

«Company»
«Company_Name»
«Title» «Name»
«Road»
«City»

Hocoma AG
Industriestrasse 4
CH-8604 Volketswil
Switzerland

Tel. +41 43 444 22 00
Fax +41 43 444 22 01
info@hocoma.com
www.hocoma.com

Volketswil, 29th October 2015

Important Safety Recall **Replacement campaign for main connection cable of the medical device XXX**

Dear Mr. X / Dear Ms. Y,

The safety of your patients and staff is very important to us, just as it is to you. For this reason we are contacting you today in order to continue to maintain the high safety status of your medical device. Today we need to ask you to support us in the implementation of a recall campaign, which concerns the main connection cable of your >>Produkt<<.

In a few main connection cables, routine testing has found that an important integrated ground wire was not always made correctly. Under certain circumstances, this may cause a serious threat to your patients, users and third parties. For this reason, we have decided to launch a recall campaign and replace possibly affected cables.

Our records show that your >>Produkt<< could possibly be affected. To keep your costs as low as possible, a new cable (with appropriate labeling) has been enclosed at no cost to you. Please use it to replace the possibly faulty main connection cable. The replaced cable can be disposed of in electronics stores or at collection points for waste electrical and electronic equipment. We strongly recommend that you render the cable unusable, by cutting it, for example. Under no circumstances should you continue to use it!

In your country, this recall campaign is being coordinated with the national supervisory authorities, and we are therefore required to demonstrate the complete replacement of all cables, without exception. We therefore ask you to confirm by your signature that you have received this recall notice and replaced the possibly affected main connection cable. Please send us this signature via scanned version to quality@hocoma.com or fax +41 (0)43 444 22 01

We apologize for the inconvenience and thank you in advance for your support. For further questions, please do not hesitate to contact us. Please contact our service hotline at +41 (0)43 444 22 33 or service@hocoma.com.

Sincerely,
Hocoma AG

Gery Colombo
CEO

Burkhard Zimmermann
CQO
quality@hocoma.com

Please send this document to:

Fax no. +41 (0) 43 444 22 01
E-mail: quality@hocoma.com

Hocoma AG
Industriestrasse 4
CH-8604 Volketswil
Switzerland

Tel. +41 43 444 22 00
Fax +41 43 444 22 01
info@hocoma.com
www.hocoma.com

Recall and replacement campaign for the main connection cable

Confirmation

We hereby confirm receipt of this recall notice and replacement of the possibly affected main connection cable. The replaced cable has already been disposed of.

Hospital: **completed by Hocoma**

The serial number can be found as follows:

Device number: **completed by Hocoma**



Place / date

.....

Function / position:

.....

Name:
(in block letters)

.....

Signature

.....