

Xenios AG . Im Zukunftspark 1 . 74076 Heilbronn . Germany

Rainbow Care Pte. Ltd.
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Heilbronn, 26.06.2019

Field Safety Notice - Important additional control measures for DP3 pump heads

Dear valued customer,

Hereby we issue a Field Safety Notice for:

Products concerned

Product name	Article no.	Batch no.
deltastream DP3 3/8" pump head	MEDP030001	190131M968

Problem description

The pump head gluing procedure is not fulfilling our standards. In worst case this could lead to leakage of the system.

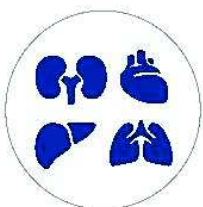
We have developed a test procedure to make sure that all products are functional. Provided this test procedure is carried out and functionality is ensured, the products may be used.

A proper and safe use of the products listed above can only be guaranteed if the following required actions are performed and show that the respective product is functional.

Action required to test if a product is affected

We advise you to proceed as follows:

- Please forward the appropriate version of the "Important additional control measures" to your customers.
- If you did not receive this information via email please contact vigilance@xenios-ag.com.



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CMO/COO Jürgen O. Böhm, MD

Supervisory Board
Dr. Olaf Schermeier,
(Chairman)
Christof Köster
Stefan Trappe

Registered Office
Heilbronn
County Court Stuttgart
HRB 743620

UST.Id.-Nr. DE286481056
St.-Nr. 65200/97008

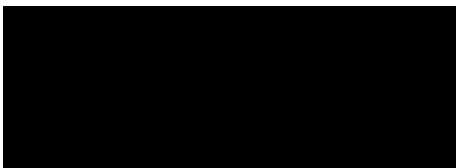
Kreissparkasse Heilbronn
Konto 304 232
BLZ 620 500 00
IBAN
DE48 6205 0000 0000 3042 32
SWIFT
HEISDE66

Please note:

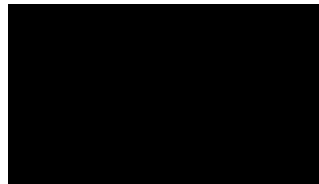
Please provide this Field Safety Notice to all who need to be aware of it, including all parties concerned within your organization.

Please confirm that you received this Field Safety Notice by completing and returning the enclosed reply form via mail or email within 7 days. Please contact us also if you have further questions about this Field Safety Notice and/or the specified measure.

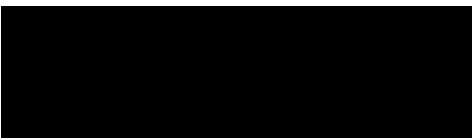
We apologise for any inconvenience caused and thank you for your cooperation!



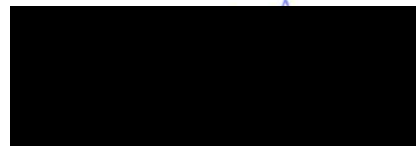
Name Dr. Andreas Terpin
Position CEO



Dr. Jürgen Böhm
CMO/COO



Name Thomas Junesch
Position Safety Officer



Alexander Becker
Head of Product and Therapy Management



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Feedback form for Field Safety Notice important additional control measures for DP3 pump heads

We do hereby confirm that the safety and corrective actions have been passed on to all relevant departments and that the Field Safety Notice and the test procedure provided has been read, understood and implemented.

Company name: _____Rainbow Care Pte. Ltd.

Department: _____

Responsible person: _____

_____/_____
City Date Signature



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Important additional control measures!

iLA active kits / iLA active iLA kit



 WARNING	The following procedure for visual AND leak testing of the DP3 pump head MUST be performed prior to each use of the patient kit. <i>Non-observance of this procedure can lead to serious injury or even death of the patient!</i>
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Please note:

1. Visual inspection of DP3 Pump Head:

Please check the bonding of the DP3 pump head before using the patient kit.



