Box A: Reprocessing the MAJ-855 tube and the GI endoscope's auxiliary water channel

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Introduction: As much as any other lesson, the reprocessing breaches identified at the three VAMCs in Murfreesboro, Augusta, and Miami (see: *case 3*, p. 2) teach the importance of proper use and reprocessing of both the Olympus MAJ-855 auxiliary water tube and the colonoscope,† including its auxiliary water channel.[13,20]

Purpose: The MAJ-855 tube has two purposes.[27] First, it may be used to supply the GI endoscope's auxiliary water channel with (sterile) water for flushing the GI tract's mucosa, which may be required to enhance visibility during the clinical exam.[20] (Flushing may be achieved manually via a syringe or using an automated water pump.[27]) Second, the MAJ-855 tube may be used as an adapter to reprocess the GI endoscope's auxiliary water channel.

Recommendations: The following recommendations provide guidance to reprocess the MAJ-855 tube and auxiliary water channel both manually and using an automated endoscope reprocessor (AER). *Refer to the operator's manual of the GI endoscope for more detailed instructions.*

I. Initial quality-assurance verifications:

A. Verify whether any GI endoscopes in inventory feature an auxiliary water channel that uses a MAJ-855 tube for flushing (i.e., Olympus 160 and 180 series: 3 models of gastroscopes, 13 models of colonoscopes).[20]

B. Confirm that the MAJ-855 tube and the GI endoscope's auxiliary water channel are both being reprocessed after each clinical case, in accordance with their manufacturer's instructions.[20]

➡ *Caution: If it was connected to the GI endoscope's auxiliary water channel during the clinical case, the MAJ-855 auxiliary tube requires reprocessing, regardless of whether this channel (and tube) was used or flushed with water.*[20]

C. Prior to GI endoscopy, visually verify that the MAJ-855 tube is fitted with the correct green, *double*-winged (one-way flow) valve (with which the MAJ-855 tube was originally manufactured and shipped).[13,20]

➡ *Caution #1*: *Do not remove this green, double-winged valve from the MAJ-855 tube. This valve is crucial to the MAJ-855 tube's safe and effective use.*[13,20]

➡ *Caution #2: Do not use the MAJ-855 tube if it is fitted with a similarly-shaped, green, single-winged (two-way flow) connector, which is intended for use only with the Olympus MH-974 washing tube. Use of the MAJ-855 tube fitted with the MH-974 tube's single-winged connector is contraindicated.*[13,20]

II. Manual reprocessing of the MAJ-855 tube and the auxiliary water channel using a syringe:

A. Use a (30 ml) syringe to clean and high-level disinfect (and water rinse and forced-air dry), manually and simultaneously, the MAJ-855 tube and the GI endoscope's auxiliary water channel (to which this tube is connected;† *see:* main article) in accordance with the GI endoscope manufacturer's instructions.[13,20]

□ *Note*: The manufacturer's procedure and set-up for manually reprocessing the auxiliary water channel via the MAJ-855 tube are similar to those of the same manufacturer for manually flushing this channel with water during the exam via the MAJ-855 tube.[20]

III. Automated reprocessing of the MAJ-855 tube and the auxiliary water channel using an AER:

A. Some manufacturers suggest that their AER model(s) may be used to reprocess: (a) the auxiliary water channel via (and while simultaneously reprocessing) the MAJ-855 tube; and/or (b) the MAJ-855 tube by itself (i.e., while not connected to the GI endoscope).

➡ *Caution #1:* The use of an AER to reprocess the MAJ-855 tube, whether connected to the GI endoscope's auxiliary water channel or by itself, however, is ordinarily not recommended (*see:* Section III. C, below).

➡ *Caution #2:* The MAJ-855 tube's restrictive one-way valve, though of importance during the exam, can hinder the flow of reprocessing fluids through this tube's lumen, limiting the AER's effectiveness for reprocessing the MAJ-855 tube and, if it is connected to the GI endoscope, the auxiliary water channel.

B. Other manufacturers, however, may recommend that their AER model(s) be used to reprocess the GI endoscope's auxiliary water channel via a different adapter—known as the (Olympus) MH-974 washing tube (or its equivalent)—while the MAJ-855 tube is reprocessed by itself (manually or using an AER).[27]

➡ *Caution*: The MH-974 tube is fitted with a green, single-winged, two-way connector. *Do not confuse this connector, or use it interchangeably, with the MAJ-855 tube's double-winged, one-way valve* (*see*: Section I.C, above).[13,20,27]

□ *Note #1*: According to its manufacturer, the MAJ-855 tube can be manually reprocessed by itself, either using a syringe to achieve high-level disinfection or a steam autoclave, or using an AER.[20] (Steam sterilization of the MAJ-855 tube may require the purchase of

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† A diagram showing the MAJ-855 tube connected to the GI endoscope to flush water through its auxiliary water channel is provided at: *www.MyEndoSite.com*/letters/MAJ-855.pdf

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additional tubes to maintain an adequate inventory.)

