

Product: NOVA
Serial Numbers concerned: ALL systems
Nature of action: Medical Device Check

Date: June 2018

We hereby inform you about a verification action to be performed on all NOVA systems

After an incident occurred in an installed equipment in the field, a potential safety problem has been detected that could lead to the breakage of the two steel cables that support the equipment to its roof anchor. Due to this, the equipment might fall and cause harm to the patient, user or third parties.

The main cause of this problem is an excessive wear of the vertical pulley where these steel cables are located. When the wear is not uniform in both grooves of this pulley, the distance between the steel cables is not constant. In the most unfavorable case, this irregular wear could cause the cables to approach and rubbing against each other over time to the rupture point.

After the initial analysis made by SEDECAL, system manufacturer, it has been decided to initiate this security field action in order to control this potential risk.

As a precautionary measure and before technical service intervention, if the user of the equipment observes an abnormal displacement in the vertical axis or any suspicious noise during the vertical movement, we ask you not to use it until your Technical Service verify proper system operation.

SEDECAL will provide all its direct clients with a specific service instruction to carry out this field verification. This verification should be done as soon as possible, given the potential consequences, should your system be affected.

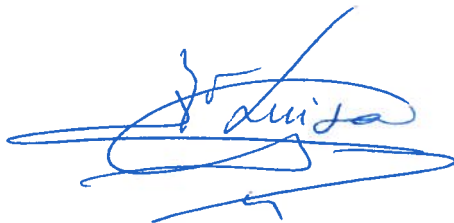
The Health Authorities have been informed of this verification action.

In case you need more information, you can communicate with your usual contact at SEDECAL.

We kindly ask you to send us the attached document signed, as acknowledgment of receipt for this notification, understanding the problem described and its importance.

We are very grateful for your understanding and collaboration.

Sincerely,



María Luisa Gómez de Agüero

Quality and Regulation Manager/ Technician Responsible SEDECAL, S.A.



RECEIPT ACKNOWLEDGMENT

June 2018

Please return this document signed by email to calidad-clientes@sedecal.com, in the shortest time possible to file this acknowledgment.

Thanks in advance for your collaboration.

Company Name: _____

Address: _____

Manufacturer Reference: CAPA 18-020

Affected Product: _____

I confirm that I have received and understand this Urgent Security Information.

SIGN:

DATE:



Central Offices: C/ Pelaya, 9 - 13
Pol. Ind. "Río de Janeiro"
28110 Algete (Madrid)
Tel: (+34) 916 280 544
Fax: (+34) 902 190 385
Email: quest@sedecal.com