Fresenius Kabi
Else-Kröner-Str. 1
F-61352 Bad Homburg (Germany)
E-mail : medicaldevice-vigilance@fresenius-kabi.com

FIELD SAFETY NOTICE

Recommendation to implement Exelia software version 1.2.3

Date: January 30, 2025

Subject: Field Safety Notice regarding new Exelia software version 1.2.3

Affected Products: Exelia SP; Exelia VP; Exelia Combox; Exelia Therapy Manager

Dear Customer / Health Care Professional,

Fresenius Kabi recently released software version 1.2.3, which includes enhanced functionalities and corrections to issues identified in earlier software versions. These malfunctions include flickering screens and software errors 15.10.8 and 16.19.62. Despite these malfunctions, the system alarms have consistently operated correctly, ensuring the safety of the patients.

As part of our ongoing commitment to quality and reliability, we strongly recommend implementing software version 1.2.3 on your Exelia devices to prevent certain potential technical issues. During the update process, Fresenius Kabi staff will also inspect your hardware to ensure the continuation of safe operations.

Please contact your local Fresenius Kabi representative to schedule these updates.

Information regarding technical error alarms in Exelia can be found in accompanying documents (Information for Use and Technical Manuals). The attachment of this FSN (entitled "User - Information - Exelia Infusion Station – January [28], 2025) compiles important information regarding how to identify and address potential malfunctions in various Exelia versions. This attachment is an integral part of this FSN and should also be read and followed carefully.

Fresenius Kabi is committed to continuing to deliver the highest standards of service, product quality, and reliability. We sincerely thank you for your understanding and cooperation during this updating phase.

Kindly assure within your organization that all relevant persons are informed about this letter and the actions as described.

PLEASE COMPLETE THE ENCLOSED "URGENT FSN RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY.

Fresenius Kabi
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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

If you have any further questions concerning this FSN including its attachment, please contact your Sales representative or our Quality department.

Sincerely,

i.A. Stefan Schmidt
Senior Manager – Global MedTech Vigilance
Quality MedTech

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SECTION A: Hospital / Facility Details

Please fill out the information below and send the completed form to Fresenius Kabi.

Name of Hospital / Facility:		
Hospital / Facility Address:		
Telephone Number:		

SECTION b

☐ I have read and understand the information provided in the letter.

Signature:	
Date:	

USER INFORMATION

Exelia Infusion station

January 28, 2025

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Technical fixes thanks to Exelia 1.2.3

Exelia 1.2.3 corrects noteworthily the following issues:

Software failure: **The untimely display of 2 or 3 alternating screens** and/or **Altered display of texts and values** that could result in a technical error **16.18.39** that could stop the infusion in the worst case has been corrected in the Exelia 1.2.3 version.

Software failure: A cause of **technical error 15.10.8** has also been fixed. The scenario that led to this technical error is as follows: an occlusion is detected by the syringe pump. The syringe pump initiates a back-pumping sequence to reduce the pressure in the tubing and thus limit the risk of boluses when the occlusion is released. If the user removes the syringe during the backpump, applying light pressure to the syringe head, then reinstalls the syringe, confirms it and restarts the infusion, and then changes the infusion rate, then a technical error 15.10.8 occurs, stopping the infusion in progress.

In order to avoid this technical error in Exelia software versions 1.2.1 or lower, please always wait for the occlusion alarm to sound before handling the syringe. (The sound is triggered at the end of the backpump.)

Software failure: A cause **of technical error 16.19.62** has also been fixed: the module's APU board could be saturated with messages from the Exelia Combox and run out of memory space to store them.

Malfunctions concerning Exelia SP or Exelia VP

1. Untimely display of 2 or 3 alternating screens and/or Altered display of texts and values

*Information applicable **to Exelia 1.2.1 only.***
Patch Availability with Exelia Software Release 1.2.3

1. Description

The software may suddenly display two different screens alternately (e.g., syringe installation screen and home screen) or prevent a value from being set.
It could also happen that the values suddenly become unreadable, or appear frozen for several seconds or even minutes. The infusion continues normally.

2. Potential impact on infusion

Inability to program the infusion. If an infusion is in progress, it is necessary to transfer the infusion to another device and then turn off the device. In the worst-case scenario, a technical error 16.18.39 could occur with a potential infusion stop.

3. Means of detection

Display of 2 or 3 screens alternating unexpectedly and/or Altered display of texts and values and/or frozen screen.

4. Methods of deletion or management

If the event occurs, transfer the infusion to another device, then press the ON/OFF button until the module turns off, i.e. for 3 seconds or for 20 seconds if the switch-off is not effective in 3 seconds. Then turn the module back on and it can continue to be used if no fault is reported when it is re-ignited.

