

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Pressure Shifts and Incorrect Pressure Readings for Medex™ LogiCal® 5 ml Closed Blood Sampling System Sets and Medex™ HemoDraw® Plus Closed Blood Sampling Sets with LogiCal® Pressure Monitoring System

Affected Device:	LogiCal® 5ml Closed Blood Sampling System Sets and HemoDraw® Plus Closed Blood Sampling Sets with LogiCal® Pressure Monitoring System
Type of Action:	Removal
Date:	05 March 2020
Attention:	Clinical users of, and Distributors of the LogiCal® 5ml Closed Blood Sampling System Sets and HemoDraw® Plus Closed Blood Sampling Sets with LogiCal® Pressure Monitoring System
Affected devices:	A full list of affected model numbers is included in Attachment 2.

Dear Customer,

The purpose of this Field Safety Notice is to advise you that Smiths Medical has initiated a voluntary Field Safety Corrective Action for LogiCal® 5ml Closed Blood Sampling System Sets and HemoDraw® Plus Closed Blood Sampling Sets with LogiCal® Pressure Monitoring System listed in Attachment 2.

REASON FOR FIELD SAFETY CORRECTIVE ACTION:

Smiths Medical became aware that customers utilizing the LogiCal® 5ml Closed Blood Sampling System Sets and HemoDraw® Plus Closed Blood Sampling Sets with LogiCal® Pressure Monitoring System may experience pressure shifts and incorrect pressure readings during patient monitoring.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

RISK TO HEALTH:

If the pressure measurement is inaccurate this could lead to the administration of inappropriate therapy. If it is determined that the sensor is giving incorrect pressure readings, other hemodynamic monitoring systems may be used which may lead to a delay in therapy.

It may be difficult for users to determine if the device is giving incorrect pressure measurements.

Smiths Medical has received no reports of deaths or serious injuries related to this issue.

INSTRUCTIONS TO CUSTOMERS AND DISTRIBUTORS:

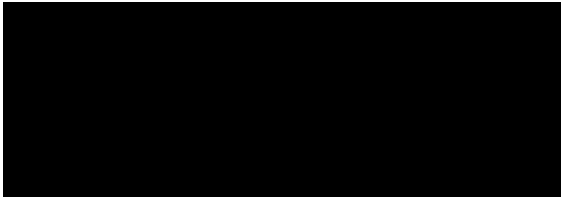
1. Locate, quarantine, and determine the amount of unused affected product in your possession by referring to Attachment 2 - List of Affected Products.
2. Complete the accompanying Response Form (Attachment 1) within 10 days of receipt and return it to fieldactions@smiths-medical.com or fax to 1 (952) 400-5654. The completed form must be returned even if you do not have any affected product in your possession.

3. All affected product must be returned to Stericycle for processing. Pre-paid return shipping labels and shipping instructions are included with this Field Safety Notice. Include a copy of your completed Response Form inside EACH BOX of returned product to facilitate processing. Ensure boxes are sealed and labeled with your facility name prior to shipping.
4. **DISTRIBUTORS: If you have distributed potentially affected devices to your customers, please immediately notify them of this Field Safety Corrective Action by forwarding them a copy of this Field Safety Notice. All communication to Smiths Medical must be completed by the distributor. Please do not permit your end user to respond directly or return devices to Smiths Medical.**

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

If you have any questions regarding this notification, please contact Smiths Medical via email at fieldactions@smiths-medical.com

Sincerely,



Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442
fieldactions@smiths-medical.com

Enclosure: Attachment 1 –Response Form
Attachment 2- List of Affected Products

ATTACHMENT 1



MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

Pressure Shifts and Incorrect Pressure Readings for Medex™ LogiCal® 5ml Closed Blood Sampling System Sets and Medex™ HemoDraw® Plus Closed Blood Sampling Sets with LogiCal® Pressure Monitoring System

Please assist us in executing this Field Safety Corrective Action by completing and returning this Response Form as soon as possible. This will serve as confirmation that you have received and understand the attached Field Safety Notice and will allow us to ensure that we have reached all customers who may be affected by this Field Safety Corrective Action.

Please acknowledge receipt of the attached Field Safety Notice by completing and returning this Response Form to fieldactions@smiths-medical.com within 10 days of receipt.

Part Number	Lot Number	Quantity to be Returned (individual units)

**Please attach list of additional products if necessary.*

I certify that I have read and understand the information in the attached Field Safety Notice.

Name and Title (Please Print)	Signature and Date	Facility Name and Address
Email Address	Telephone Number	

Attachment 2
List of Affected Product

Model Number	Name
DPSHC0076	CBSS 2-fach Druckmesset mit Option
DPSHC0081	CBSS 5 ml, Antishunt proximaler Entnahmeport 60 cm
DPSHC0082	CBSS 5 ml, dreifach proximaler Entnahmeport 60 cm
DPSHC0083	CBSS 5 ml, einfach proximaler Entnahmeport 60 cm
DPSHC0084	CBSS 5 ml, zweifach proximaler Entnahmeport 60 cm
DPSHC0090	CBSS-5ML Zweifach set
DPSHC0091	CBSS-5ML Antishunt set, (172/15cm)
DPSHC0092	CBSS-5ML, Triple set, (172/15cm)
DPSHC0093	CBSS-5ML, Single Set, (172/15cm)
DPSHC0094	CBSS-5ML, Double set, (172+15cm)
MX961E181P1	LogiCal 5ml Closed Blood Sampling System 183cm, 1x Line, 1 x Sampling Site, Pole Mounted
MX961E211P1	LogiCal 5ml Closed Blood Sampling System 213cm, 1x Line, 1 x Sampling Site, Pole Mounted
MX961H182P1	HemoDraw Plus Closed Blood Sampling Set with LogiCal Pressure Monitoring System 183cm, 1x Line, 2x Sampling Sites, Pole Mounted
MX961H212P1	HemoDraw Plus Closed Blood Sampling Set with LogiCal Pressure Monitoring System 213cm, 1x Line, 2x Sampling Sites, Pole Mounted
MX962E211P1	LogiCal 5ml Closed Blood Sampling System 213cm, 2x Line, 1x Sampling Site, Pole Mounted
MX962H182P1	HemoDraw Plus Closed Blood Sampling Set with LogiCal Pressure Monitoring System 183cm, 2X Lines, 2X Sampling Sites, Pole Mounted
MX962H212P1	HemoDraw Plus Closed Blood Sampling Set with LogiCal Pressure Monitoring System 213cm, 2x Lines, 2x Sampling Sites, Pole Mounted
MX96AE181P1	LogiCal 5ml Closed Blood Sampling System 183cm, 1X Line with Anti-shunt Stopcock, 1X Sampling Site, Pole Mounted
MX96AE211P1	LogiCal 5ml Closed Blood Sampling System 213cm, 1X Line, 1X Sampling Site with Anti-shunt Stopcock, Pole Mounted