The New AAMI ST91: An Updated Standard for Flexible Endoscope Processing

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- This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.

Objectives

- Discuss the updated national standard, ANSI/AAMI ST91, highlighting key differences between the 2015 version and latest version.
- Identify current best practices in the processing of flexible endoscopes as outlined in ST91
- Outline how engineering quality assurance parameters into endoscope processing can help to reduce Hospital Acquired Infections (HAI) and Surgical Site Infections (SSI) and help to determine if an endoscope is patient ready

AAMI WG84

- ANSI/AAMI ST91 – 2021
  - Published on March 3rd, 2022.
- TIR 99
  - Out now!
  - Processing of US probes & dilators.

AAMI

Focused changes to ST91

- Attention to detail in wording – e.g., “should” and “shall”
- Inclusion of peer-reviewed research and FDA MAUDE database citations
- Emphasis on certification, training, and competencies
- Direction for physical design
- Management of “high-risk endoscopes”
- “Point of use treatment” (vs. “precleaning”)

Focused changes to ST91

- Enhanced visual inspection, cleaning verification, borescopic inspection
- Recommendations against manual disinfection
- Drying post processing
- Clean handling and storage
- Embedded quality monitoring
- Sterilization
- Multiple informative appendices

What do the words mean within an AAMI Document?

Must = describes "unavoidable" situations, including those mandated by government regulation.

Shall = requirements strictly to be followed to conform to the recommended practice.

Should = indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required.

May = indicates that a course of action is permissible within the limits of the recommended practice.

Can = a statement of possibility or capability.

References to support recommendations

- Focused effort to include references from RESEARCH – extensive bibliography
- MAUDE database citations

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

MAUDE database

- "…reports of adverse events involving medical devices".
- "…voluntary reports since June 1993…"
- "user facility reports since 1991…"
- "distributor reports since 1993…"
- "manufacturer reports since August 1996…"
- "…searchable database data contains the last 10 year's data".

"Mandatory reporters: manufacturers, importers and device user facilities.

Voluntary reporters: health care professionals, patients and consumers."

Certification, training, and competencies

CERTIFICATION - Processing personnel should be certified within two years of employment; and maintain that certification.

EDUCATION, TRAINING and COMPETENCIES – prior to independent role, annually, at designated intervals, when new scopes, processes or products are introduced.

Training components identified – to include standard precautions and hand hygiene.

