

The Interactive Visual Navigator System for Flexible Fiberoptic Endoscope Reprocessing

BACKGROUND

Flexible fiberoptic endoscopes (FFE) are sophisticated reusable medical equipment (RME) used to identify and evaluate the function of internal organs and cavities, and to locate and biopsy tumors in them. FFEs have lighted cameras that allow visual examination and may have internal channels for the application of suction, delivery of air or water, and for biopsy and other operative procedures. Once the tube is inserted into the body, it is exposed to various pathogens and potentially harmful bacteria. Before reuse, endoscopes must undergo a decontamination process to remove these microorganisms so the next patient is not exposed to them. There are over 20 million gastroenterology (GI) endoscopic procedures performed annually in the United States¹. It is estimated that infections associated with GI endoscopy occur at a rate of 1 in almost 2 million procedures² and that the source of these infections is either failure to follow established reprocessing guidelines, or use of defective equipment³.

Endoscope reprocessing is a complex process typically consisting of precleaning, leak testing, manual cleaning, high-level disinfection/sterilization, and rinsing and drying (with alcohol flush)⁴. While some departments in a hospital have individual sterilization capability, it is more common that a Sterile Processing Service (SPS) area processes all RME. These areas are typically divided into decontamination, assembly and packing, sterile storage and distribution areas⁵. Used RME is collected and taken to the decontamination (“dirty”) area where it is sorted and soaked, if required. Personnel working in the decontamination area should wear protective clothing including a scrub uniform covered by a moisture-resistant barrier, shoe covers, rubber or plastic gloves and a hair covering. During manual cleaning processes, personnel should wear safety goggles and a face mask. Once the RME is cleaned and decontaminated, it is moved to the assembly and packaging (“clean”) area where it is put back together and prepared for either issue (for immediate use), storage, or further processing, such as high-level disinfection.

The specific steps within this process depend on make and model of the endoscope, and the type of sterilization used. Because there are a number of endoscope manufacturers producing a variety of models for different procedures, correct reprocessing according to manufacturers specifications presents a challenge to technicians. A study that investigated the usability of reprocessing instructions indicated that novice technicians were unable to correctly disinfect and sterilize FFEs using traditionally-supplied instructions⁶.

The risk of improper reprocessing of FFE has prompted organizations around the world to develop guidelines and recommendations in an effort to reduce associated infection^{3,7-11}. Although these guidelines specify characteristics of proper decontamination, they do not indicate how to achieve it. This requires facilities to implement the recommendations in whatever manner they can. The guidelines consistently emphasize 1) staff training, 2) following manufacturers’ instructions, and 3) proper storage of clean, sterilized and disinfected equipment.

Between January 1 and September 30, 2010, the Veterans Affairs (VA) Office of Inspector General reviewed 45 VA facilities for compliance with VA standards for RME practices and identified six areas for improvement¹². The Interactive Visual Navigator (IVN™) system was

developed by the Veterans Administration in collaboration with Wayne State University to address three of these six areas. They are: standard operating procedures (SOPs) are current, consistent with manufacturers' instructions, and located within the reprocessing areas; employees consistently follow SOPs, supervisors monitor compliance, and annual training and competency assessments are completed and documented; and processes for consistent internal oversight of RME activities are established to ensure senior management involvement¹².

This paper presents the considerations and decisions made in the development and implementation of IVN™ for use in improving clinical practice operations and outcomes. It also describes observational results from the pilot site, recommendations for future versions, and conclusions based on the initial implementation.

DEVELOPMENT

IVN™ was conceived as a method of addressing three of the six areas for improvement identified by the House Committee on Veterans Affairs in response to a review of the RME practices in 2010. It consists of software to present proper reprocessing instructions and collect data, networked hardware to contain the software and display the instructions and data that is collected and displayed during system use. In order to maintain consistency, the equipment reprocessing instructions are stored on a central server and disseminated as needed. Data collected on individual endoscopes and technicians are centrally stored as well. The end user hardware is installed in the Sterile Processing Service (SPS) area so technicians can interact with it using its touch screen, keyboard or mouse.

