

19 May 2026

VOLUNTARY MEDICAL DEVICE FIELD SAFETY ALERT NOTIFICATION

**T-RAC™ II (Terumo Recording and Automatic Blood Collector)
Incorrect Operator’s Manual Content**

Dear Valued Customer:

Terumo Blood and Cell Technologies is initiating this Voluntary Medical Device Field Safety Alert Notification for T-RAC II devices (catalog numbers ME-TRAC2JR, ME-TRAC2, and ME-TRAC2W) to notify you of discrepancies between the T-RAC II operator’s manuals and the touch screen prompts on the device.

REASON FOR THE FIELD SAFETY ALERT NOTIFICATION

This Voluntary Medical Device Field Safety Alert Notification is being undertaken to eliminate confusion between the currently released versions of the T-RAC II operator’s manuals and the prompts that appear on the device touch screen. The on-screen instructions for all T-RAC II device configurations are accurate. If you have received this letter, it has been determined that your facility currently has a T-RAC II device with one of the catalog numbers listed above.

Eight differences have been identified in the operator’s manual that do not align with the device’s touch screen prompts. Table 1 below shows the incorrect information on the left, in red, and the correct version from the corrected operator’s manual on the right.

Table 1. Current Operator’s Manual Versus Corrected Operator’s Manual

Page No	Current Description in the T-RAC II-Wifi Version 8 Operator’s Manual (Part No. 1000053175)	Corrected Description in the T-RAC II-Wifi Version 8 Operator’s Manual (Part No. 1000097333)
7	T-RAC II WiFi includes an RF Transmitter that works on frequency bands [2400 MHz – 2483.5 MHz], [5150 MHz] and [5725 MHz – 5825 MHz]. It is compatible with IEEE 802.11 standard “a,” “b,” “g,” and “n” and emits less power than 100 mW of power.	T-RAC II WiFi includes an RF Transmitter that works on frequency bands [2400 MHz – 2483.5 MHz]. It is compatible with IEEE 802.11 standard “b,” and “g,” and emits less power than 100 mW of power.
33 See note below*	<ol style="list-style-type: none"> For safety reasons, you cannot manually change the clamp’s state between venipuncture and the ‘needle removal’ stage. If the selected donation volume is incorrect, touch this button to correct it. Using this button, the inputs of other events can also be reviewed and altered. 	<ol style="list-style-type: none"> If the selected donation volume is incorrect, touch this button to correct it. Using this button, the inputs of other events can also be reviewed and altered. This donation volume was selected in the previous step. Touch STOP to cancel the donation at this point.

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
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	<p>3. This donation volume was selected in the previous step.</p> <p>4. Touch STOP to cancel the donation at this point.</p>	
<p>*NOTE: The update regarding the clamp state applies to all three catalog numbers: ME-TRAC2JR, ME-TRAC2 and ME-TRAC2W (operator’s manual part no. LC-7468en, Rev 8, pg. 31; and updated operator’s manual part no. 1000053175, pg. 33), while all other updates listed in this table are applicable only to catalog number ME-TRAC2W (T-RAC II-Wifi Version 8).</p>		
52	<p>All alarms aud Yes / No Default: Yes Yes: All alarms are audible, including alarms that occur when a donation is not in progress. No: Only alarms that occur during donation are audible.</p> <p>End alarm Off / Mel / MeIR / Mon / MonR (Default: Mel) Off: No audible alarm at the end of donation. Mel: Melody (1x) MeIR: Melody (repeating until user shuts it down) Mon: Monotone (1x) MonR: Monotone (repeating)</p>	<p>Alarm volume 1 / 2 / 3 / 4 (Default: 4) Audible volume of the alarms.</p> <p>Button volume 0 / 1 / 2 / 3 / 4 (Default: 1) Audible volume when touching a button on the touch screen or on the remote control. When set to 0, no audible signal is given.</p> <p>End alarm Off / Mel / MeIR / Mon / MonR (Default: Mel) Off: No audible alarm at the end of donation. Mel: Melody (1x) MeIR: Melody (repeating until user shuts it down) Mon: Monotone (1x) MonR: Monotone (repeating)</p>
60	<p>15 Alarms and Error Messages Various alarms occur on T-RAC II. Alarms that occur during donation are always audible. Alarms that occur at other times can be configured to be audible or not in the program setting “All alarms aud.” Make sure the alarm volume is adjusted so alarms are audible in the ambient operating conditions of the device.</p>	<p>15 Alarms and Error Messages Various alarms occur on T-RAC II. Alarms that occur during donation are always audible. Make sure the alarm volume is adjusted so alarms are audible in the ambient operating conditions of the device.</p>
63	<p>Donation finished: time reached Indicated by: Touch screen: Message indicates “TARGET NOT REACHED.” Constant yellow border around the touch screen. Clamp: Closes automatically. Antenna: Purple constant. Audible: No. TOMEs alarm number: 4 Cause: The maximum donation time has been reached. Solution: Touch Next to continue.</p>	<p>Donation finished: time reached Indicated by: Touch screen: Message indicates “TARGET NOT REACHED.” Turns the progress bar yellow (informational signal). Clamp: Closes automatically. Antenna: Purple constant. Audible: No. TOMEs alarm number: 4 Cause: The maximum donation time has been reached. Solution: Touch Next to continue.</p>
64	<p>Battery error Indicated by: Touch screen: Message “BATTERY ERROR” Flashing yellow border around touch screen. Antenna: Yellow constant. Audible: Yes. TOMEs alarm number: 8 Cause: A problem with the battery has been detected. Solution: Connect T-RAC II to the mains or replace the battery. Turn off the device before replacing the battery unless it is connected to the mains.</p>	<p>Battery error Indicated by: Touch screen: Message “BATTERY ERROR” Flashing yellow border around touch screen. Antenna: Yellow flashing. Audible: Yes. TOMEs alarm number: 8 Cause: A problem with the battery has been detected. Solution: Connect T-RAC II to the mains or replace the battery. Turn off the device before replacing the battery unless it is connected to the mains.</p>
70	<p>17.2.2 Check of the Alarm Function Regularly check the alarm function.</p>	<p>17.2.2 Check of the Alarm Function Regularly check the alarm function.</p>

