The LICOX® System

Brain Tissue Oxygen Monitoring System
Overview

- General presentation
- Product description
- Troubleshootings & Maintenance
- Reminder
- Literature
The LICOX® System

General Presentation
What is the LICOX® system?

- Measures interstitial brain tissue oxygenation pressure ($P_{bt}O_2$ in mmHg) and brain tissue temperature ($^\circ$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.
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
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
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.
How to interpret the data?

• Normal: 25-35mmHg

• Risk of bad clinical outcome*:
  • $P_{bt}O_2 < 15\text{mmHg}$ for 30 minutes
  • $P_{bt}O_2 < 10\text{mmHg}$ for 10 minutes

• $P_{bt}O_2 < 5\text{mmHg}$ - High mortality*

• $P_{bt}O_2 < 2\text{mmHg}$ - Neuronal death*

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 $P_{btO_2}$**

---


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**


LICOX® System: Product description

The LICOX® CMP Monitor
LICOX Monitor Features

- The CMP monitor displays a digital oxygen and temperature reading.

- The Licox CMP monitor has no alarm system, therefore the low \( P_{btO_2} \) alarm is managed through a connection to the bedside monitor.

- The LICOX\textsuperscript{®} CMP Monitor can be:
  - used as a stand alone monitor with: \( P_{btO_2} \) & Temperature displays
  - connected to bedside monitors with: \( P_{btO_2} \) display only (via LICOX Monitor Link LML1)
LICOX® CMP monitor: Front Panel

1. Smart card slot
2. \( P_{btO_2} \) probe port
3. Temperature dial
4. Temperature probe port
5. Screen (oxygen & temperature reading)
6. Handle release bolt

The LICOX® CMP Monitor

June 2011

CONFIDENTIAL – PROPERTY OF INTEGRA
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
LICOX® System: Product description

The LICOX® Probes & Kits
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)*
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***

- Oxygen Probe
- Temperature probe
- 3 Lumen introducer


---

CONFIDENTIAL – PROPERTY OF INTEGRA
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
Features of the probes

- **Accuracy**
  - Oxygen measurement accuracy at 37°C:
    - $P_{bt}O_2$ 0-20 mmHg accuracy is ± 2 mmHg
    - $P_{bt}O_2$ 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
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 $2^\circ-10^\circ$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.
LICOX® System: Product description

Connections
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**.
Bedside monitors connection: **NL950MCXX**

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

(See cable matrix on NeuroMonitoring catalogue)
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
• …
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
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.
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.
Troubleshooting & Maintenance

• Difficult placement of probes
  o Be sure the dura has been incised & burr hole has been cleaned of debris.
  o Do not tight compression cap prior to probe placement

• Low or zero $P_{btO_2}$ reading
  o 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
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 $P_{btO_2}$ value as shown in Table 1 of the CMP Monitor Operation Manual ($P_{btO_2}$ 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:
- $P_{bt}O_2$: 0.0mmHg
- $T_{SET}$: 22°C

**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
Reminder

LICOX® System

Reminder
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
Reminder

- **Temperature compensation**: The change in probe $P_{bt}O_2$ sensitivity 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
LICOX® System

Literature
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.

Monitoring of brain tissue PO2 in traumatic brain injury: effect of cerebral hypoxia on outcome.
Bardt T, Unterberg A, et al.

Extended neuromonitoring: new therapeutic opportunities?
Zauner A, Doppenberg E, et al.

Relationship of brain tissue PO2 to outcome after severe head injury.
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.

Available in 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.