

May 2012

Target audience: Medical Engineers / Biomedical Engineers

Affected device	<p>Volumed μVP7000 Premium, Volumed μVP7000 Classic Plus Volumed μVP7000 Lite</p> <p>Syramed μSP6000 Premium Syramed μSP6000 Classic Plus</p>
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Description of the problem:

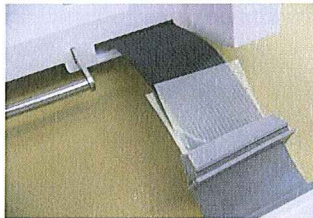
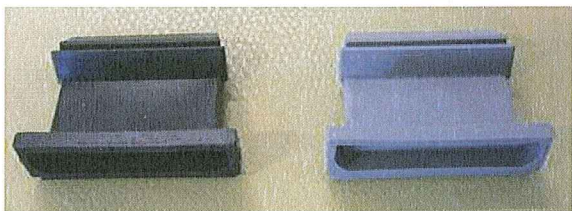
The ribbon cable, which connects the display PCB with the main PCB of the above mentioned pumps, may show aging effects after a certain time. This aging effect reveals mainly in stiffening of the isolation of the ribbon cable where the ribbon cable is in contact with the hinge.

Detailed tests at *arcomed ag* have shown the following things:

- **Intensive used pumps:** opening and closing the door more than 10'000^d times may lead to small cracks of the isolation to the stiffened parts of the ribbon cable. These cracks can lead to fluctuation of the contrast of the LCD and later failure of control elements.
- **Normal used pumps** (100 – 200 infusion sets per year) the above mentioned stiffening has no impact on the functioning of the pump. No cracks could be found at the stiffened parts of the isolation of the ribbon cable.

The stiffening of the isolation of the ribbon cable can be prevented by insertion of two special plastic foils between the hinge and the ribbon cable as shown in picture 1.

In the case of Volumed® μ VP7000 it was also necessary to optimize the hinge. Therefore *arcomed ag* has developed a new hinge for the special plastic foil (picture 2) and it is recommended to use this new optimized hinge together with special plastic foils.

	
<p>Picture 1: Special plastic foils to prevent the stiffening of the insulation of the ribbon cable.</p>	<p>Picture 2: <u>left</u> (black, old hinge) <u>right</u> (grey, new hinge, optimized for the special plastic foils)</p>

Flat ribbon cable complete (with hinge and plastic foil) can be ordered at *arcomed ag* (item number 70242 for Syramed μ SP6000 and item number 76269 for Volumed μ VP7000).

Please send us the serial numbers of the pumps repaired.

^d corresponds to 13 times opening and closing of the door per day

Advise on action to be taken by the Medical Engineers / Bio Engineers

arcomed ag recommends during the periodical maintenance of the pump to check the ribbon cable according to list below and if necessary to change the ribbon cable:

Note:

Between Volumed μ VP7000 infusion pump and Syramed μ SP6000 syringe pump two approach were applied due to different High Flex ribbon cables and fixing situations:

1.) Volumed μ VP7000 Premium / Classic Plus:

The following situations must be distinguished:

Serial Number	Frequency of pump use / Status of ribbon cable	Action
all Serial Numbers after 76521106	Ribbon cable between two special plastic foils and grey hinge was used	No action taken
all Serial Numbers before 76521106	Normal used pump with a use of up to 200 set per year and less than 4 years old.	No action taken
	Intensive used pump or more than 4 years old.	Controll of the ribbon cable: a) no visible damage of the isolation; Action according to <u>annex A</u> b) Cracks in the isolation of the ribbon cable and strong stiffened part of the cable Action according to <u>annex B</u>

2. Volumed μ VP7000 LITE:

The following situations must be distinguished:

Serial Number	Frequency of pump use / Status of ribbon cable	Action
all Serial Numbers after 38751104	Ribbon cable between two special plastic foils and grey hinge was used	No action taken
all Serial Numbers before 38751104	Normal used pump with a use of up to 200 set per year and less than 4 years old.	No action taken
	Intensive used pump or more than 4 years old.	Controll of the ribbon cable: a) no visible damage of the isolation; Action according to <u>annex A</u> b) Cracks in the isolation of the ribbon cable and strong stiffened part of the cable Action according to <u>annex B</u>

