

Overview of the 3M™ Clean-Trace™ ATP Monitoring System

- LX25 Luminometer & Quality
Control Data Manager(QCDM)

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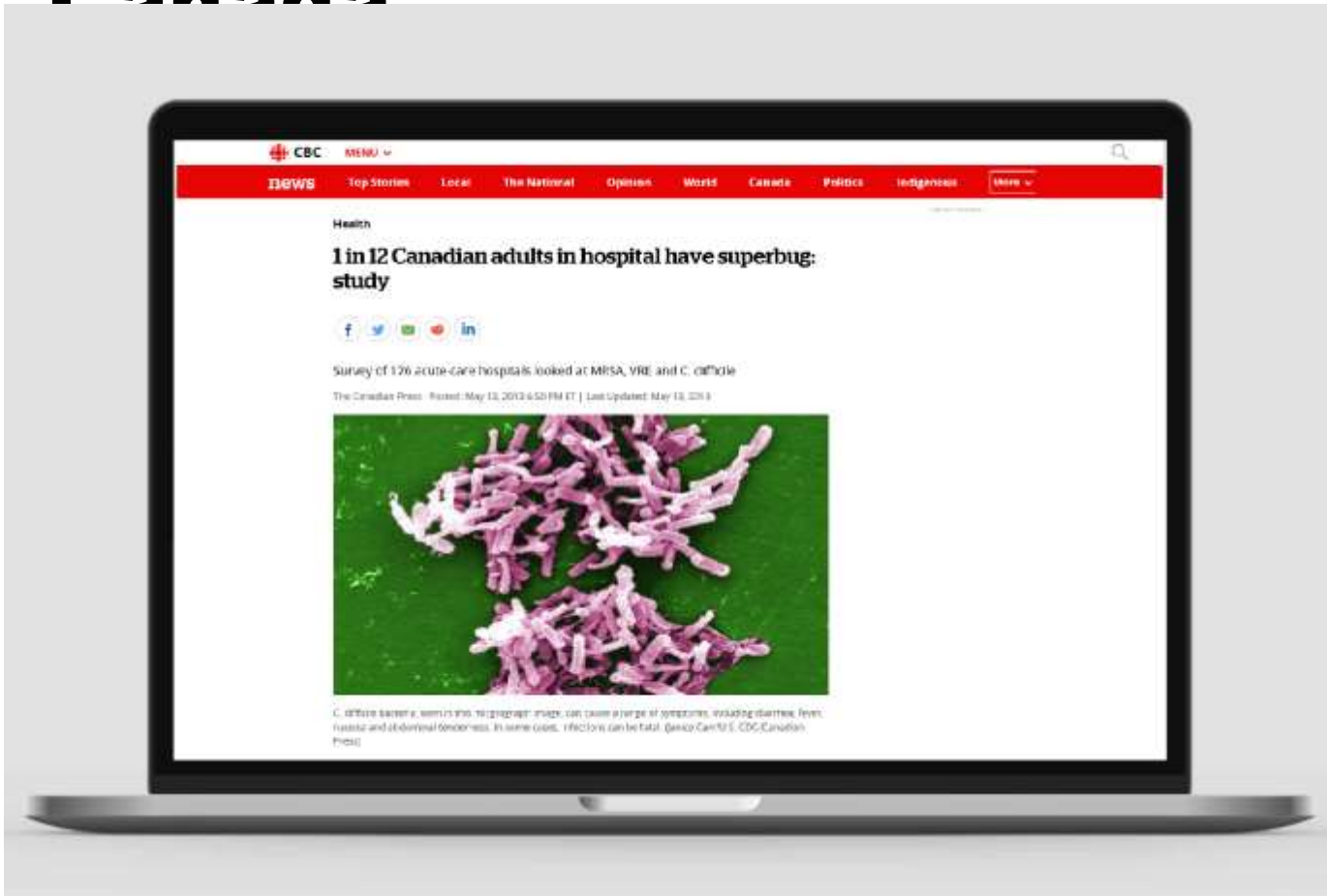
Objectives

- **The Importance of Cleaning**
- **3M™ Clean-Trace™ LX25 and QCDM**
- **CDC, CSA Guidelines Z314-2018 edition**
- **Product/Software Features**
- **3M Implementation suggestions**



Why Cleaning and Clean Monitoring is Important

Why is cleaning making the news? HAIs, Superbugs... Canada



Every year:

- > 220, 000 Canadians develop infections during a hospital stay
- On average, these infections kill 22 patients every day
- Hospitalized patients are more susceptible to infection
- Cost range from \$2,000 to \$20,000 each
- Massive burden on health care in Canada, and its getting worse

Manual cleaning is important!

