

MCC/23/002/IU: Open service ports for Flow Family Anesthesia systems

Products affected:

Product	Article number	Serial number
Flow-i	6677200, 6677300, 6677400, 6888520, 6888530, 6888540	See consignee list EVU-246963
Flow-c	6887700	See consignee list EVU-246963
Flow-e	6887900	See consignee list EVU-246963

Description of the issue

Internal tests at Getinge have revealed a cybersecurity related vulnerability which potentially could lead to Denial of Service (DoS) attack, tampering or remote code execution via remote login to the Flow Family Anesthesia systems which could lead to hazardous situations.

Connected/Remote Services is part of an offered service plan that Getinge has created for hospitals to get digital access to equipment data. Connected/Remote services also enables service teams to troubleshoot issues and schedule proactive maintenance.

For system version 4.7 and below the service is named Remote Services and only offers wired connection through the Ethernet port on Flow Family Anesthesia systems.

From system version 4.8 and above, the service is named Connected Services and is offered through both wired connection via the Ethernet port on Flow Family Anesthesia systems or connection via Getinge Connect module.

This cyber security vulnerability is only possible to exploit during a short period of time of start- up and file transfer (to connected services) when the device is connected to the hospital network directly via the Ethernet port on the Flow Family Anesthesia systems with an Ethernet cable. If a Getinge Connect module is used, the Flow Family Anesthesia systems is not affected by this vulnerability.

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As of today, Getinge has no indications of patient or operator events, nor data breaches related to this issue.

Potential hazards

Potential hazards include the possibility to tamper with language files and remote code execution into the anesthesia machines resulting in panel disruption during running and/or cause misleading information on the screen which may lead to inappropriate changes of settings or the need to change anesthesia machines during the case.

Precautions

As there are no alarms to detect these hazards, anesthesia personnel may not be able to recognize the problem and handle the situation accordingly.

If you suspect that your anesthesia system is tampered with or otherwise been exposed to potential hazards described in this letter, please contact your local Getinge representative for reinstallation of software

Corrective action

For users with system version 4.8 and above:

If you have a Getinge Connect module (X10/X20) connected to the Ethernet port on the Flow Family Anesthesia system, no action is required.



Getinge Connect module X10 / X20

If your Flow Family Anesthesia system is connected to Connected Services directly via the Ethernet port on the Flow Family Anesthesia system:

Please follow the steps described in Annex 1

Please contact your local Getinge representative if you wish to activate Connected Services with a Getinge Connect module.

For users with system version 4.7 and below:

If your Flow Family Anesthesia system is not connected to Remote Services, no action is required. Do not connect an Ethernet cable to use Remote Services.

If your Flow Family Anesthesia system is connected to Remote Services:

Please follow the steps described in Annex 1

A Getinge Connect module is not available for system version 4.7 and lower. Please contact your local Getinge representative if you wish to activate Connected Services in the future with a Getinge Connect module (requires system version 4.8 and above).

Please complete & return the attached acknowledgement form.

Distribution

The respective competent health authorities have been informed about this communication and issue.

This Getinge Field Safety Notice distribution must include those individuals that need notification within your organization - or any organization where the potentially affected devices have been transferred. Please keep notice of this and subsequent communications to ensure that the appropriate corrective actions are taken while using the device. It is understood that failure to respond to this Field Safety Notice or to proceed with the corrective action requests described above may dispense Getinge from any liability connected with or arising out of this Field Safety Notice. The submission of this notice shall not be construed as an admission of liability for the issue described herein and its consequences.

We apologize for any inconvenience that this may have caused and will do our best effort to provide a reasonable solution as swiftly as possible.

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

Sincerely,

Malin Graufelds
Director Product Mgmt. Anesthesia
Maquet Critical Care AB

Jerker Åberg
Director Regulatory Affairs & Product Compliance
Maquet Critical Care AB

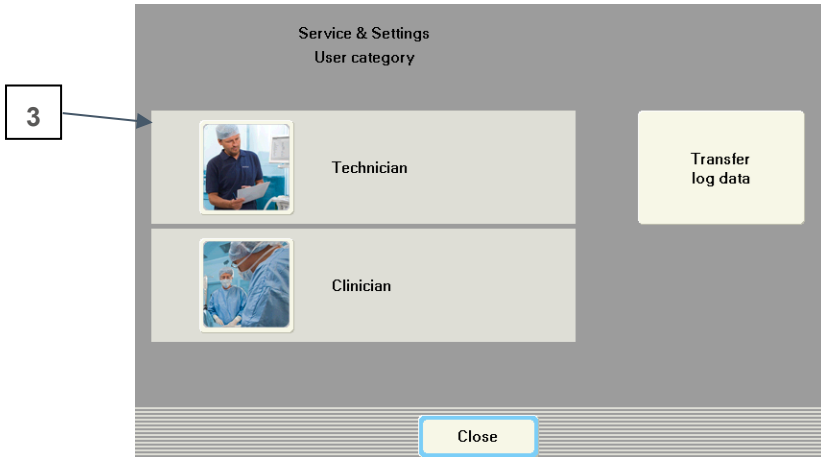
MX-9036 - MCC_23_002_IU FSN Open service ports Version: 01 Approved at 2023-11-30 by:
Jerker Åberg u2773956; Malin Graufelds u2823494,
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Annex 1

For users with system version 4.8 and above:

