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Zaventem, June 19th, 2024

URGENT FIELD SAFETY NOTICE
VOLUNTARY FIELD CORRECTIVE ACTION
Horizon X-Ray Bone Densitometer (DXA)

FSN Ref: MISC-09879-EUR-2101 Rev. 004
FSCA Ref: 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 for a small number of systems that have been served 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
UDIs Impacted: 15420045505384; 15420045505698; 15420045505827; 15420045505834; 15420045505865.
Refer to Annex III for the detail of Horizon Serial Numbers Impacted

Description of the product problem and hazard identified

During standard compliance test, 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.

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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:

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. Nor patients that are in use of an electronic medical device by the time of the scan.

Users with the same clinical profile, do 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.

If you are a distributor, please inform your customers of this Field Safety Notice (refer to the IQVIA Acknowledgment Form for further instructions).

For additional support, please contact Hologic's Technical Support (information below),

Direct Markets (Contact for Customers)

Country	Phone Number	email
Austria	0800 29 1919 or local +43 720 710 811	TSbsh@hologic.com
Germany	0800 589 1635 or local +49 3222 109 65 91	
Italy	800 786308 or local +390694801337	
Portugal	800841034 or local +351300506262	
Spain (including Canary Islands and Andorra)	900988004 or local +34932204047	
Switzerland	0800 29 8921 or local +41 215 880 145	

Indirect Markets (Contacts for Distributors)

Country	Phone Number	email
EMEA	+32 2 711 45 45	Be-techsupport@hologic.com

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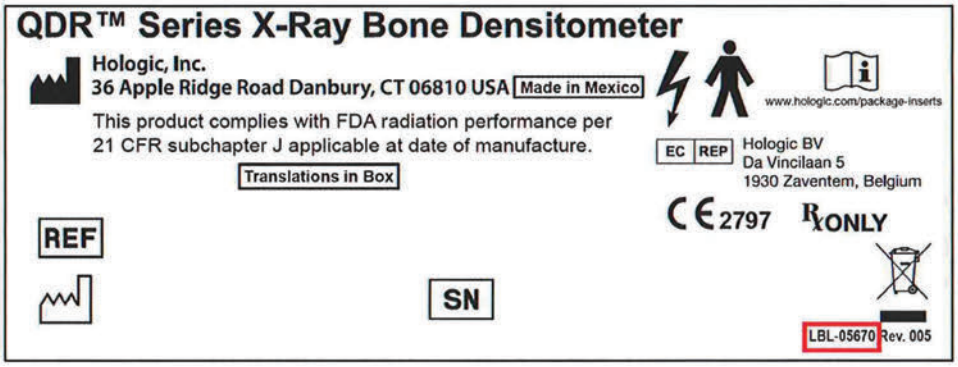
Annex I: Systems Identification Instructions

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 serial number of the System is listed on Annex III to this letter, which means that
  - The System was manufactured from 11/March/2022 and later or,
  - The System was served for motor replacement and is part of the serial numbers impacted.

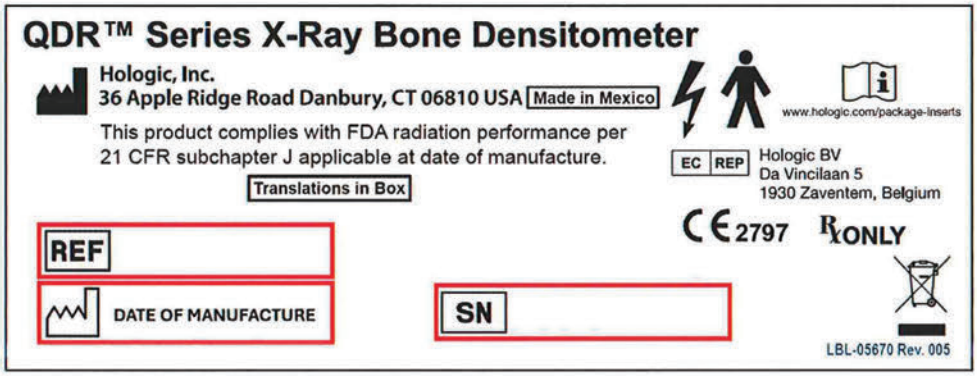
In order to identify the information of your Horizon X-Ray Bone Densitometer System you would need to consult the Main Label content as described below:

1. The Main Label is located on the back side of the frame, the label number is LBL-05670 and that 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.



