

Document Detail

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Document No.: 9000-HHE-2021-38[1]
Title: Teneo Treatment Center
Comment: US, Canada & Japan: Class 3 recall
Status: CURRENT
Effective Date: 18-Nov-2021

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
9000-Initiating Location Head of QA/RA Initiating Location Head of QA/RA	Michael Justen	15-Nov-2021 11:43 am	GMT
9000-Regulatory Approver Corporate-Regulatory Approver	Michael King	15-Nov-2021 11:35 am	GMT
9000-Head of Corp Legal Corporate Head of Legal	Justin McCarthy	16-Nov-2021 6:35 pm	GMT
9000-VP QARA Vice President of Quality Assurance and Regulatory Affairs	Khalid Raja	16-Nov-2021 6:38 pm	GMT
9000-RM Group Head of QA/RA Responsible Manufacturer Group Head of QA/RA	Martin Schoedel	17-Nov-2021 7:45 am	GMT
9000-RM Group Head Responsible Manufacturer Group Head	Jan Siefert	18-Nov-2021 7:55 am	GMT

1.0 EXECUTIVE SUMMARY

PRODUCT NAME	<i>Teneo Treatment Center</i>
INITIATING GROUP/LOCATION	<i>E&I+Digital - Group</i>
RESPONSIBLE/PHYSICAL MANUFACTURER CONDUCTING MARKET ACTION	<i>Sirona Dental Systems GmbH / Bensheim</i>
PRODUCT MANUFACTURED BY	<i>Sirona Dental Systems GmbH / Bensheim</i>
ISSUE DESCRIPTION	<i>Bearing pin might come loose and Patient Seat of the Unit might swivel back</i>
ISSUE TRIGGERED BY	<i>n.a.</i>
QUANTITY IMPACTED	<i>2151 devices in the field (based on the numbers from the delivery notes).</i>

2.0 DETAILED PRODUCT INFORMATION

- [Teneo Treatment Center](#)



The dental patient chair is used to bring a patient into various positions for treatment. The chair consists of a head rest, and the patient seat and the chair basis. The chair is mounted on the floor. A motorized adjustment of the height and tilt angle of the seat is possible.

3.0 DETAILED ISSUE DESCRIPTION

The patient seat is connected to the basis of the unit with a bearing pin, which allows the movement and rotating of the chair in vertical direction.

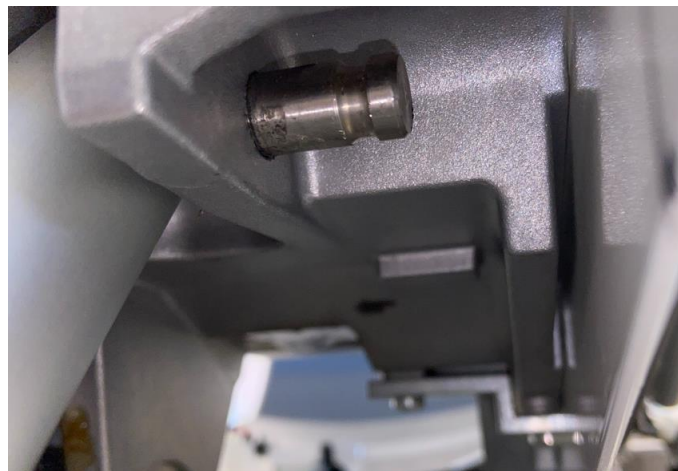
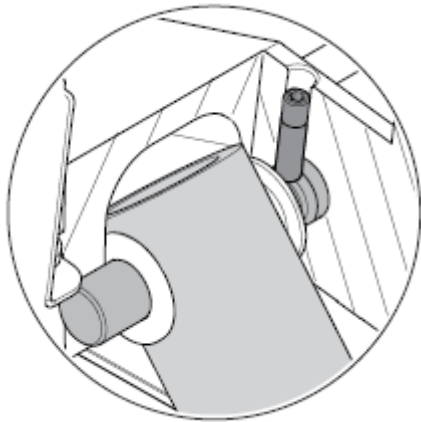
It happened one issue (No.: 8000573478) in Germany in April 2021 (without any patient impact), which was reported from the customer to BfArM. This case was evaluated to be a single fault issue production failure.

