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URGENT-FIELD SAFETY NOTICE
2015-03-09

Please forward this information to all relevant users, biomedical staff in and risk management department concerned in your facility

Subject: Suction module (Auxiliary O_2 & Suction module) sometimes can't be activated

Products affected:

Product	S/N
Auxiliary O_2 and Suction module, 6679847	1-925

Dear Valued Customer,

The purpose of this letter is to inform about a potential problem caused by that the Auxiliary O_2 & Suction module sometimes can't be activated by the On/Off switch. The auxiliary O_2 part of the module is not affected. There are no reported injuries.

Our records indicate you have received one or more of these devices. Please inform us of the quantity of units you have and the disposition of units that you no longer have.

Description

MAQUET has discovered that the Auxiliary O_2 & Suction module sometimes can't be activated by the On/Off switch leading to a lack of suction function. The auxiliary O_2 part of the module is not affected.

Potential hazards

Lack of suctioning function when needed can lead to difficulties to keep the airways free by extracting body fluids from the stomach and airways.

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Precautions

After the suction module has been tested during the system check out keep the suction module turned on and regulate the suction with the far right knob, the vacuum setting.

Corrective action

A field action is initiated to implement an improved Auxiliary O_2 & Suction module on installed base. This Field Safety Notice is only applicable until the unit has been updated with the improved Auxiliary O_2 & Suction module.

We apologize for any inconvenience this may cause you and we will do our outmost to carry through this action as swiftly as possible.

Should you have questions or require additional information, please contact your local MAQUET representative.

Sincerely,

Peter Wedar
Global Product Manager Anesthesia

Lars Berken
Vice President Quality Management

MAQUET Critical Care AB
SE-171 54 Solna, Sweden
www.maquet.com

Document title	Doc-ID
Hardware Update Auxiliary O_2 and Suction Unit	MX-6195

UPDATE INSTRUCTIONS MCC/15/001/IU

PRODUCT: AUXILIARY O_2 AND SUCTION MODULE (FLOW-i)

TITLE: HARDWARE UPDATE AUXILIARY O_2 AND SUCTION MODULE

ISSUE DATE: 2015-03-09

UPDATE TYPE: IMMEDIATE

COMPLETION DATE: 2016-03-09

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1 RESPONSIBILITY OF SSU/SSP

1.1 PLANNING

This update is mandatory. The MAQUET Sales & Service Unit (SSU) and the Sales & Service Partner (SSP) are responsible for planning of performance of the update and ordering necessary material in order to fulfill the implementation according to:

- Immediate Update: Promptly, within the specified completion time frame.

1.2 IMPLEMENTATION

The SSU/SSP is responsible for coordinating the customer completion date and placing material orders in a timely manner. The SSU/SSP is responsible for regulating the issuance of update orders to Field Service Engineer (FSE) along with all necessary information.

If a system cannot be updated because:

- it is not affected
- it cannot be located
- the customer refuses the update

this information must be reported by authorized personnel from SSU/SSP to MAQUET Critical Care (MCC).

1.3 REPORTING AND MONITORING

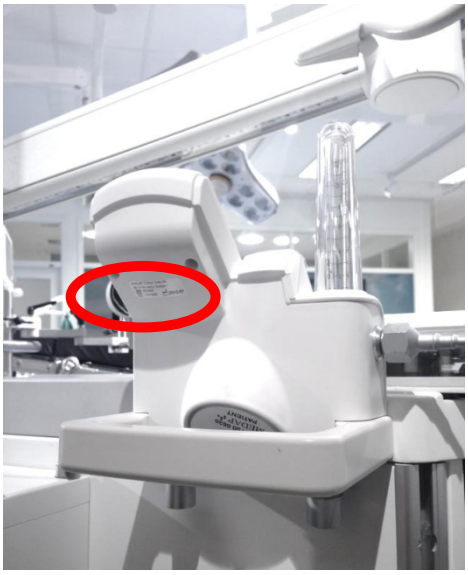
Reporting and monitoring of this update is required and it contains of two parts to be addressed by the SSU/SSP:

1. **Device correction letter** intended for the US market and **Field Safety Notice** intended for the rest of the world, which is an information letter to the customer. The distribution of the Device correction letter / Field Safety Notice to all concerned customers shall be confirmed to our Quality Department using the Confirmation of Distribution. Refer to the following documents:
   - EVU-149161 Device correction letter
   - EVU-149162 Field safety notice
2. **Update Action**, as described in this Update Instructions, is the actual update to be performed by the FSE/Biomed:
   - The SSU/SSP is responsible for monitoring the completion date and the number of updates completed.
   - The Auxiliary O2 and Suction Module – P/N 66 79 847, is traced in MBase and reporting must be performed in MBase. If the unit is not found in MBase the update must be reported via Update-Reporting.MCC@maquet.com.
   - There is no need to wait with the reporting until the very last unit has been updated, we appreciate a continuous reporting from you.

