

FIELD SAFETY NOTICE– **IMPORTANT**

MV-FR-PORTURO-2020001 (ACP-31)

Montpellier, May 26, 2020

Dear Customer,

This safety notice contains important information that requires all your attention.

This document is intended to inform you about:

- the risk that we have identified on an equipment that we have manufactured and which, according to our records, is in your possession, as well as,
- provisions that we ask you to implement in order to remove this risk

I- Information on Affected Devices

This notice concerns all the devices listed below that were manufactured between 2010 and 2015 (market life of this product range).

References concerned	Serial Number concerned (*)
PHENIX PORTABLE DRAINER	All the serial numbers starting by the letters « CA » - CA XXXXXXXX
PHENIX PORTABLE PHYSIO	All the serial numbers starting by the letters « CB » - CB XXXXXXXX
PHENIX PORTABLE PHYSIOSTIM	All the serial numbers starting by the letters « DA » - DA XXXXXXXX
PHENIX PORTABLE URO	All the serial numbers starting by the letters « CC » - CC XXXXXXXX
PHENIX CONTACT 2	All the serial numbers starting by the letters « CE » - CE XXXXXXXX
PHENIX CONTACT 2 URO	All the serial numbers starting by the letters « CF » - CF XXXXXXXX
PHENIX CONTACT 4	All the serial numbers starting by the letters « CG » - CG XXXXXXXX
PHENIX CONTACT DOLPHITONIC	All the serial numbers starting by the letters « DF » - DF XXXXXXXX

(*) Details regarding the serial numbers: the first 2 characters (in black and bold) are fixed; the following 7 digits (characters XXXXXXXXX in blue) are variable alphanumerical characters.

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II- Reason for the Field Safety Corrective Action (FSCA)

Description of the identified problem:

It has been reported to us that some devices caught on fire , while plugged into AC power to charge the device's internal battery.

The lithium battery integrated into the product burst into flames, damaging the device. In all of the cases observed (6 cases since the first placing on the market in 2010), the flames generated by the battery were contained by the device housing and did not generate damage to the user, to a patient or to a third party.

Identified risk :

Although so far, no significant damage has been reported in the 6 identified cases, we cannot exclude the risk of propagation of the flames to the environment in which the device is located if this incident were to occur again. A battery ignition could lead to a risk of incident.

III- Actions to be taken to control the risk

In order to eliminate this risk, we ask that you proceed with the removal of the battery integrated in your device by following the instructions mentioned below. The device will still be functional using the external AC power, supplied with the device.

Operating mode :

- Step 1: Open the shutter located on the rear face of your device. Use a cross headed screwdriver to remove the screw that holds the shutter.
- Step 2: disconnect the battery by lightly pulling the connector and remove it from its location.
- Step 3: Reposition the shutter and put the fixing screw back with a cross-headed screwdriver.
- Step 4: The device is functional again using its external power supply. The battery must be placed in a suitable trash can so that it can be recycled.



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Please make sure that this notice is communicated to the person concerned (within your office for example). If the equipment has been sold to a third party, please forward this safety notice directly to them or provide us with their contact details in order for us to do so.

For any questions related to this safety notice or to the identification of the concerned devices, do not hesitate to contact our « Support / after sale » team through e-mail sav@vivaltis.com or by phone at +33 (0)4 67 27 48 43.

The regulatory authorities concerned have been informed of this safety notice.

We apologize for the inconvenience caused and we thank you in advance for your help in solving this problem. Rest assured that maintaining a high level of safety and quality is our main priority as well as the satisfaction of our customers.

Sincerely,

Yan Christin
Quality & Regulatory Affairs manager



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**Acknowledgement of receipt of the field safety notice
Referenced MV-FR-PORTURO-2020001 (ACP-31)**

I, the undersigned hereby confirm that I have taken into account the provisions mentioned in the above mentioned Safety Notice.

Company :	
Last name / First name:	
Address :	
E-mail :	
Phone :	
Signature :	
Date :	

Please complete this form and return it to us by post or by email at servicequalite@vivaltis.com within 3 weeks of the receiving date.

Note: It is important that this form is returned to us quickly so that we can follow the progress of the corrective measures taken.