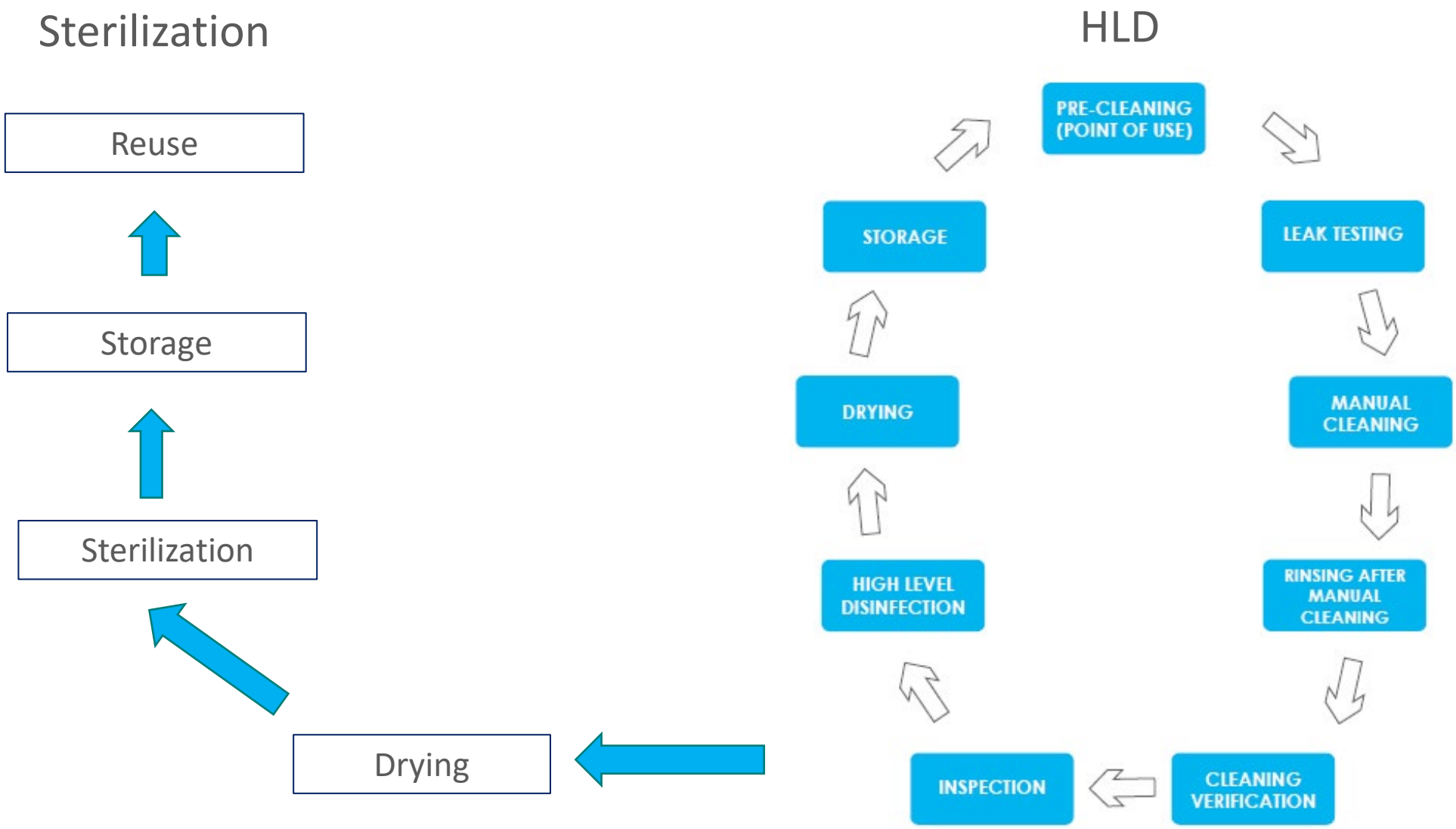
Design of endoscope processing areas

- Unidirectional flow from dirty to clean
- Two room design – to separate manual cleaning from disinfection/sterilization processes
- Designated drying area
- Physically separate area for endoscope storage
- Restricted traffic
- Ideally three sinks; but minimally two - or one sink with two separate basins:
    1. leak testing and manual cleaning;
    2. only rinsing.
- Instrument air with a pressure regulator
- Space requirements for each area/process

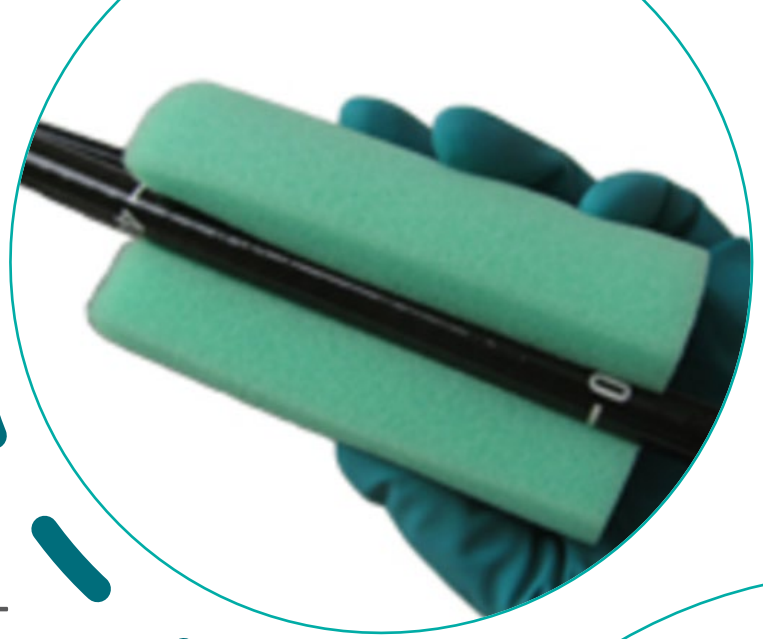
Management of “high-risk endoscopes”

- Definition:
  - Associated with infectious outbreaks.
  - Difficult to process.
- Includes:
  - Elevator channel endoscopes, bronchoscopes, ureteroscopes, cystoscopes, EBUS scopes.
  - Others as determined by facility
- Require:
  - Cleaning verification testing every cycle.
  - Prioritization in risk assessments.

Endoscope Processing Workflow – HLD / Sterilization



“Point of use treatment”
(vs. “precleaning”)



To reflect everything done at point of use – including precleaning:

- Disconnecting accessories.
- Preparing handoff communication.
- Preparation for transport.

