
Voluntarily initiated field corrective action associated with Membrane Changers and their Inserts

Date: May 2, 2019
Distribution: SenTec end-customers
Implementation: Immediate

Dear SenTec customers,

SenTec has become aware of an issue associated with Membrane Changers and their Inserts and, therefore, has voluntarily initiated a corrective action. We herewith request your assistance in conducting this corrective action.

Description of the issue

The Membrane Changer (in the following referred to as “MC”) allows changing the membrane and electrolyte of V-Sign™ and OxiVenT™ Sensors (refer to the SDMS Instruction Manual, HB-005771-m; and the Directions for Use, HB-005147-k and HB-007415-c). The MC offers the option of reuse by replacing its Insert after use (refer to the Directions for Use, HB-006147-b).

Due to a manufacturing issue of the electrolyte cartridge of certain Membrane Changer Inserts, there is an increased chance (approx. 5%) of **no electrolyte or a reduced amount of electrolyte being applied to the sensor during the membrane change procedure** if a MC with such an Insert is used.

In case of *no electrolyte*, the membrane appears with whitish areas/spots upon completion of the membrane change procedure. In such a case, another membrane change procedure shall be performed. The PCO₂ performance of a sensor without electrolyte will be deteriorated.

Please note that during subsequent use, built-in sensor diagnostics in most cases will trigger appropriate alarms/messages and replace PCO₂ readings by “---” or mark them to be unstable or questionable.

A *reduced amount of electrolyte* may result in trapped air under the membrane upon completion of the membrane change procedure. This is an indication for a membrane change, according to the Directions for Use (HB-005147-k and HB-007415-c), and another membrane change procedure shall be performed.

However, a membrane change procedure with a reduced amount of electrolyte may also result in a normal appearing sensor. The reduced amount of applied electrolyte can result in a reduced lifetime of the membrane due to dried out electrolyte or the occurrence of trapped air under the membrane.

Please note that during subsequent use, the sensor may function correctly, or show an increased drift in the PCO₂ readings.

Note: The SenTec Digital Monitoring System (SDMS) is indicated for continuous, non-invasive monitoring in adult, paediatric and neonatal patients. *No decisions on therapy or treatment of a patient shall be based on this monitoring alone.*

Note: Drift compensation is available V-STATS™, enabling the elimination of PCO2 drift from the dataset.

Check your Sensors

Please check the membrane of all your V-Sign™ and OxiVent™ sensors before and after each use and after changing the membrane, according to the SDMS instruction manual (HB-005771-m). Change the membrane of sensors that show whitish membrane areas/spots or any other irregularities as described in the Directions for Use (HB-005147-k and HB-007415-c) and SDMS Instruction Manual (HB-005771-m).

In case of doubt, a membrane change procedure should be performed.

Affected products/lots

Table 1 and Table 2 (next page) list all affected products/lots. These products/lots were shipped by SenTec to its distributors between mid-September 2018 and end of April 2019. Please note that indicated lots contain affected Inserts to a varying degree.

Note: Products/lots that are not listed are not affected by this corrective action.

Table 1 Affected Starter Set Products/Lots.

Product Name	Standard Starter Set	Standard Starter Set w/o Gas	Neonatal Starter Set	Neonatal Starter Set w/o Gas
Product Code	SSET	SSET_nG	SSET-N	SSET-N_nG
# affected products	2 Changers each	2 Changers each	2 Changers each	2 Changers each
Affected Lot Numbers	180932	180972	181089	181068
	180959	190078		
	181019			
	181082			
	190005			
	190041			

From the starter sets, only the unused MC's shall be returned. As a replacement, you will receive one MC-SET for every returned starter set MC.

Table 2 Affected MC and Insert Products/Lots.

Product Name	Membrane Changer (reloadable)	Membrane Changer Insert	Membrane Changer Set
Product Code	MC-R	MC-I	MC-SET
# affected products	9 Changers each	5 Inserts each	1 Changer plus 1 Insert each
Affected Lot Numbers	180763	180759	180961
	180834	180766	181097
	180872	180788	190053
	180874	180814	
	180876	180830	
	180970	180831	
	180993	180837	
	181011	180839	
	181016	180868	
	181031	180869	
	181034	180870	
	181045	180918	
	181072	180933	
	181087	180938	
	181103	180941	
	181141	180984	
	190080	180994	
	190141	180996	
	190203	181014	
		181027	
		181035	
		181059	
		181070	
		181083	
		181092	
		181100	
		181142	
		190003	
		190016	
		190028	
	190032		
	190073		
	190088		
	190100		
	190125		

Replacement of affected products

For all affected products/lots (listed in Table 1 and Table 2) you currently have in stock, SenTec will – in collaboration with its distributors – provide replacement as soon as possible, free of charge. We therefore kindly request you to localize/identify any affected product within your institution. Should you have any affected products/lots on stock, contact your local SenTec distributor to

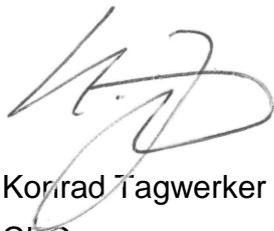
- a) coordinate the return of the affected products/lots and
- b) coordinate replacement of those products/lots as well as
- c) obtain instructions how you can continue to use the SenTec Digital Monitoring System (SDMS) while waiting for replacement.

Contact information

Please contact your local SenTec representative (<https://www.sentec.com/about-us/distributors/>) if you have any questions regarding this voluntary field corrective action and/or the related product replacement.

We apologize for any inconvenience this may cause and appreciate your cooperation. Please be assured that maintaining a high level of product quality and customer satisfaction is our highest priority. We are therefore initiating the replacement of your affected stock with new products, which meet the high quality standards that you are familiar with when using SenTec Products.

Yours sincerely,



Konrad Tagwerker
CEO



Caroline Möller, PhD
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