SenTec AG
Phone +41 61 / 726 97 60
Fax +41 61 / 726 97 61
info@sentec.com
www.sentec.com

Initial Report regarding a Field Corrective Action

Class 1 FIELD SAFETY CORRECTIVE ACTION

Customer information regarding potential problems with certain serial numbers of the SenTec Monitor (SDMS). Customer action required.

1. Administrative information – Recipient of report

Date of this report:	Sept. 22nd 2016
Internal reference number assigned by the manufacturer:	CR-2016-142
USA: FDA Report number (according to 21CFR806.10 c1):	3004149774-9/22/16-001-C
Incident reference number and name of the co-ordinating NCA Competent Authority (if applicable):	NA, no incident has occurred.

List of Competent Authorities this report is submitted to:
Europe:
Switzerland, UK

Rest of the world:
USA

2. Information on submitter of the report

Status of submitter: Manufacturer

3. Manufacturer information

Manufacturer name: SenTec AG

Manufacturer's contact person: Dr. Sabine Mangold (sabine.mangold@sentec.com)

Address:
SenTec AG
Ringstrasse 39
CH-4106 Therwil
+41/61 726 97 78

4. Authorised Representative information

Name of the Notified Body (EU): SGS
Notified Body (NB) ID-number: 120

The Authorised Representative's (Notified Body) contact person: Dr. André Gadow
Address:
Systems and Services Certification
SGS Société Générale de Surveillance SA
Technoparkstrasse 1
8005 Zürich
Switzerland
Phone: +41 (0)44 445 16 80
andre.gadow@sgs.com

SenTec AG
Phone +41 61 / 726 97 60
Fax +41 61 / 726 97 61
info@sentec.com
www.sentec.com

US Agent/ Official Correspondent: S. Gorski, Imagenix, Inc.
Address:
P.O. Box 399
Eagle WI 53119
USA
Mobile: +1 (414) 7374596
Other: +1 (262) 5942114
stephengorski@me.com

5. Medical device information

Intended use: The SenTec Digital Monitoring System (SDMS) is intended for the continuous and non-invasive monitoring of transcutaneous carbon dioxide partial pressure (tcPCO2), transcutaneous oxygen partial pressure (tcPO2), oxygen saturation (SpO2), and pulse rate (PR) in adult and pediatric patients as well as for tcPCO2 and tcPO2 monitoring in neonatal patients.

Commercial name: SDMS (SenTec Digital Monitoring System)

Classification:
EU: Class II b, according Rule 10, dash 3, annex IX, MDD 93/42/EEC

USA: Class II, DPZ (Oximeter, ear), DQA (Oximeter), LKD (Monitor, carbon dioxide, cutaneous), KLK (Monitor, oxygen, cutaneous, for infant not under gas anesthesia), LPP (Monitor, oxygen, cutaneous, for uses other than for infant not under gas anesthesia).
Device listing number: D257570, D113627, D066666, D066665.

6. Affected Material

The following SenTec products may potentially be affected:
SenTec Digital Monitor (SDM)

The following serial numbers may be affected:
SenTec Digital Monitor (SDM) with the sequential Serial Number (SN) 306497 to SN 306571, manufactured in May/June 2016.

Detailed list of distributors (including contact data) and countries the affected material was shipped to customers: see Annex I of this document.

SenTec AG
Phone +41 61 / 726 97 60
Fax +41 61 / 726 97 61
info@sentec.com
www.sentec.com

7. Description of FIELD SAFETY CORRECTIVE ACTION

7.1 Background information

When was the problem observed: SenTec AG received the information on 13th Sept 2016 by SenTec Inc. Additional tests on Sept. 14th at the distributor SenTec Inc. (US) showed that the incident should be treated as a systematic failure which justifies a field safety corrective action.

How the problem was observed: During the incoming goods inspection at the distributor.

Description of the problem:
The SenTec Digital Monitor (SDM), part of the SenTec Digital Monitoring System (SDMS), is equipped with an integrated calibration unit, the so called docking station module, allowing a fully automatic PCO2 sensor calibration. Among other components, this docking station module contains a pressure regulator fixed to a brass block.[1] The pressure regulator is fixed with two (2) screws to the brass block, tightened with a defined torque of 80 Ncm. In the SDM where the problem was observed, one (1) of the screws had fallen out so that a rattling noise was heard when moving the device.
SenTec AG observed during the production of this lot of docking station modules that in some cases the screw connection did not tolerate the applied nominal torque. This observation was addressed in a nonconformity report (internal number: NCR-070). The measure was taken to inspect all connections with a torque wrench up to nominal torque and, if a device failed the test, to replace its screws by longer ones (Engineering Change Notice: AA-007965). For the further manufacturing of docking station modules, the length specification of the screws was changed accordingly (i.e., longer screws have been used since the problem occurred) as a preventive action as per Engineering Change Notice AA-007965. To our knowledge, this is the first instance in which an attachment problem has been identified in the ~13 years of the SDM production and service history. The company is being preemptive in managing this and for the reasons stated we believe the problem exposure is limited to the specific identified serial numbers.