- All soil must be removed from devices as most disinfectants and sterilants do not penetrate through organic matter
- Soil can protect microbes from disinfection and sterilization
- Surviving microbes have potential to be transmitted to another patient, causing infection
- Recommended practices, Standards and Guidelines are beginning to emphasize the importance of monitoring cleaning efficacy
 - **Canadian Standard Association (CSA)**
 - **Centers for Disease Control and Prevention (CDC)**
 - **Association of periOperative Registered Nurses (AORN)**
 - **Association for the Advancement of Medical Instrumentation (AAMI)**



Why monitoring is important!

- **Ensure compliance** to your facility's established procedures are followed every day
- **Identify problems** and assess patient risk
- Ensure processes are under control and **effective**
- Focus and drive cleaning **process improvement**
- Use as a tool to assist with **staff training and competency**

Just because it looks clean does not mean it is clean...

**You can't see biological residues.
You can't see biofilm or microbes.
You can't see inside long narrow lumens.**



**Flexible
Endoscopes (Endo)**



**Surgical
Instruments (SI)**



**Environmental
Surfaces (Evs)**

Environmental Surfaces

One of the greatest infection risks to a patient entering a healthcare facility is acquiring a pathogen from a prior room occupant who was infected or colonized with a multi-drug resistant organism (MDRO).

- Hospital rooms and equipment may be complex in design and difficult to clean.¹
- Patients are the largest contributors to pathogens present in the near-patient environment.²
- Compliance to established cleaning protocols can be as low as 50%, leaving behind contaminated surfaces for the next room occupant.^{3,4}

1. Olivia Ellis et al. 2018, How to better monitor and clean irregular surfaces in operating rooms, Am J Infect Control 46:906-12.

2. Ruth Carrico, Ph.D., RN, FSHEA, CIC. Environmental Services Infection Prevention and Control Bundle. Clean Spaces Healthy Patients Webinar. January 2012. <http://cleanspaces.site.apic.org/events/tools-and-resources>.

3. Boyce, J.M. et al. 2012. Monitoring the Effectiveness of Hospital Cleaning Practices by Use of an Adenosine Triphosphate Bioluminescence Assay. Infect Control Hosp Epidemiol. Vol.30, No. 7 pp. 678-84.

4. Carling, P.C. et al. 2010. Eval hygienic cleaning in health care settings: What you do not know can harm your patients. Am J Infect Control 38:S41-50.

Environmental Surfaces

- Pathogens that are not removed or killed during cleaning and disinfection persist on environmental surfaces for weeks to months.⁵
- Contaminated environmental surfaces are an important source for transmission of healthcare-associated pathogens such as *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant enterococci (VRE).⁴
- Healthcare workers can contaminate their hands by touching contaminated surfaces and then transfer pathogens to their patients via touch.^{4,5}

4. Donskey, C., et al. 2012. Daily Disinfection of High-Touch Surfaces in Isolation Rooms to Reduce Contamination of Healthcare Workers' Hands. *Infect Control Hosp Epidemiol*. Vol. 33, No. 10 pp. 1039-1042.

5. Otter, J.A. 2011. The Role Played by Contaminated Surfaces in the Transmission of Nosocomial Pathogens. *Infect Control Hosp Epidemiol*. Vol. 32, No.7, pp. 687-99.

