Urgent Field Safety Notice (FSN)

Valon TT (TT 532 and TT 577) manufactured from 04/2018 onwards

Date: 2022-07-08

For Attention of:

Distributors of Valon TT (TT 532 and TT 577)

Manufacturer:

Meridian Medical Oy
Elannontie 5
01510 Vantaa
Finland
https://www.meridian.ch/

Contact person:

…
i.znidar@meridianmedical.eu,

Dear Customer,

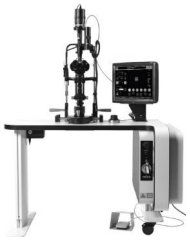
Due to an incident with a Valon TT laser, we would like to inform you that the operating surface of the touch screen must be completely clean at all times.

Please see the details below.

Please contact us with any queries using the contact details above.

1. Information on affected devices

1.1. Device type
Laser photocoagulator



1.2. Primary clinical purpose of the device
Valon TT is used for ophthalmic photocoagulation treatments.

1.3. Device model/catalogue/part number
Valon TT (TT 532 and TT 577)

1.4. Affected serial or lot number range
Affected are TT models with manufacturing date from 04/2018 with the newer capacitive touch screen.

2. Reason for Field Safety Corrective Action (FSCA)

2.1. Description of the product problem
None.

2.2. Hazard giving rise to the FSCA
Foreign material adhering to the touch screen may affect and adjust the treatment settings. It is a typical feature of all capacitive touch screens that even a drop of water on the touch screen causes the screen to react as it was a finger.

2.3. Probability of problem arising
Very low.

2.4. Background on issue
The incident was caused by the physician unnoticedly applying some Viscotear's eye gel to the touch screen, which unintentionally affected the treatment settings. This incident was a single reported event in 11 years since Valon TT is on the market.

3. Type of action to mitigate the risk

3.1. Actions to be taken by the distributor
Inform the users of TT models with manufacturing date from 04/2018 about this FSN.
Deadline: 31 August 2022.

3.2. Action to be taken by the user

Take note of amendment of instructions for use (IFU), when available.

Consider the following advices:

- Residues of any kind must be removed from the touch screen before starting treatment.
- The operating surface of the touch screen must be completely clean at all times.
- It is recommended to use SmartWheel instead of touch screen when performing treatment.

3.3. Is distributor reply required?

Yes.
Distributors should notify the manufacturer that the users have been informed about this FSN.
Distributors should send the reply to the contact person of the manufacturer: i.znidar@meridianmedical.eu.
Deadline: 31 August 2022.

3.4. Action being taken by the manufacturer

IFU change.
Deadline: 31 August 2022.

3.5. Is the FSN required to be communicated to the patient /lay user?

No.

4. General Information

4.1. FSN Type

New.

4.2. Further advice or information already expected in follow-up FSN?

No.

4.3. The competent authority has been informed about this communication to customers.

Yours sincerely,

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