Date: 21 May 2024

Urgent Field Safety Notice
DataLinQ 2PAD

This form is based on the Field Safety Notice as provided by the European Commission, Rev1 Sept 2018 [link]

For attention of:

Country	Customer/Hospital	Contact
NL	Albert Schweitzer Ziekenhuis	
NL	Canisius Wilhelmina Ziekenhuis	
NL	Elkerliek Ziekenhuis	
NL	Nij Smellinghe	
NL	OLVG	
NL	UMC Utrecht + WKZ	naar;
NL	Van Weel Bethesda (Curamare)	
NL	Wilhelmina Ziekenhuis	
NL	ZGT	
NL	Saxenburgh	
NL	Meander Medisch centrum	
NL	Deventer Ziekenhuis	

Contact details of local representative (name, e-mail, telephone, address, etc.)	
Company:	
Contact:	
Email:	
Phone:	

Urgent Field Safety Notice (FSN)
DataLinQ 2PAD
Risk addressed by FSN

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

1. Information on Affected Devices*	
1. Device Types*	DataLinQ 2PAD, consists of a touchscreen and the DataLinQ USG. The touchscreen is used for the operation of the 2PAD and (wireless) connectivity. The USG is the data-hub which connects to pacemaker programmers and which transmits data to the touchscreen. This is a non-sterile product.
2. Commercial name(s)	DataLinQ 2PAD
3. Unique Device Identifiers(s) (UDI-DI)	08719689142049
4. Primary clinical purpose of device(s)*	DataLinQ is intended to be used by professional users for data collection, report generation, storage and processing from bedside, point of care biomedical devices, like, but not only, pacemaker programmers and clinical information management systems. DataLinQ is not intended for monitoring purposes, nor is it intended to control any of the biomedical devices and information systems with which it interconnects. DataLinQ can be used in networked environment or a as standalone system. Data may be provided or received from/to 3rd part systems, via multiple formats (e.g. HL7, DICOM, XML).
5. Device Model/Catalogue/part number(s)*	DataLinQ brochure DLT1-193-BA.003_EN
6. Software version	DataLinQ 2PAD V4.0.x
7. Affected serial or lot number range	n/a
8. Associated devices	n/a

2. Reason for Field Safety Corrective Action (FSCA)*	
1. Description of the product problem	With the distribution of 2PAD v4.0.1 and v4.0.2 an incorrect data configuration was made available for the Medtronic programmer exports.
2. Hazard giving rise to the FSCA*	Misrepresentation of data
3. Probability of problem arising	Very likely, probable at all sites affected by FSN

4. Predicted risk to patient/users	Misrepresentation of data might lead to wrongful assessment of device or patient status
5. Further information to help characterize the problem	N/A
6. Background on Issue	This issue was registered by OLVG (Amsterdam, NLD) on 11 Apr 2024, which has been formalized in complaint #18208.
7. Other information relevant to FSCA	-

3. Type of Action to mitigate the risk*	
1. Action To Be Taken by the User*	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Identify devices that might be affected by FSA, so that software update of the device can be scheduled.
2. By when should the action be completed	19-04-2024 Plan customers: Update Patch being scheduled from week 17(next week) Fysicon expect the turn around time for the deployment of the updates (as result of the holiday season) to take up to 3 to 4 weeks 02-05-2024 Patch updates performed except of three clients on which we are waiting for their availably
3. Particular consideration for:	-
Is follow-up of patients or review of patients' previous results recommended?	No
4. Is customer Reply Required? *	No
(If yes, form attached specifying deadline for return)	-
5. Action Being Taken by the Manufacturer	☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None ☐ Product Removal ☐ On-site device modification/inspection
6. By when should the action be completed	Excepted end of June 2024

7. Is the FSN required to be communicated to the patient /lay user?	No
8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	No Not appended to this FSN

4. General Information*	
1. FSN Type*	New
2. For updated FSN, reference number and date of previous FSN	2404 5455, Your reference number: Fysicon, request FSCA report
3. For Updated FSN, key new information as follows:	Ref NB IT; 2093816 final FSCA report
4. Further advice or information already expected in follow-up FSN? *	Yes
5. If follow-up FSN expected, what is the further advice expected to relate to:	Software update to be provided
6. Anticipated timescale for follow-up FSN	Patch v4.0.3 available as of Apr 16, 2024
7. Manufacturer information (Contact details of local representative can be found on page 1 of this FSN)	a. Company Name: b. Address:
8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers*	Yes, on Apr 19, 2024 • IGJ, Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd), • Notified Body Kiwa Dare,
9. List of attachments/appendices:	-
10. Name/Signature	

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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*