MEDICALgorithmics
INNOVATIVE SOLUTIONS IN MEDICINE

Urgent Field Safety Notice

Commercial name of the affected product:

PocketECG PC Client software

Unified Arrhythmia Diagnostic System PocketECG IV, type P4TR-CE-ADS

FSCA-identifier (e.g. date): *2025-01*

Type of FSCA:

Clarifications in Instructions for Use to remind users how to inspect PocketECG devices before each use, as ensuring the device functions properly is crucial for accurate monitoring and patient safety. Update the Jira ticketing system by adding a warning reminding end users that manual ECG data uploads and operations involving patient information require verification of the patient data assigned to the uploaded ECG

Date: *2025-04-01*

Attention: *Distributors*

Details on affected devices:

Device involved in the incident: PocketECG IV, type P4TR-CA-ADS, serial number TR4923-01784A. Sold to the client on: 2023-10-06.

Software used: PocketECG PC Client, version 9.90

Description of the problem:

On 2025-01-08, manufacturer Medicalgorithmics S.A. became aware of a serious incident that occurred in Australia.

The PocketECG IV device is designed to operate in online mode, and the PocketECG PC Client software assumes this setup when automatically linking ECG data with patient data.

The PocketECG IV, type P4TR-CA-ADS in the case in question, was not operating in online mode, and the following sequence of events led to the incident:

1. *The device did not transmit a single file during the ECG monitoring test.*
2. *The customer initiated a new monitoring session for a different patient using the same device instead of:*
    a. *Downloading the previous session's data and submitting a Jira ticket to Medicalgorithmics for upload, and*
    b. *Reporting the device problem and sending it in for investigation regarding the signal transmission failure.*
3. *During the second test, the device again failed to transmit any ECG data.*

The Australian customer did not report any problems with the device, conducted several tests with a malfunctioning device, and then submitted files for upload. The device, despite not transmitting data to the remote server, continued saving files to the SD card—this prevented data loss. Devices that don't transmit ECG data after a test should have their data manually uploaded by Medicalgorithmics and be sent in for diagnostics to determine the cause of the failure (via Jira ticket and device return for service repair).

The PocketECG IV device used for the ECG test was sent to the manufacturer to verify whether there was any malfunction of the device. Based on the results of the service analysis and software logs, the main reason for the lack of data transmission was damage to the SIM card slot, which led to interruptions in cellular network connectivity. Additionally, the device had an expired security certificate in its software.

Due to device malfunction caused by:

- *an expired security certificate (requiring a software update), and*
- *physical damage to the SIM card slot,*

the device was unable to transmit data to the remote server and it should be reported to the Medicalgorithmics and be sent in for diagnostics to determine the cause of the failure (via Jira ticket and device return for service).

Potential risk

If the patient report contains incorrect data, it can lead to an inaccurate diagnosis and serious deterioration in the state of health of a patient, e.g. surgical intervention.

The current mechanisms implemented in the PocketECG PC Client software responsible for linking patient data with ECG data, provide a secure matching process. However, there is no effective mechanism to prevent the repeated use of a malfunctioning PocketECG IV device by the customer that can be introduced to the product.

Advise on action to be taken by the user:

Fill out the customer response form to acknowledge receipt of the Field Safety Notice dated [2025-04-01] relating to the above product.

All customers are to perform regular inspection of all devices utilized for daily patient's monitoring according to the following instruction.

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Inspection instruction of the PocketECG IV devices

The user should inspect the PocketECG IV devices and its accessories before each use to ensure proper functionality, as correct device operation is essential for accurate monitoring and patient safety.

If you encounter any problems or device malfunction, please immediately contact the PocketECG manufacturer at technical@medicalgorithmics.com or report the problem using the available ticketing system, and send the device for repair.
Prior to starting a recording session, the user should check the device and it's accessories in accordance with the following instruction.

1. **Visual inspection.**
   a. Inspect the patient ECG cable bends, cuts and cracks on the enclosure of transmitter.
   b. Inspect the cracks on the enclosure of transmitter, charger and batteries. Verify whether the battery label is not damaged.

Caution. Inspect the device and all accessories before each use.

