Urgent Field Safety Notice

Trade name of the product concerned: **TU2000 TRYTABLE**

Date: **11/05/2026**

FSCA identifier: **FSCA-02/26**

Type of action:

UDI-DI: **04020012, 04020014, 04020017, 04020018, 04020026, 04020021, 04020009, 04020010, 04020011, 04020001, 04020025, 04020013, 04020003, 04020005, 04020016, 04020023, 04020028, 04020008, 04020020, 04020019, 04020015, 04020024, 04020022, 04020006, 04020027, 04020029, 04020030, 04020031**

SN: **32090012, 32090014, 32090017, 32090018, 32090026, 32090021, 32090009, 32090010, 32090011, TR05617, 32090025, 32090013, 32090003, 302090005, 32090016, 32090023, 32090028, 32090008, 32090020, 32090019, 32090015, 32090024, 32090022, 302090006, 32090027, 32090029, 32090030, 32090031**

Manufactured: **18/07/2024 – 17/03/2026**

Dear Customer,

The manufacturer has identified an error in the user manual. In section **10.4 Area for radiological examinations**, the dimensions of the surface intended for radiology are listed incorrectly:

9.4 Area for radiological examinations

The examination chair has a backrest adapted for radiological examinations. The surface of the backrest intended for radiology shall be a rectangle with dimensions of 580 × 429 mm and its location shall not be axially symmetrical to the axis of the chair. This is due to the location of the backrest actuator.

The whole area is schematically marked in the following figure.

The correct dimensions for the radiology area are **540 x 429 mm**. If the radiological examination is performed outside this area, the X-ray image will show the clips used to secure the synthetic leather.

Potential risk to patients/users:

There is low probability that the doctor will not notice the distortion in the image, and the clips in the image will affect the interpretation of the image and, consequently, the diagnosis.

Required actions:

1. **Action required from distributors/importers:**

Please send your customers the updated version of the user manual (04/2026) immediately and notify them of the change in the dimensions of the X-ray area.

Please fill out the response form below (Appendix 1) and send it to the manufacturer. (Alternatively, you can use the link provided in the e-mail for electronic confirmation).

2. Action required from the end user

Please fill out the response form below (Appendix 2) and send it to the manufacturer or your supplier. (Alternatively, you can use the link provided in the e-mail from your supplier for electronic confirmation.)

Transmission of this field safety notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

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

Manufacturer contact details:

MEDKONSULT medical technology s.r.o.
Pasteurova 67/15
779 00 Olomouc
Czech Republic

Contact person:
Jana Ruszó Černá
Email jc@mmtsystems.com
tel.: + 420 608 535 697

We apologise for any inconvenience caused.

Jana Ruszó Černá
Regulatory Affairs Manager

This notification has been forwarded to the relevant regulatory authority.

Appendix 1: Response form for distributors

Company:	
Contact person:	
Email:	
Tel. no.:	
Signature	

I confirm that I have received the information and forwarded it to the following customers:

Organisation name	Product serial number	Date of contact	Contact person

Appendix 2: Response form for users

I confirm that I have received the information:

Hospital/facility:	
Name:	
Email:	
Tel. no.:	
Signature	