	<p>1. On the settings menu, and make sure that the program setting "All alarms aud." is set to "Yes." Refer to chapter 14 for more information.</p> <p>2. Turn off T-RAC II by pressing the on/off button and holding for 3 seconds.</p> <p>3. Remove the battery and make sure T-RAC II is still connected to the mains.</p> <p>4. Turn on T-RAC II by pressing the on/off button.</p> <p>5. An alarm should sound and the antenna LED should be illuminated.</p>	<p>1. Turn off T-RAC II by pressing the on/off button and holding for 3 seconds.</p> <p>2. Remove the battery and make sure T-RAC II is still connected to the mains.</p> <p>3. Turn on T-RAC II by pressing the on/off button.</p> <p>4. An alarm should sound and the antenna LED should be illuminated.</p>
72	<p>19 WiFi Setup</p> <p>Each T-RAC II WiFi device must be set up separately in order to communicate with the wireless access point. Complete these steps:</p> <ol style="list-style-type: none"> 1. Set the IP address of an Ethernet port of a PC on 192.168.1.100 and the subnet mask on 255.255.255.0. 2. Connect the Ethernet port of T-RAC II, which is marked as shown, directly to the Ethernet port of the PC. 	<p>19 WiFi Setup</p> <p>Each T-RAC II-Wifi device must be set up separately in order to communicate with the wireless access point. Complete these steps:</p> <ol style="list-style-type: none"> 1. Set the IP address of an Ethernet port of a PC on 192.168.1.100 and the subnet mask on 255.255.255.0. 2. Connect the Ethernet port of T-RAC II, which is marked as shown, directly to the Ethernet port of the PC. 

RISK TO DONOR OR OPERATOR

An internal Health Hazard Evaluation (HHE) has been conducted to assess the issues described in Table 1 above. The risks associated with these issues are considered low. The inconsistency between the operator’s manual and the device’s touch screen prompts may lead to user confusion and misinterpretation if following the operator’s manual. The on-screen instructions for all T-RAC II devices are accurate, and adherence to them enables its proper and intended use.

REMAINING ACTIONS BEING TAKEN BY TERUMO BLOOD AND CELL TECHNOLOGIES

1. Terumo Blood and Cell Technologies is actively notifying affected customers of these potential misinterpretations of the functionality of the device when following the operator’s manual.
2. Corrective and preventative actions have been initiated related to this issue, including an update to the operator’s manual for the T-RAC II-Wifi device, ME-TRAC2W.

ACTIONS REQUIRED BY HEALTHCARE PROVIDERS

1. Distribute this notification according to your procedures.
2. Continue to use your T-RAC II system at your location in accordance with the device **touch screen prompts**. Please report any issues associated with the use of this device.
3. The anticipated release date of the new operator’s manual is estimated to be in June 2026. Upon release, you can visit <https://terumo.eifu.com> to view and download the corrected version of the T-RAC II-Wifi Version 8 operator’s manual and discard the operator’s manual that was originally shipped with the product.

IMPORTANT: Please complete the attached acknowledgement and return it to your local Terumo BCT representative by June 30, 2026. The return of the acknowledgement is critical to confirm that your organization has received this important Voluntary Medical Device Field Safety Alert Notification.

We are committed to providing you with the highest level of support and to maintaining open communication regarding our products. We appreciate your continued partnership and look forward to serving you. Should you have any questions, please contact your local Terumo BCT representative for further assistance.

Sincerely,

Rachel Leong

Rachel Leong
Quality Manager, Asia Pacific

VOLUNTARY MEDICAL DEVICE FIELD SAFETY ALERT NOTIFICATION

T-RAC™ II-Wifi (Terumo Recording and Automatic Blood Collector) Version 8
Incorrect Operator's Manual Content

Acknowledgement and Receipt Form

Response Is Required

I have read and understand the instructions provided in the Field Safety Alert Notification letter of May 2026.

Yes ___ No ___

I have additional questions. I would like a Terumo Blood and Cell Technologies representative to contact me.

Yes ___ No ___

Are there any adverse events (serious injury or death) associated with this field action on the T-RAC II device at your location that have not been previously reported?

Yes ___ No ___

If yes, please explain:

Facility Name: (Please print) _____

Facility Address: _____

City _____ State _____ Zip Code _____

Print Name/Title: _____

Signature: _____

Telephone: _____ Email Address: _____