Root cause of the problem: According to the findings in NCR-070, minor changes of components (chamfer) have led to the problem (for this production series, a new package of screws was used). Potential mechanical and/or temperature stress or vibration during the transport may have led to the eventual separation of the screw although the connection had passed the torque test (see above).

Potential scenarios: A detached screw can lead to partial separation of the pressure regulator from the brass block. Consequently, a leakage of the pneumatic system (docking station module) may arise, detected and indicated as error message (“docking station fault”) by the device (built in diagnostics).
A completely separated screw, being no longer in its place and loose inside the monitor, can potentially create uncontrolled electrical connections, including short circuits, with the risk of smoldering or fire and electrical shock (patient and/or operator).

Hazard for the user: In the worst case, the hazard is considered high because the user (patient and clinical staff) can be exposed to smoldering or fire and electrical shock.

Risk for the user: The risk is considered medium, since the probability of the worst case is low and the detectability for the user is high (rattling noise). In most cases the monitor will not be able to measure, and the lacking measurement functionality will be detected by the user and the monitor will be decommissioned for service. In these cases, there is neither risk for the patient nor for the operator (user).

7.2 Description of the FIELD SAFETY CORRECTIVE ACTION

SenTec AG advised its distributors as well as all end-customers (via their distributors) to take the following IMMEDIATE actions:

[1] The pressure regulator operates at a very low pressure. So the identified leak, where it may occur, is a very low pressure leak which is detected by the system.

SenTec AG
Phone +41 61 / 726 97 60
Fax +41 61 / 726 97 61
info@sentec.com
www.sentec.com

On distributor level:
- Stop distribution of affected products with the specified serial numbers
- Follow detailed instructions according to notice RF-008154 (applicable to distributors outside the USA/Canada) or, respectively, RF-008156 (applicable to distributors in the USA/Canada) provided by SenTec (see attachments).

On end-customer level:
- Localize/identify within the institution the affected products
- Immediately remove the devices from use
- Contact the local distributor for replacement

End customers received from their distributors the notice RF-008153 (applicable to customers outside the USA/Canada) or, respectively, RF-008155 (applicable to customers in the USA/Canada) (see attachments).

List of actions initiated by SenTec AG:

What	When
SenTec Inc. (US) performed tests (rattling test of devices and torque test at nominal torque + 10%) to find out if whether it could be a systematic failure.	Sept. 14th 2016
First information by email to the distributors who received potentially affected devices to stop distribution	Sept. 15th 2016
Providing notice to relevant distributors with instructions how to proceed (see attachments): - Notice RF-008154 (applicable to distributors outside the USA/Canada) - Notice RF-008156 (applicable to distributors in the USA/Canada)	Sept. 16th 2016
Providing notice to relevant end-users with instructions how to proceed (see attachments): - Notice RF-008153 (applicable to customers outside the USA/Canada) - RF-008155 (applicable to customers in the USA/Canada)	All end users informed on Sept. 16th 2016 by SenTec distributor (remark: outside of the USA, no potentially affected devices have been shipped to end customers, see Annex I).
Organization of the return of the devices	Since Sept. 16th 2016, ongoing

Countries affected by this Field Safety Corrective Action: USA.
Except for the USA, no potentially affected devices have been shipped to end customers, see Annex I.

8. List of relevant distributor contacts

DISTRIBUTOR	COUNTRY	CONTACT
SenTec Inc.	USA	Sina Kohlbrenner sina.kohlbrenner@sentec.com +1 636 343 0000 ext#1204
SLE Ltd.	UK	Mercidita Clark MClark@sle.co.uk +44 (0)208 681 1414 Ext. 682
ResMed European Operations B.V.	The Netherlands	Vanessa Dussour-Gely vanessa.dussour-gely@resmed.fr +33 (0)1 60 183 571
Temple Healthcare	Australia	Tim Gresham timg@templehealthcare.com.au +61 2 4858 0690

SenTec AG
Phone +41 61 / 726 97 60
Fax +41 61 / 726 97 61
info@sentec.com
www.sentec.com

9. Annexes

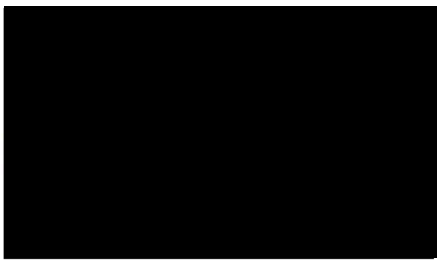
Annex I: Detailed distribution list of the affected material

10. Attachments

- SenTec AG End-Customer information "Mandatory initiated field corrective action associated with SenTec Monitors" (RF-008153)
- SenTec AG Distributor information "Mandatory initiated field corrective action associated with SenTec Monitors" (RF-008154)
- SenTec Inc. End-Customer information "Mandatory initiated field corrective action associated with SenTec Monitors" (RF-008155)
- SenTec Inc. Distributor information "Mandatory initiated field corrective action associated with SenTec Monitors" (RF-008156)

I affirm that the information given above is correct to the best of my knowledge.

