

Graz, Nov 19, 2015

URGENT FIELD SAFETY NOTICE

Task Force[®] Monitor 2015-11-FSCA

Dear customer,

An internal production check of the Task Force[®] Monitor 3040i by CNSystems Medizintechnik AG revealed a non-conformity of the oscillometric blood pressure measurement (NBP) taken on the subject's upper arm.

The affected devices (see list) may measure inaccurate systolic and diastolic blood pressure values for the NBP upper arm measurement. However, patients and users are at no time exposed to hazard by the device itself.

With this safety notice we want to inform you about the following topics:

- Affected devices
- Description of non-conforming functionality and impact on measurements
- Short-term measures for safe use in the field
- Repair of the affected devices by CNSystems

CNSystems has decided to perform a voluntary recall of the affected devices and to return the devices after repair (free of charge).

We are very sorry for any inconvenience this situation might cause to you and will strive to repair your device as soon as possible. We allow ourselves to enclose 20 free sets of electrodes to your Task Force[®] Monitor to compensate the inconvenience caused.

The non-conformities subsequently described have already been reported to the competent authorities by CNSystems Medizintechnik AG.

With kind regards,



Bernd Wellisch, Chief Operations Officer

If you have questions or concerns about the further operation of your device, please contact us immediately:

CNSystems Medizintechnik AG
 Reininghausstraße 13
 8020 Graz
 Telephone: +43 316 723456 - 33
 Fax: +43 316 723456 - 2
 Email: fsca@cnsystems.com

Serial Numbers of affected devices:

003040i-2014-161-001-GG-0000	003040i-2014-161-002-GG-0000
003040i-2014-161-003-GG-0000	003040i-2014-161-004-GG-0000
003040i-2014-161-005-GG-0000	003040i-2014-161-006-GG-0000
003040i-2014-161-007-GG-0000	003040i-2014-161-008-GG-0000
003040i-2014-161-009-GG-0000	003040i-2014-161-010-GG-0000
003040i-2014-161-011-GG-0000	003040i-2014-161-012-GG-0000
003040i-2014-161-013-GG-0000	003040i-2014-161-014-GG-0000
003040i-2014-161-015-GG-0000	003040i-2014-161-016-GG-0000
003040i-2014-161-017-GG-0000	003040i-2014-161-018-GG-0000
003040i-2014-161-019-GG-0000	003040i-2014-161-020-GG-0000
003040i-2014-161-021-GG-0000	003040i-2014-161-022-GG-0000
003040i-2014-161-023-GG-0000	003040i-2014-161-024-GG-0000
003040i-2014-161-025-GG-0000	003040i-2015-101-001-GG-0000
003040i-2015-101-002-GG-0000	003040i-2015-101-003-GG-0000

Description of non-conforming functionality:

CNSystems has realized that in the devices listed above, two electronic components were incorrectly fitted on the circuit boards for the oscillometric upper arm blood pressure measurement by one of our suppliers.

This can lead to the measurement of incorrect oscillometric upper arm blood pressure values in some subjects – mainly in tall and slim persons (overestimation of systolic blood pressure, underestimation of diastolic blood pressure).

Since the values of the oscillometric upper arm blood pressure are taken as reference values for the calibration of the continuous blood pressure measurement (measured with finger sensor), the absolute values of the blood pressure waveform may also be affected.

Use of the Task Force® Monitor before repair:

As long as your device has not been repaired, the Task Force® Monitor can safely be used in the meantime if all of the following points are observed without any exception:

- The values of the systolic and diastolic blood pressure must not be used for diagnostic purposes. Please perform an independent reference measurement (e.g. with a separate oscillometric blood pressure device).
- As the value for the mean blood pressure remains unaffected, there is no negative impact on derived parameters such as Total Peripheral Resistance (TPR).
- Morphology and dynamics of the blood pressure wave are not affected.
- All parameters measured with ECG or ICG (e.g. heart rate, stroke volume, cardiac output) are also not affected.
- All persons who work with the Task Force® Monitor must be informed about this non-conformity and about the measures for a safe device operation.

Repair of affected devices by CNSystems:

CNSystems has decided to perform a voluntary recall of the affected devices and to return the devices after repair (free of charge).

The repair of the affected devices will be performed at the CNSystems headquarters in Graz, Austria. Of course, we strive towards a fast handling of your repair (turn-around time is approximately 5 working days including pick-up and return transports).

To be able to keep the process as easy as possible, please make sure to include all components listed in the attached packing list.

For organizing pick-up and return, please send us an email with the following information to office@cnsystems.com:

- Contact person (name and telephone number)
- Pick-up address
- Serial number of your Task Force® Monitor
- Favored date for pick-up

Please, acknowledge the receipt of this safety notice including the measures for a safe use of the Task Force® Monitor with the attached form – per fax (+43 316 723456 - 2) or email (fsca@cnsystems.com).

For further questions please do not hesitate to contact us any time via phone +43 316 723456 - 33 or via email fsca@cnsystems.com.