

Saint Priest, August 20, 2014

Subject: URGENT – FIELD SAFETY NOTICE – DEVICE CORRECTION
Medical devices: Integra® Licox® PtO2 Monitors
Reference: LCX02, LCX02R
Legal Manufacturer: Integra LifeSciences (Ireland) Ltd, IDA Business & Technology Park, Sragh, Tullamore, Offaly, Ireland
Affected Serial numbers: please see table below

Dear Customer,

Integra LifeSciences (Ireland) Ltd (Integra) has identified that the USB port on the Licox® PtO2 monitor does not consistently provide the user the ability to extract the PtO2 trend data to commonly available external USB drives. The monitor displays an error message "Error Code 3051", "Sensor Board Failure". Please note that you can safely continue to use the monitor and clear this error message by following the steps described in section 1 below.

The Integra® Licox® PtO2 (LCX02) 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.

The Integra® Licox® PtO2 (LCX02R) Monitor measures oxygen partial pressure and temperature in tissue. It provides a trend display of oxygen partial pressure, which, in combination with other monitoring parameters, provides an estimation of tissue oxygenation and perfusion close to probe placement.

There have been no reports of patient injury or other adverse patient health consequences; as extracting this trend data through the USB port is generally not used during patient treatment, it is unlikely that an adverse patient health consequence would occur.

Out of an abundance of caution, Integra is voluntarily initiating this Field Safety Corrective Action to correct the affected **Licox® PtO2 Monitors** by updating the software to address the problem. The Serial Numbers of the monitors that require correction are listed on the table below. Integra will provide further directions regarding the software update when it is available.

Description of affected product	Reference	Affected Serial Numbers
Integra® Licox® PtO2 Monitors	LCX02	2131101152; 2131101147; 2131101148; 2131101155; 2131101156; 2131101157; 2131101149; 2131101153; 2131101158; 2131101159; 2140101181; 2131101160; 2131101161; 2140101168; 2140101169; 2140101171; 2140101173; 2140101175; 2131001102; 2140101176; 2140101177; 2140101180; 2131101154; 2140201191; 2140201198; 2140301204; 2140301203; 2140301209; 2140301206; 2140301211; 2140301216; 2140301222.
	LCX02R	2130901046; 2131201163; 2140201189; 2140101179; 2131201165; 2140101170; 2130901038; 2131201162; 2140101174; 2140101178; 2140201186; 2130901054; 2131201164; 2140101172; 2131201166; 2131201167; 2140401227; 2140201182; 2140201183; 2140201188; 2140201184; 2140201187; 2140201193; 2140201194; 2140201195; 2140201197; 2140201196; 2140301210; 2140301213; 2140301215; 2140301218; 2140301220; 2140401229; 2140401237.

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Integra LifeSciences Services (France)

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Our records indicate that you received one or more Integra® Licox® PtO2 Monitor(s) with affected serial numbers that will require this software update.

Integra kindly asks you to do the following:

1. Please review your inventory and verify if you have Licox® PtO2 Monitors (LCX02 or LCX02R) with a Serial Number listed in the table above.

If so, you may continue to use the monitor until Integra provides the software update to address the issue. During this time, please be aware that you may not be able to extract the PtO2 trend data through a commonly available external USB drive. You will know this is the case if the monitor displays an error message 'Error Code 3051, Sensor Board Failure'.

If you receive this error while attempting to extract PtO2 trend data to a USB drive, you can clear the error code and resume use of the system without losing previous data by performing the following steps:

- Remove the USB drive from the Licox® PtO2 Monitor;
- Turn off the Licox® PtO2 Monitor;
- Turn the Licox® PtO2 Monitor back on.

2. Once the audit of your inventory is achieved, please complete the attached Acknowledgement and Return Form:

- a. If you do NOT have monitor(s) with an affected lot number on the list:

Tick the box: **I do not have any monitor with an affected Serial Number in my inventory.**

- b. If you do have monitor(s) on the affected lot number list:

Tick the box: **I do have monitors with an affected Serial Number in my inventory.**

Please circle the affected lot number(s) and record the total quantity corresponding to the lot number(s) you have.

3. Please complete the other information on the **Acknowledgement and Return Form** & return it promptly as per instructions on the form.

Please note that you can safely continue to use the monitor(s), until scheduled service, being aware that if you choose to extract PtO2 trend data to a USB drive, you may have an error message 'Error Code 3051, Sensor Board Failure' that can be cleared by following the steps described in section 1.

Once your Acknowledgement and Return Form is received and if you have identified affected product(s), our Customer Service will contact you to schedule the service and provide temporary loaner monitor(s) while your monitor(s) is(are) updated.

The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information.

We also recommend that you keep a copy of this notification and a signed copy of the acknowledgement form for your records.

National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

Please note that your National Competent Authority has been alerted of this Field Safety Corrective Action.

Thank you for your cooperation with this Field Safety Corrective Action and for returning the attached Acknowledgement and Return Form.

For any questions or concerns, please contact Angélique Aubert at the following e-mail address:
angelique.aubert@integralife.com.

Sincerely,



Angélique AUBERT
Compliance Coordinator
Europe, Middle-East & Africa

ACKNOWLEDGMENT AND RETURN FORM

Medical devices: Integra® Licox® PtO2 Monitors

Reference: LCX02, LCX02R

Legal Manufacturer: Integra LifeSciences (Ireland) Ltd, IDA Business & Technology Park, Sragh, Tullamore, Offaly, Ireland

Affected Serial numbers: please see table below

Please Complete and Return Promptly

Please fill out this form and return by email or fax:

By fax/telecopy: +33 (0)4 37 47 59 30 or by e-mail: emea-fsca-neuro@integralife.com

I have received, read and understood the information provided in the Integra Field Safety Notice regarding **Integra® Licox® PtO2 Monitors**.

My inventory has been reviewed and the results are as follow (*please tick the appropriate answer*):

Yes, I do have monitors with an affected Serial Number in my inventory.

Please fill out in the table below:

Description of affected product	Reference	Affected Lot Numbers	Quantity
Integra® Licox® PtO2 Monitors	LCX02	2131101152; 2131101147; 2131101148; 2131101155; 2131101156; 2131101157; 2131101149; 2131101153; 2131101158; 2131101159; 2140101181; 2131101160; 2131101161; 2140101168; 2140101169; 2140101171; 2140101173; 2140101175; 2131001102; 2140101176; 2140101177; 2140101180; 2131101154; 2140201191; 2140201198; 2140301204; 2140301203; 2140301209; 2140301206; 2140301211; 2140301216; 2140301222.	
	LCX02R	2130901046; 2131201163; 2140201189; 2140101179; 2131201165; 2140101170; 2130901038; 2131201162; 2140101174; 2140101178; 2140201186; 2130901054; 2131201164; 2140101172; 2131201166; 2131201167; 2140401227; 2140201182; 2140201183; 2140201188; 2140201184; 2140201187; 2140201193; 2140201194; 2140201195; 2140201197; 2140201196; 2140301210; 2140301213; 2140301215; 2140301218; 2140301220; 2140401229; 2140401237.	

No, I do not have any monitor with an affected Serial Number in my inventory.

With this form,

- I confirm that I have received this Field Safety Notice and that I intend to fully comply with it;
- I confirm that this Field Safety Notice has been circulated to appropriate people within my healthcare facility;
- I ensure that all the affected products will be shipped back to Integra for the scheduled service.

Please complete contact point details on next page.

Contact point details

Customer/Site Name	Customer Contact Name
Street Address	
City, Country, Postal Code	Telephone
Email	
Fax	Signature