Flexible endoscopes are difficult to reprocess



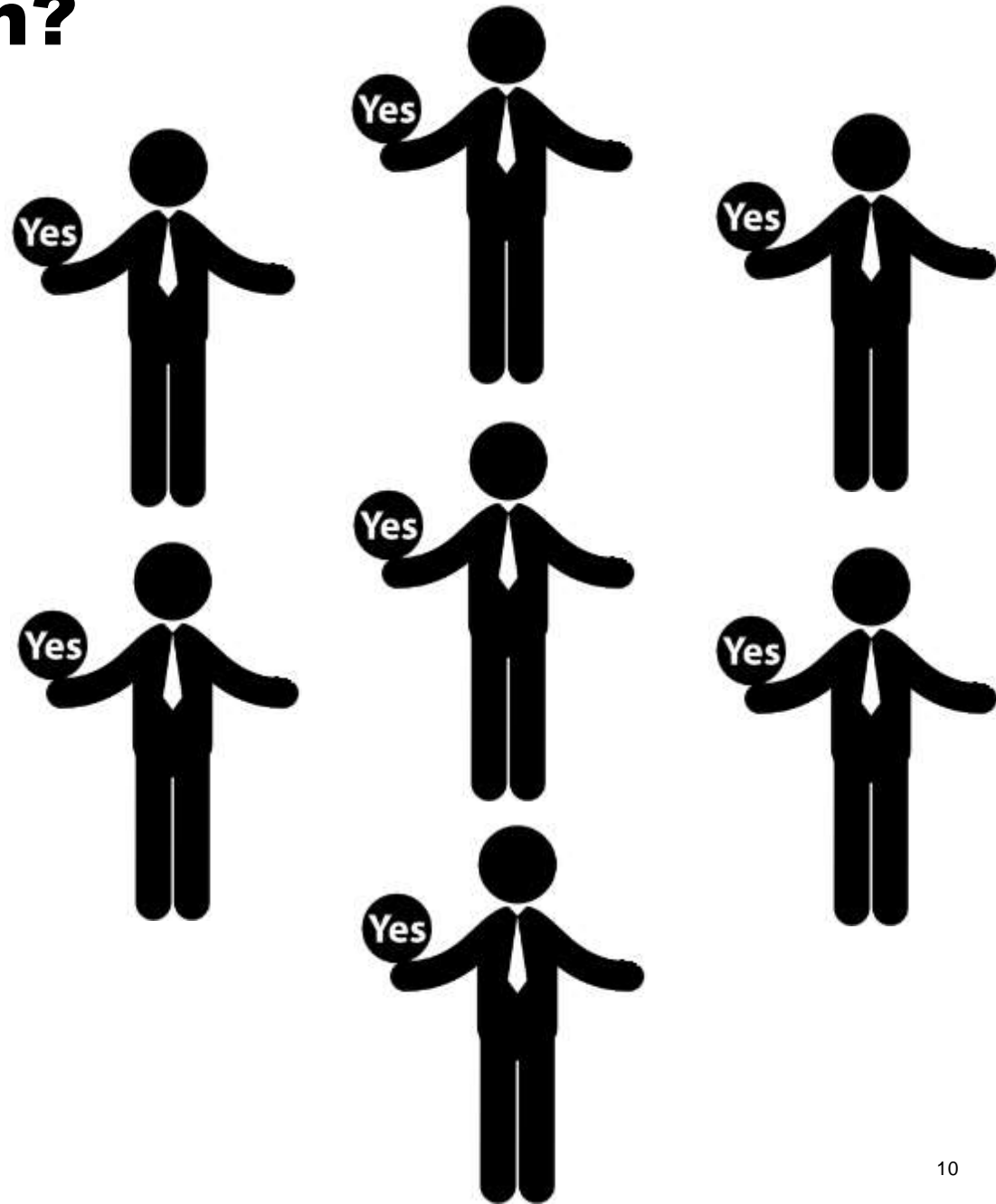
- Complex design
- Multiple long, narrow channels that are difficult to clean
- Lack of consistent, effective training
- Lack of time and resources for adequate reprocessing
- Visual inspection not adequate to monitor efficacy of reprocessing
- >130 steps involved in reprocessing!

Rutala, WA, Weber, DJ. ERCP scopes: What can we do to prevent infections? *Infect Control Hosp Epidemiol* 2015;36:643–648

What does everyone agree on?

FOCUS ON MANUAL CLEANING

- It is a problem
- It is critical for success of High Level Disinfection (HLD) and sterilization
- Lack of proper manual cleaning contributed to outbreaks
- It can be improved
- Evaluate effectiveness of cleaning procedures
- Use validated, real-time indicators of cleaning efficacy
 - [3M™ Clean-Trace™ ATP Monitoring System](#)





Product Details

3M™ Clean-Trace™ System components by application

**Flexible
Endoscopes
& Lumened
Instruments**

**Environmenta
l Surfaces**

**Surgical
Instruments**

Hardware
3M™ Clean-Trace™
Luminometer LX25



Consumables
3M™ Clean-Trace™ ATP Surface Test
3M™ Clean-Trace™ ATP Water Test H2O
UXC



3M™ Clean-Trace™
ATP Surface Test



Software
3M™ Quality Control
Data Manager (QCDM)



3M™ Clean-Trace™ Luminometer LX25

- Modern look and feel
- Ergonomic design fits comfortably in the hand and provides easy test sample insert
- Intuitive colour touch screen and interface
- Results automatically uploaded to 3M™ QCDM via WiFi
- Quantitative RLU measurement and easy to interpret Pass/Fail result
- **Rapid readout ≤ 10 seconds**

BENEFIT: Easy & efficient to use!

Access the LX25 **Operational Manual**
[3M.com/CleanTrace](https://www.3m.com/CleanTrace)



Storage and shelf life

Clean-Trace™ ATP Surface and ATP Water Test

Shelf Life of Clean-Trace™ ATP Surface Test:

10 months from date of manufacture. Storage of Clean-Trace™ ATP Surface Test under conditions other than what is recommended will decrease the shelf life of product.

Shelf Life of Clean-Trace™ ATP Water Test:

12 months from date of manufacture. Storage of Clean-Trace™ ATP Water Test under conditions other than what is recommended will decrease the shelf life of product.