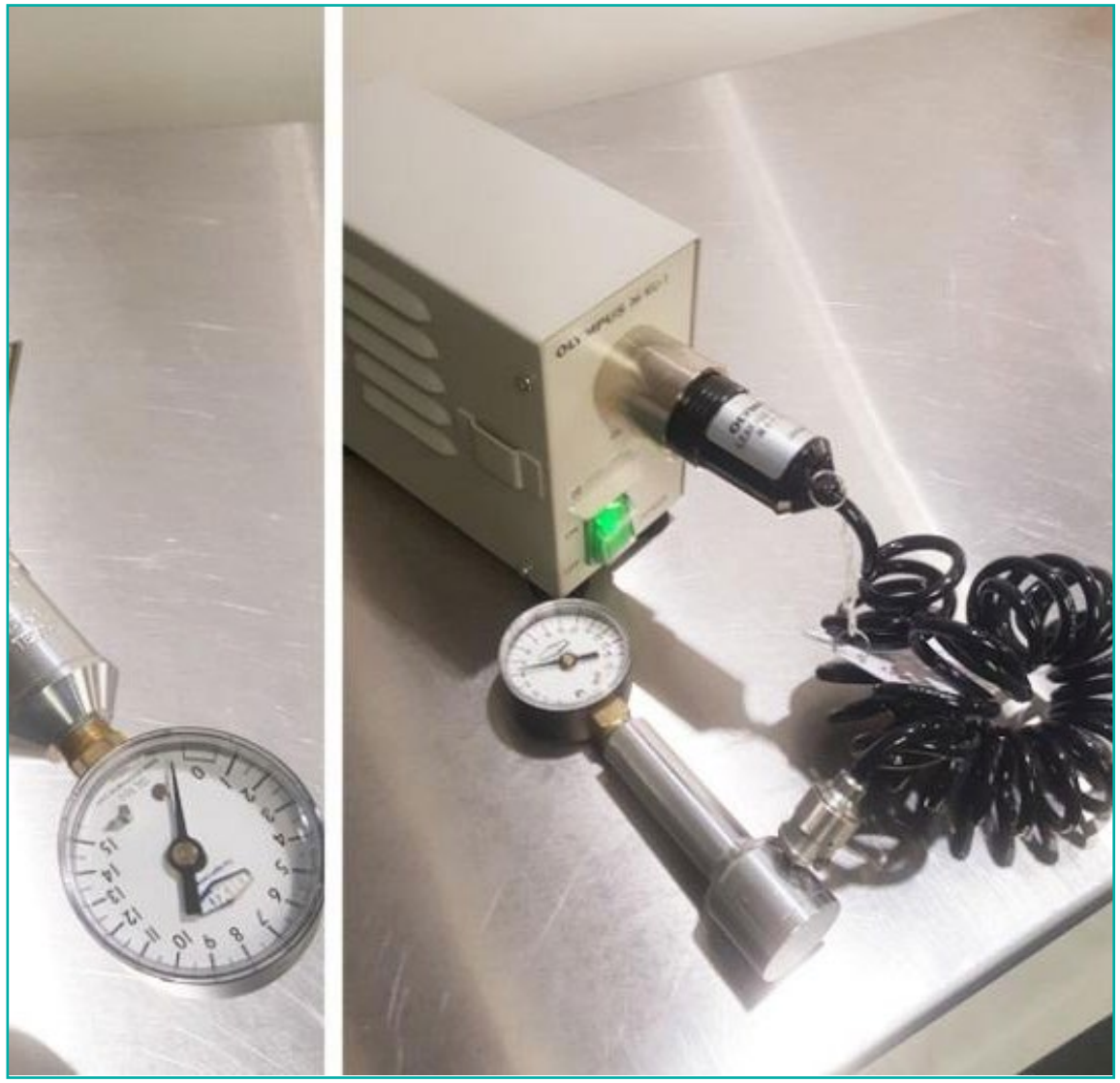
Soiled transport

- Delayed processing protocol reinforced.
- Scopes kept moist for transport.
- Transport container or cart:
  - Nonporous
  - Leak-proof on sides and bottom
  - Puncture-resistant
  - Labeled as biohazard

Leak Testing

- Daily pressure output validation for automated and manual leak testers.
- Follow manufacturer IFU.
- Documentation of testing.

- When a leak is discovered –
  - Follow endoscope manufacturer IFUs for processing.
  - Tag the scope.
  - Remove from use.



Cleaning

Manual

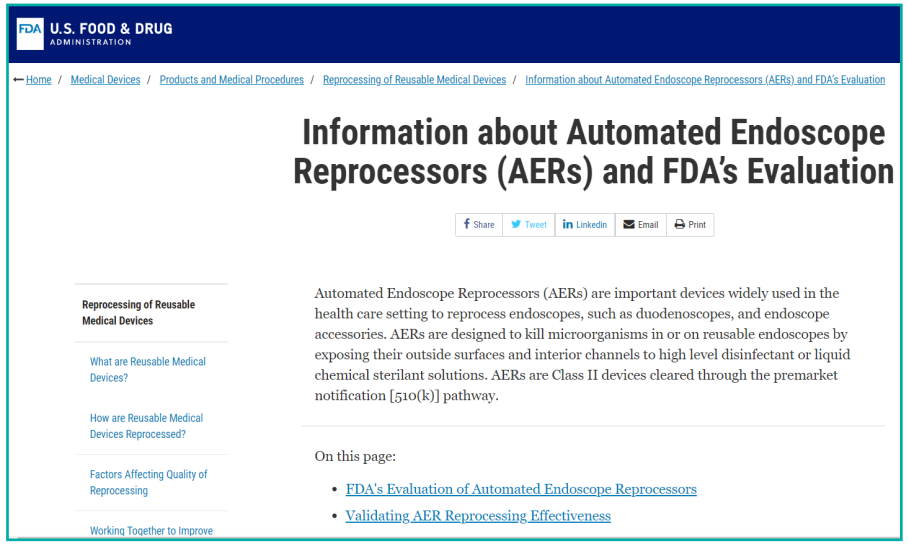
Delayed processing protocol reinforced.

Utility water rinse.

