

To the attention of Medical Device
Vigilance responsible / Central Pharmacy
/ BioMedical Engineer



Saint Priest, April 22, 2015

Subject: URGENT – FIELD SAFETY NOTICE – SAFETY INFORMATION

Medical devices: Integra® Licox® PtO2 Monitor

Integra® Camino® ICP Monitor

Reference: CAM02 & LCX02/LCX02R

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

Affected serial numbers: All serial numbers are involved.

Dear Customer,

Integra LifeSciences has identified through a limited number of complaints that the speaker in the CAM02/LCX02/LCX02R monitors may potentially malfunction and if this occurs, the monitors will stop providing an audible tone at start-up or at alarm points during use.

For neurocritical care applications, this does not affect the ability of the monitor to provide the signals for these tones and alarms to the bedside monitor at all times. When it is connected to a bedside monitor (available only for neurocritical care applications), the monitor will provide the tones and alarms as identified in the Chapter 3 of the CAM02 User's Manual or Chapter 4 of the LCX02 User's Manual. Please use the following links to access the user manuals: www.integralife.com/CAM02_Manual and www.integralife.com/LCX02_Manual.

A corrective action to eliminate the potential speaker malfunction has been identified and is currently being verified for implementation. Once verified, Integra will contact you with instructions to implement the corrective action.

There has not been any report of a patient injury or adverse health consequences as a result of such a failure. In light of the above, **Integra is initiating this field safety notice to be confident you have the ability to hear the audible tones and alarms.**

We recommend you follow the instructions below:

- 1) For neurocritical care applications, where a bedside monitor is available for use, connect it to that monitor as identified in Chapter 3 of the CAM02 User's Manual and Chapter 4 of the LCX02 User's Manual. If you require a PMIO cable or adapter for your bedside monitor, please contact your local customer service Integra at **+44(0)126.4312.725**.
- 2) Where a bedside monitor is not available for use:
For CAM02: Check the continued function of the speaker on an hourly basis by decreasing the High ICP Alarm Limit to a value that is lower than the patient's displayed Mean ICP value (e.g. 15 mmHg). This will trigger the high ICP alarm after 5 seconds. Once the speaker emits the alarm tone, change the High ICP Alarm Limit back to the desired level. If the speaker does not emit the alarm tone, we recommend you stop using the monitor and contact your local customer service Integra at **+44(0)126.4312.725**. For detailed instructions on setting the high ICP alarm limit, refer to chapter 4 of the User's Manual.

For LCX02/LCX02R: Check the continued function of the speaker on an hourly basis by increasing the PtO2 Alarm Limit to a value that is higher than the patient's displayed PtO2 value (e.g. 30 mmHg). This will trigger the low PtO2 alarm if the patient's displayed PtO2 value remains below the Low PtO2 Alarm Limit for more than 5 seconds. Once the speaker emits the alarm tone, change the Low PtO2 Alarm Limit back to the desired level. If the speaker does not

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Integra LifeSciences Services (France)

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emit the alarm tone and a bedside monitor is not available, we recommend you stop using the monitor and contact your local customer service Integra at **+44(0)126.4312.725**. For detailed instructions on setting the Low PtO2 Alarm Limit, refer to chapter 5 of the User's Manual.

- 3) When performing start-up of the CAM02, LCX02 and LCX02R monitors according to the User's Manual, absence of a tone indicates that the speaker is not working. If a tone is heard during start-up, please keep in mind that the speaker can fail during use. If a tone is not heard at start-up or at any expected time and you do not have the ability to connect to a bedside monitor, we recommend you stop using the monitor and contact your local customer service Integra at **+44(0)126.4312.725**.

Description of affected product	Reference	Affected serial Numbers
Integra® Licox® PtO2 Monitor Integra® Camino® ICP Monitor	LCX02/LCX02R CAM02	All serial numbers

We are notifying you of this Field Safety Notice as **our records indicate that you received one or more Integra® Licox® PtO2 Monitor and/or Integra® Camino® ICP Monitor.**

Please ensure that this Field Safety Notice is distributed to the appropriate surgery team(s) within your institution.

Please fill in, sign and return the attached Field Safety Notice Acknowledgement and Return Form.

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

Integra recommends you also maintaining a copy of this notification and 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 Notice.

Thank you for your cooperation with this Field Safety Notice.

For any questions or concerns, please contact the following e-mail address:
emea-fsca-neuro@integralife.com.

Sincerely,

Angélique AUBERT
Compliance coordinator
Europe, Middle-East & Africa

FIELD SAFETY NOTICE ACKNOWLEDGMENT AND RETURN FORM

Medical devices: Integra® Licox® PtO2 Monitor
 Integra® Camino® ICP Monitor
Reference: CAM02 & LCX02/LCX02R
Legal Manufacturer: Integra LifeSciences (Ireland) Ltd, IDA Business & Technology Park, Sragh,
 Tullamore, Offaly, Ireland
Affected serial numbers: All serial numbers are involved.

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 Monitor and Integra® Camino® ICP Monitor**.

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.

Please complete contact point details below.

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