Gentuity, LLC, March 16, 2026

URGENT: MEDICAL DEVICE RECALL – REVISED OPERATOR MANUAL
for SOFTWARE WITH THE POTENTIAL TO DISPLAY REPEATED FRAMES

<Gentuity HF-OCT Console Software Version 21.11 to Version 23.3.13 >

(1) Attention to Customer:

Customer Name
Device Name
Street Address
City, State, Zip Code

Dear Device Customer,

(2) Purpose of this letter

*The purpose of this letter is to notify you that Gentuity LLC. is implementing a **correction** (in accordance with 21CFR 806) related to the potential for repeated frames during HF-OCT pullback when using the Gentuity HF-OCT Imaging System (software version 21.11 to 23.3.13) with the Vis-Rx and Vis-Rx Prime Micro-Imaging Catheters. This correction is intended to ensure that users are fully informed of how to recognize, avoid, and mitigate this condition to maintain accurate longitudinal (length) measurements during OCT imaging.*

*This communication provides information describing the issue and its potential impact on clinical measurements, instructions for safe and proper device use to minimize any risk to patients, required user actions to identify and exclude repeated frames during pullback; and confirmation that this is a **correction only**, not a product removal.*

Intended Use:
The Gentuity® HF-OCT Imaging System with Vis-Rx Prime 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® Prime Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx® Prime Micro-Imaging Catheter is also intended for use prior to or following transluminal interventional procedures. The Vis-Rx® Prime Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.

(3) Reason for the Voluntary Recall:

Product Concern:
*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**.*

When this 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 (ie, length) measurements*** *if the user does not adjust the measurement start point to exclude the repeated frames.*

- **Frequency of failures and complaints:** *Since 2022, Gentuity has received 14 complaints related to repeated frames* ***from*** **5,169** ***catheters.*** *Of these, 4 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 frames artifact contributed to the selection of a* ***non-optimal stent length*** *(estimated occurrence of 0.02%).*

  HF-OCT imaging is used in conjunction with other clinical modalities (e.g., angiography) for stent planning and is ***not intended to be used as the sole method*** *for determining stent length selection.*

- **Magnitude of the error, if applicable**: *When the repeated frames condition occurs, the potential magnitude of measurement error (approximately 8 to 10 mm) is limited to the length of the segment including repeated frames in the distal part of the pullback.* In one reported case, this resulted in an approximate 10 mm overestimation of the length of a lesion, which subsequently contributed to a longer stent being implanted than was clinically optimal.

Adverse events (that is, injuries, deaths): *There have been* ***no injuries, deaths, or other adverse clinical outcomes*** *reported in any of the 14 complaints because of this issue. The single complaint involving sub-optimal stent length selection was documented as not resulting in patient harm.*

(4) Risk to Health:

*The reported device issue involves the occurrence of **repeated frames during the HF-OCT pullback**, which can lead to **inaccurate longitudinal length measurements** if the user does not recognize and exclude the stationary segment before performing measurements. The potential impacts are as follows:*

Impact on Patients

1. Potential for Suboptimal Treatment Decisions
*If a measurement is made on a distal segment of the pullback that includes repeated frames, the system may overestimate the length of the measured segment. This may result in the clinician selecting a **longer stent than is clinically necessary, resulting in sub-optimal treatment.***

*Note: The limited magnitude of the potential measurement error, the availability of multiple imaging modalities for lesion assessment, and the procedural safeguards inherent to PCI practice (including angiographic verification of stent length prior to deployment) contributes to a significant reduction in the overall risk of such a **sub-optimal treatment.***

2. No Evidence of Immediate Patient Injury in the Reported Case
*In the reviewed complaint data (2022–2026), there were **no reports of patient injury, emergent complications, or adverse events** associated with this failure mode. Nonetheless, incorrect length measurement is considered a **potential malfunction that may** influence treatment choices.*

Impact on Health-Care Providers

1. Potential Delay in Treatment
If repeated frames are recognized intra-procedurally, the operator may need to:

- *Re-measure the vessel segment in an area that excludes repeated frames.*
  *These steps can contribute to **increased procedure time**, although no delays were reported in the referenced case.*

2. Increased Cognitive Burden and Workflow Interruption
When HF-OCT output does not match angiographic impressions or clinical expectations, the operator must use clinical judgement incorporating all information from angiography as well as HF-OCT to make an optimal treatment decision. This may:

- *interrupt workflow,*
- *increase cognitive demand on the operator,*
- *require repeated image review, and*
- *cause temporary uncertainty about the accuracy of system outputs.*

3. Training or Technique Reinforcement Requirements
*Because accurate length measurement relies on the user repositioning the measurement start point to exclude repeated frames in the distal segment of the pullback, additional user education may be required. Gentuity addressed this need through a **technical bulletin and/or updated operator manual instructions** (section 7.16) to reinforce recognition and proper handling of the condition.*

When the HF-OCT pullback starts, the system must synchronize catheter movement with image acquisition. If this synchronization is delayed, the system may capture several identical frames before physical movement of the catheter begins. These repeated frames in the distal segment of the pullback may be mistakenly interpreted as real anatomical length, causing length measurements to appear longer than they actually are.