 ***If the adhesive area of the housing connection is milky-cloudy, do NOT use the patient kit!***

Milky-cloudy discoloration of the adhesive area:	Proper bonding:
	

2. Leak test DP3 Pump Head:

Supplement to the Instructions for Use, section Preparation/Priming/De-airing:


Proceed to the last step in the section Preparing/Priming/De-airing, then proceed as follows:

1.	Check that the patient kit is free of air. If necessary remove residual air from the system by tapping and performing additional priming.	
2.	Crosswise clamp the tubing segment between the DP3 pump head and the oxygenator using two clamps (Cross Clamping).	
3.	Increase the speed up to 9000 rpm. Note: Due to the pressure build-up, relatively strong vibrations can occur.	
4.	Check the pump head for leaks for approx. 60 seconds.  <i>If a leak is identified on the DP3 pump head, do NOT use the patient kit!</i>	
5.	If no leak is identified, decrease the speed to 0 rpm or 2000 rpm (depending on the information in the Instructions for Use) and open the clamps. The patient kit can be used.	

You can now proceed with the preparation process as described in the Instructions for Use of the respective patient kit.

Important additional control measures!

Medos Support Sets / Customized Tubing Sets



 WARNING	The following procedure for visual AND leak testing of the DP3 pump head MUST be performed prior to each use of the patient kit. Non-observance of this procedure can lead to serious injury or even death of the patient!
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Please note:

1. Visual inspection of DP3 Pump Head:

Please check the bonding of the DP3 pump head before using the patient kit.



 **If the adhesive area of the housing connection is milky-cloudy, do NOT use the patient kit!**

Milky-cloudy discoloration of the adhesive area:	Proper bonding:
	

2. Leak test DP3 Pump Head:

Supplement to the Instructions for Use, section Preparation/Priming/De-airing:


Prime and de-air the patient kit according to the Instructions for Use, then proceed as follows:

1.	Check that the patient kit is free of air. If necessary remove residual air from the system by tapping and performing additional priming.	
2.	Crosswise clamp the tubing segment between the DP3 pump head and the oxygenator using two clamps (Cross Clamping).	
3.	Increase the speed up to 9000 rpm. Note: Due to the pressure build-up, relatively strong vibrations can occur.	
4.	Check pump head for leaks for approx. 60 sec.  If a leak is identified on the DP3 pump head, do NOT use the patient kit!	
5.	If no leak is identified, decrease the speed according to the information in the Instructions for Use and open the clamps. The patient kit can be used.	

You can now proceed with the preparation process as described in the Instructions for Use of the respective patient kit.

Important additional control measures!

Novalung kits / iLA active iLA kit IPS / i-cor puls kit



 WARNING	The following procedure for visual AND leak testing of the DP3 pump head MUST be performed prior to each use of the patient kit. <i>Non-observance of this procedure can lead to serious injury or even death of the patient!</i>
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Please note:

1. Visual inspection of DP3 Pump Head:

Please check the bonding of the DP3 pump head before using the patient kit.



 ***If the adhesive area of the housing connection is milky-cloudy, do NOT use the patient kit!***

Milky-cloudy discoloration of the adhesive area:	Proper bonding:
	

2. Leak test DP3 Pump Head:

Supplement to the Instructions for Use, section Preparation/Priming/De-airing:

Proceed to the last step in the section Preparing/Priming/De-airing, then proceed as follows:

1.	Check that the patient kit is free of air. If necessary remove residual air from the system by tapping and performing additional priming.	
2.	Crosswise clamp the tubing segment between the DP3 pump head and the oxygenator using two clamps (Cross Clamping).	
3.	Increase the speed up to 9000 rpm. Note: Due to the pressure build-up, relatively strong vibrations can occur.	
4.	Check the pump head for leaks for approx. 60 seconds.  <i>If a leak is identified on the DP3 pump head, do NOT use the patient kit!</i>	
5.	If no leak is identified, decrease the speed to 2000 rpm and open the clamps. The patient kit can be used.	

You can now proceed with the preparation process as described in the Instructions for Use of the respective patient kit.