

URGENT – FIELD SAFETY NOTICE

Sonolith® i-move – Dysfunction Software on remote control HMI1

1- Description et reason for the corrective action

Dear customer of Sonolith® i-move,

During the commissioning of a Sonolith® i-move system, an EDAP TMS France representative found that the energy level of the shock waves could differ from that demanded by the user when all the following conditions were met successively:

- Selection of the minimum power of 1% on the HMI 1 via the level arrows or the central slider.
- New pressing on the central slider (this action causes the disappearance of the power display).
- Action on the shooting command

This dysfunction only appears if the user sets the power with the remote control fitted to the Sonolith® i-move system (IHM1); this dysfunction does not appear if the user sets the power with the touch screen present on some machines (HMI2).

The difference in power between that required and the one delivered will occur on only a few shots, the time that the remote control of the Sonolith® i-move system and the computer present in the machine synchronize.

The computer will automatically correct the power during this synchronization.

To remedy this problem, a representative of EDAP TMS

France will contact you to schedule a visit to your establishment and update the remote control software on your Sonolith® i-move system.



2- Health risk

The risk is to deliver to the patient a shockwave power higher than the value of 1% required by the user resulting in an unexpected pain.

No adverse effects related to this problem have been reported to us. This safety advisory and the corresponding corrective action are only precautionary measures.

3- Products concerned

Some equipment only in the Sonolith i-Move range (TMS 232551) are concerned by this safety information. The list of equipment concerned, identified by their serial number, is presented in **Appendix A**.

4- Measures to be taken by the user

Please take the following measures:

1. Transmit this letter to your local medical device vigilance correspondent, urologist, purchasing and biomedical engineering staff, and your medical personnel who perform therapeutic procedures with Sonolith® i-Move devices.

2. Ensure urologists and assistants using the Sonolith® i-move system read and understand the contents of this letter.
3. We ask you to not use the minimum power adjustment via the HMI1 remote control of your Sonolith® i-move until your EDAP TMS France representative has intervened on it to update the software of the remote control in **version 2.13**.
4. Your Sonolith® i-move may have already been updated.
We therefore ask you to verify that the version of the software on your Sonolith® i-move system is version 2.13 (see description of the verification page 3 – RECEIPT ACKNOWLEDGMENT FORM – Safety information).
If you do not have this version, please contact our Customer Care Center (CCC) at +33 (0) 4.72.15.31.50 or ccc@edap-tms.com.
5. Once the corrective action has been completed, inform the appropriate personnel.
6. Complete the enclosed acknowledgment form and return it to EDAP TMS France by e-mail or fax in accordance with the instructions therein.
7. Please keep a copy of this letter and the acknowledgment form in your records.

5- Measures taken by EDAP TMS France

1. This problem was identified by EDAP TMS France during a machine installation and was corrected immediately with the release of a new software version (**v 2.13**).
2. A copy of this Safety Information will be sent to customers with the relevant Sonolith® i-move systems.
3. A representative of EDAP TMS France will contact customers with affected Sonolith® i-move systems to schedule an on-site visit and update the necessary software on the affected systems.

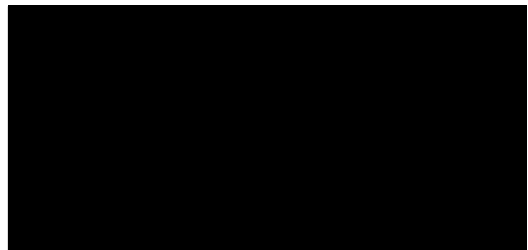
EDAP TMS France representatives will be available by phone to answer any questions related to this safety information.

6- Additional information and assistance

For additional information or assistance with this safety information, please contact your EDAP TMS France representative or the EDAP TMS France technical service at the following numbers:
Phone : +33 (0) 4.75.15.31.50 or Fax : +33 (0) 4.72.15.31.51 or Email : ccc@edap-tms.com

Please note that the relevant ANSM regulatory authority has been informed of this safety information.
Yours sincerely,

EDAP TMS France
Parc d'activités La Poudrette Lamartine
4 Rue Du Dauphiné
69120 Vaulx en Velin - France



RECEIPT ACKNOWLEDGMENT FORM

Security information

Corrective action - medical device

Sonolith® i-move - Dysfunction Software on remote control HMI1

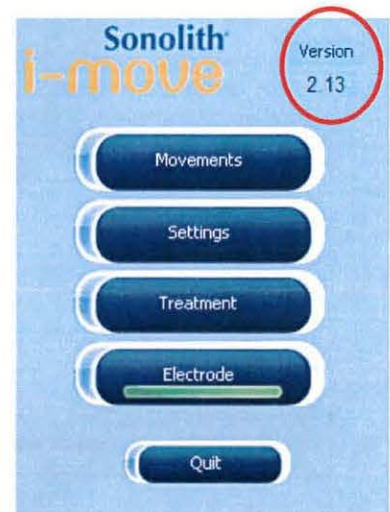
PLEASE COMPLETE ALL INFORMATION REQUIRED AND RETURN THE FORM IMMEDIATELY

1. I have received and consulted this notice.
2. I made sure that all the staff concerned were fully informed about the content of this notice.
3. We confirm that the software version installed on the remote control (HMI1) of our Sonolith® i-move equipment is up to date (version 2.13):

To access the software version installed on the remote control (HMI1), please follow these steps:

- Start the Sonolith® i-move, wait for the end of the initialization.
- After about 30 seconds, the home page appears on the screen on the remote control, and the version number is displayed at the top right (as shown in the image opposite).

4. I will contact EDAP TMS France in case of questions and / or update necessary to the following email or phone / fax numbers:
Phone : +33 (0) 4.75.15.31.50 / Fax : +33 (0) 4.72.15.31.51
Email : ccc@edap-tms.com



Name of the hospital : _____

Serial number : _____

Name & Function (in capitals) : _____

Signature : _____

Phone number : _____

e-mail : _____

Date : _____

APPENDIX A

How to find the serial number of my Sonolith i-move?



Country	Serial number	Country	Serial number	Country	Serial number
France	SIMF015	France	SIMV142	Germany	SIMV032
	SIMV017		SIMV051R		SIMV036
	SIMV021		SIMV136		SIMV052
	SIMV024	Netherlands	SIMV011		SIMV093
	SIMV026		SIMV033		SIMV086
	SIMV030	Belgium	SIMS125		SIMV103
	SIMV031	Poland	SIMT013		SIMV139
	SIMV055		SIMV049		SIMV147
	SIMV056	SIMS127	SIMV153		
	SIMV084	Slovakia	SIMS067		SIMV161
	SIMV111	Estonia	SIMV168	SIMT189	
	SIMV126	Czech republic	SIMT170	Switzerland	SIMV165
	SIMV135	Italy	SIMV018		SIMV166
	SIMV003R		SIMV071	Norway	SIMV099
	SIMV039R		SIMV085		SIMT195
	SIMV159	Germany	SIMV016	Cyprus	SIMT028
	SIMV182		SIMV025		