Upgrade all your Exelia devices to the latest software version “Exelia 1.2.3”.

2. Miscellaneous technical error codes (e.g. 16.18.39)

Information applicable to Exelia 1.2.1 and 1.2.3

1. Description
Technical errors are a safety measure when the device detects an electromechanical or software failure. They are identified by codes that allow a technician to help find the cause.

Refer to the list of main codes for technical errors on the next page.

It should be noted that if a module in the process of infusion associated with an infusion relay detects a technical failure (red screen with error code), the syringe pump waiting for a relay immediately takes over. A high-priority "broken relay" alarm goes off in parallel to warn the user, but the infusion continues well.

2. Potential impact on infusion
Inability to program the infusion or infusion stop in the worst case.

3. Means of detection
High priority alarm.

4. Methods of deletion or management
Write down the error code, then isolate the device and contact a biomedical technician.

Additional recommendation:
Please always wait for the occlusion alarm sound to trigger before handling the syringe.
Risk of technical error 15.10.8 during infusion with Exelia software versions 1.2.1 or lower.

Do not program at the same time (< 2 seconds) on the Therapy Manager and on the module
Ex: Prime on the module and press "End prog" on the Therapy Manager
Ex: Selecting a module at the Therapy Manager at the same time as turning on/off the module

List of main codes for technical errors on Exelia SP/ VP

If you have any questions about a code not listed below, please contact your Fresenius Kabi representative or check into the Technical Manuals of each device.
"Y" and "Z" replace numbers that provide clarification for investigations.

After isolating a device, a Fresenius Kabi representative will have to take the logs in order to investigate and confirm the actions to be taken.

Error code	Meaning	Expected action
2.1.3	Buzzer-related fault, detected during self-test	Write down the error code, then isolate the device and contact a biomedical technician.
2.1.4	Speaker-related fault, detected during self-test	Turn the unit off and on again, making sure it is not on a surface that could obstruct the speaker located under the module (example: a bed). If the device turns back on without error, you can use it. Otherwise, write down the error code and then isolate the device and contact a biomedical technician.
2.1.6	Battery failure; battery not charging properly, detected during self-test	Turn the device off, plug it into the mains and turn it back on. If the device turns back on without error, you can use it on battery or AC. If it is used on battery, check the remaining autonomy displayed on the dedicated pictogram and in the "Battery" menu. If not, write down the error code and then isolate the device and contact a biomedical technician to change the battery.
3.1.4	Battery-related failure that no longer communicates its status to the module	Write down the error code, then isolate the device and contact a biomedical technician to change the battery.
3.1.8	Electronic board failures	Write down the error code, then isolate the device and contact a biomedical technician.
2.1.12	Flex failures of the "HMI" board in the door	Write down the error code, then isolate the device and contact a biomedical technician.
6.1.1	Failure related to the rotary dial being detected as remaining pressed	Write down the error code, then isolate the device and contact a biomedical technician.
15.y.z 16.y.z	Software defect. Investigation necessary to determine the cause.	Write down the error code, then isolate the device and contact a biomedical technician.
30.3.0	The device's infusion status LEDs are likely broken.	Write down the error code, then isolate the device and contact a biomedical technician. The "DPU" electronic board will probably have to be changed.
30.7.0 30.7.1 30.7.2	Exelia SP: Force sensor failure	Write down the error code, then isolate the device and contact a biomedical technician. Maintenance operations are underway to change the pusher arms when necessary.
30.9.52 30.10.0	Linear sensor failure	Write down the error code, then isolate the device and contact a biomedical technician. The linear sensor and/or the "DPU" electronic board will probably have to be changed.
30.11.1	Backup battery failure	Write down the error code, then isolate the device and contact a biomedical technician. The backup battery will need to be replaced by a Fresenius Kabi technician.
Failsafe	*A failsafe is manifested by a black screen, a flashing red LED, and the sound of the buzzer.* Software or electronic failure	Isolate the device and contact a biomedical technician.

Malfunctions regarding use with the Exelia Therapy Manager

3. "Loss of communication with module X" and "Communication error. (Reinstall). / "OFF"

Information applicable to Exelia 1.2.1 and 1.2.3
Patch availability: software and electromechanical enhancements available

1. Description
A yellow alarm is displayed on the Exelia Therapy Manager

, with a message "Communication Error (Reinstall)" or "OFF" in place of the module, and a question mark appears on the module.

This can happen briefly when the module is connected: simply wait a few seconds for the synchronization to take place.
This can also happen if the syringe is removed while a delayed start is in progress.