A movement of the bearing pin only happens during the movement of the unit. In comparison to the affected number of devices and the daily movements for each device you can calculate a certain probability as follows:

With 2151 affected units in the field used, with approximately 10 patients a day and minimum 2 times usage of the patient chair per patient and 220 working days per year:

$2151 \times 10 \times 2 \times 220 = > 9,5$ million load cases of this part per year compared to 5 relating complaints without any patient harm.

A spot check investigation within the affected population the market, initiated after issue 8000573478 showed that there were 5 of 20 devices where this bearing pin has moved out of its original position. The movement of that bearing pin in one direction is uncritical, because of an internal stop plate. If the bearing pin moves into the opposite direction it might totally move out of the bearing bore hole. In this case the patient seat might swivel backwards.



4.0 QUANTITY OF PRODUCT IMPACTED (IF KNOWN)

There are 2151 Teneo devices in the market, where such a bearing pin is assembled.

ISSUE INVESTIGATION and ROOT CAUSE (IF KNOWN)

The investigation of the issue has pointed out two major reasons for the loosening:

- The headless screw for fixation was assembled in a way that it does not fit into the milled groove,
- Or the fixation adhesive that should permanently keep the headless screw in its position failed or was insufficiently assembled.

5.0 ISSUE RISK ANALYSIS

DESCRIPTION OF HEALTH HAZARD	The falling out of the bearing pin, only if the pin moves in the direction without stop plate might lead to backwards swiveling of the patient seat. If the bearing pin falls off in the upper seat position the patient can exit the chair without any risk. If the bearing falls off in the patient lying position, the patient seat swivels backwards, which might lead to fall injuries of the patient.
CLINICAL IMPLICATIONS	Not fully foreseeable The internal fall study has pointed out that it is unlikely to get a minor injury. (refer to document „Einschätzung des Schadensausmaßes am Beispiel der Behandlungseinheit Teneo“ dated 2021-05-26)
EXISTING HEALTH OR PHYSICAL CONDITIONS THAT CAN POTENTIALLY COMPOUND BY THIS ISSUE	N/A
IMPACT TO SPECIFIC POPULATION OF PATIENTS OR CLINICIANS	N/A
IMMEDIATE AND LONG RANGE CONSEQUENCES	In a worst-case scenario, the patient might be slightly injured and need adequate medical support for recovery.

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6.0 HEALTH HAZARD RISK LEVEL

RISK LEVEL	RISK DESCRIPTION
<input type="checkbox"/>	5 The health consequence is life threatening (death has or could occur).
<input type="checkbox"/>	4 The health consequence is such that it can result in, or has the potential to result in, permanent impairment of a body function or a permanent damage to a body structure.
<input type="checkbox"/>	3 The health consequence is such that it requires, or has the potential to require, medical or surgical intervention. There is no long-term health impact on the patient. Health impact is not long term if it is reversible within a 2-year time period.
<input checked="" type="checkbox"/>	2 The health consequence is such that it can lead to, or has the potential to lead to, a transient discomfort or product complaints or some other form of dissatisfaction, or the health consequence is such that it causes additional/unplanned interventions or corrections during the course of a treatment or after a treatment with no health risk to the patient. (*) (refer to internal fall study document „Einschätzung des Schadensausmaßes am Beispiel der Behandlungseinheit Teneo“ dated 2021-05-26)
<input type="checkbox"/>	1 There is no health consequence but there is a potential for customer dissatisfaction or complaints.

7.0 RATE DETECTABILITY

LEVEL	DETECTABILITY DESCRIPTION
<input type="checkbox"/>	CERTAIN All users shall identify the issue prior to use of the device.
<input type="checkbox"/>	HIGH Most users shall identify the issue prior to use of the device.
<input checked="" type="checkbox"/>	MEDIUM Some of the users are expected to identify the issue prior to use of the device.
<input type="checkbox"/>	LOW Most users are not expected to identify the issue prior to use of the device.

8.0 HEALTH HAZARD CONCLUSION

A field action shall be started to exchange the *bearing pin in the field*. While replacing the short bearing pin by a longer one, the chair geometry guarantees that the pin cannot move out of the bearing hole anymore, even when the screws come lose or are not present.

