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Zaventem, August 14th, 2024

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

FSN Ref: MISC-10091-EUR-2101 Rev. 001
FSCA Ref: FA-00247 – Out of Scope

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.

You previously received notification advising of a voluntary field corrective action on our Horizon Bone Densitometry Systems for a non-conformance identified during standard compliance testing. This non-conformance pertained 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.

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.

After further review of the systems identified as in scope, it has been confirmed that the following systems fall outside the date range of manufacture that is identified in this field corrective action and have not been serviced for a motor replacement in the past 2 years. Therefore, one or more of your systems does not require remediation or a change to clinical practice. Normal use of these unimpacted systems can be resumed.

Refer to Annex I: Not Impacted Serial Numbers Confirmation

Only systems manufactured from March 11, 2022 and later, and the ones serviced for motor replacement with the new motors ASY-15686, are in scope of this field corrective action. All systems manufactured before that date are in compliance with IEC 60601 limits for electromagnetic compatibility.

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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 Acknowledgment 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
Germany	0800 589 1635 or local +49 3222 109 65 91	
Italy	800 786308 or local +390694801337	
Portugal	800841034 or local +351300506262	
Spain	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 71145 45	Be-techsupport@hologic.com

On behalf of [redacted]

[redacted]

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Annex I: Not Impacted Serial Number Confirmation

HORIZON-A Not Impacted Serial Numbers					
France	305837M	Netherlands	305883M	United Kingdom	305882M
Iceland	305915M	Switzerland	305894M		

HORIZON-C Not Impacted Serial Numbers					
Switzerland	305851M	United Kingdom	305627M	United Kingdom	305930M

HORIZON-CI Not Impacted Serial Numbers					
Belgium	305710M	Germany	305750M	Italy	305751M
France	305386M	Greece	305602M	Italy	305753M
France	305614M	Greece	305708M	Italy	305755M
France	305711M	Greece	305709M	Italy	305756M
France	305748M	Greece	305749M	Serbia	305613M
France	305752M	Greece	305760M	South Africa	305916M
France	305757M	Italy	305628M	Spain	300220M
Germany	305320M	Italy	305705M	Spain	301857M
Germany	305712M	Italy	305713M	Spain	304111M
Germany	305746M	Italy	305745M	Spain	305936M

HORIZON-W Not Impacted Serial Numbers					
France	305805M	Italy	305806M	Kuwait	305797M
France	305808M	Italy	305858M	Spain	300759M
France	305857M	Italy	305881M	United Kingdom	305937M
Greece	305859M	Italy	305952M		

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HORIZON-WI Not Impacted Serial Numbers					
Belgium	305886M	Greece	305939M	Italy	305893M
Belgium	305891M	Hungary	305873M	Italy	305940M
Egypt	305860M	Iran	305538M	Italy	305949M
Estonia	305887M	Iran	305539M	Morocco	305920M
France	305540M	Iran	305787M	Portugal	305917M
France	305867M	Iran	305791M	Portugal	305918M
France	305885M	Iran	305871M	Slovakia	305884M
Germany	305875M	Israel	305888M	Spain	305665M
Greece	305541M	Italy	305798M	Spain	305938M
Greece	305868M	Italy	305874M	Switzerland	200019
Greece	305872M	Italy	305892M		

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