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Date: 19/03/2020

# Urgent Field Safety Notice
# AC power supply module

For Attention of*: MK-MED AG Medizintechnik

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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# Urgent Field Safety Notice (FSN)
# AC power supply module

## Risk addressed by FSN

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | A Power supply module that provides a power source to the Base Unit  |
| 1. | 2. Commercial name(s) |
| | AC power supply module |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | N/A |
| 1. | 4. Primary clinical purpose of device(s)* |
| | The Power supply Module is the Warrior power source. The Warrior is a blood and fluid Warmer device. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | QACPLUS1000 |

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| 1. | 6. Software version |
| | N/A |
| 1. | 7. Affected serial or lot number range |
| | ACM00068, ACM00091, ACM00092 |
| 1. | 8. Associated devices |
| | N/A |

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| | **2 Reason for Field Safety Corrective Action (FSCA)*** |
| 2. | 1. Description of the product problem* |
| | Following customer complaints on Electromagnetic disturbance on ECG monitor and higher than expected patient leakage current we confirmed that a new electrical disturbance is present in few of the latest batches of the AC power supply units, an off-the-shelf IEC60601-1 certified medical-grade component, embedded in our AC module. The disturbance increased the leakage current beyond the allowable limits. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | A Leakage current beyond the allowable limits can risk the patient |
| 2. | 3. Probability of problem arising |
| | N/A |
| 2. | 4. Predicted risk to patient/users |
| | N/A |
| 2. | 5. Further information to help characterise the problem |
| | N/A |
| 2. | 6. Background on Issue |
| | N/A |
| 2. | 7. Other information relevant to FSCA |
| | It was further verified that the disturbance is stemming from the Power Supply and is not present in battery-operable mode. |

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| | **3. Type of Action to mitigate the risk*** | |
| **3.** | **1. Action To Be Taken by the User*** | |
| | ☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device<br>☐ On-site device modification/inspection<br>☐ Follow patient management recommendations<br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br>☒ Other ☐ None<br>Provide further details of the action(s) identified. QinFlow instructed impacted customers to refrain from using the affected AC Power Supply Module until the company will rework the affected units. | |
| 3. | 2. By when should the action be completed? | N/A |

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| 3. | 3. Particular considerations for: Choose an item.<br><br>Is follow-up of patients or review of patients' previous results recommended?<br>No<br><br>Provide further details of patient-level follow-up if required or a justification why none is required | |
| 3. | 4. Is customer Reply Required? * No<br>(If yes, form attached specifying deadline for return) | Choose an item. |
| **3.** | **5. Action Being Taken by the Manufacturer**<br><br>☐ Product Removal ☒ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br><br>The units will be re-Worked By QinFlow's engineer as soon as they are collected by the distributor | |
| 3 | 6. By when should the action be completed? | As Soon as the affected units are connected by the local distributor |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | No |
| 3 | 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? | |
| | Choose an item. Choose an item. | |

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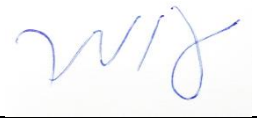
| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | N/A |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | N/A | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | Yes |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | Follow up FSN is expected to be issued upon the re-work process in Switzerland | |
| 4 | 6. Anticipated timescale for follow-up FSN | N/A |
| 4. | 7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Quality In Flow (QinFlow) |
| | b. Address | 11 Ha'avoda street, Rosh Ha'ayin, Israel |
| | c. Website address | www.qinflow.com |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes | |
| 4. | 9. List of attachments/appendices: | If extensive consider providing web-link instead. |
| 4. | 10. Name/Signature | **Omer Pechter**  |

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

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