AXIUM MTECH
MEDICAL DEVICE SOLUTIONS

Urgent:

Field Safety Notice with

Field Safety Corrective: Device Exchange

Product:	Compat Ella® Pump
Reference:	**SKU** 12272020 **EAN** 7613036471152
FSN Identifier:	**FSN-25001**
Date:	19th June 2025
Action Type:	Device Exchange / Reinforcement of Patient Monitoring Recommendations
SN impacted:	See Annex I
To the Attention of:	Distributors, Vigilance Officers, Medical Device Officers
Subject:	Non operative pump after full battery discharge

Device Description:

Compat Ella® Pump reference 12272020

The Compat Ella® enteral feeding pump is intended to be used for the delivery of enteral tube feed and hydration at controlled rates to the gastrointestinal system. It is intended for use with adult and pediatric patients requiring enteral feeding and hydration in home and professional healthcare environments.

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Reason for Preventive Product Recall

Axium MTech SA has identified a potential issue affecting certain pumps that may have been manufactured or serviced using a defective batch of batteries.

Preliminary investigations indicate that affected pumps may **fail to restart** after a **full battery discharge**, even when reconnected to a charger. As a result, the pump may become **non-operational**, interrupting therapy.

At the time of this communication, **no adverse patient incidents** have been reported in your country. However, based on our internal risk assessment, **a failure to restart the device** could lead to **delays in therapy**, which may pose a **serious risk to patient health**, particularly in cases where continuous enteral nutrition or hydration is critical.

Although no clinical harm has been reported, Axium MTech has decided, as a **precautionary measure**, to initiate this FSCA in line with our commitment to product safety and regulatory obligations.

Actions to be taken by the distributor

You, as distributors, are required to take the following actions:

1. **Inventory Check and Quarantine**
    - Identify and **quarantine** all affected units in your possession based on the serial numbers listed in **Annex I**.
2. **Customer Notification**
    - Inform all affected customers/end users **within 48 hours** of receiving this FSN.
    - Use the FSN template provided in **Annex II**, ensuring all highlighted fields are completed.
    - We recommend using the **Customer Reply Form** attached in **Annex IV** to confirm receipt and action taken by the user.

3. **Coordination of Replacements**

   - Coordinate with Axium MTech to arrange the **shipment of replacement devices** and return of affected units contacting customerservice@axium-mtech.com
   - Returned devices must be **clearly marked "FSCA-25001"** and shipped to Axium Mtech's distribution centre at the following address: ***Promedia Medizintechnik***

     A. Ahnfeldt, Marienhütte 15

     Siegen 57080

     GERMANY

4. **Confirmation of Receipt**

   - Complete and return the **Distributor Reply Form (Annex III)** to the following email address: quality@axium-mtech.com
   - This form must be submitted **within 7 days** of receiving this FSN.

Action	Deadline
Customer Notification	Within 48 hours of FSN receipt
Submission of Distributor Reply Form	Within 7 days
Closure of all replacement/return activities	By 31st August 2025

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📞 Contact Information:

If you have questions regarding this Field Safety Notice or require assistance with the replacement process, please contact:

Email: quality@axium-mtech.com

We thank you for your support and collaboration in implementing this Field Safety Corrective Action. We apologize for the inconvenience caused and thank you for your continued cooperation and commitment to patient safety.

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Annex I

SN Impacted
See the file provided in your local language

Annex II – FSN for customer/end user

Urgent:

Field Safety Notice with

Field Safety Corrective: Product Recall

Product:	Compat Ella® Pump
Reference:	**SKU** 12272020
	EAN 7613036471152
FSN Identifier:	**FSN-25001**
Date:	Add the effective date of communication to customer/end user
Action Type:	Product Recall / Reinforcement of Patient Monitoring Recommendations
SN impacted:	Add the SN number impacted per each customer/end user
To the Attention of:	Healthcare professionals, end users
Subject:	Non operative pump after full battery discharge

Device Description:

Compat Ella® Pump reference 12272020

The Compat Ella® enteral feeding pump is intended to be used for the delivery of enteral tube feed and hydration at controlled rates to the gastrointestinal system. It is intended for use with adult and pediatric patients requiring enteral feeding and hydration in home and professional healthcare environments.

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Reason for Preventive Product Recall

Axium MTech SA has identified a potential issue involving a defective batch of batteries that may have been used during the manufacturing or servicing of certain pumps.
Preliminary investigations indicate that the serial numbers affected by this FSCA may fail to restart after a full battery discharge, even when reconnected to a charger.
As a result, the pump may become non-operational.
At the time of writing, no incidents with patient impact have been reported in your country.
However, based on our risk assessment, this issue could potentially lead to a delay in therapy and a serious deterioration in the patient's condition.
For this reason, Axium MTech has decided to initiate this Field Safety Corrective Action (FSCA).

Health Care Professional / Patients recommendations

1. **You may continue using the device with caution** until a replacement unit is delivered.

2. **Do not allow the battery to fully discharge.** We strongly recommend always maintaining the battery charge level above 25% (i.e. at least one bar visible on the display).

3. Your distributor/supplier will coordinate the shipping of a **replacement device** as soon as possible,

Device Exchange Process

1. Once received coordinate with your distributor/supplier on the way **to return the defective device.** Please ensure the returned device is clearly identified as a "FSCA-25001".
2. **Complete and return the attached Customer Reply Form** to your local distributor/supplier confirm receipt of this Field Safety Notice and to ensure proper coordination of the replacement and return process.

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Annex III

Template for a Field Safety Notice Distributor/Importer Reply Form

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	**FSN-25001**
FSN Date*	19/06/2025
Product/ Device name*	Compat Ella® Pump
Product Code(s)	12272020
Batch/Serial Number (s)	

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	quality@axium-mtech.com
Distributor/Importer Helpline	-
Postal Address	Allée de la petite prairie 4, Nyon 1206 Switzerland
Web Portal	-
Deadline for returning the Distributor/Importer reply form*	7 days from the receipt of the FSN

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	

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☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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Annex IV

Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

5. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-25001
FSN Date*	Pre-filled by distributor
Product/ Device name*	
Product Code(s)	
Batch/Serial Number (s)	Pre-filled by distributor

6. Customer Details	
Account Number	-
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

7. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed	Qty:	Lot/Serial Number:	

	affected devices – enter number destroyed and date complete.	Qty	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

8. Return acknowledgement to sender	
Email	Pre-filled by distributor
Customer Helpline	Pre-filled by distributor
Postal Address	Pre-filled by distributor
Web Portal	Pre-filled by distributor
Fax	Pre-filled by distributor
Deadline for returning the customer reply form*	Pre-filled by distributor

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.