- *Note #2:* Shorter in length (10 in.) than the MAJ-855 tube (4 ft.), the MH-974 washing tube features a connector that does not impede fluid flow and facilitates the AER's connection to the auxiliary water channel, as some manufacturers of AERs recommend.[13,27]

C. The following guidance is provided if the medical facility (e.g., its GI endoscopy unit) is considering to use an AER model to reprocess the MAJ-855 tube either while connected to the auxiliary water channel or by itself, separate from the GI endoscope:

a. Obtain from the AER manufacturer's quality assurance department a statement confirming that it has performed the necessary validation and verification tests (e.g., *microbiologic tests* performed under *worst-case* simulated in-use conditions) demonstrating, per FDA regulations, that the AER model can reprocess (including water rinsing and air-purging) the MAJ-855 tube (with its restrictive one-way valve firmly in place).

b. Alternatively, obtain from the manufacturer a letter confirming that the FDA has granted its AER model a 510(k) clearance to reprocess the MAJ-855 tube.

- If such a statement or letter is obtained, clarify with the manufacturer whether its AER model can be used to reprocess the MAJ-855 tube connected to the auxiliary water channel, or only by itself, separate from the GI endoscope. (If by itself, clarify whether the AER can simultaneously reprocess two MAJ-855 tubes.)

- If such a statement or FDA clearance letter is not provided to the medical facility, then the manual reprocessing of the MAJ-855 tube is advised (after *each* clinical case; *see:* Section II, above), although the automated reprocessing of the auxiliary water channel (using an adapter other than the MAJ-855 tubing, such as the MH-974 washing tube) would presumably be appropriate, unless otherwise indicated.

- *Note:* Some manufacturers may claim that their AER model(s): (a) are validated for reprocessing the auxiliary water channel via the MAJ-855 tube; (b) can reprocess the MAJ-855 tube, but only by itself (i.e., not while connected to the GI endoscope's auxiliary water channel) and one at a time (not two of them simultaneously in the same basin); or (c) cannot reprocess either the auxiliary water channel via the MAJ-855 tube or the MAJ-855 tube separately, by itself. ➡ *Medical facilities are advised to verify which of these scenarios applies to their AER model(s).*

IV. **Additional instructions are provided on p. 7, which is available only in this newsletter's *on-line* version.**

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and concluded that a breach associated with an *extremely low* risk of infection—for example, *case 2*, above, about which 1812 patients *were* notified—is different from and apparently poses a significantly *greater* risk of patient harm[8] than a breach associated with a *negligible* infection risk—for example, *case 4*, above, about which *no* patients were notified.[15]

In short, it is confusing, if not incongruous and unsound, that affected patients were not notified of the *VA Caribbean Healthcare System's* several confirmed breaches. As a precaution and in accordance with the VHA's other published risk assessments, patient-disclosure policies, and directives, notification of these affected patients is recommended.[11,15]

Recommendations: Several highlighted recommendations are provided in Table 1 (p. 3) to reduce the risk of healthcare-acquired infections associated with the specific types of breaches recently identified at a number of medical facilities within the U.S. (and Caribbean) and which are discussed herein. This table's listing of these recommendations—which completes the discussion provided in, and is to be read in conjunction with, this newsletter's *April-May-June, 2010,* issue—complements, and is neither all inclusive nor a replacement for, manufacturers' instructions. **The End** [*Article by*: L.F. Muscarella Ph.D.] *(Continued on pages 7 and 8, which are available only on-line. See: box, below.)*

➡ The **REFERENCES** to this newsletter's main article, box articles, and tables are available at:

www.myendosite.com/htmlsite/2011/refs01-0411.pdf

Thank you for your interest in this newsletter, which I founded. *I have addressed each topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*
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IV. **Additional instructions *(continued from p. 6):***

