



Urgent Field Safety Notice

EP-TRACER 38 and EP-TRACER 102

Internal reference number 2201

Rework of devices in the field is needed, clinical use can be continued.

Date: 12 May 2022

Attention: Field Safety Corrective Action for Electrophysiological Measurement System EP-TRACER 38 and 102, legally manufactured by CardioTek BV.

Devices affected:

The table below lists the serial numbers of the EP-TRACER devices affected.

Description of the issue:

The EP-TRACER requires certain creepage distances and air clearances.

During an internal investigation of a device that had failed under a test-specific high voltage condition of a third party – obviously without a patient present – we identified a position at which the mentioned distances were not met.

The EP-TRACERS affected have a manufacturing date of 01 January 2019 or later.

To date, CardioTek has not received any similar reports other than the complaint about the above-mentioned device.

Risk assessment:

- Unless other fault conditions exist (e.g. interrupted earth), the position by itself (at which the distances are not met) does not present a danger. There were no complaints received which could be related to this issue.
- The likelihood of occurrence of the failure conditions for exceeding the creepage limit and emitting hazardous voltages to the applied part applied is extremely low.
- The probability of risk to the patients is extremely low.

Corrective action

The corrective action is to attach a reinforced insulation sheet.



The corrective action will be implemented either by onsite rework on the premises of the customer or end user or at the CardioTek manufacturing site in Sittard (NL). A trained employee of CardioTek or a certified service partner will perform the corrective action on a date that is mutually agreed by all parties involved. CardioTek will contact the customer or end user to schedule an appointment for the rework. The device can be still be used as intended.

Communication about Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation who is in possession of an impacted device as mentioned in the list below.

Please forward this notice to other organisations who may be impacted by this action.



Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Mr Jens Martens
Director Quality and Regulatory Affairs and Person Responsible for Regulatory Compliance
09 May 2022
E-mail: qm.ra@schwarzercardiotek.com

The undersign confirms that this notice has been submitted to the appropriate Regulatory Agency

Signature

Mr Jens Martens	12 May 2022	Director QARA and PRRC	
Mr Frank Peter-Klein	12 May 2022	CEO	



The following lists the impacted EP-TRACER devices.

Device Type	SN
EP-TRACER 38	2019-1-01
EP-TRACER 38	2019-1-02
EP-TRACER 38	2019-1-03
EP-TRACER 38	2019-1-04
EP-TRACER 38	2019-1-05
EP-TRACER 38	2019-1-06
EP-TRACER 38	2019-2-01
EP-TRACER 38	2019-2-02
EP-TRACER 38	2019-2-03
EP-TRACER 38	2019-2-04
EP-TRACER 38	2019-2-05
EP-TRACER 38	2019-3-01
EP-TRACER 38	2019-3-02
EP-TRACER 38	2019-3-03
EP-TRACER 38	2019-3-04
EP-TRACER 38	2019-3-05
EP-TRACER 38	2019-3-06
EP-TRACER 38	2019-3-07
EP-TRACER 38	2019-3-08
EP-TRACER 38	2019-3-09
EP-TRACER 38	2019-3-10
EP-TRACER 38	2019-4-01
EP-TRACER 38	2019-4-02
EP-TRACER 38	2019-4-03
EP-TRACER 38	2019-4-04
EP-TRACER 38	2019-4-05
EP-TRACER 38	2019-4-06
EP-TRACER 38	2019-4-07
EP-TRACER 38	2019-4-08
EP-TRACER 38	2019-4-09
EP-TRACER 38	2019-4-10
EP-TRACER 38	2019-5-01
EP-TRACER 38	2019-5-02
EP-TRACER 38	2019-5-03
EP-TRACER 38	2019-5-04
EP-TRACER 38	2019-5-05
EP-TRACER 38	2020-1-01
EP-TRACER 38	2020-1-02
EP-TRACER 38	2020-1-03
EP-TRACER 38	2020-1-04
EP-TRACER 38	2020-1-05
EP-TRACER 38	2020-1-06
EP-TRACER 38	2020-1-07
EP-TRACER 38	2020-1-08

