FSN Ref: FSN_ANIOS_MODULE HDE/HDAI_2107_EN_DISTRIBUTOR FSCA Ref: AN-FSCA-007

Date : July 29th, 2021

Urgent Field Safety Notice
MODULES ENDOSCOPIQUES VERSIONS HDE AND HDAI

To the attention of Laboratoires ANIOS distributors or representatives of MODULES ENDOSCOPIQUES VERSIONS HDE AND HDAI

Contact LABORATOIRES ANIOS
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1. Information on affected devices

Commercial name	MODULE ENDOSCOPIQUE
Primary purpose of device	Device used for manual pre-disinfection, cleaning and disinfection of endoscopes.
Device models	HDE and HDAI versions

2. Reason for Field Safety Corrective Action

You own at least one **MODULE ENDOSCOPIQUE VERSION HDE or HDAI**.

A defect has been discovered on these models. Indeed, the basins of these modules comprise level indications which assist in the dilution of the chemical products. These level indications are present in the basins destined to be used for the cleaning and disinfection phases and are represented by colored dots or lines on the walls of the basins.
We have identified a gap between the theoretical positions of the level indications in the basins and the actual volume of water present in the basin after dilution.
Indeed, the graduations in the basin indicating volumes of 20, 15 and 10 liters are incorrect.

2 cases are possible:

Case #1: The graduations indicate **a lower volume** than the real required volume in the basin. In this case the chemicals used for reprocessing the endoscopes are **over-concentrated**.
In this case no patient risk has been identified.

Case #2: The graduations indicate **a higher volume** than the real required volume in the basin. In this case the chemicals used for reprocessing the endoscopes are **under-concentrated**.
Given that :

- The modules have been installed and used since many years without any post market data suggesting inefficient process to clean and disinfect the endoscopes despite the defect here noticed
- Microbiological surveillance of the efficacy of the cleaning and disinfection procedures shall be performed by the Users with regular routine sampling and testing of their endoscope inventory as recommended by ESGE-ESGENA guideline for quality assurance (2007) or your National Guidelines

the level of risk for patient safety caused by the defect is rated as low.

3. Type of Action to mitigate the risk

Action To Be Taken by the Distributor:

- Inform immediately the users of the potential defect
- Ask them to apply the action in the section "Action To Be Taken by the User"
- Collect the "User Reply Form" by August 27th, 2021
- Schedule an on-site visit as soon as possible to confirm the defect
- Contact Laboratoires ANIOS after the on-site visit to confirm or not the defect on the user equipment; in case of defect liaise with Laboratoires ANIOS to define a maintenance intervention at the user site to correct the defective basins.

Action To Be Taken by the User:

As long as no maintenance intervention is performed by a technician from Laboratoires ANIOS to check if your equipment shows the defect here notices (after the date of this Field Safety Notice):

- Dilute the chemical products by an alternative method other than by using the level indicators present in the basin of your module.

- Make sure your internal protocols ensure the application of best practices in manual endoscope reprocessing and that they comply with the recommendations of ESGE-ESGENA Position Statement for Endoscope Reprocessing (2018) or your National guidelines.

- Check that the reprocessing staff is specifically dedicated to the application of these recommendations, that they are properly trained in these procedures and that they are aware of the following critical points :
    - The importance of meticulous brushing as described in the instruction thus guaranteeing efficient cleaning and disinfection steps. This further guarantees the efficacy of the overall disinfection process.
    - The importance of properly monitoring and document the use of the disinfectant bath as recommended by the disinfectant manufacturer, including Minimum Recommended Concentration measurement (by using test strips for instance), temperature, contact time and number of reuse cycles (if applicable).

Action Being Taken by the Manufacturer:

As soon as the issue was identified, the manufacturing procedure was updated and transmitted to the technicians in order to correctly place the level identifications in the basins.

A technician will visit your facility to check your equipment and if required will correct the graduations in the basin.
A maintenance technician will contact you shortly to schedule this intervention.

In addition, in the framework of our quality assurance system, a technical note describing the protocol for the correction of the graduation marks in the basins has been edited and distributed to the Technical support team of Laboratoires ANIOS in order to ensure the proper steps are taken during this intervention.

4. General information

ANSM has been informed about this communication to customers.

5. Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any relevant third part supporting you in the technical support of Laboratoires ANIOS equipment.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to Laboratoires ANIOS, as this provides important feedback.

Please acknowledge receipt of the present communication by filling out and signing the enclosed "Distributor Reply Form", and sending it back to us by August 31st, 2021 along with the "User Reply Form" collected from your customers.

Dr. Mikael CAUCHE *Quality Manager*	Dr. Monique MANCHE *Vigilance correspondent*	Thomas DECOSTER *President*