Reprocessing Instruction Development

To ensure proper preparation for reuse, it is paramount that technicians follow manufacturer's instructions when reprocessing RME. The goal of IVN™ is to present these instructions in a manner that is readable and understandable so technicians may easily follow them. Manufacturers provide their instructions in a variety of manuals which rarely contain just reprocessing instructions, but rather include other model-related information concerning care. An instruction manual for one ultrasonic bronchofibervideoscope contains 178 pages, beginning with Chapter 1: Checking the Package Contents. The Reprocessing instructions begin on page 70 and end with Storage and Disposal on page 136. They include a section on the Importance of cleaning, disinfection, and sterilization and precautions about wearing appropriate personal protection equipment (PPE). The first step in Reprocessing, "Inspection of reusable equipment" begins on page 86. The instructions are mingled with Caution and Warning text containing consequences of improper step completion. This particular instruction manual contains a flowchart (including document section numbers) of the endoscope reprocessing steps on page 96. It is difficult to isolate step-by-step instructions to efficiently and effectively reprocess the RME. As a result, VA Medical Centers have developed Standard Operating Procedures (SOPs) based on the OEM instructions. Because adherence to these instructions is vital, the SOPs are laminated and displayed for use. Figure 1 shows laminated SOPs posted above the sink in an actual decontamination area.



Figure 1: Posted reprocessing instructions in a decontamination area

While making the instructions accessible, this technique results in technicians interrupting their tasks to visually search for the next instruction to follow. Once found, verbiage in the OEM instructions may contain language and sentence structure that exceeds the expected reading ability of SPS Technicians. Although they are high school graduates and have typically passed a Sterile Processing Course, over 150 endoscope models exist in the VHA system and most have separate instructions to follow. Making sure the technician comprehends the instructions is important to the success of reprocessing and is a goal of IVN™.

Prior to implementation at a site, the OEM instructions for endoscopes used at that location are isolated, chunked into units for display on a screen, and processed for usability by SPS technicians on IVN™. The eleven principles described in Wagner, et al. (1996)¹³, including clear, simple language, active voice, second person imperative and third person indicative are followed to increase the usability and reduce the grade level of the instructions. The Flesch-

Kincaid Grade Level¹⁴⁻¹⁷ was used to evaluate the writing level of the OEM and the resultant instructions shown on IVN™. To comply with the OEM instructions, each endoscope reprocessing instructions begin with the purpose, equipment, location, a description of the overall procedure and a list of needed supplies, accompanied by an image of each supply. Step 1 is to wash hands and wear a list of PPE, since that is a standard requirement for all RME reprocessing. When images are included in the OEM instructions, they are made available to SPS technicians by selecting or touching an icon. Since the technicians refer to the screen periodically, white space is used between the steps to reduce text density and decrease visual search time to find the next instruction¹⁸⁻¹⁹. Selection of a timer (hourglass icon) is mandated to continue using IVN™ when the instructions indicate to perform a step for a specific period of time. Once the instructions are completed, they are reviewed for adherence to OEM instructions and local SOPs. See Figure 2 for example IVN™ instruction displays.