- After connecting the reprocessed ("patient-ready") MAJ-855 tube to the GI endoscope, flush and prime the auxiliary water system *prior* to beginning the clinical case, verifying that water is flowing from the GI endoscope's distal tip. *Connecting the unprimed MAJ-855 tube to the GI endoscope while the procedure is already in progress can be problematic*.[13]
- If using an automated pump to flush the patient's GI tract with water via the auxiliary water channel, discard *daily* the short irrigation tube that connects the MAJ-855 tube to the flushing pump's fluid container, in accordance with the pump's instructions. *Do not reuse from day to day this short irrigation tube*.[13,20,27]
- Sterilize *daily* this automated pump's fluid container.[20] Moreover, the manufacturer recommends using sterile water to flush the GI tract via the MAJ-855 tube.[20,27]
- Consider the use of single-patient irrigation tubing (in lieu of the MAJ-855 tube) featuring a one-way valve to prevent contamination of the water bottle. ●

Box B: *Distinctions with, or without, differences?*

Although the risk assessments below are seemingly without differences, their associated actions were, at times, quite different. Whereas infection-control breaches assessed to have a *negligible* infection risk did not result in patient notification (row 4, below), others associated with similar infection risks did result in such disclosure. (A "case" refers to those 5 discussed in the main article.)

Assessed risk of infection	Number of Patients Notified	Case or Reference
(Reportedly, no risk[1-4])	(No patients notified)	*(Case 1)*
"Extremely low"[8,12]	1812	*Case 2*
"Small but not zero"[13]	More than 10,000	*Case 3*[†]
"Negligible"[15-17]	No patients notified	*Case 4*
Extremely low[10]	More than 500	*Case 5*
"Extremely remote"[19]	9000	*Ref: 19*
"Close to nil"	150	*Ref: 32*
"Minimal to non-existent"[29]	360	*Ref: 29*
"Extremely low risk"[31]	38	*Ref: 31*
"Extremely low"	15	*Ref: 32*

[†] Case 3's breaches were also assessed to have a "*low but significant risk*"[13] of infection and a risk "*substantially less than 1 in 10,000*."[13]

Box C: San Juan—A controversial risk assessment

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The Veterans Health Administration's (VHA) decision not to notify patients of the several breaches confirmed within the *VA Caribbean Healthcare System* is controversial for a number of reasons (*see*: main article). First, the medical literature and a guideline by the CDC[9] suggest that these breaches—which included the failure to high-level disinfect *semi*-critical instruments[15] (*see: case 4*, p. 4)—pose an *increased* infection risk,[16] notwithstanding both the VAOIG's assessment that they pose a "negligible" infection risk or the VHA's notification of 1069 patients of the similar failure by the Augusta (GA) VAMC to high-level disinfect *semi*-critical instruments (*see: case 3*, p. 2).[13]

Moreover, on balance, several of these breaches confirmed within the *VA Caribbean Healthcare System* might pose *more* of an infection risk than some of those confirmed at the three VAMCs in Murfreesboro, Augusta, and Miami (see: *main article*), about which the VHA notified more than 10,000 patients. For example, whereas the Murfreesboro VAMC's improper use and reprocessing of the MAJ-855 water tube (*see*: Box A), to date, has not been linked to infection,[20] the failure to leak-test flexible endoscopes (which was one of the *VA Caribbean Healthcare System's* confirmed breaches) has been previously associated with patient morbidity and mortality.[16] What's more, this healthcare system's improper disinfection of transvaginal ultrasound transducers (*see: case 4*, p. 4) reportedly poses an *increased* risk of infection of, among other agents, the human papillomavirus (HPV).[16]

Second, whereas it did not notify affected U.S. veterans of the *VA Caribbean Healthcare System's* failure to use a detergent to clean flexible laryngoscopes prior to high-level disinfection,[15,16] the VHA notified 1812 patients of the similar failure by the St. Louis VAMC's dental clinic to use a detergent to clean dental instruments prior to steam sterilization (see: *case 2*, p. 2),[8] which is confusing.

Third, the VHA's failure to notify affected patients of this Caribbean healthcare system's several confirmed breaches is inconsistent with: (a) the VHA's published "obligation" to notify patients of such potentially adverse medical events;[11] (b) the VAOIG's published commitment to "transparency";[21] (c) the VA's mission to "protect the interest of veterans";[22] and (d) "duty-based frameworks."[14] Like the VHA's published policy of a "presumptive obligation" (*see*: main article), Dudzinski et al. (2010) state that: "health care institutions have a duty to inform patients when the delivery of health care has put them at risk."[14]

And, fourth, having not notified or monitored for infection patients who were potentially affected by the *VA Caribbean Healthcare System's* several breaches, the VHA cannot be assured that there were no cases of disease transmission.[14] In closing, it can be respectfully argued that the VAOIG's (and VHA's) assessment that this healthcare system's breaches did not pose a sufficient infection risk to warrant patient disclosure is unsound (*see:* Box A, p. 10 of this newsletter's *Apr-May-Jun, 2010*, *issue*). ı