Caution. Before use inspect the casing of the device to confirm that there are no visible damages like cuts or cracks. If you notice cuts, cracks or any damage to the device, do not use it for ECG session registration, please send the device for repair.

   c. Please inspect all sections of each cable and wire to ensure there are no critical damages. If any of the evident damages mentioned above are found on any part of the wire or cable, it indicates that the cable is either already defective or may lose its electrical continuity during patient monitoring. In such cases, it is recommended to send the device for repair.

Section	Description	Criteria
1	Bend protector of the ECG cable	• Cracks, seal splitting (section 3) • insulation damages • heavy soiling that cannot be removed
2	Area directly behind the bend protector	
3	Seal of the ECG leads	
4	Segment between a clip and the ECG snap	
5	Bend protector of the ECG snaps	
6	ECG snaps	

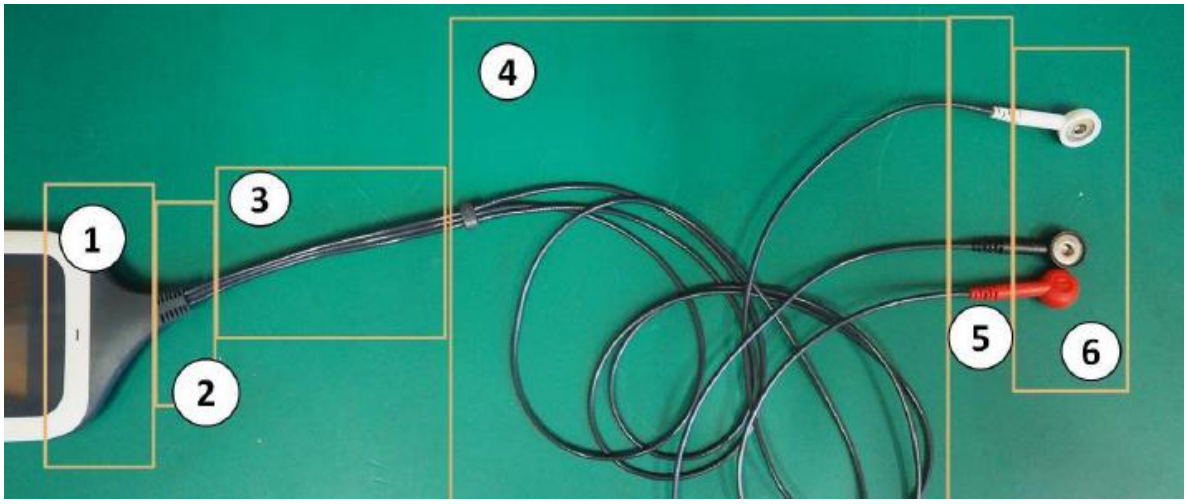


Fig. 1 Sections of cables and wires

2. Battery Check.

a. Ensure the battery is fully charged and properly inserted.

b. After placing the fully charged battery into transmitter's compartment check whether device powers up and PocketECG graphical interface is displayed.

c. The device turns on automatically. The device is ready for starting new recording session about 90 seconds after the battery is placed in battery compartment.

d. A graphical user interface comes on when the device is properly supplied with power and ready to work (for details see the figure below). Then the screen goes blank to save energy, but the device is still working.