Clean-Trace™ ATP Surface Test and ATP Water Test Storage:

- **Between 2 and 8°C** for long-term storage. Storage under any other conditions should be avoided if possible.
- Do not remove the Clean-Trace™ ATP Surface Test from the pouch until ready to use.

3M™ Quality Control Data Manager

- Intuitive, Visual Dashboards
- Mobile-Dashboard Access
- Easy, Adjustable Reporting
- Scheduled Reporting
- Preloaded info for set-up, excel upload option for high-volume entries (e.g. room numbers, scope serial numbers, names of EVS staff)

BENEFITS: Easy data analysis, view data on-the-go, efficient & effective reporting for analysis & record-keeping, streamlined set-up



Testing is as Easy as 1...2...3

Sample



Click + Shake



Measure



In less than 10 seconds, the Clean-Trace System can quantify the cleanliness of a surface or lumen sample using Adenosine triphosphate (ATP) bioluminescence.





Key Messages and Benefits

3M™ Clean-Trace™ ATP Monitoring System Key Messages

Best-in-Class Cleaning Monitoring Verification System on the Market

Why cleaning monitoring

Evidence supports and standards recommend routine cleaning monitoring

- Visual inspection cannot reliably detect contamination
- Outbreaks cause patient infection and death
- Key professional guidelines and standards include cleaning verification testing as part of a comprehensive quality control program for reprocessing flexible endoscopes and surgical instruments, and cleaning patient care surfaces
 - CSA
 - AAMI
 - AORN
 - SGNA

Why ATP and Clean-Trace™ System

3M™ Clean-Trace™ Monitoring System is an advanced cleaning verification method

- Clean-Trace™ uses ATP bioluminescence technology to provide a quantitative measurement of cleaning efficacy
 - Validated benchmark
 - Cited in multiple clinical studies
- The new 3M™ Clean-Trace™ Luminometer LX25 and 3M Quality Control Data Manager is an advanced ATP system with many new features, benefits and advantages
 - WiFi syncing
 - Modern, ergonomic design
 - Colour Touch Screen
 - Visual dashboards, improved software



Why 3M™

Be confident with 3M Quality, History, and Reputation

- 30+ years in sterilization business / from verification to sterilization
 - Knowledge and experience of reprocessing surgical instruments including endoscopes
 - Knowledge and science for infection prevention products
- Industry Expertise /advocates for higher standard of care
 - CSA, AAMI
- Training and support
 - Accredited online courses
 - Tech service support (field, phone line)

Quality Control Data Manager (QCDM) Process Overview

QCDM software with the LX25: below is the process for granting access to your customers and providing configuration support:



- Order must be received from customer before QCDM access is requested

- 

- Welcome email sent to the customer and 3M representative with unique login ID and temporary password

- 3M rep (professional services) works with customer to configure the hierarchy and set up the customer on the software
- QCDM Set up Guides available as a guide



Canadian Standards

What do the new CSA Z314-18 Standards say?

12.4 Reprocessing of Endoscopes

Section 12.4.7.2 Manual Cleaning

Section 12.4.7.2.4

Manual cleaning of flexible endoscopes should be verified using cleaning verification tests. Cleaning verification tests shall be performed according to MIFUs.

Note: Residual soil can remain and prevent effective subsequent high-level disinfection or sterilization. Cleaning verification tests can include **adenosine triphosphate (ATP)**, protein, and carbohydrates

Section 12.4.10 Visual Inspection

Section 12.4.10.3

The use of methods to measure organic residues that are not detectable using visual inspection should be considered in the health care setting's cleaning policy SOPs. Additional strategies might be required to assess specific scope configurations and include the following:

- a) Cleanliness of those parts of an endoscope that are difficult to access/difficult to see such as internal channels and crevices behind ERCP elevators;
- b) A borescope to visualize the internal surfaces of channels/lumens; and
- c) Rapid cleaning monitors to assess the presence of residual soil in channels or crevices.

Note:

- 1) A rapid cleaning monitor is a test for the presence of a substance typically found on a soiled endoscope ie. **ATP**, carbohydrate, protein, and/or hemoglobin
- 2) Enhanced cleanliness verification methods to be considered may include the use of rapid cleaning monitors (tests for the presence of a substance typically found on a soiled endoscope such as ATP, carbohydrates, protein, and/or hemoglobin) to assess the presence of residual soil in channels or crevices)

The US Centers for Disease Control and Prevention (CDC)

has encouraged hospitals to develop an environmental cleaning and monitoring program to optimize the cleaning of high-touch surfaces at terminal cleaning, as well as ensure quality control and improvement.^{6, 7, 8}

