FSCA Ref: GMEQI-26

Field Safety Notice (FSN)

Provo.X

manufactured by

GANSHORN Medizin Electronic GmbH,
Industriestrasse 6-8, 97618 Niederlauer, Germany
www. ganshorn.de

SRN: DE-MF-000006566

Date: 2024-05-23

Attention: GANSHORN and/or SCHILLER authorized distributors and their customers

A problem related to the installation of an incorrect pressure safety valve in the Provo.X revision C could lead to hazardous situations, such as misdiagnosis or delayed diagnosis.

This notice is intended to inform you about:
- what the problem is and under what circumstances it can occur.
- the actions that you as a distributor/customer can take to minimize the effect of the problem.
- the actions planned by GANSHORN Medizin Electronic GmbH to correct the problem.

We kindly ask that you read this notice carefully and send us written acknowledgement by 2024-06-30 that you have read and understood the contents of this notice. Written acknowledgement can be sent to GANSHORN Medizin Electronic GmbH via the contact details listed below.

If you need any further information concerning this FSN, please do not hesitate to contact the GANSHORN Vigilance Team: quality@ganshorn.de

For technical support, please contact support@ganshorn.de

GANSHORN Medizin Electronic GmbH apologizes for any inconveniences caused by this problem.

Sincerely,

Sirimanee Chatrojjanasakul
Head of Quality Management and Regulatory Affairs
quality@ganshorn.de
T: +49 9771 6222 6502

1. INFORMATION ON AFFECTED DEVICES	
COMMERCIAL NAME(S):	Provo.X
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	The Provo.X is a device for performing specific and unspecific bronchial provocation tests.
MODEL/CATALOGUE/ REF NUMBER(S):	Provo.X Revision A or Provo.X Revision B, which had been upgraded to Revision C.
SOFTWARE VERSION:	n/a
AFFECTED SERIAL OR LOT NUMBER RANGE:	C1012020880253, C1052020880293, C1052020880305, C1052021880408, C1062017880046, C1072018880120, C1082018880133, C1092021880433, C1092021880444, C1102017880060, C1102022880559, C1112022880599, C1112022880618, C1112022880624
UNIQUE DEVICE IDENTIFIER(S) (UDI-DI):	n/a
DEVICE TYPE:	Broncho provocations for inhalation provocation tests

2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
BACKGROUND INFORMATION AND PROBLEM DESCRIPTION	The air pressure from the safety valve for the provocation device measures approximately 1.8 bar, although the device is labeled with an operating pressure of 3.45 bar. The root cause of the operational discrepancies observed in the device was incorrect adjustment of its components by the user. This issue primarily stemmed from the user's failure to adhere to the manufacturer's instructions.
HAZARD GIVING RISE TO THE FSCA	The installation of an incorrect pressure safety valve in the Provo.X revision C could lead to hazardous situations, such as misdiagnosis or delayed diagnosis.
PROBABILITY OF PROBLEM ARISING	This error has the potential to aggravate medical conditions, possibly requiring immediate medical attention or surgical intervention.
PREDICTED RISK TO PATIENT/USERS	Most at risk are patients with undetected allergy-triggered asthma. This group can include individuals of any age but is often more concerning in younger children and elderly patients who may not adequately communicate or recognize their symptoms.

3. TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE DISTRIBUTOR / IMPORTER	1) If the aforementioned device has already been installed at the end-user's location, we require confirmation that it was installed properly in accordance with the provided instructions. If this is not the case, the distributors should acknowledge the manufacturer's message and remain vigilant during the next installation. 2) Send the signed ANNEX I – Distributor/Importer Reply Form back to GANSHORN Medizin Electronic GmbH by **2024-06-30** as confirmation that the content of this notice was read and understood and that this Field Safety Notice was distributed, read and understood by all users.
DATE FOR COMPLETION:	2024-06-30
IS THE FSN REQUIRED TO BE COMMUNICATED TO THE PATIENT / LAY USER?	No
LIST OF ATTACHMENTS	ANNEX I –Distributor/Importer Reply Form
TECHNICAL SUPPORT	For technical support, please contact your local distributor.

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. (As appropriate)
Please transfer this notice to other organisations on which this action has an impact. (As appropriate)
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 Competent Authority if appropriate, as this provides important feedback. *

The responsible National Authority has been informed about this communication of this field safety notice.

Contact person of manufacturer:

Sirimanee Chatrojjanasakul
Head of Quality Management and Regulatory Affairs
quality@ganshorn.de
T: +49 9771 6222 6502

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ANNEX I – Distributor / Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	GMEQI-26
FSN Date*	2024-05-23
Product/ Device name*	Provo.X revision C (only upgraded device)

2. Manufacturer Details	
Company Name	GANSHORN Medizin Electronic GmbH
SRN	DE-MF-000006566
Address	Industriestrasse 6-8, 97618 Niederlauer, Germany
Contact Name	Sirimanee Chatrojjanasakul
Email	quality@ganshorn.de
Telephone Number	+49 9771 6222 6502

3. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

4. Distributor/Importer (Tick all that apply)		
☐	*I confirm the receipt of this Field Safety Notice and that I read and understood its content.	Distributor/Importer to complete or enter N/A
☐	*I have identified customers that received or may have received this device	Distributor/Importer to complete or enter N/A
☐	*I attached the completed device list	Distributor/Importer to complete or enter N/A
☐	*I have carried out the actions for DISTRIBUTOR / IMPORTER as requested by this FSN.	Distributor/Importer to complete or enter N/A
☐	*I have received the completed reply form from all identified customers	Distributor/Importer to complete or enter N/A
☐	Neither I nor any of my customers have any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign here
Date*		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.