3. Syramed μ SP6000 Premium / Classic Plus:

Serial number	Frequency of pump use / Status of ribbon cable	Action
all Serial Numbers after 61031104	Ribbon cable is between two special plastic foils	No action taken
all Serial Numbers before 61031104	Normal used pump with a use of up to 200 set per year and less than 4 years old.	No action taken
	Intensive used pump or more than 4 years old.	<i>arcomed ag</i> recommend to change the ribbon cable on the occasion of the safety check and where appropriate to change the ribbon cable according to <u>Annex C</u> .

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Dr. Richard Meier
Head Quality Management
Arcomed AG,
Althardstrasse 150
CH-8105 Regensdorf
e-mail:richard.meier@arcomed.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Dr. Richard Meier
Head Quality Management

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Important Information

Concern: Flat ribbon cable check 04/2012

Company: _____ Address: _____

Name: _____ PC/City: _____

Country: _____

Herewith I confirm that I have received, read and understood this field safety notice and that I will follow the recommendation of Arcomed AG as soon as possible.

Place: _____ Date: _____

Company stamp
and
Signature: _____

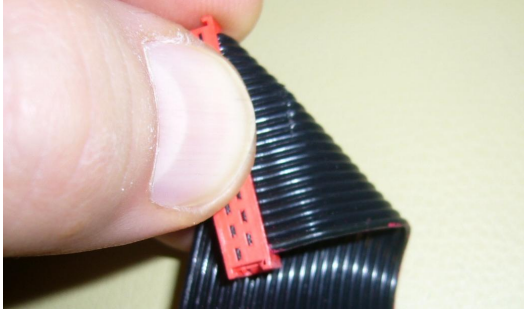


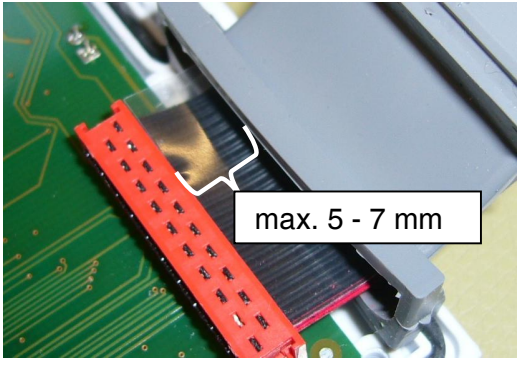
This instruction refers to the document „Field Safety Notice, FSCA identifier: Flat ribbon cable check 04/2012” and must be applied to Volumed μ VP7000 infusion pumps (Intensive used devices and devices more than 4 years old) with the following characteristics:

Safety check reveals:

- No visible damage of ribbon cable could be found;**
- No cracks in the stiffened parts of the ribbon cable;**

arcomed ag recommends to change the hinge and to add two special plastic foils above and under the ribbon cable.

The following steps should be carried out:

1.	Dismantle the door as described in the service manual, chapter 6.2.2.
2.	Slit the black hinge and remove it from the ribbon cable.
3.	<p>Turn down the ribbon cable slightly as shown in picture 1 and put over the grey hint as shown in picture 2.</p> <div style="display: flex; justify-content: space-around;"> <div data-bbox="316 965 842 1272">  <p>Picture 1: Preparing of ribbon cable for insertion of hinge.</p> </div> <div data-bbox="1002 965 1337 1249">  <p>Picture 2: Pulling the hinge over the ribbon cable</p> </div> </div>
4.	<p>Insert plastic foil between hinge and ribbon cable (picture 3):</p> <div style="display: flex; justify-content: space-around;"> <div data-bbox="368 1442 788 1805">  <p>Picture 3: Insertion of plastic foil</p> </div> <div data-bbox="911 1442 1430 1805">  <p>Picture 4: ideal placing of the foil compare to the hinge.</p> </div> </div>
5.	Reassemble the door and pay attention to the seal of the door and its correct insertion in the channel.