Drying – exterior and channels.

Automated

Reinforces FDA direction re: duodenoscopes – AER cleaning as a supplement only (to thorough manual cleaning).



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Home / Medical Devices / Products and Medical Procedures / Reprocessing of Reusable Medical Devices / Information about Automated Endoscope Reprocessors (AERs) and FDA's Evaluation

Information about Automated Endoscope Reprocessors (AERs) and FDA's Evaluation

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Reprocessing of Reusable Medical Devices

What are Reusable Medical Devices?

How are Reusable Medical Devices Reprocessed?

Factors Affecting Quality of Reprocessing

Working Together to Improve

Automated Endoscope Reprocessors (AERs) are important devices widely used in the health care setting to reprocess endoscopes, such as duodenoscopes, and endoscope accessories. AERs are designed to kill microorganisms in or on reusable endoscopes by exposing their outside surfaces and interior channels to high level disinfectant or liquid chemical sterilant solutions. AERs are Class II devices cleared through the premarket notification [510(k)] pathway.

On this page:

- FDA's Evaluation of Automated Endoscope Reprocessors
- Validating AER Reprocessing Effectiveness

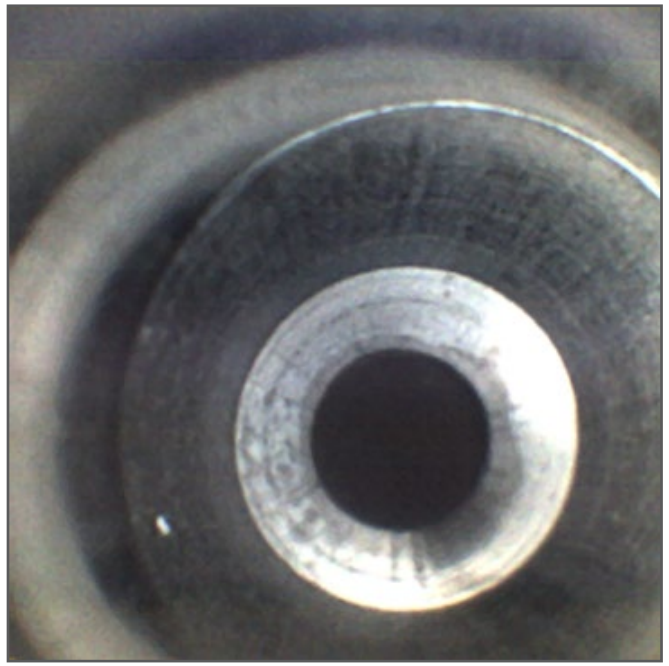
https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/information-about-automated-endoscope-reprocessors-aers-and-fdas-evaluation

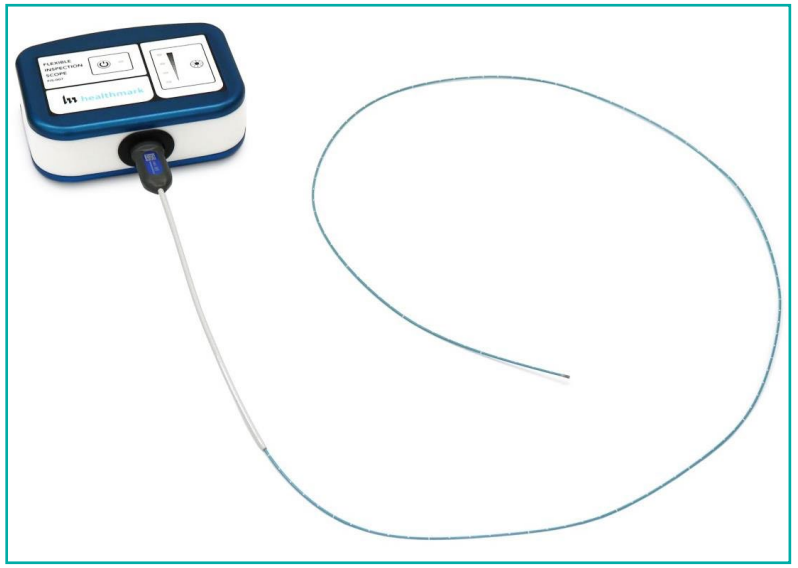
Enhanced visual inspection and cleaning verification

- Enhanced visual inspection -
  - Endoscope dried first.
  - Lighted magnification.

- Cleaning verification -
  - “High-risk endoscopes” after each use.
  - Repeated failures – send scope for evaluation/repair.

- Borescopic inspection -
  - Channels, distal tip, valve openings.
  - Follow endoscope mfr. IFUs for what to inspect.





High-level disinfection (HLD)

- Recommendations against manual disinfection.
  - Manual guidance given; but automated processing (AER) promoted.
- AER flow QC testing – as per mfr. IFU.
- Scope left in AER more than one hour – repeat HLD cycle.
- PPE used for decontam. should not be worn when handling post-AER.