1. Select *Menu* on the screen
2. Select *Service & Settings*
3. Select *Technician* and enter the code 1973 for Biomed



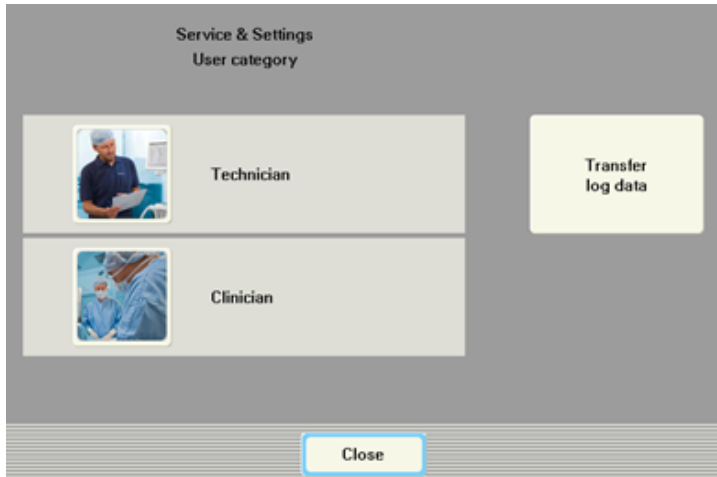
4. Select *Connected Services* on the menu to the right
5. Select *Data transfer*
6. Select *Manual*
7. Select *Close*
8. After finishing step 7: *Remove the Ethernet cable from the Ethernet port on the Flow anesthesia system and the wall socket.*



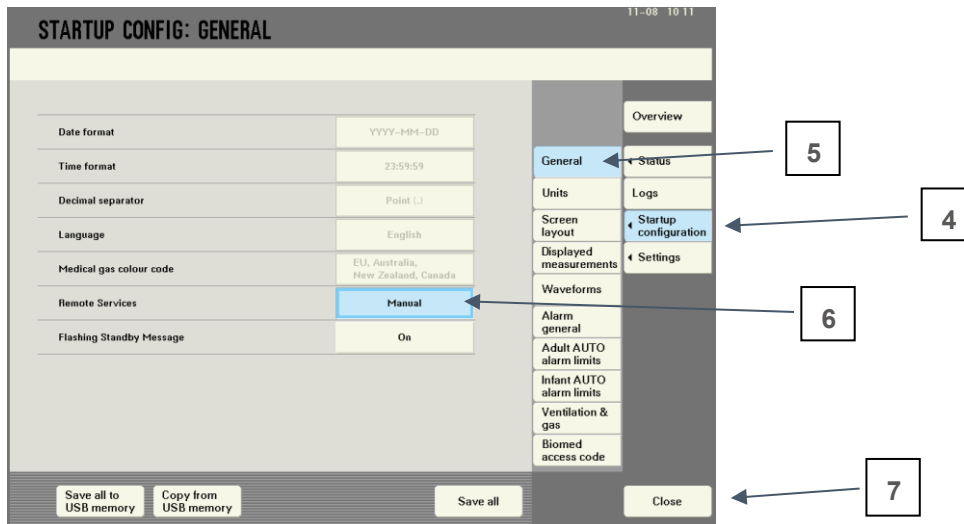
Please contact your local Getinge representative if you need assistance in performing operations above.

For users with system version 4.7 and below:

1. Select *Menu* on the screen
2. Select *Service & Settings*
3. Select *Technician* and enter the code 1973 for Biomed



4. Select *Startup Configuration* on the menu to the right
5. Select *General*
6. Under Remote Service select *Manual*
7. Select *Close*
8. After finishing step 7: *Remove the Ethernet cable from the Ethernet port on the Flow anesthesia system and the wall socket.*



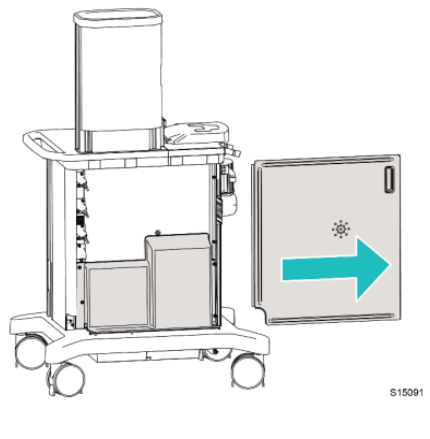
Please contact your local Getinge representative if you need assistance in performing operations above.

Flow-c/e cover removal:

To access the ethernet port at the back of the Flow -c & Flow-e unit, please follow the instruction below. Remember to close the cover after the operation is completed.

Follow this procedure:

1. Pull the sliding door all the way to the right.



Prerequisite tasks:

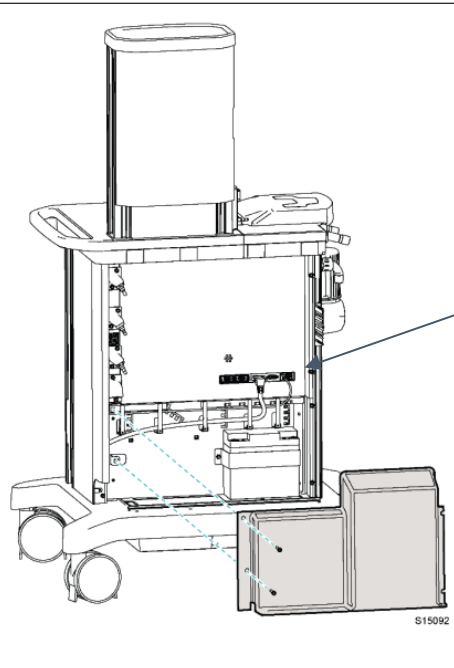
- Removal of any accessories that may hinder the removal of the sliding door

Necessary tools:

- 5 mm hex key

Follow this procedure:

1. Loosen the two screws on the right side of the cover.
2. Unscrew the two screws on the left side of the cover.
3. Carefully lift off the cover over the guide rail on the carrier.



Ethernet port