END

This instruction refers to the document „Field Safety Notice, FSCA identifier: Flat ribbon cable check 04/2012” and must be applied to Volumed μ VP7000 infusion pumps (Intensive used devices and devices more than 4 years old) with the following characteristics:

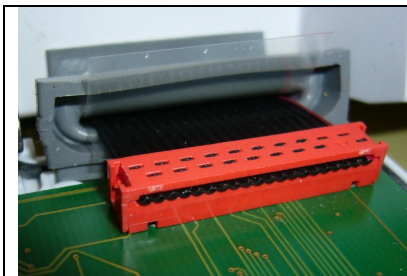
Safety check reveals:

Visible damage of ribbon cable could be found;

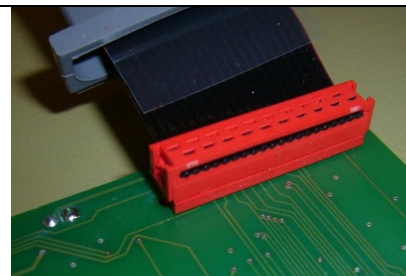
Cracks in the stiffened parts of the ribbon cable;

arcomed ag recommends to change the ribbon cable. Mount a new ribbon cable complete with plastic foil and new grey hinge.

Prior to start the change process, please check if the ribbon cable is connected to the display print with aid of a fix connector (picture 3) or via a separable connector (picture 4).



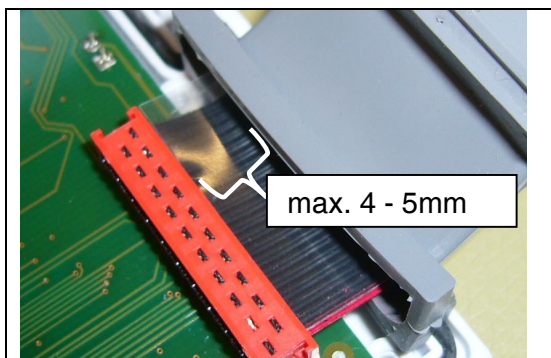
Picture 3: Fix connector



Picture 4: Separable connector

- A) If the ribbon cable has a connector as shown in picture 3, than please send the ribbon cable with the display print to the following address:

arcomed ag Tech. Support
 Althardstrasse 150
 CH-8105 Regensdorf
- B) If the ribbon cable has a connector as shown in picture 4, than please proceed as follows:
 - Dismantle the ribbon cable for the main PCB as well as from the display PCB. (See service manual 6.2.1 and 6.2.2).
 - Check the new ribbon cable if plastic foils are between the hinge and the ribbon cable.
 - Connect the new ribbon cable to the display PCB and be aware that the upper plastic foil sticks out of about 4 – 5mm from the hinge. (Picture 5).
 - Reassemble the door as described in the service manual chapter 6.2.2.



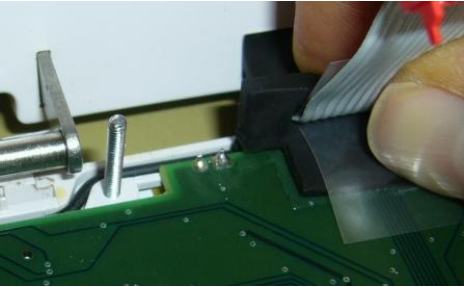
Picture 5: Ideal placing of plastic foil compare to hinge and connector

END

This instruction refers to the document „Field Safety Notice, FSCA identifier: Flat ribbon cable check 04/2012” and must be applied to Syramed µSP6000 infusion pumps with the following characteristics:

Intensive used device or device more than 4 years old.

arcomed ag recommends to change the ribbon cable. Mount a new ribbon cable complete with polyester foil and new grey hinge.

1.	Disconnect the ribbon cable form main PCB as well as from display PCB as described in service manual chapter 6.2.2.
2.	Control if the new ribbon cable is delivered with two polyester foil.
3.	Connect the ribbon cable to the display PCB and pay attention that the upper polyester foil sticks out of the hinge of about 5 – 7 mm.
4.	<p>Glue the new hinge to the display PCB (see photo below)</p>  <p>As glue <i>arcomed ag</i> recommends HENKEL: SICOMET ® 8400.</p>
5.	Reassemble the door and connect it to the pump

END