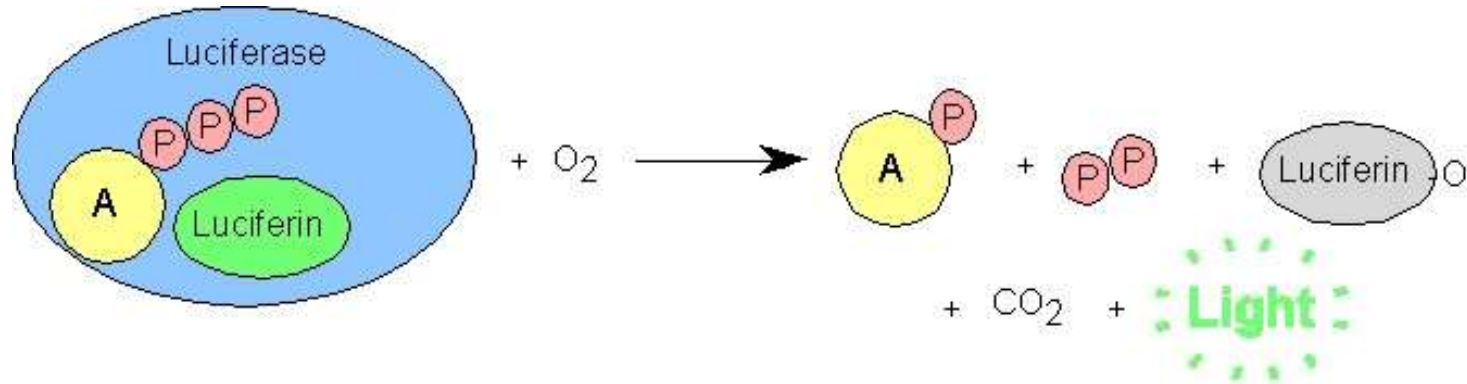
6. Sehulster, L.M.; Chinn, R.Y.W.; Arduino, M.J.; Carpenter, J.; Donlan, R.; Ashford, D.; Besser, R.; Fields, B.; McNeil, M.M.; Whitney, C.; Wong, S.; Juranek, D.; Cleveland, J. Guidelines for environmental infection control in healthcare facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Chicago, IL; American Society for Healthcare Engineering/American Hospital Association; 2004.

7. Siegel, J.D.; Rhinehart, E.; Jackson, M.; Chiarello, L. Healthcare Infection Control Practices Advisory Committee. Management of multi-drug-resistant organisms in healthcare settings. 2006
<http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf>.

8. Guh, A.; Carling, P.C. and Environmental Evaluation Workgroup. December 2010. Options for Evaluating Environmental Cleaning. <http://www.cdc.gov/HAI/toolkits/Evaluating-Environmental-Cleaning.html>.

ATP bioluminescence

- All three applications (Endo, Env, SI)
- Competing in the Food Safety area for many, many years
- All use the same luciferase enzyme system that converts ATP to a light signal



Compare performance

- Sampling: swabs, surfactants and extractants
- Enzyme system: Efficiency of light signal generation
- Luminometer: Light detection mechanism
- Data Management: software and reporting system

Dr. Michelle Alfa, Ph.D., FCCM

Dr. Alfa worked for Diagnostics Manitoba for over 20 years and was the Medical Director for the Clinical Microbiology Discipline. She was also a Principal Investigator at the St. Boniface Research Centre for over 25 years. She is currently retired but remains a Professor in the Department of Medical Microbiology, University of Manitoba.

Over the past 28 years her primary area of research has been related to Hospital-acquired infections, specifically related to i) improving reprocessing of complex medical devices and ii) monitoring disinfection/cleaning of the healthcare environment to reduce the risk of infection transmission.

Dr. Alfa has over 150 publications, has received many awards for her teaching of Medical Students. In addition, she has received the “Distinguished Microbiologist” award from Canadian College of Microbiologists, and the “Research Innovation” award from the University of Manitoba.

Research by Dr. Michelle Alfa

- Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels.
 - Objective: validate the 3M™ Clean-Trace™ ATP water test method for monitoring manual cleaning of flexible endoscopes
 - Conclusion: our data validated that flexible endoscopes that have completed manual cleaning will have <200 RLU's by the 3M™ Clean-Trace™ ATP test.
 - <https://www.ncbi.nlm.nih.gov/pubmed/22980510>

Q. How are Pass/Fail numbers determined?

They are based on validation with results provided in published clinical studies.

References

Ofstead CL, et al. Assessing residual contamination and damage inside flexible endoscopes over time. 2016. Am J of Infect Control. 44: 1675-7.

Ofstead CL, et al. Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes. 2017. Am J of Infect Control. 45: e26-e33.

Alfa MJ, Fatima I, Olson N. Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels. 2013. Am J Infect Control. 41: 245-8.

