Rev 1: July 2020
FSN Ref: FSN 2020-00001 FSCA Ref: FSCA 2020-00001

Date: 27 Jul 2020

# Urgent Field Safety Notice
# OMNI II Programmer with OMNI Smart Application Software (4.4.9.0)

For Attention of*: All Physician and Allied Health Care Provider Users of the OPTIMIZER Smart System

| Contact details of local representative (name, e-mail, telephone, address etc.) * |
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# Urgent Field Safety Notice (FSN)
# OMNI II Programmer with OMNI Smart Application Software (4.4.9.0)
# Risk addressed by FSN

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | Device Programmer |
| 1. | 2. Commercial name(s) |
| | OMNI II Programmer with OMNI Smart Application Software |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 00810003380036 |
| 1. | 4. Primary clinical purpose of device(s)* |
| | To interrogate and program the OPTIMIZER Smart IPG |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | 10-A604-3-EU,10-A604-3-US, 10-A604-3-BR, 10-A604-3-AU, 10-A604-3-RU |
| 1. | 6. Software version |
| | 4.4.9.0 |
| 1. | 7. Affected serial or lot number range |
| | All OMNI II Programmers with OMNI Smart Application Software 4.4.9.0 manufactured and/or upgraded after October 2016 |
| 1. | 8. Associated devices |
| | OPTIMIZER Smart IPG |

| 2 Reason for Field Safety Corrective Action (FSCA)* | |
|---|---|
| 2. | 1. Description of the product problem* |
| | %Therapy values are incorrect on hard copy Zebra printer output. Values are correct on display screen of programmer. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | Physician may use incorrect %Therapy values to adjust IPG therapy intensity if the print-out is used instead of the screen display on the programmer. |
| 2. | 3. Probability of problem arising |
| | Problem is highly likely to occur with users using Smart Application software 4.4.9.0 in the clinic. |
| 2. | 4. Predicted risk to patient/users |
| | Risk to patient is minimal and it represents indirect harm |
| 2. | 5. Further information to help characterise the problem |
| | NA |
| 2. | 6. Background on Issue |
| | Discrepancy in values for the Display screen and printout was observed in the clinic and reproduced with stock inventory by the manufacturer. Since it would not be standard of care practice to reduce the %Therapy delivered to patient and an increase in therapy presents no harm, risk to patient is minimal and represents indirect harm. The only potential harm would be if %Therapy were low and physician did not take action to increase therapy. The %Therapy total and 24 hours are usually close and it is not |


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| | expected that this scenario will occur even if the numbers are transposed on the print out and the physician uses it to decide care for the patient and not the display screen. |
| 2. | 7. Other information relevant to FSCA |
| | This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA. |

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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. | |
| 3. | 2. By when the action should be completed? | Specify where critical to patient/end user safety<br>Identifying affected devices – July 27, 2020<br>Quarantining affected devices – September 1, 2020<br>Implementing software upgrade fix – November 1, 2020 |
| 3. | 3. Particular considerations for: Choose an item.<br>Is follow-up of patients or review of patients' previous results recommended? Patient review of previous results is not necessary because only current results play a role in determining effectiveness of therapy. | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |
| **3.** | **5. Action Being Taken by the Manufacturer**<br>☐ Product Removal ☐ On-site device modification/inspection<br>☒ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br>Provide further details of the action(s) identified. | |
| 3 | 6. By when should the action be completed? | November 1, 2020 |
| 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? | |
| | No 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 | Provide reference and date of previous FSN if relevant |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | Summarise any key difference in devices affected and/or action to be taken. | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | No |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | Eg patient management, device modifications etc | |
| 4 | 6. Anticipated timescale for follow-up FSN | For provision of updated advice. |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Only necessary if not evident on letter-head. |
| | b. Address | Only necessary if not evident on letter-head. |
| | c. Website address | Only necessary if not evident on letter-head. |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | If extensive consider providing web-link instead. |
| 4. | 10. Name/Signature | Deborah Morley Ph.D.<br>Vice President Regulatory Affairs and Quality Assurance |

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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.



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