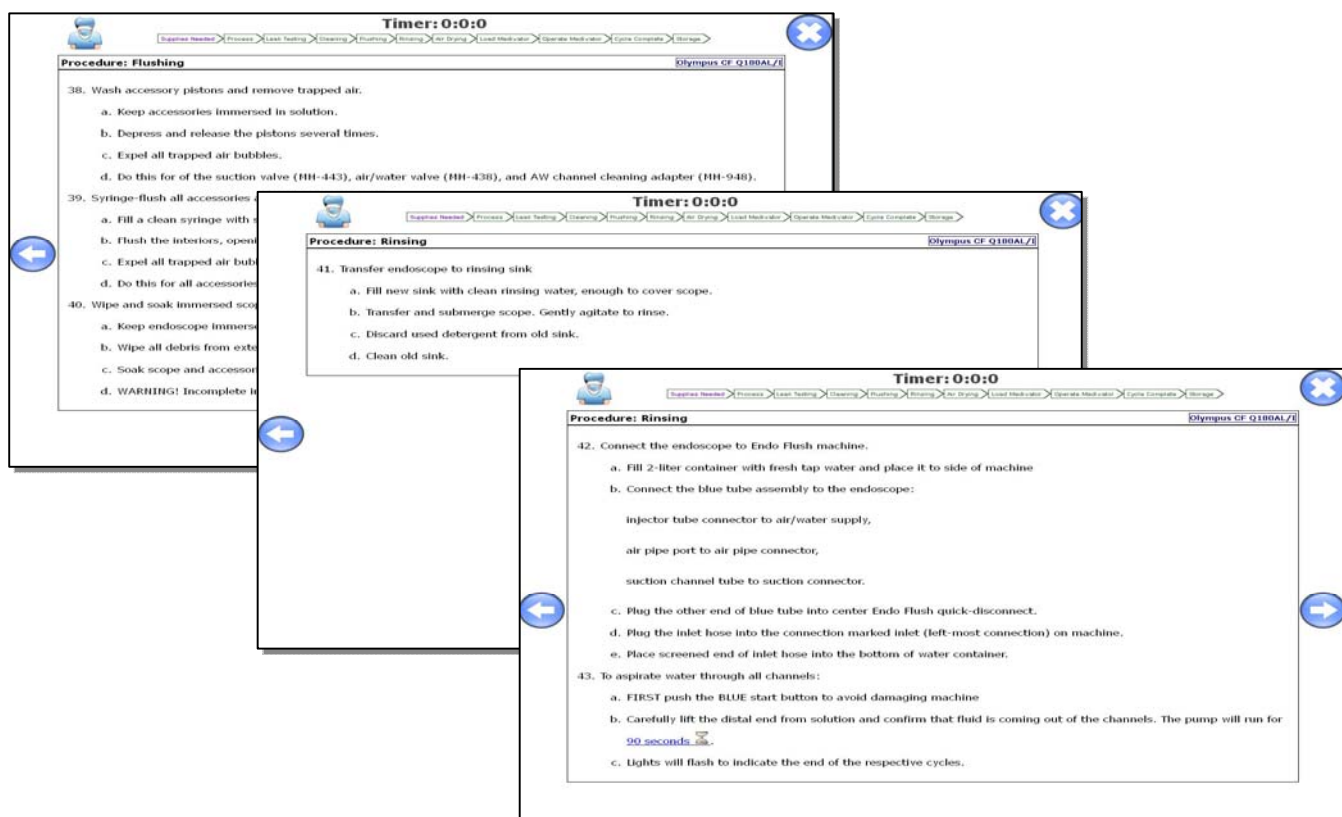


Figure 2. Work instruction screenshots from the IVN™

Installation Design considerations

Making IVN™ accessible to technicians in the SPS areas depends on the layout of the facility, special considerations of a sterile environment, and consideration for the physical attributes of technicians. Because many choices for IVN™ installation are facility specific, flexibility was a central concern. When these requirements were considered, it was decided that a hermetically-sealed touch screen secured with an adjustable wall mount bracket best meets the height and location needs of the variety of technicians in a facility. There are several acceptable medical grade personal computers with a 17 inch display available that are sealed for dust-free and waterproof operation. Some casings contain an antimicrobial additive to fight surface bacteria²⁰.

The reason a sealed unit was selected for IVN™ is to reduce contamination if it is ever taken from the SPS area. For example, if it is removed for a repair or other reason, technicians must decontaminate it before it is returned to the SPS area. This is possible with a hermetically sealed unit by spraying with a decontaminant and wiping it clean. It is recommended that each IVN™ unit also include a medical grade keyboard and mouse.

