

URGENT FIELD SAFETY NOTICE - myoncare

Manufacturer: ONCARE GmbH
Subject: myoncare Software:
The use of scores with pre-filled "0" values in the "Multiple Choice" and "Ranking" components can lead to miscalculations in the health indicator.

Affected Products: myoncare BASIC (versions 1.6 – 1.6.1)
Article number / UDI: ON01010107 (myoncare v1.6) with UDIs
1.6: (01)04260658860043(11)220421(10)ON01010107
1.6.1: (01)04260658860043(11)220706(10)ON01010107

Date of this notice: August 04, 2022
Author of this notice: [REDACTED]
ONCARE reference number: CAPA-008
Necessary measures: Information to users about measures to take; Correction of affected products by ONCARE through software update

Summary

We would like to inform you about a software malfunction within the myoncare software (version 1.6 onwards) which affects all products shipped between April 2022 and July 31, 2022. Specifically, this software malfunction affects the medical device 'Careplan Manager' which is part of all myoncare BASIC products.

Myoncare is medical software for monitoring and diagnostic support. In this function, it offers "scores", which allow users to introduce a multi-level factoring of how to rank or value single components and their corresponding individual answer options. In order to activate this functionality, users have to activate the "scores" toggle button on the right sidebar of every caretask component (for example a question) and select the corresponding values. The affected components are 'single choice', 'multiple choice' and 'ranking'. Only those component templates which initially did not have activated scoring but had scores assigned to the answer options AND the score of the last (most bottom) answer option is "pre-filled" with '0' (meaning is not manually changed to '0') are affected.

ONCARE did not receive any reports regarding negative consequences for patient treatment arising from this malfunction. This product notification shall provide you with relevant user information on the circumstances in which the malfunction occurs and which measures ONCARE is planning to initiate in order to permanently correct the malfunction.

Impact

In this scenario, when the caretask is answered by the patient from the mobile application or by the healthcare professional from the web application so that this answer option with the pre-filled '0' is selected as well as any other answer option which is not '0', the score of the component will not be calculated. This means that this component of the caretask is not contributing to the overall score of the caretask which may lead to a faulty score and potentially an incorrect health indicator (if activated). An incorrect health indicator can lead to an incorrect prioritization (i.e. sorting of patients) in the patient list.

Elements whose scores are completely newly created by the user, as well as elements that do not contain a score with value “0”, are not affected by this malfunction. Other features and functionalities of the software are also not affected.

Dedicated conditions for the occurrence of the issue, as well as the affected product functionalities, are described in the following sections.

Details including root cause

A detailed technical investigation into the issue revealed, that the issue is a missing server-side verification that the number of objects in an array (i.e. answer options of the component) matches the number of different scores associated with the component in the database.

In this scenario, when the caretask is answered by the patient from the mobile application or by the healthcare professional from the web application so that this answer option with the ‘0’ is selected as well as any other answer option which is not ‘0’, the score of the component will not be calculated. This means that this component of the caretask is not contributing to the overall score of the caretask which leads to a faulty score and potentially an incorrect health indicator (if activated). Since the bug is associated with previously generated component templates of the said types used in caretasks, the effect on the health indicator increases with the number of those component templates used in a caretask. This issue does not appear in cases in which the WebApp user generates all caretask components newly or chooses only other component types. This issue also does not occur if the WebApp user chooses a previously generated template that already had scoring activated.

Single choice components are only technically affected without impact on the score or health indicator because, if the selected answer has the score 0, there is no contribution to the overall score. If the answered option has a score different than 0, the answer option is scored correctly.

Scores and the health indicator are clearly declared to not be intended as the sole basis for medical decision making in the user interface of the web application and in the instructions for use.

ONCARE is currently in the process of developing a software fix which permanently corrects this scenario, thereby preventing it from re-occurring in the future by means of implementing technical measures (i.e. consideration of pre-filled “0” values). Once the software fix is available, all customers will receive a free software update to address the malfunction.

Recommended measures

Retrospective verification:

Determine the caretask components ‘multiple choice’ and ‘ranking’ for which scores were activated. If the score options have the value “0”, evaluate whether any subsequently initiated medical measures – based on the patients’ health indicator – for the corresponding patients were adequate.

Corrective measures to be taken by the user:

1. In order to guarantee safe use of the device, ONCARE recommends that answer options of affected components with predefined scores with value “0” shall be manually overwritten to “0” before being used further.

2. Oncare recommends that affected and still active caretasks shall be withdrawn, predefined scores with value "0" shall be manually overwritten to "0" and then the caretask has to be reassigned to the patient.
3. Support ONCARE with scheduling the software update which permanently corrects the software malfunction once the software fix is available.

Corrective measures taken by ONCARE:

1. Customers receive this product notification to make them aware of the malfunction
2. ONCARE will contact every customer (starting CW36/2022) to schedule and perform a software update which permanently corrects the software malfunction.

Please inform all personnel within your organization that uses myoncare on the content of this product notification. Make sure to keep this notification on file until all corrective measures were successfully completed at your site.

Please confirm receipt and understanding of this notification via e-mail to vigilance@myoncare.com.

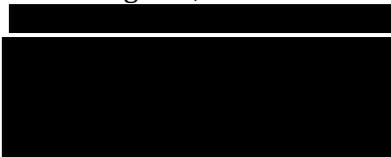
We sincerely apologize for any inconvenience caused by this notification and appreciate your cooperation. Reach out to our Vigilance Team in case you have questions or require further information (availability: Monday through Friday 9.00 AM – 5.00 PM, except on public holidays).

Email: vigilance@myoncare.com

Address: Balanstr. 71a, 81541 Munich, Germany

August 04, 2022

Kind regards,



Europe: The undersigned confirms that the responsible European authority was informed regarding the content of this product notification.