Field Safety Notice

Xenios console - “#206/ #208 -Technical Failure, Flow Measurement” alarm message

Affected Devices:	Sensor boxes Item number: Xenios sensor box 38350044 Xenios sensor box ECG 38350050 Xenios sensor box (CN) 38350391 MDC sensor box MEMDC0022 Novalung sensor box F30000163
Reference No:	FSCA-2024-001-Xenios console_Flow measurement alarm
Attention:	Risk / Safety Managers, Distributors, Physicians, Perfusionists, Intensive care nurses and other users of these devices
Reason:	Reported flow measurement alarms during procedure

Date: March 11th, 2024

Dear Valued Customer,

This letter is to inform you about a voluntary field correction. Xenios identified an issue pertaining to your Xenios sensor box, which is a component of your Xenios console (Item Numbers: 38350043, 38350390, MEMDC0021, F30000162). In certain rare instances, you may experience error messages #206 (yellow) and #208 (red) “technical failure, flow measurement” during use of the Xenios system.
The error messages #206 (yellow) and #208 (red) imply that the communication between flow sensor and sensor box is interrupted.

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An interrupted communication between flow sensor and sensor box might lead to disabled flow measurement, backflow- and air bubble-detection.

If you experience either failure code (#206/#208) your device will continue to operate. The adjusted pump speed will be maintained by the system. The essential performance of the Xenios system to provide respiratory and cardiopulmonary support by extracorporeal circulation and physiologic gas exchange is not impacted by the flow measurement error messages.

To date, there have been no adverse events and no patient injuries reported. In the highly unlikely event that air should enter the circuit, during this occurrence, there is a potential risk for air embolism. Furthermore, a backflow or blood flow reduction may occur. For this reason, the user should closely monitor the circuit during use.

The company's efforts to solve the rare fault pattern in the field by replacing a cable were not effective. Therefore, the power supply of the flowboard was redesigned. This change will be implemented in the field for the affected sensor boxes mentioned in Attachment 1.

This issue has been corrected in all sensor boxes manufactured on October 18th, 2021 and later.

Actions to be taken by the user:

- You will be contacted by the local service organisation to schedule servicing of the affected sensor box on your Xenios console. FMC will update the affected sensor boxes at no charge.
- In the rare event #206/#208 alarms occur, perform the following:
    - silence the alarms intermittently using the audio pause button. If you have continued alarms, it is recommended to replace the entire console.

Refer to the instructions in Attachment 3 to start backup operation and switch to another Xenios console.

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Please complete and return the attached Confirmation Form (see Attachment 2) to XXX@freseniusmedicalcare.com (*Please adapt locally*)

Distribution of this Field Safety Notice:

Please provide this Safety Notice to all those who need to be aware within your organization. In case you have transferred products to a third party, please pass this information on to them and also inform the below mentioned contact person.

Contact reference person:

In case of any further questions do not hesitate to contact us:

xenios-fsn@freseniusmedicalcare.com.

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agency in your country which is aware of these actions.

We sincerely apologize for any inconvenience. Xenios is committed to ensure that our products and services consistently meet the highest standards of quality and safety for patients and healthcare providers.

Sincerely yours,

Christian Peis
Sr. Director
Product Center Responsible Heart, Lung & TA

Thomas-Helge Junesch
Corporate Safety Officer,
Vigilance & Risk Manager

Enclosures:
Attachment 1: Affected Product List
Attachment 2: Customer Reply Form
Attachment 3: Procedure to solve the issue if either alarm #206 / #208 occurs

Attachment 1
Affected Product List

FSN: Xenios Console – “#206/ #208 -Technical Failure, Flow Measurement” alarm message

Product Code	Product Description	Serial Numbers
38350044	Xenios sensor box	XCON0170 to XCON1073
38350050	Xenios sensor box ECG	XECON0208 to XECON0340
38350391	Xenios sensor box (CN)	XCON0001 to XCON0047
MEMDC0022	MDC sensor box	MDCON0355 to MDCON0524
F30000163	Novalung sensor box	XCONUS0001 to XCONUS0124

Please refer to Attachment 2 for affected systems at your site.