Monitoring water quality

- The water quality identified in manufacturers' IFUs is what needs to be used during each stage of endoscope processing.
- Consult manufacturer IFUs for:
  - Endoscope and accessories
  - AER
  - Processing chemicals
- Facility monitoring and control of water quality.
- Repairs to water utilities should always result in quality testing for downstream automated systems (e.g., AERs).
- Water quality testing as standard part of follow-up for endoscope processing failures.
- Periodic microbial monitoring of AER final rinse water quality

Drying

- Need to dry scopes prior to storage or reuse.
- Never stored wet.

- Minimum of 10-minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air.
- Active drying, even post-AER.

- Monitor with drying verification tests.

- Dedicated informative annex on drying.

Storage and clean handling

- Cabinets:
  - PREFERRED - internal channel drying cabinets.
  - AT A MINIMUM - conventional cabinets with HEPA-filtered air circulating.
- No endoscope storage in procedure room or processing room.
- Hand hygiene and clean gloves when handling.
- Keep valves together with the endoscope as a unique set
- Post-HLD/patient ready tag ON THE SCOPE.
- Multidisciplinary risk assessment re: “hang time”.

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https://www.medivators.com/products/endoscope-reprocessing/endoscope-transport-and-storage/endodry-storage-and-drying-system

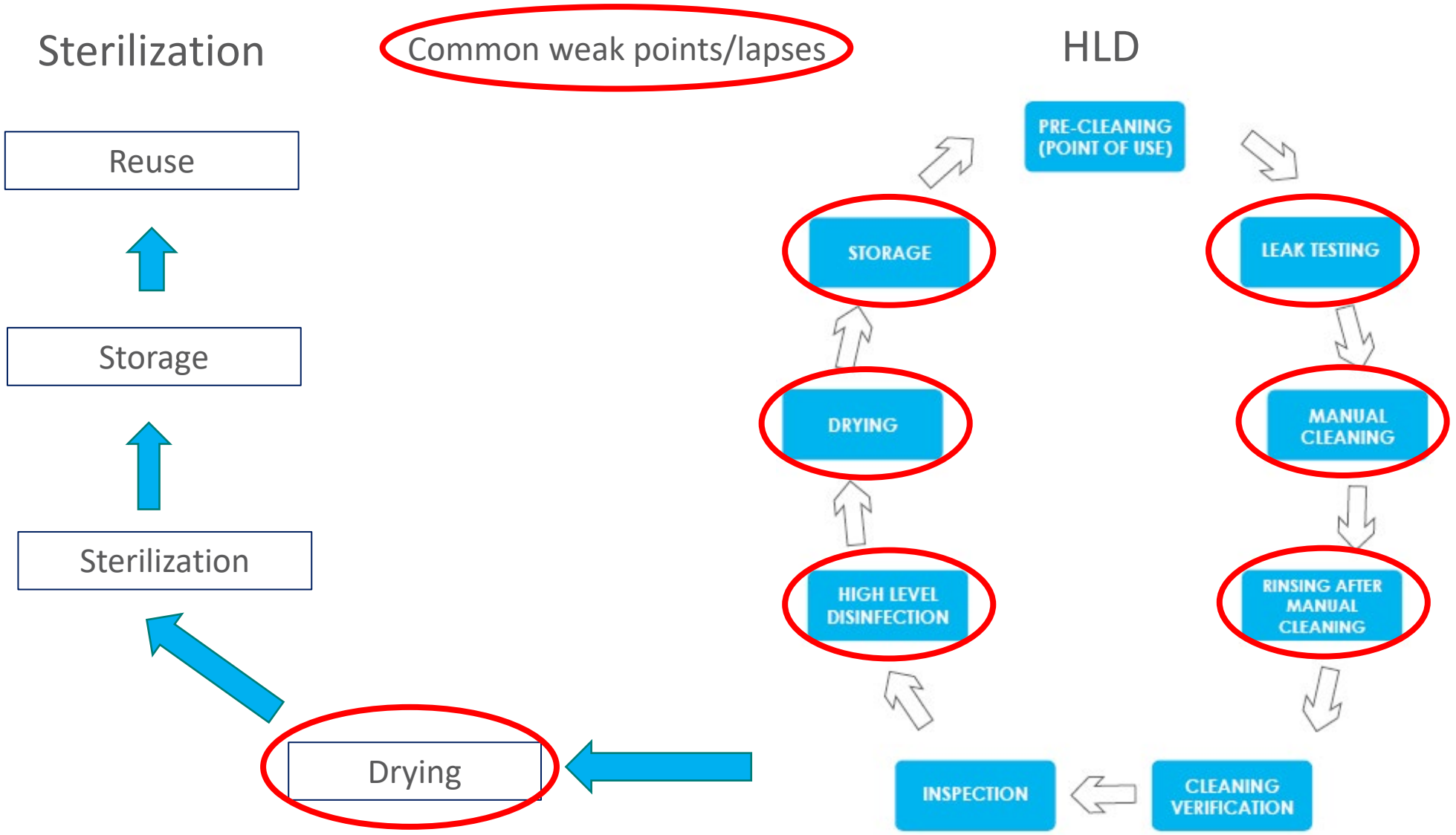
https://www.medivators.com/products/endoscope-reprocessing/endoscope-transport-and-storage/endodry-storage-and-drying-system

Additional highlights

Recommendations for:

- Monitoring the manual cleaning process
- Monitoring automated cleaning processes
- Management of loaner scopes and scopes routing to/from repair.
- Multidisciplinary QA and safety program.
- Risk Assessments.
- Documentation and record keeping.
- Device repair and loaned scopes.

