tissue or hematoma or a sulcus of the brain.
- Maintenance interval for LICOX® CMP Monitor: Once per year

INTEGRA LIMIT UNCERTAINTY

Check of separated probe's functionality:

STEP 1

Insert the smart card



STEP 2

Insert the probes into the test tube

STEP 3

Connect the probes to their respective cable

STEP 4

Check the expected $P_{bt}O_2$ value as shown in **Table 1** of the *CMP Monitor Operation Manual*

($P_{bt}O_2$ value depends on the temperature and the barometric pressure)

Check CMP Monitor and Cable functionality:

Test set BC10R

(Compatible with oxygen only, not for temperature)

STEP 1

Set the temperature at the code switch to 22°C.

STEP 2

Connect the $P_{bt}O_2$ probe to the blue cables

STEP 3

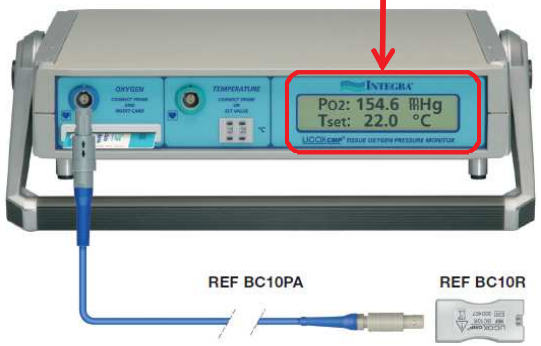
Insert the **test smart card**

STEP 4

Connect the **test plug ref.BC10R** to the blue probe cable

STEP 5

The value must be the same on this display:



STEP 6

Disconnect the test plug and leave the test card.

The value must be:

- $P_{bt}O_2$: **0.0mmHg**
- T_{SET}: **22°C**

LICOX® System

Reminder

INTEGRA
LIMIT UNCERTAINTY

Reminder

- Oxygen probes must always be stored between 2°C and 10°C.
- Use the drill bit that comes in the kit.
- Retain the calibration card from the oxygen probe package and insert it into the slot on the front of the CMP monitor.
- Each introducer lumen is labelled i.e. “PO2” or “Temp” or “ICP”.
- The oxygen and temperature probes have pre-determined* insertion depths, so they are secured to the introducer systems by Luer-Lock connectors.
- Ensure correct opening of the dura to avoid bad placement.

*Except if tunnelized with a LICOX® parenteral probe guide

INTEGRA
LIMIT UNCERTAINTY

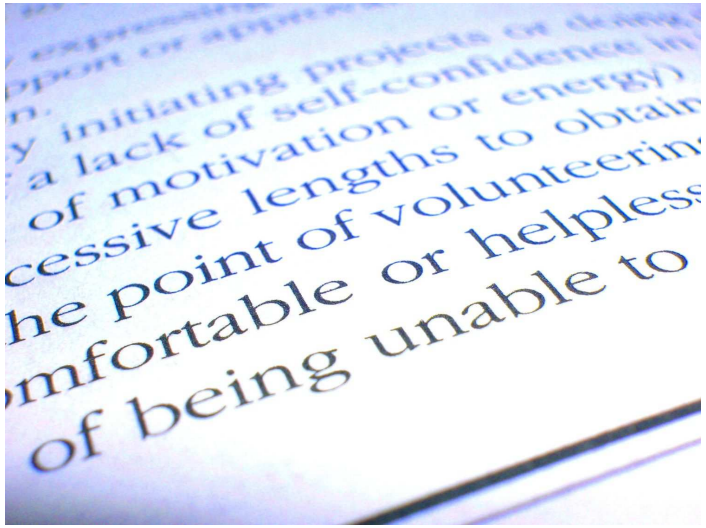
Reminder

- Temperature compensation : The change in probe $P_{bt}O_2$ sentivity with change in temperature is approximately 4% per °C. Therefore the temperature of the $P_{bt}O_2$ probe must be supplied to the LICOX® CMP.
  - If temperature probe is used, $P_{bt}O_2$ is automatically compensated for temperature. *(set the dial at "00" as brain temperature will be displayed)*
  - If you do not use a temperature catheter, the patient's body core temperature may be set at the temperature dial on the front panel of the LICOX® CMP Monitor in °C. Patient's body core temperature needs, to be input each hour.
- There are no alarms on the LICOX® monitor so it must be connected to the patient bedside monitor in order to use the bedside monitor alarm system if desired to set a $P_{bt}O_2$ alarm.
- Be aware of probe run-in time: After insertion, the stabilization time may be as long as 2 hours.
- Be sure to follow a safe removal technique

INTEGRA
LIMIT UNCERTAINTY

LICOX® System

Literature



INTEGRA
LIMIT UNCERTAINTY

Brain tissue oxygen monitoring in traumatic brain injury and major trauma: Outcome analysis of a brain tissue oxygen-directed therapy.
Narotam PK *et al*.
J Neurosurg. 2009; 111:672-682,

Reduced mortality rate in patients with severe traumatic brain injury treated with brain tissue oxygen monitoring.
Stiefel MF *et al.*
J Neurosurg. 2005; 103:805-811.

Monitoring of brain tissue PO2 in traumatic brain injury: effect of cerebral hypoxia on outcome.
Bardt T, Unterberg A, et al.
Acta Neurochirurgica.1998;71(Suppl):153-156.

Extended neuromonitoring: new therapeutic opportunities?
Zauner A, Doppenberg E, et al.
Neurological Research.1998;20(Suppl 1):85-90.

Relationship of brain tissue PO2 to outcome after severe head injury.
Valadka A, Gopinath S, et al.
Critical Care Medicine.1998;26(9):1576-1581.

INTEGRA
LIMIT UNCERTAINTY

CONFIDENTIAL – For internal use by Integra and Integra product line distributors only. Do not disseminate to the public. This presentation must not be given or copied to end users or end customers and shall remain the property of Integra LifeSciences.

PRODUCTS FOR SALE IN EUROPE, MIDDLE-EAST AND AFRICA ONLY – ILS 01-06-002-01-11

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

INTEGRA
LIMIT UNCERTAINTY