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Attachment 2 -
Customer Reply Form

FSN: Xenios Console – "#206/ #208 -Technical Failure, Flow Measurement" alarm message

Affected Devices: Sensor boxes
Part number:
Xenios sensor box 38350044
Xenios sensor box ECG 38350050
Xenios sensor box (CN) 38350391
MDC sensor box MEMDC0022
Novalung sensor box F30000163

Clinic Representative: _____

Clinic Name: _____

Clinic Address: _____

City, State: _____

Country Postal Code: _____

Please complete for regulatory effectiveness check:

I have read the attached notification and understand the instructions that I am given:

Signature: _____

Print Name: _____

Date: _____

Please return this customer reply form via one of the following methods:

- Return this signed form to your Fresenius Medical Care Representative

Email the signed form to XXX@freseniusmedicalcare.com *(Please adapt locally)*

Attachment 3 -
Procedure to solve the issue if either alarm #206 / #208 occurs

Note: Replace console, in case of alarms #206 / #208.
The alarm situation indicates that:
- blood flow measurement, air bubble and backflow detection
- optional flow regulation and optional zero flow in case of air bubble detection are disabled.

If the clinical situation allows, remediate the cause of the alarm as described below.
Maintain the adjusted prescribed pump speed. Monitor the patient and its vital parameters closely!
Plan to replace the console with your team while the console maintains the preset pump speed (emergency mode).

Prerequisite for replacing the console:
Only use the console with fully charged battery packs.

1. **Start backup operation (Section 2.11. Emergency mode)**
   1. Remove a battery pack from battery pack compartment.
   2. Reduce pump speed rpm.
   3. Clamp tubing to avoid backflow.
   4. Stop pump drive on console.
   5. Disconnect pump drive cable from sensor box.
   6. Connect pump drive cable to battery pack.
   7. Start pump drive pressing ON/OFF  key on pump drives user interface.
   8. Increasepump speed (rpm) according to the previous setting by pressing the pump speed  key on pump drives user interface.
   9. Remove clamp from tubing.
   10. Adjust pump speed to the prescribed rpm

2. **Exchange console**

After starting the Backup operation:

1. Disconnect all IPS cables, flow/bubble sensor and temperature sensor (if used) from the sensor box.
2. Remove the sensor box from the compact holder by pressing on the upper lever.
3. Turn off the console by:

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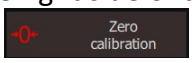
   a. Pressing and holding the ON/OFF  key on the control panel for at least three (3) seconds.
   b. Disconnect the AC power cable from the power supply.
4. Hold the console firmly and pull the locking pin at the bottom of the power supply to remove it.
5. Pull the console towards the back to remove it from the Xenios trolley N.
6. Place the new console to the top of the Xenios trolley N and push it forward.
7. Pull the locking pin and then release it to secure the console into place.
8. Attach the new sensor box to the right side of the compact holder.
9. Connect the IPS cables, flow/bubble sensor and temperature sensor (if used) to the sensor box.
10. Turn on the console by:
    a. Plugging the AC power cable into the power supply and switching the main power switch to the ON [I] position.
    b. Pressing the ON/OFF  key on the control panel.
11. Select the prescribed treatment mode and tubing kit used for treatment.
12. Press  button to bypass the priming and preparation procedure.
13. Clamp the tubing to avoid backflow.
14. Disconnect the pump drive cable from the battery pack and immediately connect the pump drive cable to the new sensor box.
15. Confirm the message displayed on the touchscreen “connections were interrupted” by pressing  buttom.
16. Press the PUMP  key on the control panel to start the pump drive.
17. Perform zero adjustment of the flow/bubble sensor via the flow parameter submenu (Section 4.5.3. Flow [all profiles]):

    a. Tap the flow display.
    b. Switch to second submenu window “Flow parameter” pressing the  arrow on the right side of the submenu window.
    c. Press 

button to adjust flow/bubble sensor.
18. Adjust the pump speed using the center knob according to the previous setting.
19. Open the clamp on the tubing.
20. Adjust pump speed to restore the prescribed blood flow.

When changing the console, it is also necessary to zero adjust the pressure measurement.
Depending on the tubing kit used, follow the corresponding instructions for use.