Rev 1: September 2018
FSN Ref: FSN2026-001 FSCA Ref: FSCA2026-001

FSCA Date: 27 April 2026

# Urgent Field Safety Notice

## Gentuity HF-OCT Console Software Version 21.11 to Version 23.3.13

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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| Quality Department Nipro Medical Europe NV, Blokhuisstraat 422800, Mechelen, BELGIUM, T: +32 15 263 500; quality@nipro-europe.com |

Gentuity, LLC

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# Urgent Field Safety Notice (FSN)
# Gentuity HF-OCT Console Software Version 21.11 to Version 23.3.13

## Risk addressed by FSN

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | Gentuity HF-OCT Console |
| 1. | 2. Commercial name(s) |
| | Gentuity HF-OCT Console |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 00859910007032 |
| 1. | 4. Primary clinical purpose of device(s)* |
| | The Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter is intended for intravascular imaging and is indicated for use in coronary arteries in patients who are candidates for transluminal interventional procedures. The Vis-Rx Micro-Imaging Catheter is also intended for use prior to or following transluminal interventional procedures. The Vis-Rx Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx Micro-Imaging Catheter is also intended for use prior to or following transluminal interventional procedures. The Vis-Rx Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | G10-01 |
| 1. | 6. Software version |
| | 21.11 through 23.3.13 |
| 1. | 7. Affected serial number range |
| | 22H0107 to 26B0200 |
| 1. | 8. Associated devices |
| | None |

| 2 Reason for Field Safety Corrective Action (FSCA)* | |
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| 2. | 1. Description of the product problem* |
| | The affected software contains a defect in which the HF-OCT console may generate repeated, unintended duplication of frames during the initial (distal) portion of the pullback. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | When duplication of frames occurs, the same image is repeated over several frames at the beginning (i.e., most distal) section of the pullback, and the stationary segment is incorrectly included in the system's longitudinal distance calculation. This may result in inaccurate longitudinal (i.e., length) measurements if the user does not adjust the measurement start point to exclude the repeated frames. |
| 2. | 3. Probability of problem arising |
| | Since 2022, Gentuity has received 14 complaints related to repeated frames from 5,169 catheters placed on the market worldwide. Of these, 4 of the 5,169 (0.08%) were related to incorrect longitudinal measurement that could have resulted in a potential treatment selection risk; however, only 1 of these involved a clinical decision in which the repeated |

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| | frames artifact contributed to the selection of a non-optimal stent length (estimated occurrence of 0.02%). |
| 2. | 4. Predicted risk to patient/users |
| | The patient received a coronary stent longer than what was deemed to be clinically optimal. The complaint indicated that there was no patient impact. Based on the low frequency of occurrence, the limited clinical impact associated with stent length selection alone, the availability of multiple imaging modalities for lesion assessment, and the presence of routine procedural safeguards (angiographic visualization of radio-opaque stent length markers during stent deployment), this issue does not represent a new or increased risk to patient health and remains within the Low residual risk category. |
| 2. | 5. Further information to help characterise the problem |
| | N/A |
| 2. | 6. Background on Issue |
| | On 3-NOV-2025, Gentuity became aware of a complaint from their Japanese distributor (Goodman) reporting that, during a procedure performed by Dr. Sugaya at Hanaoka Hospital, a stent was implanted with a longer length than would have been clinically optimal. The physician attributed the stent length selection to repeating image frames observed during HF-OCT pullback. The physician also raised concerns regarding the accuracy of longitudinal measurements, specifically within the central 80% of the pullback. The physician indicated that, in his perspective, the event warranted organizational review due to its impact on the procedure. |
| 2. | 7. Other information relevant to FSCA |
| | NA |

## 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*

☐ *On-site device modification/inspection*

☐ *Follow patient management recommendations*

☒ *Take note of amendment/reinforcement of Instructions For Use (IFU)*

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| ***1. Action To Be Taken by the User**** | Users may continue to use the HF-OCT system.<br>Gentuity is providing this field safety notice along with an updated Operator Manual (section 7.16 in attachment) with instructions to all HF-OCT users, instructing operators on safe handling, on how to recognize and mitigate the repeated frames condition, during pullback.<br><br>The updated manual provides:<br>1. Guidance to verify that the image is changing along the length of the pullback before initiating longitudinal measurements;<br>2. Instructions to identify and exclude repeated frames at the start (i.e., most distal segment) of pullback;<br>3. Steps to remeasure if measurement accuracy is uncertain; and<br>4. Training reinforcement for all operators.<br><br>These user level actions ensure safe continued use of the device.<br><br>Users are advised to carry out the following actions: |