Endoscope Processing Workflow – HLD / Sterilization



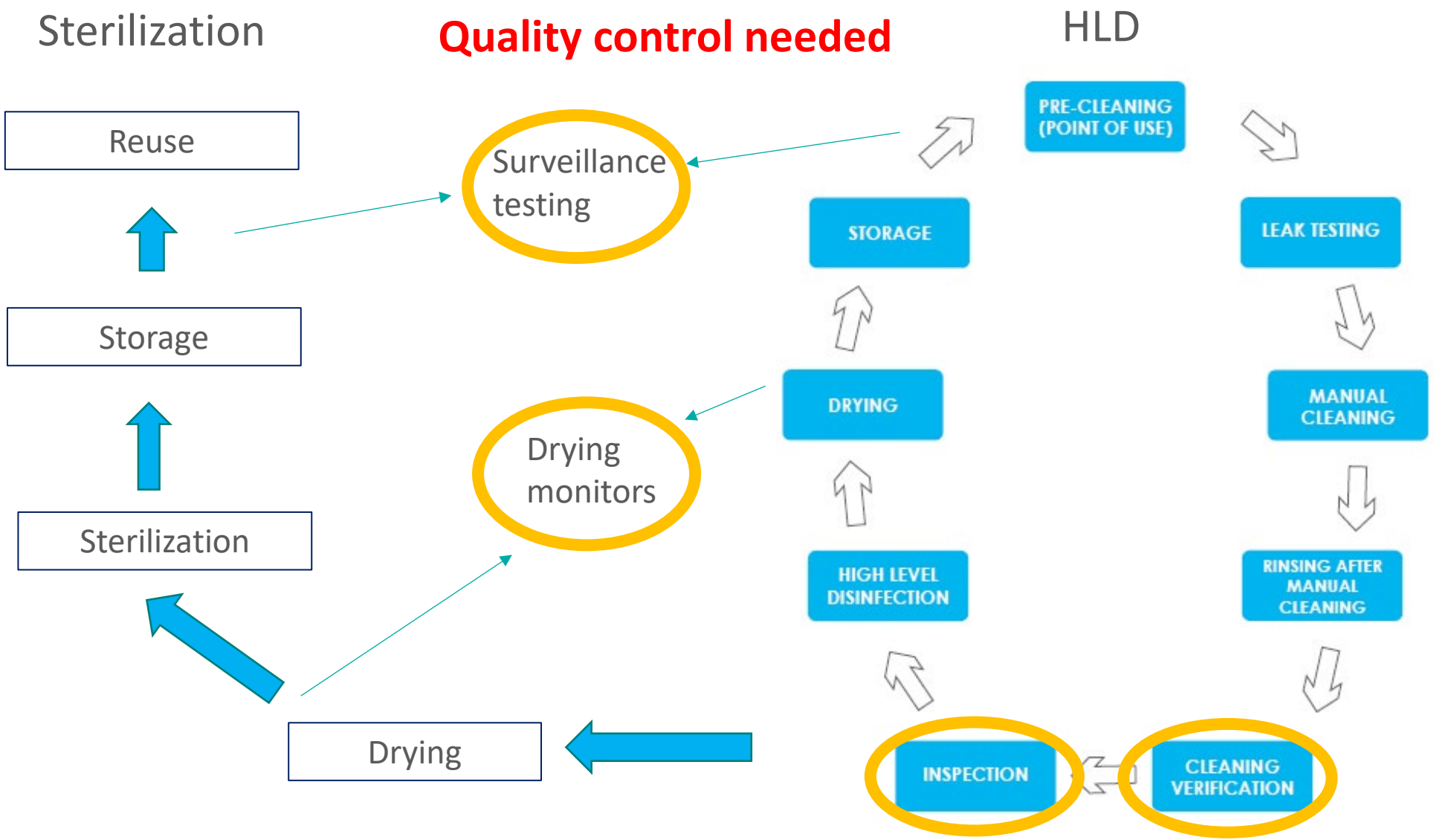
Two deaths reported
5/6/16

Endoscope manufacturer informed that following ERCP procedures, six patients were infected with E. coli, and two of the six patients expired.

- A borescope was used to inspect the biopsy and suction channels.
  - Brown stains and scrape marks were found on the biopsy channel interior at 5 cm from the distal end.
  - The suction channel had similar brown stains at various locations.
- Manufacturer leak testing confirmed a leak "where the c-body was missing glue".