UPDATE INFORMATION

2.1 SYSTEMS/PRODUCTS AFFECTED

Affected product: Auxiliary O_2 and Suction Module – P/N 66 79 847
Affected units: S/N 00000001 - 00000925
A MAQUET serial number label is attached on the backside of the module.



2.2 REASON FOR THE UPDATE

In January 2013 a revised version of the suction module was released. One of the components that were changed was the On/Off function of the module. During 2014 complaints has been received with the symptom that the On/Off function not always was working. During investigation of some of the returned units it was detected that an internal O-ring could slip off the valve and by that cause an obstruction of the drive gas to the suction unit. This has been corrected by changing both the valve and the valve seat. A Device Correction letter / Field Safety Notice describing this issue, has been distributed to all concerned users.

2.3 PREREQUISITES

N/A

2.4 SPECIAL TOOLS / DOCUMENTS

- Standard service tools.
- Update Instruction, this document.
- Auxiliary O_2 and Suction Module Installation instruction.
- FLOW-i User's manual.
- FLOW-i Service manual.

2.5 ORDERING INFORMATION

Place an order as follows for each system to be updated:

P/N 68 83 730 Exchange Auxiliary O_2 and Suction module
List the system Serial Number on the order.

2.6 CONTENTS OF THE UPDATE KIT

P/N 68 83 730 Exchange Auxiliary O_2 and Suction module, includes one Auxiliary O_2 and Suction Module, one filter and two screws. No tubing or handle is included.

2.7 RETURNS

The replaced Auxiliary O_2 and Suction Module must be returned to MCC after completed update. Request for RMA according to the MSupport application:

SSU:

1. In MSupport system select “Create RMA” and “Other”.
   Link: https://msupport.maquet.com/RMA.aspx?RMAType=Other&Department=Service&RMAMode=New
2. Refer to ‘MCC/15/001/IU’ as Failure Description or Comment, follow the instructions given in the application.
3. Request for an RMA.
4. When the returned unit is received in Solna, evaluated and approved, a credit is issued referring to the replacement order references

SSP:
Please contact Maquet to receive an RMA number.

2.8 SPARE PARTS HANDLING

N/A

3 UPDATE IMPLEMENTATION

3.1 WORK & CHECK STEPS

1. Check if the system is affected by this update. Refer to '2.1 Systems/Products Affected'.
2. Ensure that the backup gas cylinders are closed, if present.
3. Disconnect the central gas supply hoses from FLOW-i.
4. Open the Auxiliary O_2 flowmeter regulatory valve. Start the suction with the On/Off switch and adjust the suction with the Suction unit regulatory valve, this action will decrease the pressure inside the system. Refer to FLOW-i User's manual, Chapter 7.12.
5. Remove the two gas hoses connected to the Auxiliary O_2 and Suction Module. Refer to Auxiliary O_2 and Suction Module Installation instruction.
6. Remove the two screws underneath the handle holding the Auxiliary O_2 and Suction Module.
7. Remove the Auxiliary O_2 and Suction Module - P/N 66 79 847.
8. Mount the Exchange Auxiliary O_2 and Suction Module - P/N 68 83 730 including the filter.
9. Tighten the two screws and connect the two gas hoses to the Auxiliary O_2 and Suction Module as described in the Installation instruction.
10. Connect the central gas supply to FLOW-i.
11. Perform a 'System checkout' and a 'Manual check of Emergency ventilation system' according to instructions in the User's Manual.
12. Document the update in the System Logbook, if applicable.
13. Report completion of the update. Refer to '1.3 Reporting and monitoring'. Note that serial number of the FLOW-i unit and serial number of the Exchange Auxiliary O_2 and Suction Module must be included in the report.

3.2 CUSTOMER INFORMATION

Inform the customer of the purpose of this Update; refer to '2.2 Reason for the Update'.
Also inform the customer that the issue described in the Device Correction letter / Field Safety Notice has now been remedied.