Rev 1: September 2018

FSN Ref: FSN-2025-01 FSCA Ref: FSCA-2025-01

Date: 16:JAN:2025

Urgent Field Safety Notice
TBS iNsight v3

For Attention of*:TBS iNsight v3.x users operating on Hologic Horizon machines and TBS iNsight v3.x Hologic distributors and service technicians

Contact details of local representative (name, e-mail, telephone, address etc.)*
Mr Giorgio Zoia, medimaps group SA. Email: gzoia@medimapsgroup.com. Address: HiFlow, chemin du Champ-des-Filles 36A, 1228 Plan-les-Ouates, Geneva, Switzerland.

Urgent Field Safety Notice (FSN)
TBS iNsight v3
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	TBS iNsight is a Medical Device software that is installed on bone densitometers for analysis of bone microarchitecture and bone health management
1.	2. Commercial name(s)
	TBS Osteo
1.	3. Unique Device Identifier(s) (UDI-DI)
	+B214OSTBSI3120, +B214OSTBSI3110, +B214OSTBSIV310, +B214OSTBSIV300
1.	4. Primary clinical purpose of device(s)*
	TBS iNsight™ is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the antero-posterior spine DXA examination file and calculates a score (Trabecular Bone Score - TBS) that is compared to those of the age-matched controls. The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture. TBS provides information independent of BMD value; it is used as a complement to the data obtained from the DXA analysis, the clinical examination and risk factors in the diagnosis of osteoporosis. TBS iNsight™ provides as an option an assessment of 10-year fracture risk. It provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the WHO's FRAX® Fracture Risk Assessment Tool, after adjustment for the TBS. The tool has been validated for Caucasian and Asian men and post-menopausal women between 40 and 90 years old. The results can be used by a physician in conjunction with other clinical risk factors as an aid in the management of secondary osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk. The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time. TBS is indicated as an aid, in conjunction with other clinical factors, in the assessment and management of primary and secondary osteoporosis.
1.	5. Device Model/Catalogue/part number(s)*
	TBS iNsight v3.x / pn: OS-TBSi
1.	6. Software version
	V3.x
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Recent analyses have identified a potential variability in calculations from fast array scans compared to array scans when operating on Hologic Horizon machines. This variability is usually less than the least significant change and is more likely to occur for patients at

	either end of the BMI range or those undergoing significant weight change. In some cases, this may result in an overestimation of TBS.
2.	2. Hazard giving rise to the FSCA*
	TBS is used as an aid for patient management by clinicians and should not be used alone for diagnostic purposes. Variability in TBS calculations may influence the interpretation of values in specific cases, potentially impacting clinical decision-making. The risk associated with this variability is the potential for slight underestimation of risk of fracture and hence, undertreatment, but this is mitigated by the fact that TBS should never be considered alone according to clinical guidelines and therefore is only one element considered in the broader clinical context, alongside BMD measurements and other clinical risk factors.
2.	3. Probability of problem arising
	The analysis variability is most likely to occur when using TBS with fast array scans on Hologic Horizon machines. The probability of harm is assessed to be significantly lower than 0.3, as only overestimated values within specific ranges are expected to potentially influence clinical conclusions. At this time, a more precise probability cannot be determined.
2.	4. Predicted risk to patient/users
	While the risk is not assessed as critical, and the device remains suitable for clinical use under normal conditions, we have determined that the identified risk associated with the use of the device for calculations from the fast array mode, with Hologic Horizon machines and in specific patient categories, is not desired or tolerable. Specifically, patients at the extremes of the BMI range or undergoing significant weight changes may experience variability in TBS estimations. Therefore, as a precautionary measure, we have decided to adopt a conservative approach to mitigate any potential clinical impact.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The issue was recently discovered by conducting a preventive internal investigation. The preventive action was triggered by a suspicious result obtained in off label and non-clinical use of the TBS iNsight device. The variability in calculations occurs due to the distinct scan acquisition method used in fast array mode compared to array mode. This method can introduce differences in captured data, particularly in patients with extreme BMI or significant weight changes and is specific to the fast array process on these devices. The issue does not impact scans acquired in array mode or the Hologic Horizon device itself. Further, the issue does not impact GE or Osteosys DXA devices.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device
	☐ On-site device modification/inspection
	☒ Follow patient management recommendations
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)
	☐ Other ☐ None

	To reduce variability in calculations from fast array scans on Hologic Horizon machines and mitigate the newly identified risk, clinicians are advised to consider using the standard array mode for TBS calculations, where feasible, until the update becomes available. The forthcoming software maintenance release will incorporate an enhanced correction factor for fast array scans, ensuring a more tailored correction between the two scan modes and greater accuracy across the BMI range.	
3.	2. By when should the action be completed?	Upon reception of this notice
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Medimaps will issue a maintenance release of the software by the end of February in the worst case and deploy it progressively in the field. The exact plan will be further communicated to customers.	
3	5. By when should the action be completed?	The associated FSCA for strongly recommended software update should be completed in 6 months starting from the release of the update version in February 2025.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4	3.	
4	4.	
4.	5. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**medimaps group SA**
	b. Address	**Chemin du Champ-des-Filles 36A, 1228 Plan-les-Ouates, Switzerland**
	c. Website address	**https://www.medimaps.ai**
4.	6. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
	7. List of attachments/appendices:	**Feedback form**
4.	8. Name/Signature	**Giorgio Zoia, VP of Regulatory Affairs and Quality Assurance**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all organisation where the potentially affected devices have been transferred: the DXA manufacturer (Hologic), direct customers, distributors and field partners. Awareness on this notice and resulting action will be maintained through customer communications for an appropriate period of time until the end of the FSCA to ensure effectiveness of the corrective action. Customers are requested to report problem-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-2025-01
FSN Date*	January 14, 2025
Product/ Device name*	TBS iNsight v3
Product Code(s)	+B214OSTBSI3120, +B214OSTBSI3110, +B214OSTBSIV310, +B214OSTBSIV300
Batch/Serial Number (s)	N/A

2. Customer Details	
Account Number	
Device Version*	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation[1]		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	(1)
☐	I performed all actions requested by the FSN.	(1)
☐	The information and required actions have been brought to the attention of all relevant users and executed.	(1)
☐	Other Action (Define):	
☐	I do not have any affected devices.	(1)
☐	I have a query please contact me (e.g. need for replacement of the product).	

[1] Customer to complete or enter N/A where (1)

Print Name*	
Signature*	
Date*	

4. Return acknowledgement to sender	
Email	clientcare@medimapsgroup.com
Customer Helpline	+1-608-669-9113
Postal Address	Medimaps group SA, chemin du Champ-des-Filles 36A, 1228 Plan-les-Ouates, Switzerland
Web Portal	https://www.medimaps.ai
Deadline for returning the customer reply form*	January 31, 2025

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.