CAPA NUMBER

APPROPRIATE MARKET ACTION PATH

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9.0 GROUP/LOCATION PRODUCT SURVEILLANCE COMMITTEE RECOMMENDATION FOR MARKET ACTION

COUNTRY/REGION	DECISION		
<input checked="" type="checkbox"/> USA	<input type="checkbox"/>	Class 1 Recall	
	<input type="checkbox"/>	Class 2 Recall	
	<input checked="" type="checkbox"/>	Class 3 Recall	
	<input type="checkbox"/>	Market Withdrawal	
	<input type="checkbox"/>	Stock Recovery	
	<input type="checkbox"/>	Advisory Notice	
	<input type="checkbox"/>	Take No Action	
	<input checked="" type="checkbox"/>	Report to Notified Body (if required)	
<input checked="" type="checkbox"/> CANADA	<input type="checkbox"/>	Type 1 Recall	
	<input type="checkbox"/>	Type 2 Recall	
	<input checked="" type="checkbox"/>	Type 3 Recall	
	<input type="checkbox"/>	Market Withdrawal	
	<input type="checkbox"/>	Stock Recovery	
	<input type="checkbox"/>	Advisory Notice	
	<input type="checkbox"/>	Take No Action	
	<input checked="" type="checkbox"/>	Report to Notified Body (if required)	
<input checked="" type="checkbox"/> EUROPEAN UNION (EU)	<input checked="" type="checkbox"/>	Field Safety Corrective Action & Field Safety Notice	
	<input type="checkbox"/>	Market Withdrawal	
	<input type="checkbox"/>	Stock Recovery	
	<input type="checkbox"/>	Advisory Notice Only	
	<input type="checkbox"/>	Advisory Notice with Market Action Noted Above	
	<input type="checkbox"/>	Take No Action	
	<input type="checkbox"/>	Issue to be reported to Notified Body?	
	<input checked="" type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/>	Notified Body Name	
	<input type="checkbox"/>	TÜV Süd / PS	
	<input type="checkbox"/>	Issue to be reported to Competent Authority?	
	<input checked="" type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/>	Competent Authority(s) Name	
<input type="checkbox"/>	BfArM		
<input type="checkbox"/> BRAZIL	<input type="checkbox"/>	Risk Type I Recall	
	<input type="checkbox"/>	Risk Type II Recall	
	<input type="checkbox"/>	Risk Type III Recall	
	<input type="checkbox"/>	Risk Type IV Recall	
	<input type="checkbox"/>	Stock Recovery	

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COUNTRY/REGION	DECISION	
	<input type="checkbox"/>	Advisory Notice
	<input type="checkbox"/>	Take No Action
	<input type="checkbox"/>	Report to Notified Body (if required)
<input checked="" type="checkbox"/> JAPAN	<input type="checkbox"/>	Class 1 Recall
	<input type="checkbox"/>	Class 2 Recall
	<input checked="" type="checkbox"/>	Class 3 Recall
	<input type="checkbox"/>	Market Withdrawal
	<input type="checkbox"/>	Stock Recovery
	<input type="checkbox"/>	Advisory Notice
	<input type="checkbox"/>	Take No Action
	<input checked="" type="checkbox"/>	Report to Notified Body (if required)
<input checked="" type="checkbox"/> AUSTRALIA	<input type="checkbox"/>	Class 1 Recall
	<input checked="" type="checkbox"/>	Class 2 Recall
	<input type="checkbox"/>	Class 3 Recall
	<input type="checkbox"/>	Market Withdrawal
	<input type="checkbox"/>	Stock Recovery
	<input type="checkbox"/>	Advisory Notice
	<input type="checkbox"/>	Take No Action
	<input checked="" type="checkbox"/>	Report to Notified Body (if required)
<input checked="" type="checkbox"/> OTHER		If applicable, indicate location and type of action needed:
	<input checked="" type="checkbox"/>	FSCA
	<input type="checkbox"/>	Stock Recovery
	<input type="checkbox"/>	Recall
	<input type="checkbox"/>	Take No Action

REASON FOR RECOMMENDATION

Even if there is a low risk for patient, user or third, there are still 2151 devices in the field, where that situation of a backwards swiveling patient seat might occur.

Name / Division:	Michael Justen QARC Initiator	Martin Schödel QARC Head	Jan Siefert Group Head
Date:	2021-11-12		
Signature:			