2. Potential impact on infusion
None if the communication is reset; otherwise, it is impossible to program the module from the Exelia Therapy Manager.
For Exelia station users with activated relays: potential deprogramming of the infusion relay in the event that a relay was programmed.

3. Means of detection
Low-priority alarm and resolution indication ("Reinstall")

4. Methods of deletion or management
Disconnect the module from the station, wait about 4 seconds, reconnect the module, and then check that the module is displayed correctly on the Exelia Therapy Manager once the data synchronization is complete. In very rare cases, the infusion will have to be stopped by the user, then the module disconnected from the station, turned off and on again. Or the Combox will have to be restarted by pressing the reset button on the back of the Combox for 1 second.

If the communication error does not disappear, isolate the affected devices (affected Exelia SP or VP, Exelia Link, and Exelia Combox) and contact a biomedical technician. After analyzing the logs, Fresenius Kabi will tell you if maintenance is required on these devices.

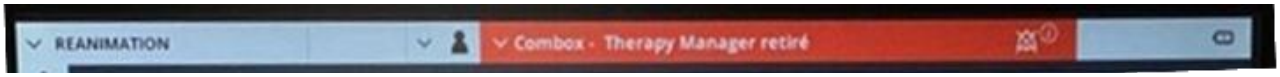
If a channel relay is unexpectedly deprogrammed, once the communication error has been resolved, the relay must be reprogrammed.

See also § "Damaged or even dismantled connection cable"

4. Damaged or even disassembled connection cable OR "Therapy Manager removed" / "Link removed" displayed on the Therapy Manager

Information applicable to Exelia 1.2.1 and 1.2.3
Patch availability: Yes, maintenance available.

1. Description
The connection cable between:
The Exelia Combox and the Exelia Therapy Manager
the Exelia Combox and the Exelia ComAdaptor (second column)
is damaged or even dismantled.
This can cause inconsistent messages on the Therapy Manager ("Therapy Manager removed" or "Link removed") and damage the devices' electronic boards.



2. Potential impact on infusion
Untimely loss of communication with potentially inability to reset it.
***For Exelia station users with relays activated**:* potential deprogramming of the infusion relay in the event that a relay was programmed.

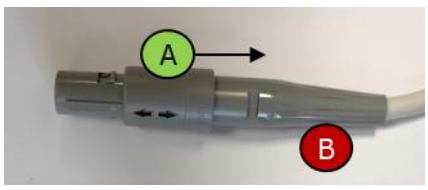
3. Means of detection
The cable is damaged, disassembled, or can be easily unscrewed and therefore disassembled.
Display of messages of loss of communication between Combox / Therapy Manager / Link and with impossibility to reset it.
Displaying a "Therapy Manager Removed" message while the Therapy Manager is connected.
Display of a "Link removed" message while the Link is connected.
Display of a message "Link 4 removed" when there is no second column.

4. Methods of deletion or management
Change the cable: new, more robust cables are available.

In the event of a persistent failure after changing the cable, contact a biomedical technician: electronic boards can be damaged by the connection of a damaged cable.

Never connect a damaged/disassembled cable, nor try to reassemble a disassembled cable: risk of deterioration of electronic components on the Exelia Combox and/or Exelia Link and/or Exelia ComAdaptor.

To avoid damaging the cable, do not force it to remove it but follow the following procedure, similar to that of a cuff for non-invasive pressure measurement:
- Enter Part A
- Gently pull it back
- Do not pull or turn part B: risk of cable disassembly which could lead to damage to the Exelia Combox or Exelia ComAdaptor



5. Technical error on the Therapy Manager

Information applicable to Exelia 1.2.1 and 1.2.3

1. Description
Technical errors report events related to a malfunction of the equipment (e.g. related to the battery, the brightness, the speaker). The device then generates a technical error. Some can only occur when the device is turned on (e.g. "Speaker failure"), others can occur as soon as the malfunction is detected.

2. Potential impact on infusion
For Exelia station users with relays activated: potential deprogramming of the infusion relay in the event that a relay was programmed.

3. Means of detection
When a technical error occurs, a high-priority alarm is triggered and a sound is played. A message is displayed on the Therapy Manager in full screen and red (e.g. "Buzzer failure", "Backlight failure", "Speaker failure", "Battery Health").
In the case of an infusion relay, a high-priority alarm is displayed on the relay module to notify the user that the relay has been deprogrammed.

4. Methods of deletion or management
In the event of a technical error:
1. Tap the Silence icon in the sidebar.
2. Restart the Exelia Therapy Manager.
On restart, if a relay was scheduled, a message is displayed on the Therapy Manager to prompt you to reprogram the relay.
3. If the self-test fails, note the error message and contact a qualified biomedical technician or Fresenius Kabi technical service.