TOMTEC Imaging Systems GmbH R-2019-001 2019 SEP 19

URGENT – Field Safety Notice

TOMTEC-ARENA
Patient Data Software Issue

Dear Customer,

We detected a problem in the TOMTEC-ARENA Software, that, if it were to occur, could pose a risk for patients. This Medical Device Correction is intended to explain:

- the problem and under what circumstances it can occur
- the actions that should be taken by a customer or user to prevent risks to patients, and
- the actions planned by TOMTEC to correct the problem.

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy of this letter with the equipment Instructions for Use.

TOMTEC recently discovered a software issue associated with the Image-Com module/clinical application package (CAP) interface for 3D application in the TOMTEC-ARENA software.

If you need any further information or support concerning this issue, please contact your local TOMTEC representative at + 49 89 321 75 740.

We reported this notice to the appropriate Regulatory Agency.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

TOMTEC apologizes for any inconveniences caused by this problem.

Sincerely,

Hans Beinke
QM & RA Officer
TOMTEC

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AFFECTED PRODUCTS	TOMTEC-ARENA version software 2.20 and lower, with modules 4D LV-Analysis, 4D RV-Function, 4D MV-Assessment, 3D Cardio-View, 4D Sono-Scan, Echo-Com, 2D Cardiac Performance Analysis, QAngio. Systems running TOMTEC-ARENA software version 2.21 or higher are not affected.
PROBLEM DESCRIPTION	Measurements from one study might be stored to another study. Affected Workflow: 1. IMAGE-COM gets launched 2. Study A gets loaded into IMAGE-COM 3. Module 1 is opened 4. Measurements are done with module 1, module 1 gets closed 5. Study B gets loaded into IMAGE-COM 6. Module 2 is opened (note: Module 1 and 2 can be the same module, but don't have to). At this point, if module 2 fails to load or shuts down unexpectedly, measurements from study 1 are stored to study 2. Known reasons for modules to not launch are: **4D LV-Analysis, 4D RV-Function:** • all color (doppler) data fail message "Color data sets cannot be loaded!" • all data with less than 10 frames per heart cycle fail message: "Number of frames per heart cycle is too low." • all data with sampling time bigger than 100.0 msec (sampling frequency < 10 Hz) fail message: "Average sampling rate in data set too low!" **4D MV-Assessment:** • all data with less than 3 frames per heart cycle fail message: "Number of frames per heart cycle is too low." **4D Sono-Scan:** • all data with size > max size (70% of the shared memory on heap) fail message: "The dataset is too large and exceeds the available memory. Application will be closed." • Volume data with less than 2 frames fail message: "The dataset is not supported by the application due to invalid volume dimensions. Application will be closed."

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	• multiframe image with missing calibrated regions fail message: “The dataset is not supported by the application because of missing calibrated region. Application will be closed.“ • multiframe image with invalid calibrated regions fail message: “The dataset is not supported by the application because of an invalid calibrated region. Application will be closed“ • doppler data which is not of type Velocity (Vel8, Tur8Vel8) OR Power (Pow8Vel8) (i.e backscatter, directional power..) fail message: “The dataset is not supported by the application. Application shutdown.“ • GE compressed data (but i think IC does not load this type of data either…) fail message: “The dataset is not supported by the application. Application shutdown.“ **4D Cardio-View, Echo-Com:** These modules are only affected if they shut down unexpectedly.
HAZARD INVOLVED	• Misdiagnosis • Unnecessary or additional testing, therapies or procedures • Delay of treatment
HOW TO IDENTIFY AFFECTED PRODUCTS	TOMTEC-ARENA version software 2.20 and lower, with modules 4D LV-Analysis, 4D RV-Function, 4D MV-Assessment, 3D Cardio-View, 4D Sono-Scan, Echo-Com, 2D Cardiac Performance Analysis, QAngio. Systems running TOMTEC-ARENA software version 2.21 or higher are not affected. How to determine the TOMTEC-ARENA software version installed on your system: To identify the software version, click the question mark on the menu bar. The software version is listed in the about box (see image below). 

