

10/02/2026

## Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue reported to the national competent authority:

### **Title: Patient-specific Parameters not considered in Quantity Consistency check in PCA “maximum total dose”**

Internal Reference: MST0110722

#### **Product name and version(s) and UDI-DI:**

**DxCare Prescriptions Multimodales** in the following countries: France, Belgium, Luxemburg, Morocco

UDI-DI: 04260693990132

Legal Manufacturer: DH Healthcare GmbH

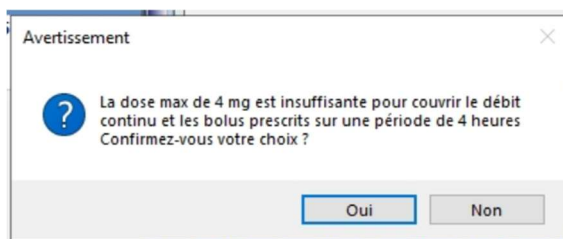
In the following versions: from 9.2021 to 9.2025.0

#### **Information:**

When prescribing a PCA expressed as a maximum total dose, there is a control that alerts the prescriber if the maximum total dose prescribed is the limiting factor for their prescription, i.e., if the basal rate + number of boluses during the refractory period is greater than or equal to the maximum total dose.

This controle does not consider any patient-specific parameters that may be used (e.g., weight, body surface area), rendering it ineffective in this context.

The controle works in the case of prescriptions in absolute value without the use of patient-specific parameters in the calculations and displays as follows:



Note: the control remains non-blocking because the prescriber may wish the additional boluses to also be limited by a maximum total dose and not only by the refractory period.

## **Actions:**

### **Actions undertaken by DH Healthcare GmbH:**

Development of a fix to take the patient-specific parameters into account in the controles.

Modification of the message displayed to the user to improve overall understanding:

Clarification of the limiting aspect of the maximum prescribed dose.

Explicit display of the number of possible boluses calculated based on:

- the refractory period entered
- the maximum dose entered

ensuring that the prescriber fully understands the purpose of the controle.

### **Recommended actions to be taken by the customer:**

Raising awareness among prescribers using the maximum total dose PCA prescription function of the importance of properly understanding the concepts of:

- maximum total prescribed dose
- number of boluses pos

Please distribute this information to all those who need to be aware of it.

Regardless of the situation described here, we would like to point out that care providers must always ensure that clinically relevant information, including prescription information, is clearly communicated and that they must use verified information (e.g., from medical devices such as monitoring systems), independent from the software being used.

**It is important that you take the actions described in this safety information and acknowledge receipt of this letter.**

If the above information does not apply to your hospital or if the device has been transferred to another organization, please indicate this on the attached feedback form and forward this Field Safety Notice to the respective organization.

Thank you for your careful attention to this matter and for your support.

If you have any questions on this matter, please consult our contact person:

Support team

+33(0) 821.044.000

[support.france@dedalus.com](mailto:support.france@dedalus.com)

**URGENT FIELD SAFETY NOTICE - <MST Number> - <Topic>**

Local legal entity name

Country / regional legal address



Sincerely,

Dr. Stephan Albers  
QARA Director – DH Healthcare