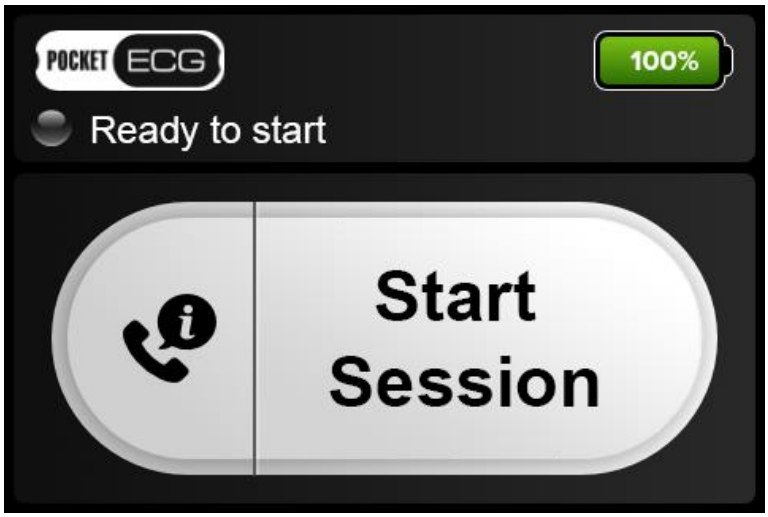


Fig. 2 Patient view' of the graphical user interface

Caution. If no image is displayed within 90 seconds after placing the battery in the battery compartment, it indicates that either the battery is fully discharged, or device does not operate correctly due to the abnormal temperature or humidity conditions, or the device itself is malfunctioning and should be sent for repair immediately.

3. Quality of the ECG signal

It is recommended to perform below presented procedure befor each use of the PocjketECG IV transmitter should check its functional efficiency and verify the correctness of displayed messages and check the condition of the equipment, especially the cables by performing the following operations:

a. Connect the ECG cables of the PocketECG transmitter the source of ECG signal, like ECG simulator (e.g. Netech MiniSim 1000 or similar) and adjust typical parameters (heart rate, amplitude) of generated ECG signal.

b. Start an ECG testing session with unlocking code typed in terminal for unlocking code.

Caution. The unlocking code is: 6 6 6 4.

c. Check for normal appearance of the waveforms with appropriate amplitude and without excessive noise. Check if signal annotations are properly displayed. If ECG simulator allows for arrhythmia simulating, you may decide to check whether they are properly detected (it will prove appropriate operation of the device).

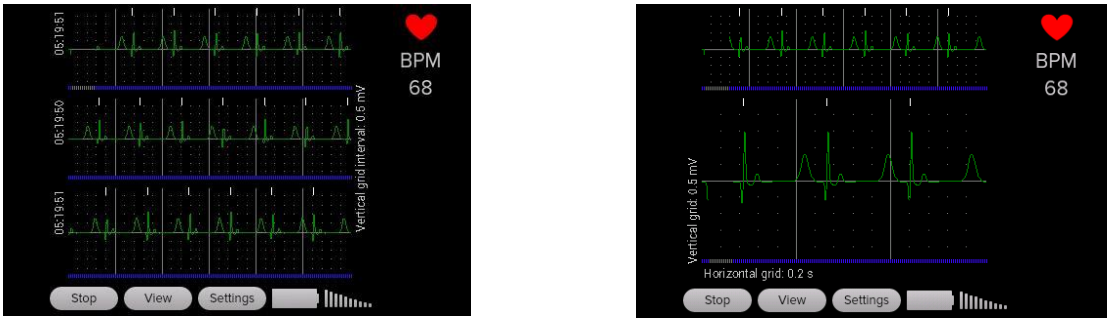


Fig. 3 Small (left) and large (right) ECG waveforms

d. Try to bend the patient cable simulating typical bending caused by patient's movements and verify whether this causes distortions of the ECG signal.

e. When the recording session begins, the ECG signal is displayed on the screen along with annotations of the classified beats and arrhythmias. The patient's heart rate is displayed in the top right corner of the screen of the PocketECG transmitter. After starting a new recording session, verify electrodes placement:

- Check the colors of the ECG clips,
- Verify the ECG signal quality for both available channels by observing the ECG signal waveform on the screen.

Caution. If the ECG signals are not presented on the PDA display and/or the 'EL' annotation is displayed, the ECG signal is not analyzed due to the overload of the PocketECG transmitter or incorrect connection between lead wires and patient's electrodes. The similar effect may occur when ECG electrodes are used and should and signal quality is insufficient.

In case any abnormalities are observed in the ECG waveform, the device may be malfunctioning and should be reported to the manufacturer immediately.

4. Wireless connectivity

a. The wireless data transmission technology, used by the mobile telephony network carriers, is utilized to transmit the ECG and acceleration data along with the results of automated signals analysis to the remote server.

Caution. The PocketECG transmitter configures the connection with the remote server automatically. If any problems with the configuration occur, please contact your PocketECG distributor or manufacturer.