A wall mounted, adjustable arm is recommended to secure the IVN™ unit to the wall for technician use. One available unit has an arm that extends 19 inches from the wall with a wide range of motion up, down and tilting 70 degrees up and 5 degrees down²¹. The recommended height for placement for the center of the bracket on the wall is 157.5 centimeters or 5 feet, 2 inches. This is based on the average eye height of United States Army personnel in 1994²². Although it is possible that the average height has changed, the range of adjustment possible with these units accommodates height differences. Figure 3 shows IVN™ in use.



Figure 3: IVN™ in use in the ‘dirty’ area of an SPS.

IVN™ Data Collection

IVN™ is a networked system that presents reprocessing instructions for endoscope models. It also collects and stores data related to specific endoscope reprocessing and storage, and data related to technician performance and competency assessment. IVN™ instructions are displayed on a 17-inch hermetically sealed touch screen computer monitor attached with a wall-mounted adjustable arm, and an optional mouse and keyboard. Each technician and manager is assigned a unique login identifier which they use to access IVN™ processes. To initiate the display of reprocessing instructions, technicians enter the final four digits of the endoscope's serial number, and a list of endoscopes matching that number appears. For each of the scopes on the list, IVN™ checks against the technician's competency profile. If an endoscope is a model that the technician has passed a competency check within the time specified (one year is the default), IVN™ allows access to the respective Work Instruction Module (WIM). If the competency check has lapsed, IVN™ presents contact information for the SPS Manager who will perform the competency check. Figure 4 contains a screen shot of the competency check and message to the technician. To proceed in reprocessing the endoscope with serial number 33333333, the technician selects the blue arrow in the "Start iNAV" column.

Within this context, competency refers to whether the technician has completed training within an acceptable time frame. IVN™ disables access to an endoscope reprocessing procedure that has a lapse in competency check until the SPS Manager records completion of a competency check by the technician for that model. Figure 5 contains a screen shot of a report on the competency of a specific technician. This report is available to the SPS Manager and the technician. This view indicates checks that have or are about to expire, by endoscope type, manufacturer and model number. The House Committee on Veterans Affairs (2011)¹² indicates that annual training and competency assessments are completed and documented motivated the once-a-year assessment requirement in IVN™.

IVN™ contains other reports to aid in scheduling of endoscope reprocessing and training. It also accommodates the VA's requirement for regular review of the step-by-step instructions presented to the SPS Technicians. IVN™ stores completion time for each step of reprocessing, which managers might use to determine performance measures as well as technician competency. Comparing recorded time with minimum time highlights technicians that are not taking appropriate time to reprocess. It may also indicate faulty work instructions.

Because manufacturers revise reprocessing instructions, IVN™ keeps a history of revision dates and notifies both technicians and SPS Managers when a review is needed. Instructions expire after one year. At eleven months following the last revision date, IVN™ displays a warning on the screen to technicians reprocessing affected endoscope models. In addition, IVN™ notifies the SPS Manager by color-coding on the Work Instruction Module (WIM) report shown in Figure 4. This feature enables a regular update of reprocessing instructions, which are subject to revisions from manufacturers as well as feedback from reprocessing practices.

