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June 2024

URGENT: MEDICAL DEVICE CORRECTION FA-00247

Dear Valued Hologic Customer,

At Hologic, patient and care provider safety are our top priority. We continually evaluate and improve our product quality and reliability.

To that end, we advise of a voluntary field corrective action on our Horizon Bone Densitometry Systems manufactured from March 11, 2022, and later, as well as a small number of systems that have been serviced for motor replacement in the past 2 years – as follows:

Product Name: Horizon X-Ray Bone Densitometer (DXA)
Models: Horizon-A, Horizon-W, Horizon-WI, Horizon-C, Horizon-CI, Horizon-A-CN, Horizon-W-CN, Horizon-WI-CN, Horizon-CI-CN
UDIs Impacted: 15420045505384; 15420045505698; 15420045505827; 15420045505834; 15420045505865.

During standard compliance tests, Hologic has identified a non-conformance in Horizon DXA devices. The non-conformance pertains to electromagnetic compatibility requirements according to the international technical standard IEC 60601 – 1 – 2 for the safety and essential performance of medical electrical equipment, where the result from the Horizon DXA System exceeded the electromagnetic compatibility limit. The initial investigation has determined the root cause to be specific hardware components in the system.

We have conducted a risk assessment and have identified potential risk to humans who have active, implanted medical devices. Additionally, there is potential risk of interference with the essential performance of other electronic medical devices in close proximity to the equipment.

Due to several variables such as the specific design of a given implanted medical device and the proximity to other electronic devices, Hologic cannot say with specificity how this identified non-conformance may affect an active implantable medical device; however, there is a risk the non-conformance may impede the essential performance of an active implantable medical device. Any potential adverse health outcomes are directly related to the intended use of the active implantable, and we are providing the following recommendations to prevent any potential undesired harm.

Recommendations:

- Do NOT scan patients that have active implanted medical devices, including but not limited to neurostimulators, pacemakers, cardiac defibrillators, continuous glucose monitors, or other bio-wearable sensors.
- Any operator who has an active implanted medical device should also refrain from operating the system at this time.
- Do NOT scan patients that are currently being treated with an electronic medical device.
- Extend this communication to all pertinent staff in interaction and/or use with the Horizon DXA System.
- Until the correction is completed, this letter and the specific warning below supersedes information provided on the Horizon DXA labeling and IFU pertaining to electromagnetic compatibility and electromagnetic interference.

As part of this notification, adhering to international standards, Hologic is communicating the residual risk identified for the Horizon DXA systems and providing the following warning to our customers:

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⚠ WARNING ⚠

Electromagnetic Emissions can be harmful to patients with an active implantable medical device or in active use of an electronic medical device.

Course of Action: DO NOT scan patients that have active implanted medical devices, including but not limited to neurostimulators, pacemakers, cardiac defibrillators, continuous glucose monitors, or other bio-wearable sensors. DO NOT scan patients that are in use of an electronic medical device at the time of the scan.

Users with the same clinical profile, should NOT operate the system at this time.

Caution: Horizon DXA System electromagnetic field can interfere with the safe and essential performance of active implantable medical devices and other electronic medical devices.

Precautions: Perform patient interview outlined in the Horizon DXA instructions for use, chapter 5, before every procedure, to make the user aware of the need of this risk mitigation recommendation.

Rectification activity by Hologic:

- We are urgently investigating the permanent rectification actions required, and we will be in contact promptly once this is defined. A service appointment will be scheduled for the remediation activity.

As additional clarification regarding the continued safe use of your Horizon DXA system, please note the following:

- This notice pertains to electromagnetic emissions, not ionizing radiation. Electromagnetic emissions are emitted by all electronic devices, such as cell phones, lights, computers, TVs, medical devices, among others.
- Further, please note that electromagnetic emissions are not generated when the system is shut down.
- Continued use of the Horizon DXA system is safe for all patients and operators that are not in the clinical profile described.
- Non-active medical implantable devices as orthopedic implants, breast implants, catheters, sutures, among similar, do not present a risk for patients that require a scan with the Horizon DXA System.

