



June 14<sup>th</sup>, 2024

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

**FSN Ref: MISC-09879-EUR-2101 Rev. 003**

**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.

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.


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- 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 on stand-by or shut down. Electromagnetic emissions are generated only while the system is in operation.
- 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.

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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<br>(including Canary Islands and<br>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 |

On behalf of

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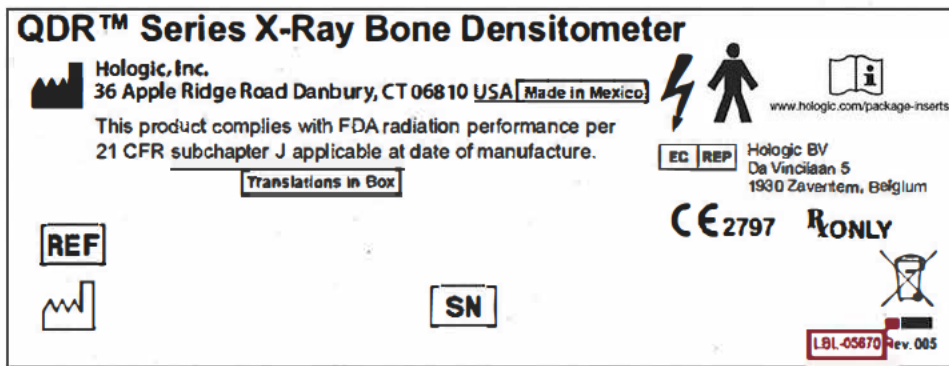
## Annex I: Systems Identification Instructions

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:

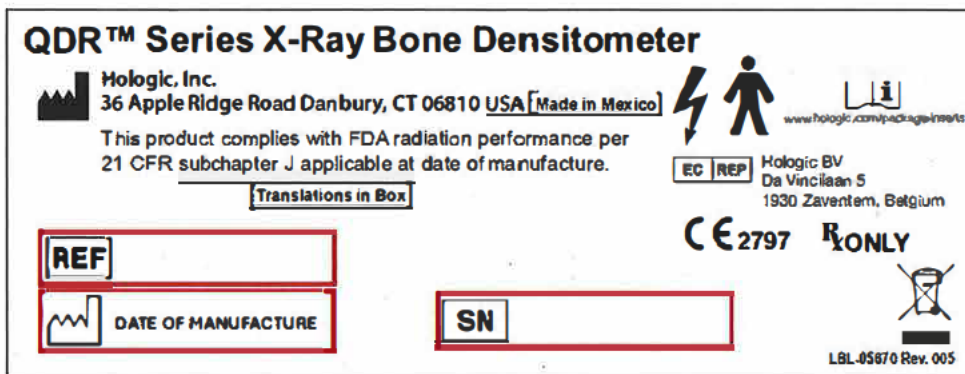
- The serial number of the System is listed on Annex III to this letter, which means that
  - o The System was manufactured from 11/March/2022 and later or,
  - o The System was served for motor replacement and is part of the serial numbers impacted.

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. "DATE OF MANUFACTURE" 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>

**Horizon Bone Densitometry System User Guide**  
Chapter 5: Performing an Exam

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## 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 | Netherlands | 306884M | Poland      | 308113M |
| Austria     | 308081M | Netherlands | 306949M | Portugal    | 307287M |
| Croatia     | 307999M | Netherlands | 306958M | Slovakia    | 306793M |
| France      | 305837M | Netherlands | 307027M | Switzerland | 305894M |
| France      | 307579M | Netherlands | 307119M | Switzerland | 308466M |
| France      | 308401M | Netherlands | 307187M | UK          | 305882M |
| Germany     | 306786M | Netherlands | 307212M | UK          | 306041M |
| Ireland     | 306845M | Netherlands | 307216M | UK          | 306091M |
| Ireland     | 307220M | Netherlands | 307291M | UK          | 306132M |
| Israel      | 308275M | Netherlands | 307295M | UK          | 306215M |
| Israel      | 308287M | Netherlands | 307484M | UK          | 306464M |
| Italy       | 306065M | Netherlands | 307534M | UK          | 306651M |
| Italy       | 306782M | Netherlands | 307624M | UK          | 307488M |
| Italy       | 307431M | Netherlands | 307676M | UK          | 307529M |
| Kuwait      | 307023M | Netherlands | 307819M | UK          | 307538M |
| Malta       | 307895M | Netherlands | 307855M | UK          | 307583M |
| Netherlands | 305883M | Netherlands | 307859M | UK          | 307620M |
| Netherlands | 305915M | Netherlands | 307934M | UK          | 307673M |
| Netherlands | 306019M | Netherlands | 307939M | UK          | 307814M |
| Netherlands | 306096M | Netherlands | 307947M | UK          | 307863M |
| Netherlands | 306220M | Netherlands | 307951M | UK          | 307867M |
| Netherlands | 306305M | Netherlands | 308003M | UK          | 307911M |
| Netherlands | 306399M | Netherlands | 308011M | UK          | 308007M |
| Netherlands | 306447M | Netherlands | 308015M | UK          | 308070M |
| Netherlands | 306486M | Netherlands | 308334M | UK          | 308089M |
| Netherlands | 306553M | Netherlands | 308470M | UK          | 308411M |
| Netherlands | 306585M | Netherlands | 308474M | UK          | 308458M |
| Netherlands | 306652M | Poland      | 306954M | UK          | 308462M |