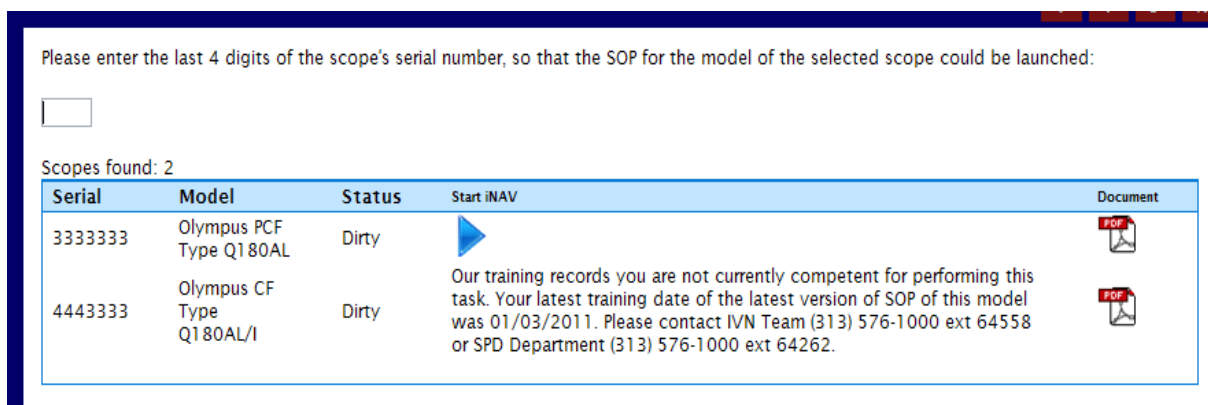


Figure 4: Screen shot of display after the last four digits of an endoscope serial number entered

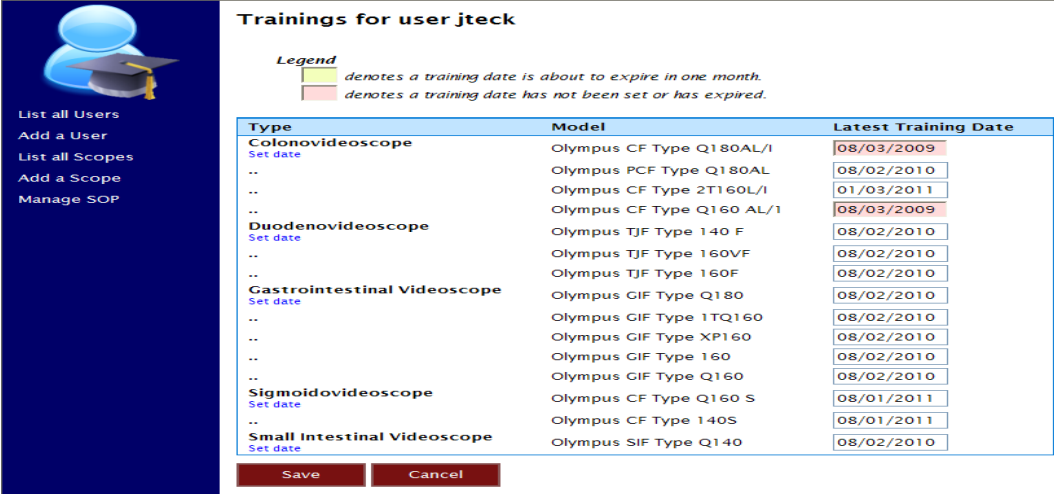
IMPLEMENTATION OBSERVATIONS

A Midwestern VA Medical Center was selected as the pilot implementation site, going live in the fall of 2012. Three observations of three experienced technicians each were performed in March and April of 2012. It is clear that the technicians have a strong preference for IVN™ over the paper SOPs that were used before as it is convenient, and because it includes a timer to direct how long critical steps take. The technicians indicated that because they are very experienced, they tend to perform the tasks in a cluster and cycle through the IVN steps once a cluster of tasks are complete. They agreed that the timers are invaluable measures.

The technicians in the dirty area of the SPS reprocess endoscopes one at a time, as it is a manual process. The technicians in the clean area, however, are able to process at one time as many endoscopes as they have sterilizing machines. Ideally, the technicians would like to have IVN™ interface with the sterilizing machines. Like IVN™, the sterilizing machines have a screen that shows the time remaining in the wash cycle. If a technician wants to start the washing cycle for another endoscope, they must start another IVN™ session and toggle between the sessions. This results in confusion when relating the sterilizing machine processing with the correct endoscope. They prefer that the sterilizing machine communicate to IVN™ directly that the washing cycle is over, so IVN™ advances to the next step. Until that is possible, they would like to have the IVN™ screen split between the endoscopes that are in the sterilizing machines. Clearly displaying the endoscope identifier at the top of each screen would allow the technicians to identify the proper screen to continue processing once the sterilizing cycle completes. Tapping on the screen should expand that IVN™ screen to continue processing direction.