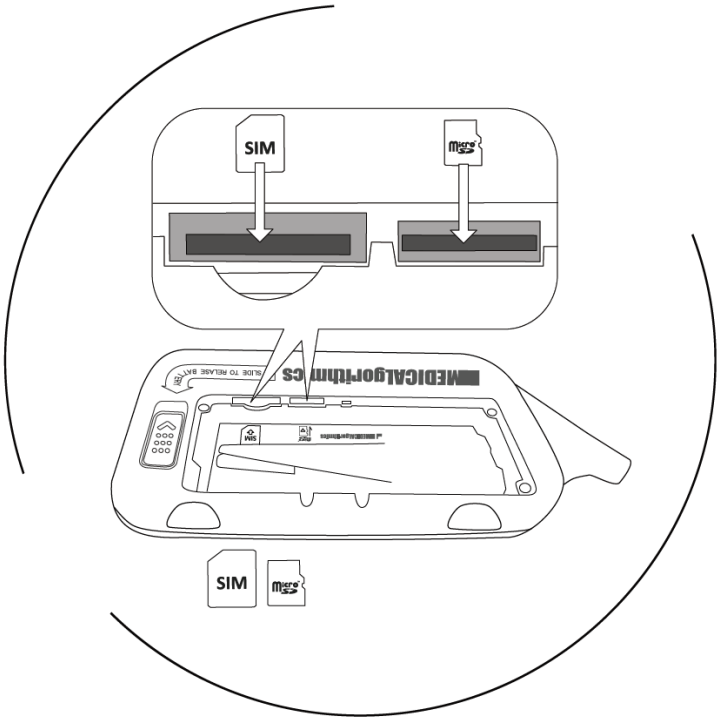
b. Ensure that the device has a stable network connection and adequate coverage for data transmission.

c. ECG signal is not transmitted if the PocketECG device is out of mobile network access. Keep the PocketECG transmitter in the area where the mobile network is accessible.

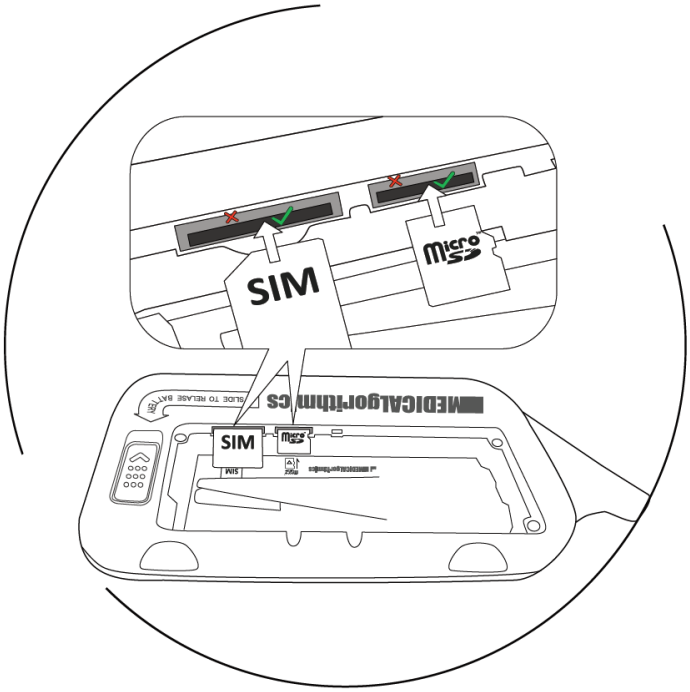
Caution. In PocketECG IV the SIM and microSD cards must be placed in its compartment before new recording session is started.

d. Make sure that the SIM and microSD cards are installed properly.