### HORIZON-C Serial Numbers

|         |         |             |         |             |         |
|---------|---------|-------------|---------|-------------|---------|
| France  | 306776M | Germany     | 307019M | Switzerland | 306945M |
| Germany | 306836M | Germany     | 307861M | UK          | 305627M |
| Germany | 306863M | Germany     | 308001M | UK          | 305930M |
| Germany | 306867M | Slovakia    | 307857M | UK          | 306842M |
| Germany | 306941M | Switzerland | 305851M | UK          | 306939M |
| Germany | 306947M | Switzerland | 306011M | UK          | 307015M |
| Germany | 306976M | Switzerland | 306760M | 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 |
| France  | 306838M |
| France  | 306844M |
| France  | 307013M |
| France  | 307017M |
| France  | 307106M |
| France  | 307127M |
| France  | 307128M |
| France  | 307245M |
| France  | 307249M |
| France  | 307250M |

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| France  | 307253M |
| France  | 307298M |
| France  | 307420M |
| France  | 307422M |
| France  | 307490M |
| 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 |

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| 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 |

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| 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 |

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|-------------|---------|
| 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 |

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|-----------|---------|
| 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 |

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|--------------|---------|
| 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 |
| Spain        | 300759M |
| Spain        | 306098M |

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|       |         |
|-------|---------|
| Spain | 306654M |
| Spain | 306935M |
| Spain | 307678M |
| UK    | 305937M |
| UK    | 306133M |
| UK    | 306837M |

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| UK | 306866M |
| UK | 306951M |
| UK | 306953M |
| UK | 306955M |
| UK | 307630M |
| UK | 307868M |

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| UK | 307921M |
| UK | 307960M |
| UK | 307963M |
| UK | 308027M |

## HORIZON-WI Serial Numbers

|         |         |
|---------|---------|
| Algeria | 306606M |
| Algeria | 306846M |
| Andorra | 306312M |
| Austria | 307932M |
| Austria | 308576M |
| Belgium | 305886M |
| Belgium | 305891M |
| Belgium | 307194M |
| Croatia | 306071M |
| Croatia | 306201M |
| Croatia | 306409M |
| Cyprus  | 306208M |
| Cyprus  | 306430M |
| Cyprus  | 306497M |
| Cyprus  | 306814M |
| Cyprus  | 306816M |
| Cyprus  | 307229M |
| Cyprus  | 308205M |
| Cyprus  | 308543M |
| Egypt   | 305860M |
| Egypt   | 305993M |
| Egypt   | 306655M |
| Estonia | 305887M |
| Estonia | 306072M |
| France  | 305540M |
| France  | 305867M |
| France  | 305885M |
| France  | 306073M |
| France  | 306230M |
| France  | 306411M |
| France  | 306657M |
| France  | 306934M |
| France  | 307191M |
| France  | 307491M |

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| France  | 308544M |
| Germany | 305875M |
| Germany | 305982M |
| Germany | 307850M |
| Germany | 308207M |
| Greece  | 305541M |
| Greece  | 305868M |
| Greece  | 305872M |
| Greece  | 305939M |
| Greece  | 305973M |
| Greece  | 305995M |
| Greece  | 306045M |
| Greece  | 306141M |
| Greece  | 306165M |
| Greece  | 306499M |
| Greece  | 306815M |
| Greece  | 306977M |
| Greece  | 307016M |
| Greece  | 307099M |
| Greece  | 307105M |
| Greece  | 307674M |
| Greece  | 307680M |
| Greece  | 307950M |
| Greece  | 307955M |
| Greece  | 307968M |
| Greece  | 308004M |
| Greece  | 308083M |
| Greece  | 308141M |
| Greece  | 308378M |
| Greece  | 308380M |
| Greece  | 308382M |
| Greece  | 308386M |
| Greece  | 308472M |
| Iran    | 305538M |