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=5456006

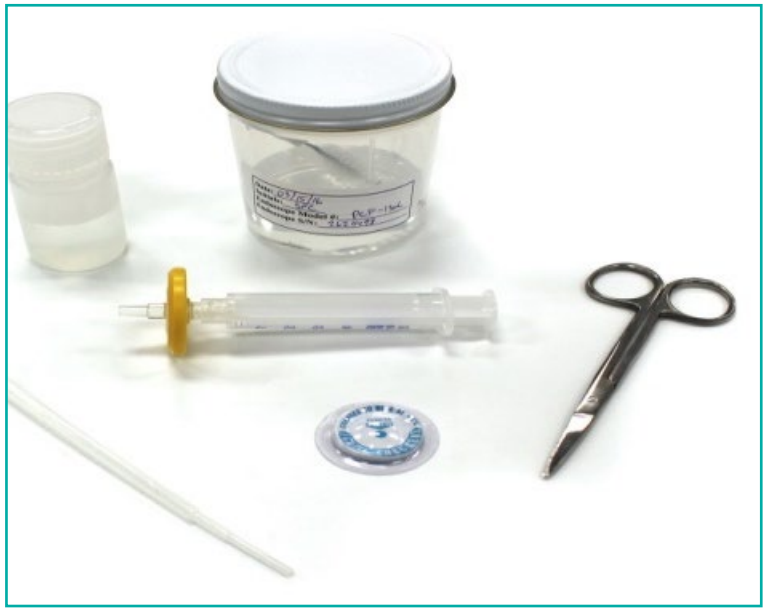
Endoscope Processing Workflow – HLD / Sterilization



Microbial Surveillance

Options include:

- Traditional culturing
- Gram negative test kits
- **Not ATP or cleaning verification tests**



AAMI ST91 - 2022:

- Voluntary; but can be used as part of an overall quality control program.
- Health care facilities consider own needs and available resources to implement.

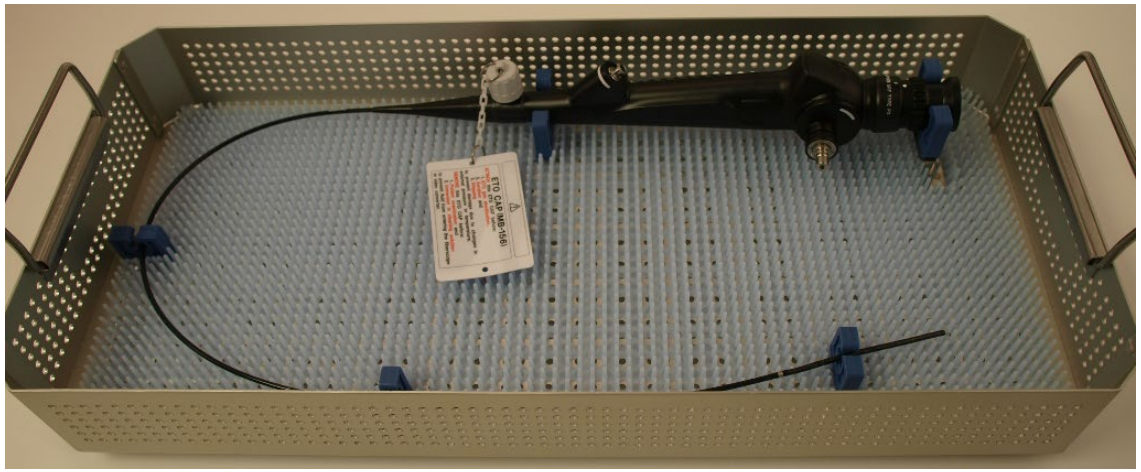
Spaulding Classification

- Critical devices
  - High risk of infection (sterile tissue)
  - Sterilization recommended
- Semi-critical devices
  - Intermediate risk of infection (non-intact skin or mucous membranes
  - STERILIZATION, if not possible then High-level disinfection
- Non-critical devices
  - Low risk of infection (intact skin)
  - Intermediate or low-level disinfection

Sterilization

- Workgroup did not require sterilization for all scopes

- It is advised that flexible and semi-rigid endoscopes used in semi-critical applications be **sterilized** prior to use
- Transition from HLD to sterilization as the standard of care may be accelerated by identifying and addressing key technical and compatibility obstacles and defining priorities and key steps
    - Contribution of reusable medical device manufacturer is essential. Partnerships between sterilizer and medical device manufacturers are encouraged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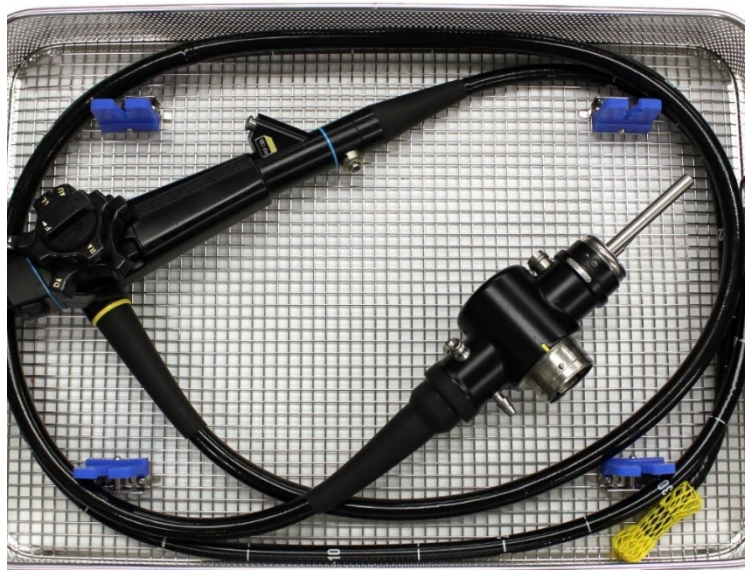