Place and Date: Therwil, Sept. 22st 2016



Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

SenTec AG
Phone +41 61 / 726 97 60
Fax +41 61 / 726 97 61
info@sentec.com
www.sentec.com

Annex I: Detailed distribution list of the affected material

Serial No.	Distributor	Delivery date (DD.MM.YYYY)	Shipped to end customer / country
306497	SenTec, Inc., US	02.08.2016	No
306498	SenTec, Inc., US	02.08.2016	Yes / US
306499	SenTec, Inc., US	02.08.2016	Yes / US
306500	SenTec, Inc., US	02.08.2016	Yes / US
306501	SLE, UK	29.07.2016	No
306502	SLE, UK	29.07.2016	No
306503	SenTec, Inc., US	02.08.2016	No
306504	SenTec, Inc., US	02.08.2016	No
306505	SenTec, Inc., US	02.08.2016	No
306506	SenTec, Inc., US	02.08.2016	No
306507	SenTec, Inc., US	02.08.2016	No
306508	SenTec, Inc., US	02.08.2016	No
306509	SenTec, Inc., US	02.08.2016	No
306510	SenTec, Inc., US	02.08.2016	No
306511	SenTec, Inc., US	02.08.2016	Yes / US
306512	SenTec, Inc., US	02.08.2016	No
306513	SenTec, Inc., US	02.08.2016	No
306514	SenTec, Inc., US	02.08.2016	Yes / US
306515	SenTec, Inc., US	02.08.2016	No
306516	SenTec, Inc., US	02.08.2016	No
306517	SenTec, Inc., US	02.08.2016	No
306518	SenTec, Inc., US	02.08.2016	No
306519	SenTec, Inc., US	02.08.2016	No
306520	SenTec, Inc., US	02.08.2016	No
306521	SenTec, Inc., US	02.08.2016	Yes / US
306522	SenTec, Inc., US	02.08.2016	No
306523	SenTec, Inc., US	02.08.2016	No
306524	SenTec, Inc., US	02.08.2016	Yes / US
306525	SenTec, Inc., US	02.08.2016	No
306526	SenTec, Inc., US	02.08.2016	No
306527	SenTec, Inc., US	02.08.2016	No
306528	SenTec, Inc., US	02.08.2016	No
306529	SenTec, Inc., US	02.08.2016	No
306530	SenTec, Inc., US	02.08.2016	Yes / US
306531	SenTec, Inc., US	02.08.2016	No
306532	SenTec, Inc., US	02.08.2016	No
306533	SenTec, Inc., US	02.08.2016	No
306534	SenTec, Inc., US	02.08.2016	No
306535	SenTec, Inc., US	02.08.2016	No
306536	SenTec, Inc., US	02.08.2016	No
306537	SenTec, Inc., US	02.08.2016	No

SenTec AG
Phone +41 61 / 726 97 60
Fax +41 61 / 726 97 61
info@sentec.com
www.sentec.com

Serial No.	Distributor	Delivery date (DD.MM.YYYY)	Shipped to end customer / country
306538	SenTec, Inc., US	02.08.2016	No
306539	SenTec, Inc., US	02.08.2016	No
306540	SenTec, Inc., US	02.08.2016	No
306541	SenTec, Inc., US	02.08.2016	No
306542	SenTec, Inc., US	02.08.2016	No
306543	SenTec, Inc., US	02.08.2016	No
306544	SenTec, Inc., US	02.08.2016	No
306545	SenTec, Inc., US	02.08.2016	No
306546	SenTec, Inc., US	02.08.2016	No
306547	SenTec, Inc., US	02.08.2016	No
306548	SenTec, Inc., US	02.08.2016	No
306549	SenTec, Inc., US	02.08.2016	No
306550	SenTec, Inc., US	02.08.2016	No
306551	SenTec, Inc., US	02.08.2016	No
306552	SenTec, Inc., US	02.08.2016	No
306553	ResMed EU, NL	09.08.2016	No
306554	ResMed EU, NL	09.08.2016	No
306555	ResMed EU, NL	09.08.2016	No
306556	ResMed EU, NL	09.08.2016	No
306557	ResMed EU, NL	09.08.2016	No
306558	ResMed EU, NL	09.08.2016	No
306559	ResMed EU, NL	09.08.2016	No
306560	ResMed EU, NL	09.08.2016	No
306561	ResMed EU, NL	09.08.2016	No
306562	ResMed EU, NL	09.08.2016	No
306563	ResMed EU, NL	09.08.2016	No
306564	ResMed EU, NL	09.08.2016	No
306565	ResMed EU, NL	09.08.2016	No
306566	ResMed EU, NL	09.08.2016	No
306567	ResMed EU, NL	09.08.2016	No
306568	Temple, Australia	07.09.2016	No
306569	Temple, Australia	07.09.2016	No
306570	Temple, Australia	07.09.2016	No
306571	Temple, Australia	07.09.2016	No