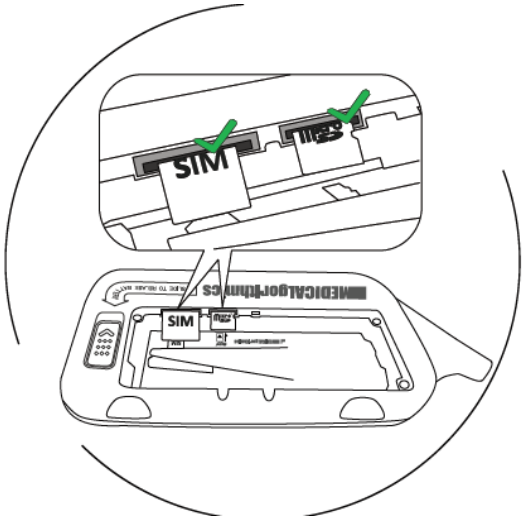
- Insert the cards into their respective compartments accordingly:

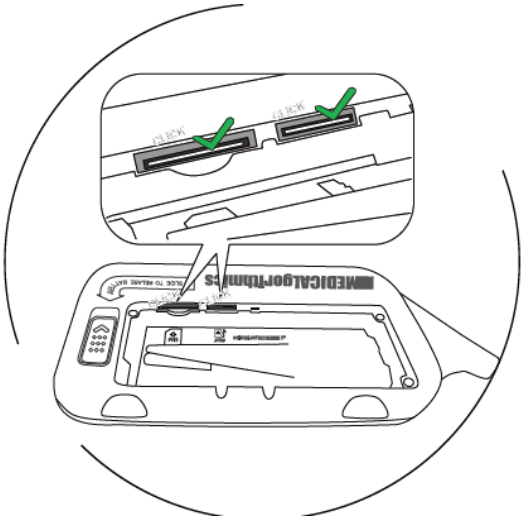


- The correct location is positioned lower than the entire gap.

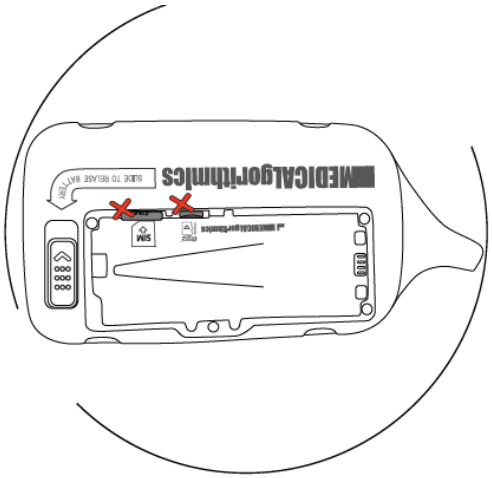


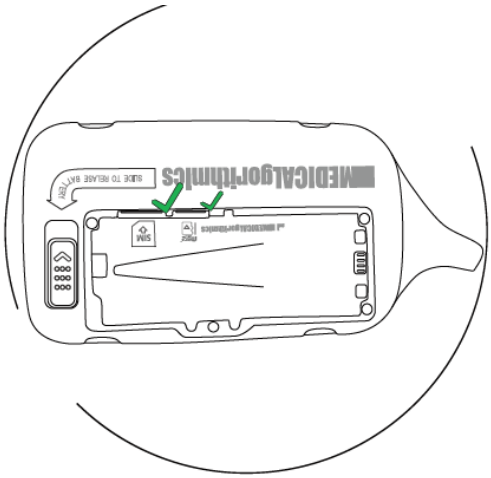
- Proper insertion of the card will be signaled by a characteristic click.





- The card should be hidden completely. Please ensure that you do not insert the card into the incorrect slot.





e. In order to check cellular network connection perform the following operations:
   - Start network testing with unlocking code typed in terminal for unlocking code.

Caution. The unlocking code is: 6 6 6 3

   - Signal quality test will be conducted for 30 seconds. As a result average signal quality will be shown as 0-3 marks, where 3 marks is a maximum signal quality.
   - After signal quality test the upload test starts automatically. The transmitter will send 10 kb of sample data do the server. There will be maximum 3 upload attempts. If none of upload attempts will be successful then the test result is failure. If the test result is failure, do not use the device for ECG session registration, please send the device for repair.

f. User can also perform transmission test using PC Client software. As a first step the test session should be started in the PC Client software. In the next step make sure that the recording session has been successfully started on the PocketECG transmitter, and listed in the PocketECG PC Client application.