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| | 1) Forward this field safety notice to all operators and individuals within your organization or department who need to be informed, particularly those users of the devices that may be affected,<br>2) Please retain a copy of this letter available for all users, file a copy in the relevant system and keep a copy of the filled-out acknowledgment form in your records and send a copy as instructed below,<br>3) verify image advancement at the start (i.e, most distal segment) of pullback,<br>4) exclude any repeated frames before setting the longitudinal measurement start point,<br>5) repeat length measurements to exclude repeated frames if initial HF-OCT length measurements are uncertain,<br>6) ensure all operators are trained on these steps.<br><br>These actions minimize the risk of inaccurate length assessment and are effective **immediately**.<br>Pending long-term mitigation (e.g., future software updates), these actions will remain in place as the **interim corrective measure**. No product removal is required, and **no product shortage** is anticipated.<br>There are **no associated private label products, kits, or -sub recalls**.<br><br>Users are instructed to acknowledge receipt of this field safety notice, fill out the attached acknowledgment form and send it back via **email (**quality@nipro-europe.com **)** by 26 August 2026 confirming that the instructions have been received, reviewed, and shared with all applicable clinical staff. |
| ***2. Further information and support*** | If you need further information or assistance regarding this medical device correction, please contact your representative at Nipro Medical Europe NV, Blokhuisstraat 422800, Mechelen, BELGIUM, at the number listed below:<br>T: +32 15 263 500 (8:00 a.m. to 6:00 p.m. CET) quality@nipro-europe.com |

☐ *Other* ☐ *None*

*Provide further details of the action(s) identified.*

3. 2. By when should the action be completed? 7 September 2026

| ID# | Actions description | Responsible | By when |
|---|---|---|---|
| 1 | Identify all affected devices listed in section 1, | Gentuity and the European Distributor Nipro Medical Europe NV | Immediately or within 10 calendar days form the receiving of the field safety notice |
| 2 | Fill the Acknowledgment Letter Distributor_Importer , including the number of devices, used at your premises. | European Distributor Nipro Medical Europe NV | Within 15 calendar days from the receipt of the present field safety notice |
| 3. | Sending via e-mail and certified mail to all customers and European Representative the FSN (all languages) and Customer reply letter (all languages), | European Distributor Nipro Medical Europe NV | Within 10 calendar days from the receipt of the FSN (all languages) and Customer reply letter (all languages), |
| 4. | Fill the and return e-mail or certified mail the Customer reply to Nipro Medical Europe NV Email quality@nipro-europe.com Telephone number +32 15 263 500 | Customers | Within 30 calendar days from receiving the filed safety notice and Customer reply letter |

3. 3. Particular considerations for: Diagnostic Imaging device

Is follow-up of patients or review of patients' previous results recommended?
No

NA

3. 4. Is customer Reply Required? * Yes
(If yes, form attached specifying deadline for return)

**3. 5. Action Being Taken by the Manufacturer**

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☒ IFU or labelling change
☐ Other ☐ None

Based on the risk evaluation and frequency of failures and complaints, as conservative approach and a protective measure to maintain patient health, the manufacturer decided to issue this Field Safety Notice to all affected customers.
The Field Safety Notice identifies the problem, the affected products, the risk factors and the actions that must be taken by the users and distributors.

3 6. By when should the action be completed? 7 September 2026

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| 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 Not appended to this FSN | |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | NA |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | NA | |
| 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: | |
| | NA | |
| 4 | 6. Anticipated timescale for follow-up FSN | NA |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Gentuity, LLC |
| | b. Address | 142 North Road, Sudbury, MA 01776 |
| | c. Website address | www.gentuity.com |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | 01. Acknowledgment letter Distributor_Importer Ver1.0.<br>02. Customer Reply Ver 1.0 |
| 4. | 1. Name/Signature | Insert Name and Title here and signature below |

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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. |

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| | 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.*<br><br>Definition:<br>'serious incident' (EU MDR 2017/745) means any incident that directly or indirectly led, might have led or might lead to any of the following:<br>(a) the death of a patient, user or other person,<br>(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,<br>(c) a serious public health threat. |

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