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Annex II: User Manual – Patient Questionnaire

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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Annex III: Horizon Serial Numbers Impacted in EMEA

HORIZON-A Serial Numbers

Austria	307684M
Austria	308081M
Croatia	307999M
France	305837M
France	307579M
France	308401M
Germany	306786M
Ireland	306845M
Ireland	307220M
Israel	308275M
Israel	308287M
Italy	306065M
Italy	306782M
Italy	307431M
Kuwait	307023M
Malta	307895M
Netherlands	305883M
Netherlands	305915M
Netherlands	306019M
Netherlands	306096M
Netherlands	306220M
Netherlands	306305M
Netherlands	306399M
Netherlands	306447M
Netherlands	306486M
Netherlands	306553M
Netherlands	306585M
Netherlands	306652M

Netherlands	306884M
Netherlands	306949M
Netherlands	306958M
Netherlands	307027M
Netherlands	307119M
Netherlands	307187M
Netherlands	307212M
Netherlands	307216M
Netherlands	307291M
Netherlands	307295M
Netherlands	307484M
Netherlands	307534M
Netherlands	307624M
Netherlands	307676M
Netherlands	307819M
Netherlands	307855M
Netherlands	307859M
Netherlands	307934M
Netherlands	307939M
Netherlands	307947M
Netherlands	307951M
Netherlands	308003M
Netherlands	308011M
Netherlands	308015M
Netherlands	308334M
Netherlands	308470M
Netherlands	308474M
Poland	306954M

Poland	308113M
Portugal	307287M
Slovakia	306793M
Switzerland	305894M
Switzerland	308466M
UK	305882M
UK	306041M
UK	306091M
UK	306132M
UK	306215M
UK	306464M
UK	306651M
UK	307488M
UK	307529M
UK	307538M
UK	307583M
UK	307620M
UK	307673M
UK	307814M
UK	307863M
UK	307867M
UK	307911M
UK	308007M
UK	308070M
UK	308089M
UK	308411M
UK	308458M
UK	308462M

HORIZON-C Serial Numbers

France	306776M
Germany	306836M
Germany	306863M
Germany	306867M
Germany	306941M
Germany	306947M
Germany	306976M

Germany	307019M
Germany	307861M
Germany	308001M
Slovakia	307857M
Switzerland	305851M
Switzerland	306011M
Switzerland	306760M

Switzerland	306945M
UK	305627M
UK	305930M
UK	306842M
UK	306939M
UK	307015M
UK	307697M

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HORIZON-CI Serial Numbers

Austria	306015M
Austria	306771M
Austria	306775M
Austria	307493M
Austria	307843M
Belgium	305710M
Belgium	307621M
Belgium	308013M
Croatia	306763M
Croatia	307197M
Cyprus	306971M
France	305386M
France	305614M
France	305711M
France	305748M
France	305752M
France	305757M
France	306014M
France	306016M
France	306066M
France	306134M
France	306162M
France	306212M
France	306232M
France	306282M
France	306356M
France	306543M
France	306586M
France	306764M
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France	306844M
France	307013M
France	307017M
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France	307245M
France	307249M
France	307250M

France	307253M
France	307298M
France	307420M
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France	307548M
France	307622M
France	307642M
France	307783M
France	307790M
France	307930M
France	307931M
France	307942M
France	308112M
France	308366M
France	308368M
France	308370M
France	308471M
France	308473M
Germany	305320M
Germany	305712M
Germany	305746M
Germany	305750M
Germany	306043M
Germany	306163M
Germany	306231M
Germany	306510M
Germany	306511M
Germany	306595M
Germany	306759M
Germany	306761M
Germany	306767M
Germany	306769M
Germany	306774M
Germany	306847M
Germany	306848M
Germany	306969M
Germany	307102M
Germany	307103M

Germany	307104M
Germany	307129M
Germany	307188M
Germany	307193M
Germany	307547M
Germany	307699M
Germany	307703M
Germany	307786M
Germany	307788M
Germany	307791M
Germany	307846M
Germany	307881M
Germany	307897M
Germany	307925M
Germany	307927M
Germany	308071M
Germany	308086M
Germany	308095M
Germany	308371M
Germany	308450M
Germany	308464M
Greece	305602M
Greece	305708M
Greece	305709M
Greece	305749M
Greece	305760M
Greece	305970M
Greece	307021M
Greece	307024M
Greece	307132M
Greece	307296M
Greece	308539M
Italy	305628M
Italy	305705M
Italy	305713M
Italy	305745M
Italy	305751M
Italy	305753M
Italy	305755M

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Italy	305756M
Italy	306012M
Italy	306042M
Italy	306067M
Italy	306068M
Italy	306082M
Italy	306085M
Italy	306090M
Italy	306209M
Italy	306211M
Italy	306613M
Italy	307550M
Italy	308008M
Netherlands	307130M
Netherlands	307189M
Poland	307192M

Portugal	306281M
Portugal	307126M
Portugal	307924M
Serbia	305613M
Serbia	306280M
Serbia	306616M
Slovakia	307896M
Slovakia	308005M
Slovakia	308114M
Slovakia	308115M
Slovakia	308446M
South Africa	305916M
Spain	300220M
Spain	301857M
Spain	304111M
Spain	305936M

Spain	305956M
Spain	307026M
Spain	307131M
Spain	307849M
Spain	308010M
Spain	308079M
Spain	308383M
Spain	308468M
Switzerland	306161M
Switzerland	306653M
Switzerland	308116M
Switzerland	308379M
UK	307252M
UK	307254M

