

Mane, 17/06/2019, FRANCE

OBJECT : WARNING LETTER

Product concerned: VIBRAMOOV Control station

Serial number involved: See list below

Subject: RECALL FOR MAINTENANCE OPERATION

Type of operation: Vibramoov cabling modification.

This letter is addressed to all users and medical facilities.

As part of the good application of the 13485 ISO Standards, TechnoConcept has to do a cabling modification in the control unit of your medical devices Vibramoov. As a consequence, after receiving this warning letter N° 19-021, **you have to unplug the device and stop using it.**

A Technoconcept employee will come quickly to collect the control units that should return to the factory for modifications.

This intervention is to ensure the optimal use of your Vibramoov device for your patients and clinicians.

We are very sorry for this inconvenience and the consequent interruption on your daily clinical use. Be sure that Technoconcept will do the maximum to return your Vibramoov control unit as soon as possible.

We remain at your disposal for every further information and we wish to assure you, dear customer, our consideration.

Quality Department
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LA TECHNOLOGIE EN MOUVEMENT

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List of devices serial numbers concerned :

China	201 00 17 000012 00
China	201 00 18 000019 00
Croatia	201 00 17 000011 00
Croatia	201 00 17 000013 00
Croatia	201 00 18 000022 00
Czech Republic	201 00 17 000008 00
Czech Republic	201 00 17 000010 00
France	201 00 16 000001 00
France	201 00 16 000002 00
France	201 00 16 000003 00
France	201 00 17 000014 00
France	201 00 16 000015 00
France	201 00 18 000024 00
France	201 00 18 000025 00
France	201 00 18 000026 00
France	201 00 18 000028 00
France	201 00 18 000029 00
France	201 00 18 000032 00
France	201 00 18 000033 00
France	201 00 18 000034 00
France	201 00 18 000036 00
Germany	201 00 16 000005 00
Germany	201 00 17 000009 00
Germany	201 00 18 000020 00
Germany	201 00 18 000023 00
Germany	201 00 18 000035 00
Italy	201 00 17 000016 00
Italy	201 00 18 000037 00
Romania	201 00 18 000027 00
Romania	201 00 18 000030 00
Russia	201 00 16 000006 00
Saudi Arabia	201 00 18 000031 00
Slovenia	201 00 18 000021 00
Switzerland	201 00 16 000007 00
Switzerland	201 00 18 000017 00
Switzerland	201 00 18 000018 00



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CONFIRMATION OF RECEIPT OF THE WARNING LETTER

**** Please return this document signed ****
as soon as possible

Please complete and return this form by postal mail, fax or by E-mail
Adress : TECHNO CONCEPT – ZA Pitaugier 04300 MANE - FRANCE
Fax : +33 492 790 861
Email : m.charpin@technoconcept.fr

I confirm that I have read Technoconcept's warning letter and have implemented the measures indicated in this letter for my device with the following serial number (SN) :

SN N° :

Owner's Visa

Date

Name

Signature