g. Check the session status in the 'supervisor view' → ‘About’ → ‘Session info’ - the '[OK]' text string indicates that the wireless connection between PocketECG transmitter and remote server has been successfully established. If instead of '[OK]' an error code is displayed in the brackets, the transmitter cannot connect to the remote server. Ensure that the Internet connection is properly configured on the phone and that it is within the mobile network range. If the '[OK]' status is displayed and the newly started recording session still cannot be found in the PocketECG PC Client application, the PC operating PocketECG PC Client does not have an active Internet connection. Consult your PocketECG distributor or service provider for support.

h. The logo of service provider is displayed on the top of the screen and phone number is displayed in the middle of the screen. There are 4 data sections displayed on the bottom of the screen placed in square brackets. Every data section contains single letter identifier:
   - S - last known signal strength,
   - T - time of last successful data transmission or "NA" if there was no successful transmission,

- F - failed data transmission counter - it is reset after successful transmission,
- R - indicates whether device was successfully registered to the network in last attempt - displays "T" or "F" - true/false.

i. In case where the PocketECG transmitter cannot maintain a permanent connection to the cellular network and the notification shown below appears on the screen, data cannot be transmitted to the remote server. Please check the SIM card and if the problem persists, report the device to manufacturer immediately.

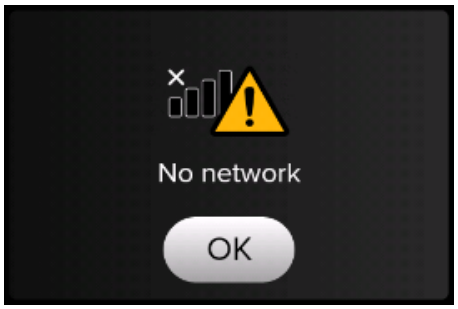


Fig. 4 „No network" notification

5. Manual ECG data upload

The PocketECG IV device is designed to operate in online mode, and the PocketECG PC Client assumes this configuration when automatically linking ECG data with patient information. In cases where the device's wireless communication fails, the PocketECG IV device continues to save files to the SD card, preventing ECG data loss despite not transmitting data to the remote server. Devices that fail to transmit ECG data following a test should have their data manually uploaded by Medicalgorithmics and be sent in for diagnostics to determine the cause of the failure.

In the case of a manual ECG data upload, a Jira ticket containing the monitoring session data should be created by the customer. The ECG data awaiting upload to the PocketECG PC Client software should be attached to the ticket along with the upload request.

The end user is required to double-check the accuracy of the information displayed in the PC Client software. The end user is responsible for verifying that the ECG data is correctly matched with the patient information following a manual ECG upload. If the patient report contains incorrect data, it can result in an inaccurate diagnosis and serious health consequences for the patient, including unnecessary surgical interventions.

6. Service

Service is provided only by Medicalgorithmics S.A. In case of any product malfunction a device shall be returned directly to manufacturer to the following address:
MEDICALGORITHMICS S.A.
Aleje Jerozolimskie 81
02-001 Warsaw, Poland
e-mail: technical@medicalgorithmics.com

Furthermore, the user is strongly recommended to follow the guidelines described in Instructions for Use for the PocketECG IV Unified Arrhythmia Diagnostic System.

Transmission of this Field Safety Notice: (If appropriate)

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. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

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

Contact reference person:

Name/organization, address, contact details

Medicalgorithmics S.A.
Aleje Jerozolimskie 81
02-001 Warszawa, Polska

regulatory@medicalgorithmics.com
The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Signature

Karolina Rudzka

Regulatory Affairs and Quality Assurance Manager
Medicalgorithmics S.A.

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2025-01
FSN Date*	2025-04-01
Product/ Device name*	Unified Arrhythmia Diagnostic System PocketECG IV
Product Code(s)	P4TR-CE-ADS
Batch/Serial Number (s)	N/A

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	Other Action (Define):			
☐	I do not have any affected devices.	Customer to complete or enter N/A		

☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	regulatory@medicalgorithmics.com
Customer Helpline	+48 22 825 12 49
Postal Address	Medicalgorithmics S.A. Aleje Jerozolimskie 81 02-001 Warsaw, Poland
Web Portal	https://www.medicalgorithmics.com/
Fax	N/A
Deadline for returning the customer reply form*	Please complete, sign, and return this form to the above email address within 30 business days of being sent by Medicalgorithmics S.A.

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.