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URGENT FIELD SAFETY NOTICE

NAME OF PRODUCT: WASSENBURG® WD440 PT endoscope washer disinfector

DATE: 1 October 2015

TYPE OF ACTION: Field Safety Corrective Action

ATTENTION: ENDOSCOPY DEPARTMENT MANAGER

Details on affected devices:
This Field Safety Corrective Action (FSCA) affects WASSENBURG® WD440 PT endoscope washer disinfectors with serial numbers from 009-001 up to and including 009-049.

Description of the problem:
If certain conditions are met, the lid of the WD440 PT can be opened on the unload (clean) side after cancelling the washing and disinfection cycle on the load side. In this situation the endoscope has not been successfully reprocessed.

The conditions that need to be met for this failure to occur are as follows:

1. The cycle on the right side of the WD440 PT system is cancelled.
2. The cancellation procedure is completed, consisting of rinsing the endoscope and entering the user ID, but the lid is not opened on the load side.
3. The cycle on the left side of the system is completed successfully.
4. The foot pedals of both the left and right sides of the system are in such close proximity on the unload side that they are pressed at the same time when the user wants to remove the successfully reprocessed endoscope.
5. The user opening the lids is unaware that the cycle on the right side of the system has been cancelled and that the endoscope is not completely reprocessed.

If all these conditions are met then it is possible that an incompletely reprocessed endoscope could be used in patient treatment.
However the risk of all conditions occurring simultaneously is small.

Advise on action to be taken by the user:
The risk of this failure occurring can be eliminated by a software update. The new version of the software has been released and Wassenburg Ireland Ltd has already contacted you to plan a date for this update.
While waiting for this update takes place, the occurrence of this failure can be prevented by the following actions:

1. When cancelling a cycle, always ensure that the lid is opened on the load side as soon as the user ID has been entered.
2. Ensure that the foot pedals of the left and right basins on the unload side are not in such close proximity that they can be pressed at the same time.

Transmission of this Urgent Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference person:
Mr Paul Morrisson
Wassenburg Ireland Ltd.
Unit D1 Santry Business Park
Santry
Dublin 9

The undersigned confirms that the Health Products Regulatory Authority has been notified of this notice.