Alfa MH, Fatima I, Olson N. The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels. 2013. Am J Infect Control. 41: 249-53.



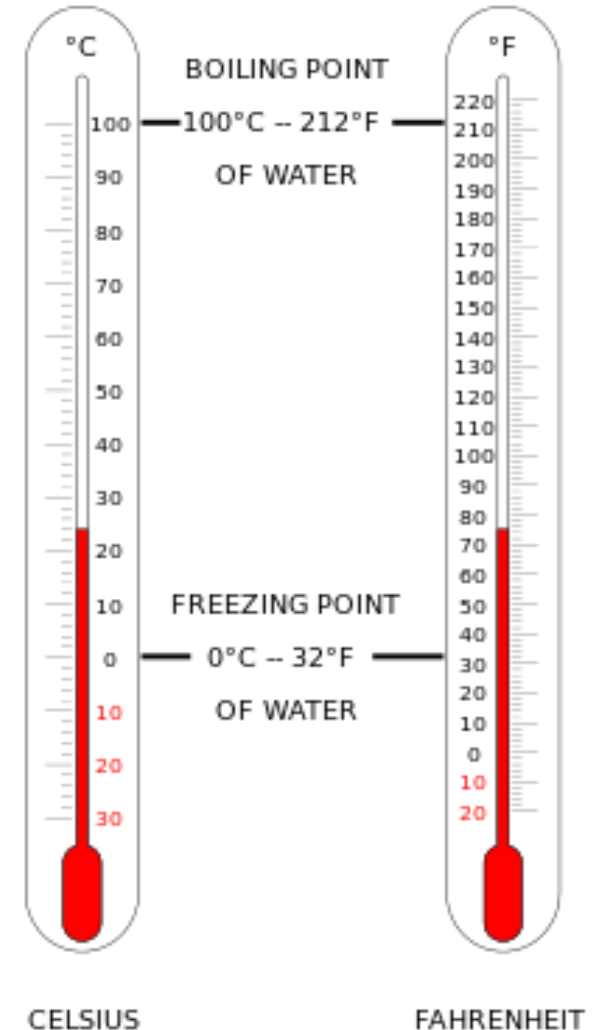
How to determine if a surface or scope is clean or dirty?

Set a Pass/Fail threshold

How can you compare cleanliness levels if the competition reads on a different scale?

Revisit the relative scale concept...

- You are familiar with this concept when measuring temperatures.
- Convert all measurements to one scale then can compare results.