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| Iran | 305539M |
| Iran | 305787M |
| Iran | 305791M |
| Iran | 305871M |
| Iran | 305962M |
| Iran | 306167M |
| Iran | 306287M |
| Iran | 306352M |
| Iran | 306432M |
| Iran | 306434M |
| Iran | 306504M |
| Iran | 306584M |
| Iran | 306587M |
| Iran | 306656M |
| Iran | 306658M |
| Iran | 306660M |
| Iran | 306802M |
| Iran | 306813M |
| Iran | 307100M |
| Iran | 307195M |
| Iran | 307198M |
| Iran | 307199M |
| Iran | 307225M |
| Iran | 307230M |
| Iran | 307236M |
| Iran | 307289M |
| Iran | 307292M |
| Iran | 307294M |
| Iran | 307412M |
| Iran | 307419M |
| Iran | 307443M |
| Iran | 307445M |
| Iran | 307546M |
| Iran | 307594M |

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|----------------|---------|
| Iran           | 308384M |
| Iran           | 308388M |
| Iran           | 308432M |
| Iran           | 308436M |
| Iran           | 308442M |
| Iran           | 308443M |
| Iran           | 308445M |
| Iran           | 308447M |
| Iran           | 308451M |
| Iran           | 308463M |
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| Iran           | 308709M |
| Iran           | 308712M |
| Iran           | 308714M |
| Iran           | 308717M |
| Iran           | 308718M |
| Iran           | 308719M |
| Iran           | 308720M |
| Iran           | 308721M |
| Iran           | 308742M |
| Islas Canarias | 306313M |
| Israel         | 305888M |
| Israel         | 306142M |
| Italy          | 305798M |
| Italy          | 305874M |
| Italy          | 305892M |
| Italy          | 305893M |
| Italy          | 305940M |
| Italy          | 305949M |
| Italy          | 305963M |
| Italy          | 306044M |
| Italy          | 306046M |
| Italy          | 306047M |
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| Italy          | 306503M |
| Italy          | 306544M |
| Italy          | 306547M |
| Italy          | 306549M |
| Italy          | 306550M |
| Italy          | 306975M |
| Italy          | 307168M |
| Italy          | 307170M |

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| Italy   | 307190M |
| Italy   | 307582M |
| Italy   | 307844M |
| Italy   | 307847M |
| Italy   | 307848M |
| Italy   | 307858M |
| Italy   | 307916M |
| Italy   | 307967M |
| Italy   | 307996M |
| Italy   | 308072M |
| Italy   | 308088M |
| Italy   | 308096M |
| Italy   | 308194M |
| Italy   | 308195M |
| Italy   | 308196M |
| Italy   | 308198M |
| Italy   | 308201M |
| Italy   | 308203M |
| Italy   | 308209M |
| Italy   | 308243M |
| Italy   | 308260M |
| Italy   | 308262M |
| Italy   | 308278M |
| Italy   | 308372M |
| Italy   | 308374M |
| Italy   | 308375M |
| Italy   | 308413M |
| Italy   | 308425M |
| Italy   | 308428M |
| Italy   | 308431M |
| Italy   | 308534M |
| Italy   | 308535M |
| Italy   | 308537M |
| Italy   | 308538M |
| Italy   | 308540M |
| Italy   | 308542M |
| Jordan  | 306104M |
| Jordan  | 308276M |
| Maïta   | 306234M |
| Morocco | 305920M |
| Morocco | 306940M |
| Morocco | 307447M |
| Morocco | 307448M |

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| 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 |
| Romania      | 306359M |
| 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 |

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|----------|---------|
| 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 |
| Spain        | 305938M |
| Spain        | 305983M |
| Spain        | 306304M |
| Spain        | 306809M |
| Spain        | 306812M |
| Spain        | 307012M |
| Spain        | 307025M |
| Spain        | 307143M |
| Spain        | 307167M |

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|-------------|---------|
| Spain       | 307169M |
| Spain       | 307221M |
| Spain       | 307633M |
| Spain       | 307635M |
| 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.