FIELD SAFETY NOTICE

Urgent Field Safety Notice

APR-04-2022 | Reference 605477

Subject: 605477 - NICCI Field Action

Addressee: All users, operators and distributors of the NICCI Technology

Products affected:

Product name	REF #	MCC REF #
NICCI Module	PC6500	6889361
NICCI Mouse	PC6510	6889371
NICCI Sensor S **NICCI Sensor M** **NICCI Sensor L**	PV6550 PV6551 PV6552	6889384 6889385 6889386
NICCI Upper Arm Cuff Tube **NICCI Upper Arm Cuff S** **NICCI Upper Arm Cuff M** **NICCI Upper Arm Cuff L** **NICCI Upper Arm Cuff XL**	PC6530 PC6531 PC6532 PC6533 PC6534	6889374 6889375 6889376 6889377 6889378

Serial/Lot numbers affected:

All serial and lot numbers of the above listed products are affected.

Description of the issue and root cause

During the review of clinical data Getinge has identified differences in the clinical performance of the NICCI Technology compared to invasive reference measurements. The NICCI Technology provides continuous non-invasive monitoring of blood pressure and other derived parameter.

The issue is described as follows:

The blood pressure values displayed by the NICCI Technology can deviate widely from the expected values. This value deviation has been observed

- as offset (constant positive or negative deviation from the expected values) and
- drift (continuous increase or decrease of values over time compared to the expected values).

The values displayed by the NICCI Technology are calibrated in intervals via NIBP calibration, which is an automatic non-invasive blood pressure measurement performed on the patient´s upper arm. A factor that may contribute to the observed drift behaviour is the extension of the NIBP calibration interval beyond the device default setting.

A root cause for the offset is seen in the inherent difference between the two measurement methods (oscillometric vs. invasive). Further root cause investigation is ongoing.

As a consequence of the above described issues, the use of the NICCI Technology may generate misleading blood pressure values which is seen as a high risk.

To date, one complaint has been received which has been traced to the same scope. No harm or clinical consequences occurred.

Potential health consequences

During the use of the NICCI Technology values may widely deviate from expected results and result in misleading values. Treatment decisions based on that can probably lead to hypotension, and occasionally in acute hypertensive emergency or hypervolemia resulting in serious adverse events: This could constitute a serious deterioration of the patient’s clinical state.

Identification of the affected medical devices

NICCI is intended to be used as an accessory for continuous non-invasive blood pressure and pulse rate measurement, and other derived parameters.

Components:

Application of the NICCI Module requires the PulsioFlex host monitor, which serves as power supply and user-interface for NICCI. PulsioFlex host monitor is not part of the Field Action.

Further essential technology configurations consist of the following components, see also Figure 1:

• NICCI monitoring units (NICCI Mouse and NICCI Sensor)

• NICCI Upper Arm Cuff (for NIBP measurements)