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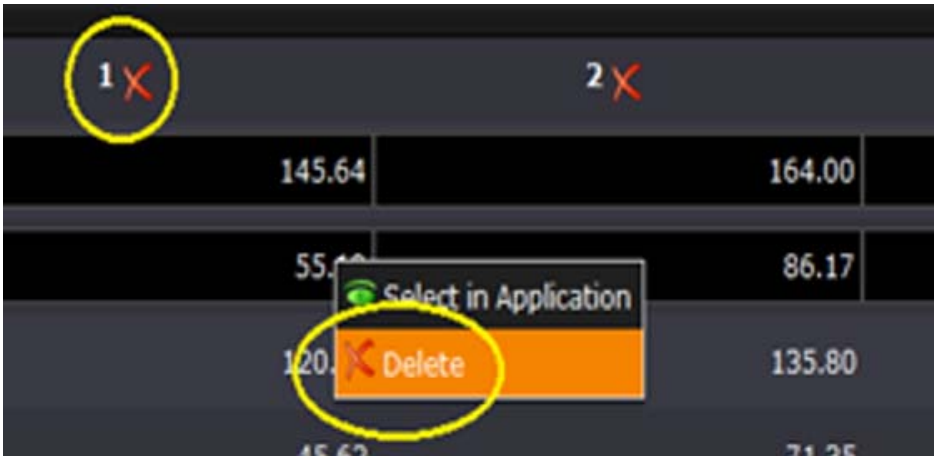
ACTION TO BE TAKEN BY CUSTOMER / USER	Action to avoid data mix up: If a CAP is initiated and the clip/image is rejected with a message being displayed (see messages described under problem description), take the following actions: 1. Close the message dialog from the CAP and move back to IMAGE-COM 2. Press the Worksheet Button ( , ) 3. Navigate through the measurements menu and check all packages (4D LVA, 4D MVA, 4D RVF, 2D CPA, 4D CV) in all groups in the exam types Adult Echo and Pediatric echo. Definition of hierarchy: • Exam Type (e.g. Adult Echo, Pediatric Echo, …) o Group (eg: Left Ventricle, Mitral Valve, Right Ventricle) ▪ Package (e.g.: 4D LVA, 4D MVA, 4D RVF, 2D CPA, 4D CV) • SubPackage (optional) o Measurement 4. Once found, delete all measurements on the above described packages by using the available delete functions.  5. All packages described above in the worksheet shall be completely empty. 6. Once finished, close the Worksheet. Please complete the included reply form on the last page and return to TOMTEC as soon as possible via email to support@tomtec.de
ACTIONS PLANNED BY TOMTEC	TOMTEC will resolve the issue by providing a software update, at no cost, to correct the issue in the software version that is currently installed on your system.

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	A TOMTEC representative will contact you to schedule the software installation.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local TOMTEC representative at + 49 89 321 75 740.

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Customer Reply Form

Please complete and email to support@tomtec.de

Contact Name	
Institution Name	
Telephone Number	
Email Address	
Facility Name	
Street Address City, State, Zip	

CUSTOMER ACKNOWLEDGEMENT:

I acknowledge that I have reviewed and understand this Urgent - Medical Device Correction Letter.

☐ **My system is not affected, because it is running a TOMTEC-ARENA software version 2.21 or higher.**

☐ **My system is affected because it is running TOMTEC-ARENA software version 2.20 or earlier. I understand the actions I need to take until my system software is updated.**

Server ID	License Number	Affected	
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No

_____ _____

CUSTOMER NAME (please print) **TITLE**

_____ _____

CUSTOMER SIGNATURE **DATE**

If you experience difficulty carrying out the instructions contained in this communication, please contact your local TOMTEC representative at + 49 89 321 75 740.