We are asking all impacted customers to acknowledge receipt of this notification. To complete this step, please complete the online Customer Confirmation Form provided by IQVIA within 3 business days of receiving this notice. Replying promptly will confirm your receipt of the notification and prevent you from receiving repeat notices.

For additional support, please contact Hologic's Technical Support at 1-877-371-4372 or skeletalhealth.support@hologic.com

Adam Gorzeman
Sr. Director of Quality
Breast and Skeletal Health Solutions

Systems Identification Instructions

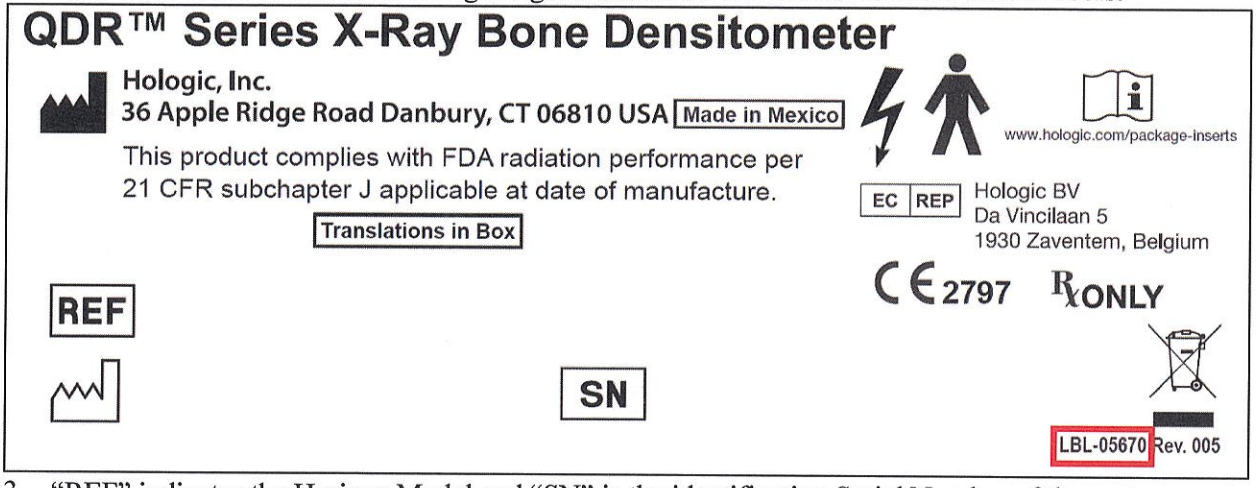
If you received this notification and have one or more Horizon System(s) in your practice, the following is the criteria to identify the systems that are impacted by this corrective field action:

- The System was manufactured from 11/March/2022 and later, or
- Your System was serviced for motor replacement and is part of the serial numbers impacted.

In order to identify the information of your Horizon X-Ray Bone Densitometer System you would need to consult the Main Label content as described below:

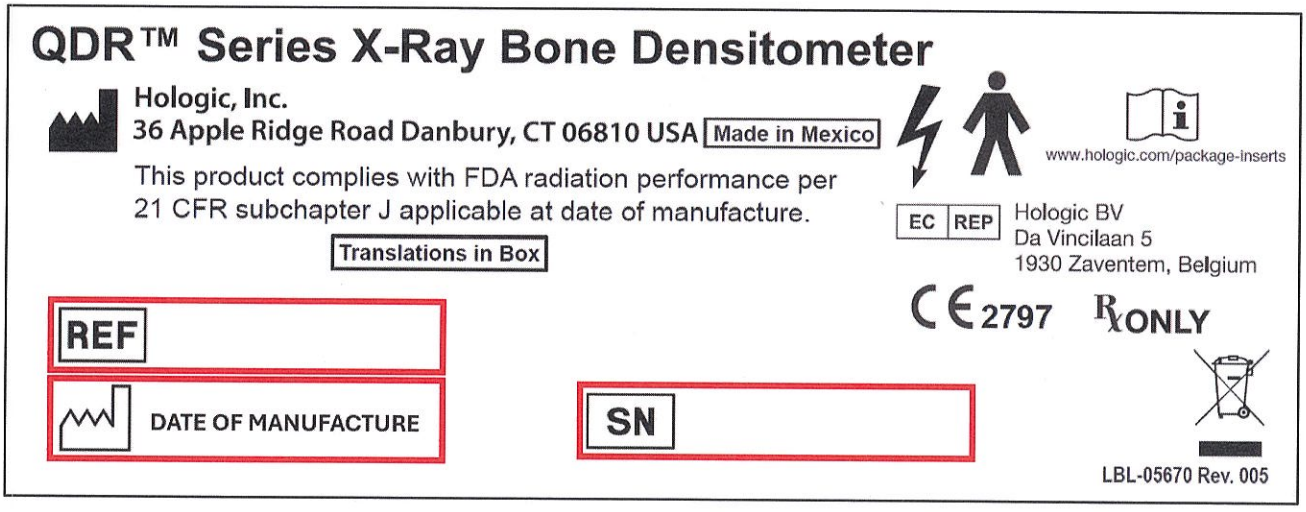
1. The Main Label is located on the back side of the frame, the label number is LBL-05670, and this identification number is located on the bottom right corner of the label, as framed in red in the following image:

2. To identify the specific system information, refer to the content that will be next to the symbols "REF" and "SN" framed in red in the following image. It can be a combination of letters and numbers.



3. "REF" indicates the Horizon Model and "SN" is the identification Serial Number of the system. "" indicates the date of manufacture of the system.

Annex I: User Manual – Patient Questionnaire



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Prior to performing a DXA scan on a patient, Horizon users should complete a patient interview as part of the Horizon X-Ray Bone Densitometer (DXA) System clinical workflow, as outlined in the Horizon Instruction for Use (IFU), Chapter 5, section 5.1 as shown in the image below:

For access to the electronic version of the Horizon Instructions for use visit:

https://www.hologic.com/package-inserts/breast-skeletal-health-products/horizon-dxa-system-package-insertsifus

Chapter 5 Performing an Exam

5.1 Patient Interview

The following is a list of questions to ask the patient (some may not apply).

Is there any chance of pregnancy?

If a patient is (or may be) pregnant, always contact the patient's physician before performing a scan.

Has the patient had any radiological procedure using the following contrast agents within the last 7 days:

- Iodine
- Barium

Radiological contrast agents used for X-ray and CT can interfere with DXA scans. In particular, oral contrasts can remain in the gastrointestinal tract for several days affecting DXA results. Intravenous iodine normally clears within 72 hours for those patients with normal kidney function.

Hologic DXA measurements have been shown in several studies to be unaffected by nuclear isotope studies, so DXA measurements can be done immediately after nuclear isotope studies as long as the studies do not also include radiological contrast agents (such as iodine and barium).

Is the patient wearing any objects in the scan area such as an ostomy device, metal buttons or snaps, or jewelry?

This may interfere in the scanning of the patient.

Has the patient had any surgery in the area being scanned?

If so, consider whether to perform the examination. For example, any of the following internal objects could interfere with the scan:

- Pacemaker leads
- Radioactive seeds
- Metal implants
- Surgical staples
- Foreign bodies; e.g., shrapnel
- Radio-opaque catheters or tubes

If the patient had surgery on a hip or forearm, then the uninjured hip or forearm should be scanned.

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Horizon X-Ray Bone Densitometer (DXA)

Online Acknowledgement Instructions

*Please complete the Online Acknowledgement Form within **three (3) business days** upon receipt of this notification.*

STEP 1: Scan the QR Code or visit the link below to access the response form

https://iqvia-response.my.site.com/mt/fca?cid=hologic-horizon

STEP 2: Enter your unique identifier

Your Consignee ID – HXBD-974

STEP 3: Enter your Serial Number

Your Serial Number(s)

306194M

STEP 4: Acknowledge the receipt of this notice & complete the form online.

Call IQVIA MedTech for any questions/concerns with response form
P: **(855) 609-2317** | E: **horizonxray-2024@iqvia.com**

Hologic has partnered with IQVIA MedTech company, to assist in this action. IQVIA MedTech specializes in providing outsourced commercial service teams and technologies for the medical device industry.

For any assistance regarding online response processing please contact IQVIA MedTech using the information above.