FCSA Ref: CO22423
FSN Ref: CO22423

Groningen, August 27, 2025

URGENT - Field Safety Notice
XVIVO Liver Assist Perfusion Set™

FSN Type: New

For attention of: Customers who have received XVIVO Liver Assist Perfusion Set™ (catalogue no 11.401) of the following batches:

Batch	Use by date
2507109	2028-02-26
2507099	2028-02-26
2510092	2028-03-07
2512114	2028-03-23
2512115	2028-03-23
2518114	2028-05-04
2518116	2028-05-04
2518115	2028-05-04

Should you have any questions or require additional information, please contact:
customersupport@xvivogroup.com

Sincerely,

Steven Boom
Person Responsible for Regulatory Compliance (PRRC)
On behalf of XVIVO

XVIVO

FCSA Ref: CO22423
FSN Ref CO22423

Groningen, August 27, 2025

URGENT - Field Safety Notice
XVIVO Liver Assist Perfusion Set™

Accuracy of pressure measurement out of specification

Dear valued customer,

Accuracy of pressure measurement out of specification has been identified for XVIVO Liver Assist Perfusion Set™ as described in this Field Safety Notice. Please adhere to the information as follows:

Information on Affected Devices:
Device type: Organ preservation sterile perfusion set (single use)
Commercial name: XVIVO Liver Assist Perfusion Set™
Primary clinical purpose of device: The XVIVO Liver Assist Perfusion Set is intended to be used for ex-vivo hypothermic and normothermic oxygenated machine perfusion to preserve and evaluate donor livers prior to transplantation.
Catalogue number: 11.401
Batches affected: LOT: 2507109, UDI: (01)08719925460678(17)280226(10)2507109 LOT: 2507099, UDI: (01)08719925460678(17)280226(10)2507099 LOT: 2510092, UDI: (01)08719925460678(17)280307(10)2510092 LOT: 2512114, UDI: (01)08719925460678(17)280323(10)2512114 LOT: 2512115, UDI: (01)08719925460678(17)280323(10)2512115 LOT: 2518114, UDI: (01)08719925460678(17)280504(10)2518114 LOT: 2518115, UDI: (01)08719925460678(17)280504(10)2518115 LOT: 2518116, UDI: (01)08719925460678(17)280504(10)2518116

XVIVO
Bornholmstraat 84 | 9723 AZ Groningen | Netherlands
Visitors: Bornholmstraat 84 | 9723 AZ Groningen | Netherlands

info@xvivogroup.com
xvivogroup.com
Company No. 01135421

Reason for the Field Safety Corrective Action (FSCA):

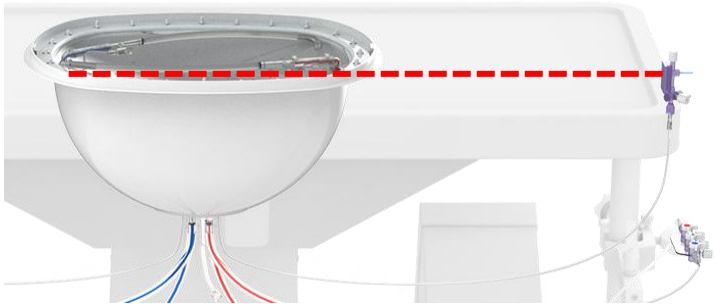
Accuracy of pressure measurement out of specification has been identified for XVIVO Liver Assist Perfusion Set™. As a consequence, this can lead to an underestimation of pressure values displayed by the system, meaning the actual pressure on the liver may be higher than what is measured. This deviation can result in increased perfusion flow and may, in some cases, trigger a high-flow alarm.
It has been determined that the XVIVO Liver Assist Perfusion Set™ of the affected batches has a reservoir with a relatively large depth. As a result, the liver may be positioned lower within the reservoir. In such cases, the height of the organ may not align with the pressure sensors of the perfusion device. Please note that the final position of the organ within the reservoir is not determined by reservoir depth alone, but by a combination of factors such as organ dimensions and perfusion fluid volume. Given the observed depth difference, the higher pressure is within safety limits of the device. However, we do ask your attention to the actions stated below.

Action to be taken by the user:

Identify whether you have XVIVO Liver Assist Perfusion Set™ from the batches affected.

At the start of each procedure, please act according to the below:

1. Check organ and sensor positioning
    - Assess the alignment of the height between the cannula and the pressure sensor: both shall be on the same level. The final position of the organ in the reservoir is defined by a combination of factors such as reservoir depth, organ dimensions and perfusion fluid volume. In case of a height difference follow the corrective measures listed below.



2. Take corrective measures
    - For HMP procedures:
        i. lower the pressure setting with 2-3 mmHg on both the hepatic artery side as well as the portal vein side.
        ii. or increase the perfusate volume in the reservoir, fill until the height of the cannula and pressure sensor is aligned.
    - For NMP procedures: lower the pressure setting with 2-3 mmHg on both the hepatic artery side as well as the portal vein side.

    Important: Do not attempt to lower or reposition the pressure sensor of the perfusion device.

Action to be taken by XVIVO B.V.:
XVIVO is working on a thorough root cause analysis and corrective measures to improve the accuracy of the pressure measurement. You can safely use the device taking the actions above into consideration.

Transmission of this Field Safety Notice
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Regulatory Authority if appropriate, as this provides important feedback.

In case new information of importance for you will be available we will let you know through an update.

As required the Regulatory Authority of your country has been informed about this notification.

Sincerely,

Steven Boom
Person Responsible for Regulatory Compliance (PRRC)