Analysis of the data gathered by IVN™ showed that the average processing time for endoscopes matches the expected time to process. This is true whether the technicians stepped through the instructions one at a time or processed the steps in a batch mode. That is, they performed the steps a few at a time and then indicated to IVN™ that they had completed the steps. Therefore, the recorded total processing times by IVN™ for endoscopes of the same model can be used as a basis to measure reprocessing productivity, the variation in processing times between technicians, and variation between different facilities can be used to do many interesting analysis. Since IVN™ kept complete records and data for all endoscopes reprocessing jobs,

including technician identification, endoscope serial number, and the complete time segment records for each step of the reprocessing process, this information is a valuable asset for possible trouble shooting and root cause analysis, whenever possible abnormality occurs.



Type	Model	Latest Training Date
Colonovideoscope	Olympus CF Type Q180AL/I	08/03/2009
Set date	Olympus PCF Type Q180AL	08/02/2010
..	Olympus CF Type 2T160L/I	01/03/2011
..	Olympus CF Type Q160 AL/I	08/03/2009
Duodenovideoscope	Olympus TJF Type 140 F	08/02/2010
Set date	Olympus TJF Type 160VF	08/02/2010
..	Olympus TJF Type 160F	08/02/2010
Gastrointestinal Videoscope	Olympus GIF Type Q180	08/02/2010
Set date	Olympus GIF Type 1TQ160	08/02/2010
..	Olympus GIF Type XP160	08/02/2010
..	Olympus GIF Type 160	08/02/2010
..	Olympus GIF Type Q160	08/02/2010
Sigmoidovideoscope	Olympus CF Type Q160 S	08/01/2011
Set date	Olympus CF Type 140S	08/01/2011
Small Intestinal Videoscope	Olympus SIF Type Q140	08/02/2010
Set date		

Figure 5: Manager's view of competencies for a specific technician

RECOMMENDATIONS

Based on the observational studies and data analysis, the following recommendations are made for future versions of the IVN™ system, in order of priority.

1. Format the display such that it is more convenient to monitor the progress of multiple disinfecting machines when reprocessing several endoscopes simultaneously. This is relevant to the final steps in scope processing in the 'clean' SPS area. The technicians suggested that IVN™ directly interface with the sterilizing machines, but until that is possible, another method may suffice.
2. Provide an 'expert' mode option, based on the number of endoscopes a technician has reprocessed. This mode would present a summary of instructions with details available by selecting an icon on the screen. It would include timers for all steps that require a specified period of time to complete.
3. Align process time collection with steps in the instructions. This allows for more accurate analysis of technician performance and the adequacy of the instructions.

These modifications should accommodate the skill set of the technicians and provide a more efficient method of properly reprocessing endoscopes.

CONCLUSIONS

IVN™ was conceived as a tool to implement a standardized method of following established guidelines and especially those specified by the VA House Committee. It incorporates

technology that allows for the collection of information and dissemination of updates in an efficient manner. IVN™ is currently implemented at a pilot site with a planned roll out to all facilities in the network over the next several years. IVN™ consists of software, networked hardware, and data that display instructions for correct reprocessing on a 17 inch (minimum) hermetically sealed touch screen. The instructions are based on manufacturer's instructions for the specific endoscope model. Each endoscope is tagged with a unique identifier. IVN™ collects data on the time to process steps and provides reports on technician certifications and dates when endoscopes were decontaminated. Based on this data, IVN™ identifies endoscopes that require reprocessing due to the length of time they are in storage. IVN™ is installed in the SPS area of facilities where reprocessing technicians can interact with it. Since the data is stored in a central location, the reports are available to managers in their office, away from the technicians that use the system. IVN™ was developed to accommodate the novice technician, including detailed instructions and images to direct reprocessing. Once a technician is sufficiently practiced, grouping the instructions together and providing fewer details allows the experienced technician to follow the instructions to efficiently reprocess endoscopes. The developers of the next version of IVN™ should consider accommodating more experienced technicians.

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