A Lens on Quality

Scope Survey at Leading Minnesota Hospital Identifies Faulty Laparoscopes in Medical Equipment Inventory

THE HIDDEN CHALLENGE

As the healthcare industry and patients embrace minimally invasive therapies, with their advantages of quick recovery times and less time spent in hospitals, endoscopes have become workhorses in clinical practice.

For hospitals and other clinical facilities, that demand translates into diverse and expanding inventories of rigid, semi-rigid and flexible endoscopes used for millions of procedures every year. Healthcare technology managers by now should be aware of two significant, well-publicized challenges with these highly used devices—endoscope reprocessing and tracking:

1. "Inadequate reprocessing of endoscopic devices and surgical instruments" appears on ECRI Institute's Top 10 Technology Hazards for 2013 (ECRI Institute, 2012), a challenge that has appeared on the list for several years.
2. The Joint Commission now requires accredited healthcare facilities to track both flexible and rigid endoscopes in their medical equipment inventories, a particular challenge with rigid endoscopes because this equipment is often replaced.

But there is a third challenge that is less recognized, but equally relevant, to endoscope performance and management:

3. **There is considerable variability in the quality of optical images from one "scope" to another—even in devices of the same type and brand. Faulty images compromise the safety and accuracy of therapeutic, diagnostic and surgical procedures, driving up risks and costs.**

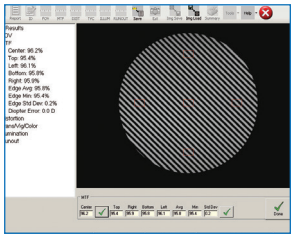
Image quality matters. High-quality images from properly functioning endoscopes contribute to patient safety and clinical care, as well as the cost-effective management and efficient serviceability of the devices themselves. Despite these substantive effects on key healthcare priorities, however, not all healthcare delivery organizations are attending systematically to the image quality of their endoscope inventories.

ABOUT THE EVALUATION

Lighthouse Imaging conducted an on-site evaluation of one hospital's entire inventory of laparoscopes—rigid endoscopes used for abdominal procedures. The goal of this evaluation was to develop a snapshot of the optical image quality of a typical hospital's inventory of endoscopes in quantifiable form, and to identify any devices in need of repair.

The evaluation included both quantitative testing and qualitative analysis. For the quantitative testing, Lighthouse Imaging used its EndoBench system, a quality tester for measuring and verifying clinically relevant optical characteristics of endoscopes. For the qualitative testing, Lighthouse Imaging conducted a visual inspection of the condition of each laparoscope in the inventory.

In all, 64 laparoscopes, consisting of seven different models, were tested. The model quantities ranged from a single device to as many as 13 devices of one



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THE GROWING ENDOSCOPE MARKET

Market research data provide an indication of the increasing demand for endoscopic care. The global endoscopy market was valued at $6.1 billion in 2011; by 2016, the market is projected to be worth $9.7 billion, with North America the largest market.
(MarketandMarkets, 2012).

specific model. No effort was made to determine the manufacturer's specifications or tolerances for each model, as these values are often difficult or impossible to ascertain.

ABOUT THE HOSPITAL

The evaluation was conducted at Fairview Southdale Hospital, a leading hospital in Edina, Minnesota. As a major surgery center, the hospital's inventory of rigid endoscopy equipment consisted primarily of 5 mm and 10 mm laparoscopes. Notable observations about this hospital's management of its endoscope inventory:

- **Supplier.** All of the laparoscopes tested came from a single original equipment manufacturer (OEM), with a mix of standard and lower-cost variants of the OEM's standard product lines.
- **Reprocessing.** The hospital follows a fairly typical workflow, where the endoscopes are low-level disinfected after use and then sent to a central sterile processing location for high-level sterilization and storage until needed. In an apparent nod to the latest Joint Commission requirements, the endoscopes are stored and transported in serialized trays. However, the trays are not unique to the particular endoscope. Thus, while the trays would prove useful for tracking a particular endoscope through one usage cycle, they would not be a guaranteed aid in identifying a problem endoscope that might be continually rotating through the usage cycle. In short, the specific serial number of each endoscope was not tracked in any identifiable way.
- **Servicing.** The hospital contracts with an independent service organization (ISO) for endoscope repair services.