QCDDM Software Demo



3M™ Quality Control Data Manager

<https://qcdm.3m.com/>



3M™ Quality Control Data Manager

 User Name

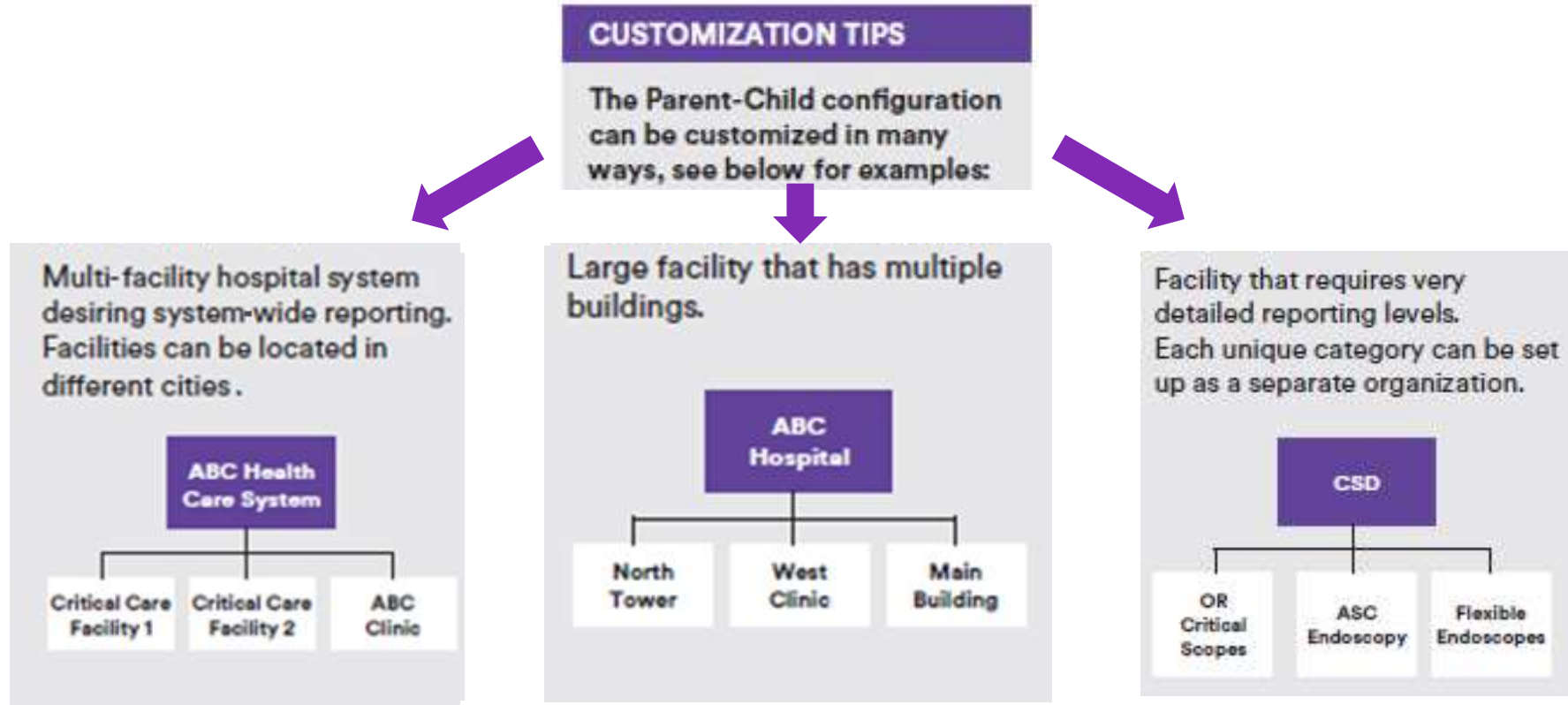
 Password 

[Sign In](#) [Forgot Password?](#)

Organization Configuration

Parent-Child

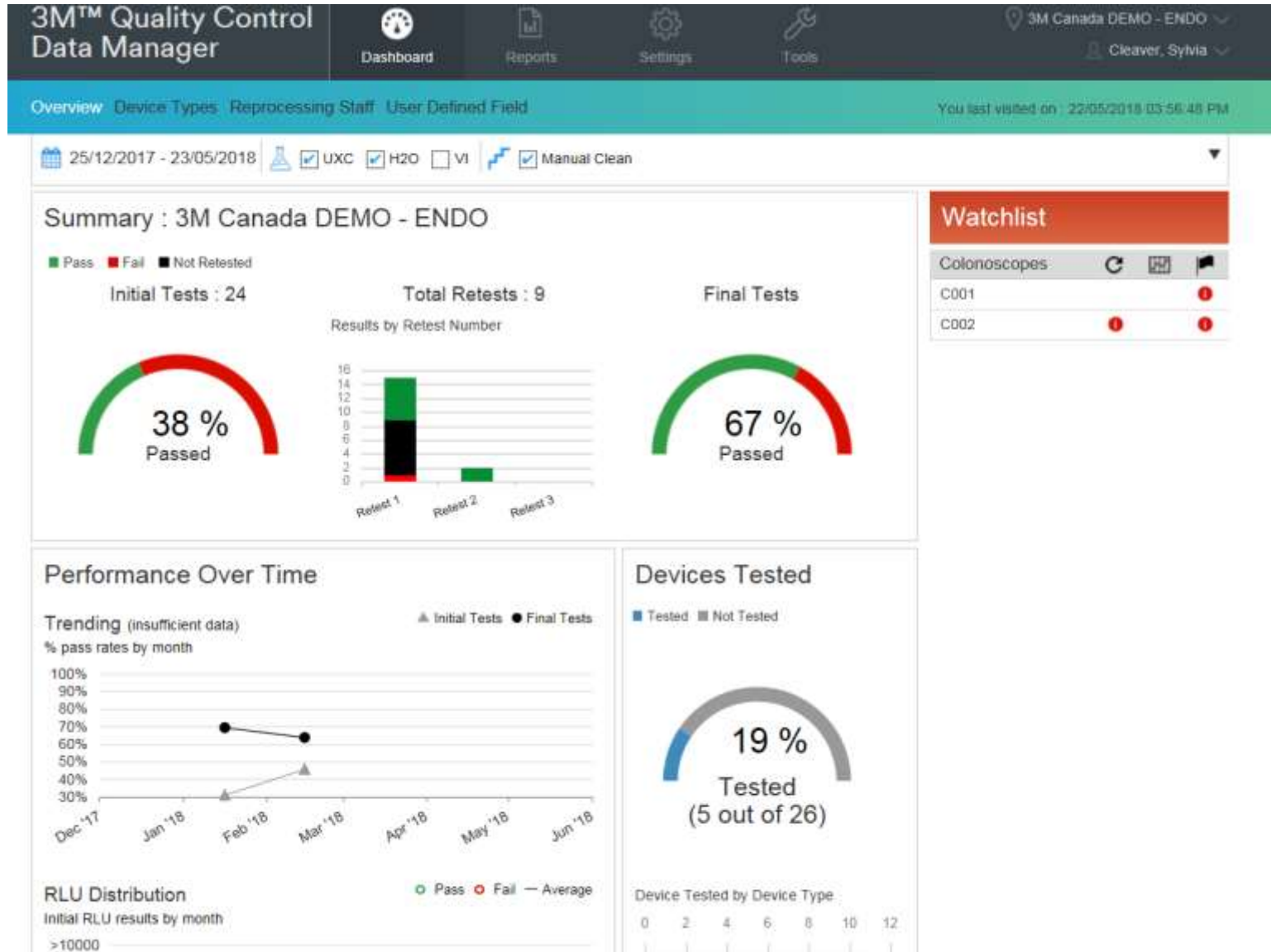
- Allows a facility to establish a consistent monitoring plan across multiple facilities, buildings and units
- Parent org defines the monitoring plan rolled out to every child org