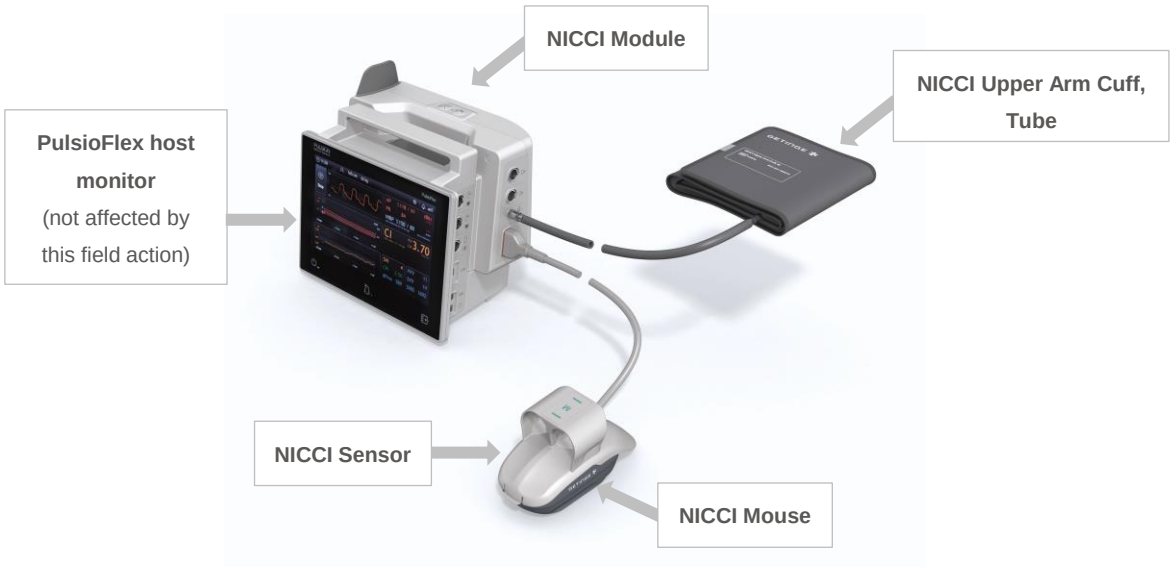

Figure 1: NICCI Technology components

Description	Product name	REF #	MCC REF #
NICCI Module Connected to the host monitor PulsioFlex PC4000 (PulsioFlex is not part of the Field Action). Exemplary picture: 	**NICCI Module**	PC6500	6889361

Description	Product name	REF #	MCC REF #
NICCI Mouse Connected to the NICCI Module. Exemplary picture: 	**NICCI Mouse**	PC6510	6889371
NICCI Sensor Connected to the NICCI Mouse. Exemplary picture: 	**NICCI Sensor S** **NICCI Sensor M** **NICCI Sensor L**	PV6550 PV6551 PV6552	6889384 6889385 6889386
NICCI Upper Arm Cuff Connected to the NICCI Module. Exemplary picture, see below. **NICCI Upper Arm Tube** Connected to the NICCI Upper Arm Cuff. Exemplary picture, see below. 	**NICCI Upper Arm Cuff Tube** **NICCI Upper Arm Cuff S** **NICCI Upper Arm Cuff M** **NICCI Upper Arm Cuff L** **NICCI Upper Arm Cuff XL**	PC6530 PC6531 PC6532 PC6533 PC6534	6889374 6889375 6889376 6889377 6889378

Affected serial/lot numbers

All serial and lot numbers of the listed products in page 1 are affected.

Our records indicate that affected products were delivered to your location. Please verify if you have any of the listed products.

In order to be able to see the labels with the REF # and product name, please disassemble the components:

- The NICCI Module label is located on the contact area to the host monitor
- The NICCI Mouse label is located on the contact area to the NICCI Sensor
- The NICCI Sensor label is located on the contact area to the NICCI Mouse

Which actions are required by the customer?

Getinge will initiate an immediate field action of all affected device units. Please

- Immediately verify, if you have any of the products listed on page 1.
- Immediately separate products listed on page 1 to prohibit any further use.
- Immediately stop using the products listed on page 1 and monitor the health status of any patient who has been monitored with the NICCI Technology closely for signs of deterioration.
- Immediately contact your Getinge local representative to plan the return of the products and financial compensation of the returned goods.
- Complete and return the attached acknowledgement form and maintain awareness of this notice and related actions until the involved products have been removed to ensure effectiveness of the corrective action.

Distribution of the provided Information

This Getinge **Field Safety Notice** needs to be distributed to those individuals within your organization who need to be aware of the issue - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and the resulting action until closure of this action.

In the case that you as customer choose not to proceed with completion of the action requirements described above, Getinge cannot accept any responsibility for safety-related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. The local responsible authority has been informed about this communication and issue.

We apologize for any inconvenience this may cause. We will do our outmost to carry through with this action as swiftly as possible.

Should you have questions or require additional information, please feel free to contact us at any time.

Best regards,

Product Manager
Pulsion Medical Systems SE

Head of Quality
Pulsion Medical Systems SE

Contact data local Getinge representative per country
[Contact Name
Contact e-mail
Contact phone]

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Referenced documents:

- Annex I – 605477 FSN Response form end customer (EN)
- Annex II – 605477 FSN Response form distributor (EN)