

CUSTOMER NAME  
CUSTOMER ADDRESS

Vicchio, dd/mm/aaaa

**Safety Notice – Urgent** ref. MED DEV 2.12.1  
*FIAB Disposable electrodes for Defibrillation series F7965*

Dear Customer,

following a complaint related to a sample of our disposable electrodes for defibrillation, concerning a possible malfunction during the use, FIAB is starting a voluntary recall of the devices REF series F7965 and F7965/PLUS (adult models), belonging to various production batches.

**Details on involved devices**

The products covered by this notice that we sent to you are indicated on the form “*Issue of information for the recall of the device – issue no. 82*” here enclosed.

**Problem description**

Possible limitation of the energy level supplied by the defibrillator, to a value lower than the value selected on a Corpus 3 defibrillation.

Even if, until today, the feedback from users and post-market surveillance did not report any similar cases (with the exception of the above mentioned complaint), considering the indication of use of these devices, FIAB has decided, as a precaution, for a voluntary recall of devices belonging to lots within a certain range. These lots have been identified by traceability of some components of the devices which may have been the cause of the malfunction.

**Actions to be undertaken from the user**

In case of involved devices are always in stock at your warehouse, see form “*Issue of information for the recall of the device – issue no. 82*” here enclosed, we kindly ask you to:

- a) identify the devices belonging to the involved REF / lots, do not use them and segregate them awaiting to be contacted by FIAB staff or representative, in order to agree the terms of their return;
- b) fill the enclosed form and send it urgently back to FIAB according to the indicated methods, reporting the actual devices in stock; please send the form back to FIAB even if there are no more available devices.

**Transmission of the present Informative Notice**

In case of the devices involved in the present Informative Notice have been distributed to other customers or to final users, we kindly ask you to keep in contact with them by forwarding the present communication, and to collect and transmit the relative replies to FIAB as soon as possible.

The present informative has to be forwarded to all the ones who need to be informed, both in your organization and in such organizations to which the potentially involved devices have been supplied.

Please maintain copy of this informative note and the resulting actions for a suitable period to assure the effectiveness of the actions required by FIAB.

**FIAB reference contacts**

International Sales Dept.  
Quality Assurance Dept.

0039 055 8497976  
0039 055 8497943

[fiab@fiab.it](mailto:fiab@fiab.it)  
[quality@fiab.it](mailto:quality@fiab.it)

We state that the present informative note has been forwarded to the interested National Competent Authorities.

Please do not hesitate to contact us for any additional information you might need and remain with best regards,

Quality Assurance Manager  
FIAB SpA

*Enclosure*

Form “*Issue of information for the recall of the device – issue no. 82*”

**ISSUE OF INFORMATION FOR THE RECALL OF THE DEVICE**

issue no. 82

For the attention of **CUSTOMER NAME**

*Reason of the communication:*

Voluntary recall of disposable electrodes for defibrillation

**REF / Description**

*Description of the reason:*

Possible fault on a component of the cable-connector

*Required action*

In case of involved devices are always in stock at your warehouse – see box “Devices supplied by FIAB”, below - we kindly ask you to:

- a) identify the devices belonging to the involved REF / lots, do not use them and segregate them awaiting to be contacted by FIAB staff or representative, in order to agree the terms of their return;
- b) fill the present form and send it urgently back to FIAB, reporting the actual devices in stock.

Once filled, please send back the present form – as soon as possible – to FIAB by fax or e-mail using one of the contacts listed below, indicating the actual devices in stock; please send the form back to FIAB even if there are no more available goods. Whether the in the form no goods in stock will be indicated, it means that all the devices have been already used, and that this fact has been checked by the person in charge to fill the form.

*Please maintain copy of this informative note and the resulting actions for a suitable period to assure the effectiveness of the actions required by FIAB.*

Devices supplied by FIAB

Code REF DESCRIPTION LOT Quantity

*Please indicate the devices at present in stock at your warehouse*

**Code REF DESCRIPTION LOT Quantity**

**Note: please fill reporting 0 (zero) even in case of no goods in stock**



FIAB, by means of its commercial offices or sales personnel in charge, will contact you in order to agree the terms of the return of the possible devices always in stock, if you have any.

*YOUR CONTACT PERSON DETAILS:*

Name: ..... Function: .....

Telephone: ..... Fax: .....

Date ..... Stamp and sign of the Customer.....

Issued by: 	SAQ FIAB SpA	Date 20/11/2014	Sign 
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