
Urgent Field Safety Notice

Apollo
FSCA-2016-01-15
Additional directions for a safe use of the device.

Buccinasco, January 15th, 2016

To: all users of Apollo tables

Details on affected devices:
Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF tables, all serial numbers

Description of the problem:
Villa Sistemi Medicali became aware that an operator got hurt while relocating a patient from table onto the patient's bed. Standing behind the table top between the left table top support arm and the detector holder, he got squeezed between the left table top support arm and the detector holder.

The analysis showed that the incidence was caused by a chain of four faults:

1.) The injured person overcame a physical barrier (the tabletop support arm, height ca. 60 cm) to access a prohibited area not intended as a working position.

2.) The directions for use (device labeling and instructions for use) did not contain an explicit exclusion of the prohibited area.

3.) The movement was activated inadvertently and continuously, and it was not released (the movement requires continuous activation).

4.) Delayed activation of the emergency stop.

The current state of the art regarding medical device safety requires a single fault proof design. In this case, a chain of four faults, three of which were outside the manufacturer's control, caused the incident. For this reason, if the directions for use (device labeling and instructions for use) contained an explicit exclusion of the prohibited area, the device would meet the applicable technical safety requirements requiring safety under any single fault condition.

Villa Sistemi Medicali SpA
Via delle Azalee, 3
20090 Buccinasco – Italy

Capitale sociale € 3.315.000
C.F. - P.IVA 10022080153
R.E.A. MI 1337218 - R.I. MI

Tel. +39 02 488591
Fax +39 02 4881844
Fax +39 02 48859206

www.villasm.com
vsminfo@villasm.com
direzione@pecvillasm.com

Advise on action to be taken by the user:
The field correction focuses on providing adequate directions for use (including device labeling) to prevent the identified chain of events.
The actions requested to the user are:

- applying on the device the additional warning and prohibition labels provided with this Field Safety Notice according to the instructions in Annex A
- reading very carefully the additional directions supplementing the IfU already supplied with the device precisely explaining:
  - the prohibited area
  - the hazard
  - countermeasures in case of a violation of the prohibition
  - the additional device labeling
- sending back to the manufacturer the attached Confirmation form (Annex B) within10 days from the receipt of this Field Safety Notice, otherwise the device will need to be shut down.

Transmission of this Field Safety Notice:
This notice needs to be passed to all users of Apollo, Apollo DRF,Apollo EZ, Apollo EZ DRF, Clinodigit EVO, Clinodigit EVO@ and to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference person:
For any information and assistance regarding this Field Safety Notice and the implementation of the corrective actions, please contact:

VILLA SISTEMI MEDICALI Technical Service
Tel. +39 02 488591
Fax +39 02 48859222
E-mail: service_support@villasm.com

Villa Sistemi Medicali confirms that this notice has been notified the appropriate Competent Authorities

Apologizing for any inconvenience you may have experienced, we send you our best regards

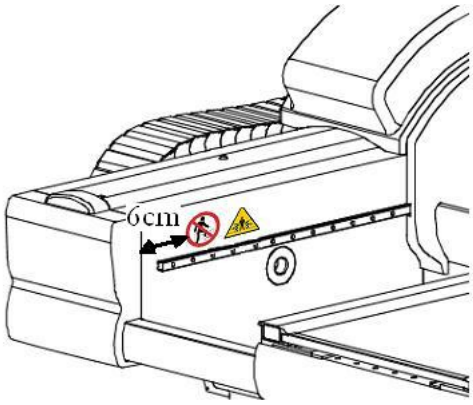
Paolo Casagrande Santin
Quality Assurance Manager
Villa Sistemi Medicali S.p.A.

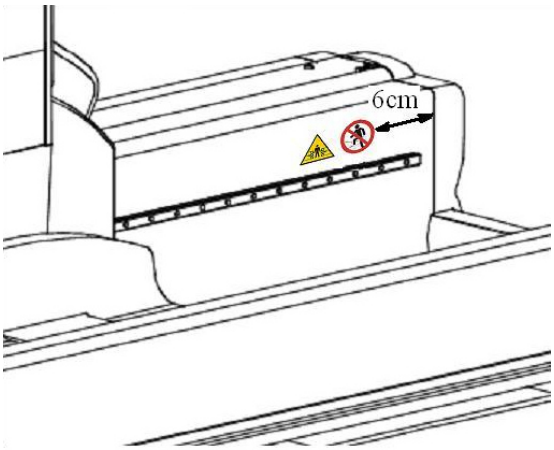
Annex A: Instruction for the implementation of the field correction

1. Composition of the kit:

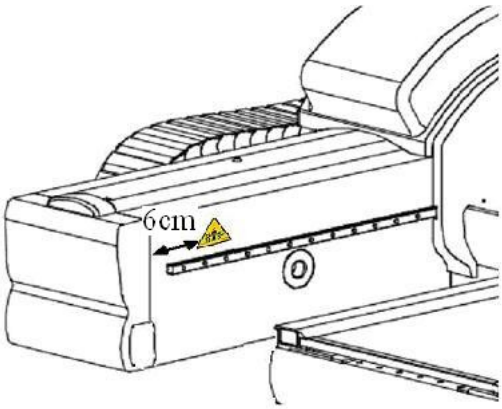
left side labels:		For Apollo OPEN version, as there is no arm in left side, remove prohibition symbol and apply only warning symbol 
right side labels:		
additional directions supplementing the IfU and the Technical documentation already supplied with the device		

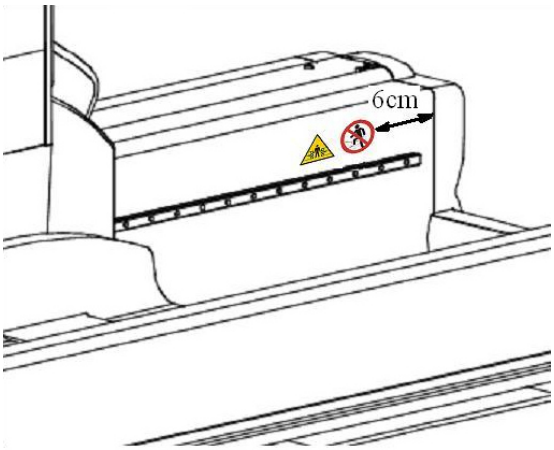
2. Where to apply the provided labels





2. Where to apply the provided labels
APOLLO OPEN version





3. Where to insert the additional directions

Insert the additional directions before chapter 3 of the User's Manual and before chapter 2 of the Service Manual.

Annex B: Confirmation Form

Please send the filled form by fax or e-mail to:
Villa Sistemi Medicali S.p.A.
Paolo Casagrande Santin
p.casagrande@villasm.com
fax +39 02 48859 303

NOTE: this Confirmation Form should be sent back to the manufacturer within10 days from the receipt of this Field Safety Notice, otherwise the device will need to be shut down.

- I have received the Field Safety Notice from Villa Sistemi Medicali together with the kit for field correction
- I have passed this notice to all those who need to be aware within my organisation or to any organisation where the potentially affected devices have been transferred
- I have applied on the device the additional warning and prohibition labels according to the instruction attached as Annex A to this Field Safety Notice
- I have supplemented the IfU and the Technical documentation with the supplied addition directions
- I have read very carefully the additional directions provided with this Field Safety Notice supplementing the IfU.

Signature: _____

Name: _____

Date: _____

Organization: _____

Address: _____

_____

_____

_____

_____

Device s/n: _____