Users may identify that the device is not operating correctly by observing the following characteristics during an HF-OCT pullback:

- ***Stationary Frames at the Start (Most Distal Segment) of Pullback:***
  The HF-OCT image appears "frozen" for several frames, with no change in the longitudinal view.
- ***Repeated Cross-Sectional Images:***
  Multiple identical slices appear consecutively, rather than changing along the length of the pullback.
- ***Unexpectedly Long Measured Length:***
  The displayed length may be significantly longer than angiographic or clinical estimation.
- ***Mismatch Between Views:***
  Cross-sectional and longitudinal views may both show lack of movement over the most distal segment of the pullback.

(5) Actions to be taken by the Customer/User:

Users may continue to use the HF-OCT system. Gentuity has issued an updated ***Operators Manual (attached)*** *instructing operators on safe handling and recognition of the repeated frames phenomenon. Users are advised to (1) verify image advancement at the start (i.e, most distal segment) of pullback, (2) exclude any repeated frames before setting the longitudinal measurement start point, (3) repeat length measurements to exclude repeated frames if initial HF-OCT length measurements are uncertain (4) ensure all operators are trained on these steps. These actions minimize the risk of inaccurate length assessment and are effective* ***immediately****.*

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. There are* ***no associated private label products, kits, or -sub recalls****.*

Users are instructed to acknowledge receipt of the Technical Bulletin by replying via ***email (complaints@gentuity.com)****, or customer service (*888-967-7628*) by April 30, 2026 confirming that the instructions have been received, reviewed, and shared with all applicable clinical staff.*

(6) Product and Distribution Information: This table is not limited to the information listed below; please insert additional information as applicable. Photographs of the product are optional.

Table of 28 Serial Numbers, Mfg. Dates, and Distribution Dates

Product Names, UDI	Mfg. Product Number/ Catalog Number	Lot/Serial Number 001567	Mfg. Date 001567	Distribution Date 001838	Quantity
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	23C0113	04/21/2023	06/06/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22J0101	09/23/2022	03/01/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	20A0202	04/07/2021	05/12/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	23F0101	06/23/2023	06/30/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22F0113	08/12/2022	08/23/2022	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22L0100	12/12/2022	08/11/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	26B0203	03/04/2026	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	26B0200	03/04/2026	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	26B0204	03/04/2026	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	26B0202	03/04/2026	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	26B0201	03/04/2026	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	25L0302	12/09/2025	N/A	1

Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22E0204	05/11/2022	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22J0102	09/26/2022	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	24H0101	08/28/2024	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	24H0102	08/28/2024	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	23K0201	10/26/2023	N/A	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	20A0203	08/20/2021	01/20/2022	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22K0306	12/06/2022	12/08/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	20A0201	01/02/2020	03/16/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	25J0200	10/07/2025	02/09/2026	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	23C0110	03/28/2023	03/30/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22K0305	12/12/2022	11/07/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	25E0100	05/27/2025	10/07/2025	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22F0110	07/26/2022	08/03/2022	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22K0304	12/15/2022	05/31/2023	1
Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	22K0302	11/03/2022	05/04/2023	1

Gentuity HF-OCT Imaging System 00859910007032	001838 / G10-01	24B0107	03/05/2024	03/18/2024	1

(7) Type of Action by the Company:

Short-term Corrective Actions (Implemented Immediately):

Gentuity is providing this letter along with an updated Operator Manual (section 7.16) with instructions to all HF-OCT users in the US instructing clinicians on how to recognize and mitigate the repeated frames condition during pullback.

The updated manual provides:

- Guidance to verify that the image is changing along the length of the pullback before initiating longitudinal measurements;
- Instructions to identify and exclude repeated frames at the start (i.e., most distal segment) of pullback;
- Steps to remeasure if measurement accuracy is uncertain; and
- Training reinforcement for all operators.

These user level actions ensure safe continued use of the device. No device removal is required.

Long-term Corrective Actions (Planned):

Gentuity is working on **software enhancements** to correct the repeated frame issue and to reduce reliance on manual user adjustment. These updates will be distributed in a future software version within 6 months. The long-term corrective action will be communicated to users once available.

No Product Removal or Shortage:
Because the issue can be fully mitigated through correct use and user instruction, **no product removal** is required, and **no product shortages** are anticipated.

(8) OTHER INFORMATION:
Authorized by:

Name: Raj S Kasbekar, Ph D

Signature: *RSKasbekar*

Title: Global Vice President, Regulatory, Quality and Clinical

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Contact Information:

Call Gentuity Customer Service at 888-967-7628 Monday through Friday, 9:00 AM to 4:30 PM, Eastern Time.

Or by email at complaints@gentuity.com

Website: www.gentuity.com/recallinfo

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer Information:
Customer Name
Street Address
Town, State, Zip Code

Gentuity® HF-OCT Imaging System

Lot/Serial numbers:

I have read and understand the recall instructions provided in the <date of> letter. Yes _ No_

Any adverse events associated with recalled product? Yes _ No _

If yes, please explain:

_____
_____
_____
_____

Affected Product Information: Include information that is applicable for affected product (Console only)).

Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number shipped to Customer	Software Version	Quantity in Use
Gentuity HF-OCT Imaging System (Console only)	G10-01		23.3.13	

Return Response Box:

Please provide any additional information, if applicable.

Questions: (when applicable)

☐ Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE email to complaints@gentuity.com, ATTN: < Raj Kasbekar>
OR
MAIL TO: ATTN: < Raj Kasbekar>, Gentuity LLC, 142 North Road, Sudbury, MA 01776