EP-TRACER 38	2020-1-09
EP-TRACER 38	2020-1-10
EP-TRACER 38	2020-1-11
EP-TRACER 38	2020-1-12
EP-TRACER 38	2020-1-13
EP-TRACER 38	2020-1-14
EP-TRACER 38	2020-1-15
EP-TRACER 38	2020-2-01
EP-TRACER 38	2020-2-02
EP-TRACER 38	2020-2-03
EP-TRACER 38	2020-2-04
EP-TRACER 38	2020-2-05
EP-TRACER 38	2020-2-06
EP-TRACER 38	2020-2-07
EP-TRACER 38	2020-2-08
EP-TRACER 38	2020-2-09
EP-TRACER 38	2020-2-10
EP-TRACER 38	2020-2-11
EP-TRACER 38	2020-2-13
EP-TRACER 38	2020-2-14
EP-TRACER 38	2020-2-15
EP-TRACER 38	2020-4-01
EP-TRACER 38	2020-4-02
EP-TRACER 38	2020-4-03
EP-TRACER 38	2020-4-04
EP-TRACER 38	2021-1-01
EP-TRACER 38	2021-1-02
EP-TRACER 38	2021-1-03
EP-TRACER 38	2021-1-04
EP-TRACER 38	2021-1-05
EP-TRACER 38	2021-1-06
EP-TRACER 38	2021-1-07
EP-TRACER 38	2021-1-08
EP-TRACER 38	2021-2-01
EP-TRACER 38	2021-2-02
EP-TRACER 38	2021-2-03
EP-TRACER 38	2021-2-04
EP-TRACER 38	2021-2-06
EP-TRACER 38	2021-2-07
EP-TRACER 38	2021-2-08
EP-TRACER 38	2021-2-09
EP-TRACER 38	2021-2-10
EP-TRACER 38	2021-2-11
EP-TRACER 38	2021-2-12
EP-TRACER 38	2021-2-13
EP-TRACER 38	2021-2-14
EP-TRACER 38	2021-2-15



EP-TRACER 38	2021-3-01
EP-TRACER 38	2021-3-02
EP-TRACER 38	2021-3-03
EP-TRACER 38	2021-3-04
EP-TRACER 38	2021-3-05
EP-TRACER 38	2021-3-06
EP-TRACER 38	2021-3-07
EP-TRACER 38	2021-3-08
EP-TRACER 38	2021-3-09
EP-TRACER 38	2021-3-10
EP-TRACER 38	2021-3-11
EP-TRACER 38	2021-3-12
EP-TRACER 38	2021-3-13
EP-TRACER 38	2021-3-14
EP-TRACER 38	2021-3-15
EP-TRACER 38	2021-5-01
EP-TRACER 38	2021-5-02
EP-TRACER 38	2021-5-03
EP-TRACER 38	2021-5-04
EP-TRACER 38	2021-5-05
EP-TRACER 38	2021-5-06
EP-TRACER 38	2022-1-01
EP-TRACER 38	2022-1-03
EP-TRACER 38	2022-1-04
EP-TRACER 38	2022-1-05
EP-TRACER 38	2022-1-06
EP-TRACER 102	2019-1-11
EP-TRACER 102	2019-2-11
EP-TRACER 102	2019-2-12
EP-TRACER 102	2019-2-13
EP-TRACER 102	2019-2-14
EP-TRACER 102	2019-2-15
EP-TRACER 102	2019-2-16
EP-TRACER 102	2019-4-21
EP-TRACER 102	2019-4-22
EP-TRACER 102	2019-4-23
EP-TRACER 102	2019-4-24
EP-TRACER 102	2019-4-25
EP-TRACER 102	2019-4-26
EP-TRACER 102	2019-4-27
EP-TRACER 102	2020-1-26
EP-TRACER 102	2020-1-27
EP-TRACER 102	2020-1-28
EP-TRACER 102	2020-1-29
EP-TRACER 102	2020-1-30
EP-TRACER 102	2020-2-26
EP-TRACER 102	2020-2-26



EP-TRACER 102	2020-2-27
EP-TRACER 102	2020-2-28
EP-TRACER 102	2020-2-29
EP-TRACER 102	2020-2-30
EP-TRACER 102	2021-1-13
EP-TRACER 102	2021-1-14
EP-TRACER 102	2021-2-27
EP-TRACER 102	2022-1-26
EP-TRACER 102	2022-1-27