HORIZON-W Serial Numbers

Croatia	308038M
Croatia	308267M
France	305805M
France	305808M
France	305857M
France	307572M
France	307704M
France	307886M
France	307919M
France	307964M
France	308025M
France	308078M
France	308454M
Germany	305957M
Germany	307962M
Greece	305859M
Greece	306070M
Greece	306933M
Greece	307956M
Greece	308031M
Greece	308456M
Islas Canarias	308036M
Italy	305806M

Italy	305858M
Italy	305881M
Italy	305952M
Italy	307096M
Italy	307423M
Italy	307878M
Jordan	306864M
Kuwait	305797M
Kuwait	306069M
Kuwait	307489M
Lebanon	308073M
Morocco	307882M
Morocco	307949M
Morocco	307952M
Palestine	307526M
Palestine	307532M
Palestine	307700M
Poland	306937M
Poland	307014M
Poland	307018M
Poland	307421M
Poland	307681M
Poland	307914M
Poland	308034M

Portugal	305984M
Qatar	307543M
Qatar	307634M
Romania	306843M
Saudi Arabia	307954M
Serbia	306216M
Serbia	308261M
Slovakia	307866M
Slovakia	307893M
Slovakia	307913M
Slovakia	307917M
Slovakia	307957M
Slovakia	308148M
Slovakia	308152M
South Africa	306170M
South Africa	306602M
South Africa	306869M
South Africa	307022M
South Africa	307196M
South Africa	307889M
South Africa	307948M
South Africa	307953M
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UK	307963M
UK	308027M

HORIZON-WI Serial Numbers

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Belgium	307194M
Croatia	306071M
Croatia	306201M
Croatia	306409M
Cyprus	306208M
Cyprus	306430M
Cyprus	306497M
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Cyprus	306816M
Cyprus	307229M
Cyprus	308205M
Cyprus	308543M
Egypt	305860M
Egypt	305993M
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Iran	307546M
Iran	307594M

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Iran	308384M
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Iran	308720M
Iran	308721M
Iran	308742M
Islas Canarias	306313M
Israel	305888M
Israel	306142M
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Italy	308203M
Italy	308209M
Italy	308243M
Italy	308260M
Italy	308262M
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Italy	308375M
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Italy	308428M
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Italy	308534M
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Italy	308537M
Italy	308538M
Italy	308540M
Italy	308542M
Jordan	306104M
Jordan	308276M
Malta	306234M
Morocco	305920M
Morocco	306940M
Morocco	307447M
Morocco	307448M

Morocco	307486M
Netherlands	306803M
Netherlands	307237M
Poland	306596M
Poland	306597M
Poland	306808M
Poland	307415M
Poland	307593M
Poland	308024M
Portugal	305917M
Portugal	305918M
Portugal	306101M
Portugal	306302M
Portugal	306303M
Portugal	306306M
Portugal	306659M
Portugal	306811M
Portugal	307217M
Portugal	307641M
Portugal	307679M
Portugal	308040M
Portugal	308467M
Qatar	306288M
Romania	306205M
Romania	306233M
Romania	306284M
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Romania	306364M
Romania	306431M
Romania	306433M
Romania	306936M
Romania	307706M
Romania	307710M
Romania	307922M
Saudi Arabia	306408M
Saudi Arabia	306412M
Saudi Arabia	307020M
Saudi Arabia	307683M
Saudi Arabia	308449M
Saudi Arabia	308740M
Saudi Arabia	308741M
Serbia	307410M
Serbia	308506M

Slovakia	305873M
Slovakia	305884M
Slovakia	306164M
Slovakia	306229M
Slovakia	306285M
Slovakia	306357M
Slovakia	306410M
Slovakia	306603M
Slovakia	306610M
Slovakia	306810M
Slovakia	306938M
Slovakia	307097M
Slovakia	307215M
Slovakia	307495M
Slovakia	307549M
Slovakia	307584M
Slovakia	307586M
Slovakia	307617M
Slovakia	307618M
Slovakia	307816M
Slovakia	307818M
Slovakia	307845M
Slovakia	307918M
Slovakia	307959M
Slovakia	308026M
Slovakia	308032M

Slovakia	308033M
Slovakia	308037M
Slovakia	308039M
Slovakia	308085M
Slovakia	308094M
Slovakia	308339M
Slovakia	308510M
Slovakia	308515M
South Africa	306140M
South Africa	306286M
South Africa	306358M
South Africa	306552M
South Africa	306554M
South Africa	306607M
South Africa	306611M
South Africa	307770M
Spain	305665M
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Spain	306304M
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Spain	306812M
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Spain	307167M

Spain	307169M
Spain	307221M
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Spain	307638M
Spain	307677M
Spain	307682M
Spain	308000M
Spain	308028M
Spain	308030M
Spain	308142M
Spain	308469M
Spain	308577M
Spain	308590M
Spain	308591M
Switzerland	200019
Switzerland	305971M
Switzerland	306166M
Switzerland	307712M
Turkey	306538M
Turkey	307773M
Turkey	307920M
Turkey	308439M
Turkey	308475M

Regarding systems that have been served for motor replacement in the past 2 years:

Units of impacted motor have been provided to EMEA Hologic distributors. The distributors will be notified by Hologic and requested to identify the systems under their responsibility which underwent motor replacement.