Develop an action plan for sterilization

- Inventory scopes – what models do you have
- Look at compatibility with sterilization methods
- Move all scopes that can be easily sterilized to sterilization!
    - Surgical flexible scopes: bronchoscopes, ureteroscopes, cysto, hystero, ENT, etc.
- Look at remaining scope inventory (GI scopes)
    - Prioritize by risk (e.g., duodenoscopes)
    - Based on FDA recommendations, do something: sterilize, culture, liquid chemical sterilization, disposable scopes.
- May need to adjust inventory levels of scopes

Informative annexes

- Alternatives for keeping cool in the processing environment
- Purchase considerations in selecting AERs and LCSPSs
- Reference material for repairs
- Manufacturer’s written instructions for use (IFU) conflict management
- Endoscope visual inspection
- User verification of cleaning processes
- Effects of simethicone on flexible endoscopes
- Safety considerations for high-level disinfectants and liquid chemical sterilants
- Endoscope microbiocidal methods
- Endoscope storage risk assessment
- Endoscope drying

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Questions?

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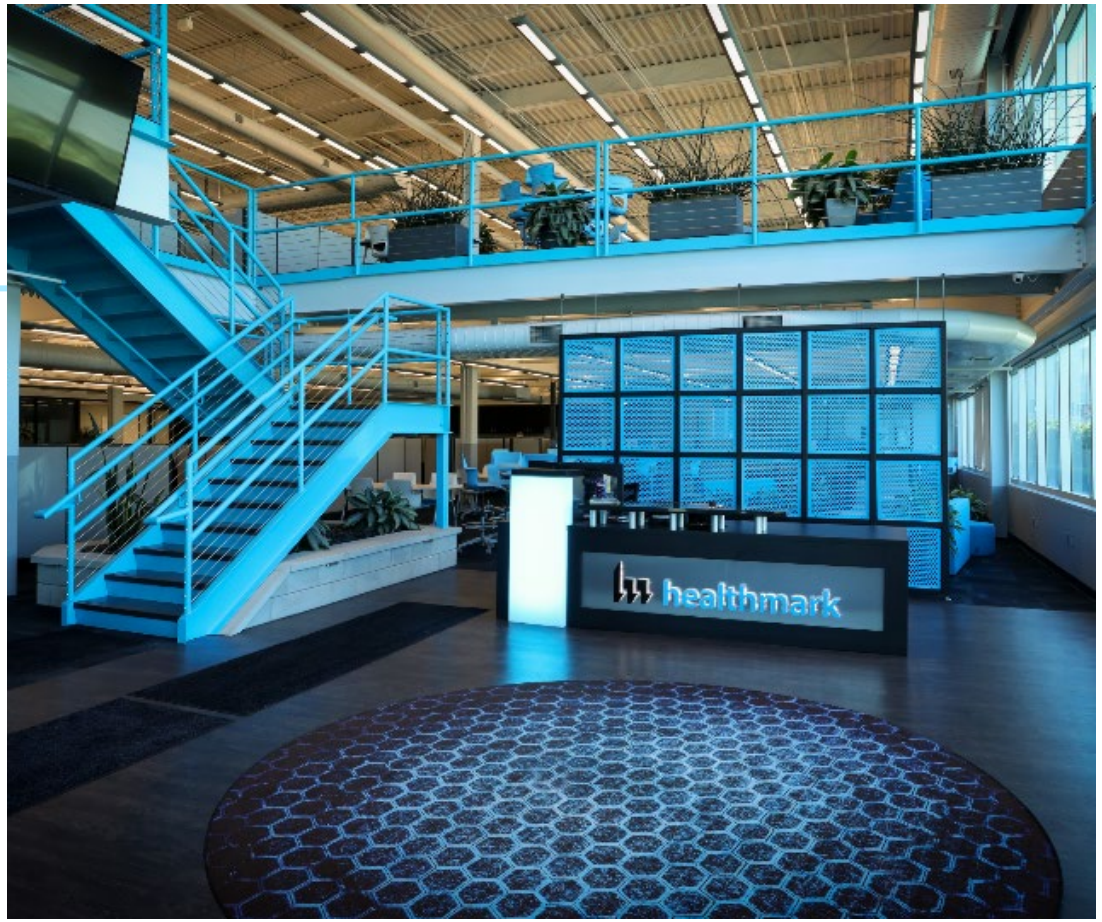

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