Generate data, dashboards and reports Audits



Dashboard overview



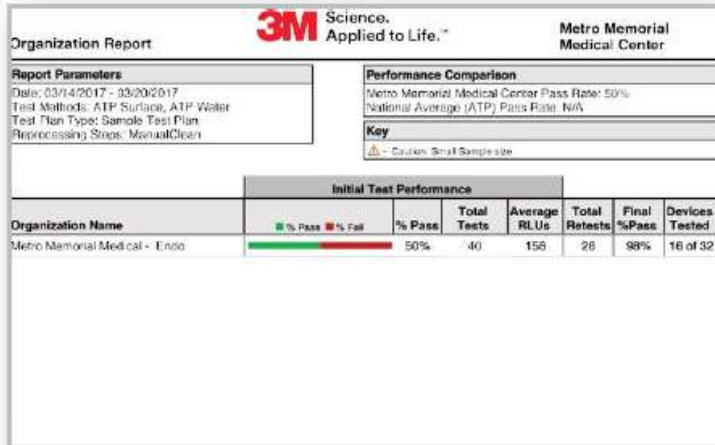
Reporting and Data Export



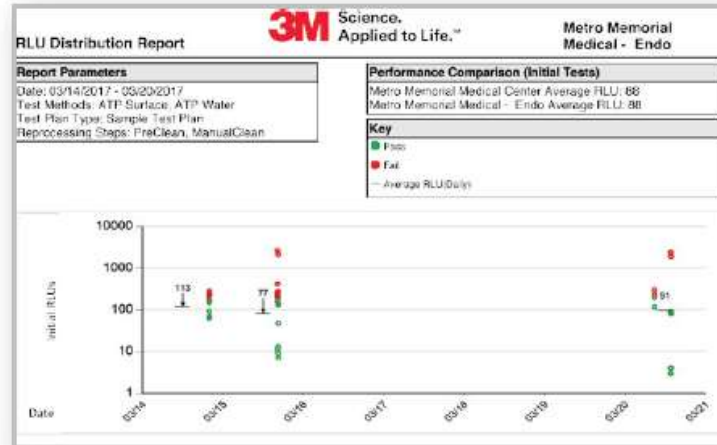
- Generate one time reports
- Schedule reports for automatic delivery to specified email addresses
- Flexibility to select date ranges and attributes to customize reports
- Ability to include data entered for visual inspection and microbial cultures
- Data export to a spreadsheet

Report Types All Applications:

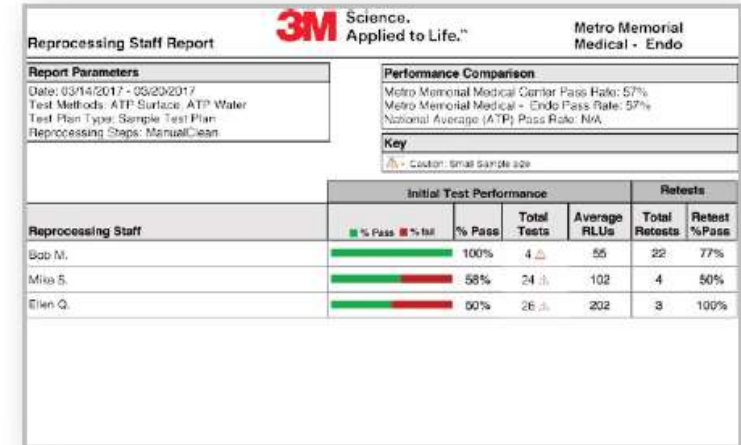
Organization Report Example



RLU Distribution Report Example



Staff Report Example



- Organization: Summary of pass/fail for entire organization
- RLU Distribution: Distribution of RLY measurements for specified date range and attributes
- Staff by user ID



Thank you