KEY FINDINGS

Quantitative Findings

More than 10 percent of endoscopes tested were deficient in image resolution. The primary quantitative measure of image quality captured by the

Sample Qualitative and Quantitative Data From Endoscope Evaluation

Insertion Diameter	ID2	Comment	MTF Center	MTF Avg	MTF Min	Real FOV
5	5MM 30 DEGREE SCOPE #4	Rough sheath, scratches, cloudy light cone;	60.89453	56.70665	49.31991	66.64188
5	5MM 30 DEGREE SCOPE #7	Smooth sheat, clear light cone; Illumination way right	56.47057	47.74843	32.95583	66.99923
5	5MM 30 DEGREE SCOPE #3	Smooth sheath, slightly cloudy light cone, distal scratches;	67.43086	58.09336	33.91906	63.42698
5	5MM 30 DEGREE SCOPE #10	Smooth sheath, slightly cloudy light cone;	68.99997	53.21842	33.22212	62.60432
5	5MM 30 DEGREE SCOPE NL	Few nicks in sheath, slightly cloudy light cone;	65.96338	53.31735	31.11135	66.72099
5	5MM 0 DEGREE SCOPE #10	Straight sheath, dust in image, cloudy light cone;	76.39864	36.71187	19.1278	98.19617
5	5MM 0 DEGREE SCOPE #NL	Smooth sheath, clear light cone, distal burr, grooved eyepiece; No data possible	0	0	0	0
5	5MM 0 DEGREE SCOPE #11	smooth sheath, clear light cone;	67.46655	60.50557	57.40477	65.62823
5	5MM 0 DEGREE SCOPE #15	smooth sheath, clear light cone;	69.10191	30.87849	19.38224	98.0467
10	10MM 30 DEGREE SCOPE #9	clean sheath, clear light cone, crack in distal tip;	55.45109	49.67388	22.40924	70.76682
5	5MM 0 DEGREE SCOPE #2	few nicks on sheath, clear light cone;	69.24702	58.10796	50.52644	64.64165
10	110MM 0 DEGREE SCOPE #2	clean sheath, clear light cone;	41.17049	35.13649	27.64621	69.94099
10	10MM 30 DEGREE SCOPE #1	slight nick in sheath, slightly cloudy light cone, sharp edge on distal tip;	46.5732	54.25162	50.0532	72.3788
4	4MM 30 DEGREE SCOPE #1	Ding in sheath, clear light cone, heavy curve in shaft;	66.40591	43.26687	31.40984	67.84637
5	5MM 0 DEGREE SCOPE #12	Ding in sheath, clear light cone;	69.03748	54.69656	45.87519	68.33895

EndoBench system is Modulation Transfer Function, or MTF. This parameter objectively quantifies the image resolution of endoscope optics using a custom, backlit optical target and calibrated camera system and software.

In this evaluation, seven of the 64 laparoscopes tested, or about 10.9 percent, were found to be deficient in image clarity and sharpness. The hospital sent the deficient devices to the ISO for servicing, with defined parameters on image quality for their repair. When they were returned, the devices were retested and measured to be of exceptional image quality.

Two of 12 endoscopes of one particular model had significant deviations in field of view. Another key quantitative value of image quality is real field of view (R-FOV), a measure of the viewable area that can be seen through the endoscope.

In this evaluation, two of the 12 laparoscopes tested had significant deviations in R-FOV, or variations in magnification, as shown in the figure below. Ten of the 12 endoscopes had a mean R-FOV of 65°, with a very tight distribution. Two of the endoscopes had R-FOV values of 98°—many times the confidence interval of the other tested devices of this same model.

This is a disturbing finding. The only likely explanation for this anomaly is that the two outliers had been repaired with incorrect imaging lenses. These two devices were among the seven endoscopes that the hospital sent to the ISO for repair. When they were returned, the devices were retested. The R-FOV values measured within approximately 10° of the main population mean.

Qualitative Findings

Wear and tear, and reprocessing, take a toll on endoscopes and image quality. A visual inspection of the external condition of all 64 laparoscopes revealed that about 25 percent of the inventory had small nicks, dents or bends in the optical sheath. A small number of the devices showed signs of slight damage to the optics, including scratches on the distal lens or "cloudiness" in the fiber optic light cone.

In addition, most of endoscopes examined had a film over the distal surface, apparently left behind by the sterilization process. This film needed to be cleaned off before acceptable and repeatable image quality test results could be obtained.

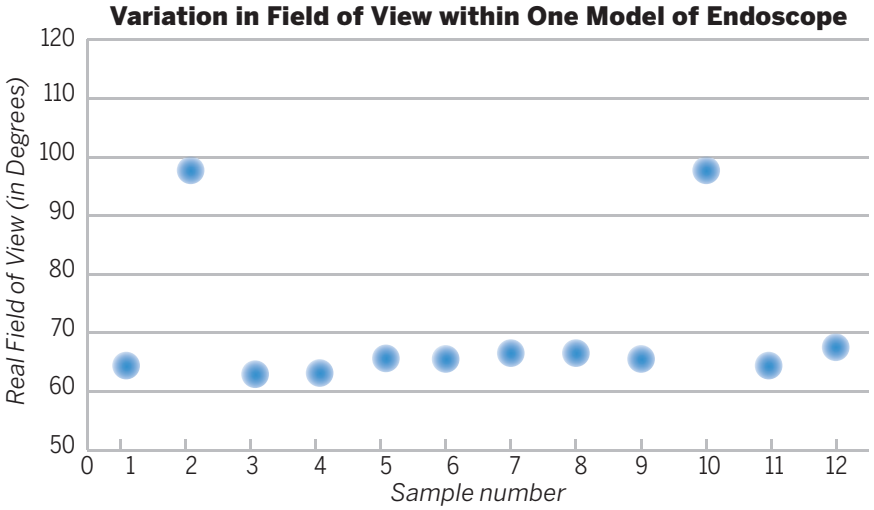


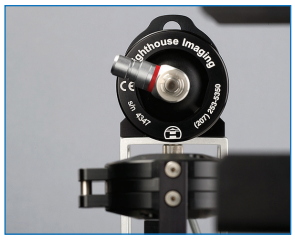
Image quality and endoscope performance are easily compromised. A final interesting data point: physical damage to an endoscope does not have to result in catastrophic failure to measurably affect image quality.

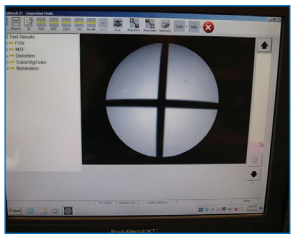
One laparoscope that passed its initial, non-sterile image testing with flying colors was sent to central sterile for reprocessing. It was returned to the testing area almost immediately for reevaluation—with a note that the device had been dropped during handling. While the device still passed the MTF test limits for image quality, it was no longer a top performer. Its image resolution was acceptable by only the slimmest of margins.

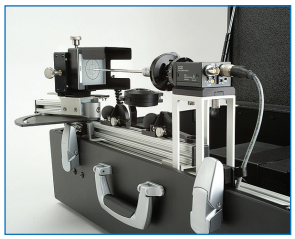
CONCLUSION

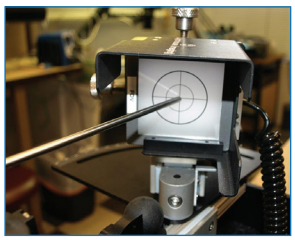
This evaluation of a typical hospital's laparoscope inventory demonstrated that visual inspection alone is necessary, but not sufficient, in examining the image quality and condition of these devices.

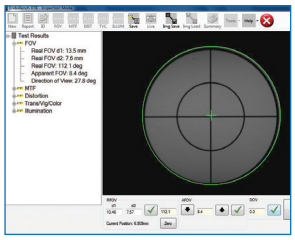
The quantitative measurements captured by the EndoBench system











identified endoscopes with deteriorated image quality due to use and handling, and defined parameters for those in need of repair. The quantitative evaluation also identified endoscopes that had been improperly repaired with incorrect image lenses at some point in their life cycle, which seriously compromised their performance. Yet these deficiencies had not been discovered during normal use or visual inspection.

Endoscopes are delicate instruments with intricate optical components—and the naked eye alone cannot accurately, reliably and consistently identify their deficiencies.

Quality assurance testing verifies image quality of endoscopes when they are new, and before and after use or repair. Quantitative measures of image quality provide information that healthcare technology managers can use to service and repair endoscopes, whether they handle services in-house or through an ISO. Consistent, high-quality endoscopic images contribute to:

- Improved patient safety and care
- Improved endoscope performance in diagnostic, therapeutic and surgical procedures
- Improved clinician satisfaction and practices
- Increased efficiency in reprocessing (no need to reprocess endoscopes that clinicians reject during patient procedures)
- Reduced equipment downtime
- Reduced costs for endoscope inventory (due to extended life of devices from quality assurance testing—and no need to keep so many "extras" on hand to compensate for deficient equipment)
- Reduced costs for troubleshooting and repair
- Improved capacity to manage endoscopes in-house, using the same calibration equipment used by OEMs and ISOs
- Availability of quantitative trend data to track endoscope inventory, servicing and repairs over time, which supports Joint Commission requirements, preventive maintenance, and procurement planning and decisions

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Lighthouse Imaging is a leading provider of optical engineering and design services for the medical device industry. Lighthouse Imaging specializes in medical optics design and assembly as an FDA-registered medical device manufacturer. Our services and expertise include endoscopic instrumentation, in-house optical testing and evaluation, optical test and measurement systems, medical illumination, fiber optic imaging systems technology, feasibility studies and product definition.

EndoBench is an endoscope image quality test system that consists of a custom-designed opto-mechanical system and software to evaluate and report the parameters that are central to a clinical environment.
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