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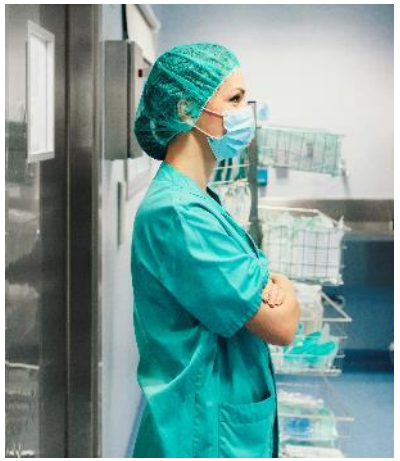


Ultrasonic Cleaning
The Sound Science

John Nies
Sr. Product Manager
1/19/2024

Belimed
Infection Control

Learning Objectives

Why we use Ultrasonics in the cleaning process?

Understanding the science behind ultrasonics

Knowing what leads to successful ultrasonic cleaning

How to troubleshoot sonic cleaning issues

What is our cleaning goal?

Remove organic contaminants

- Blood
- Proteins
- Oils
- Tissue

Strip contaminants from all instrument areas

- External & internal surfaces
- Mechanisms

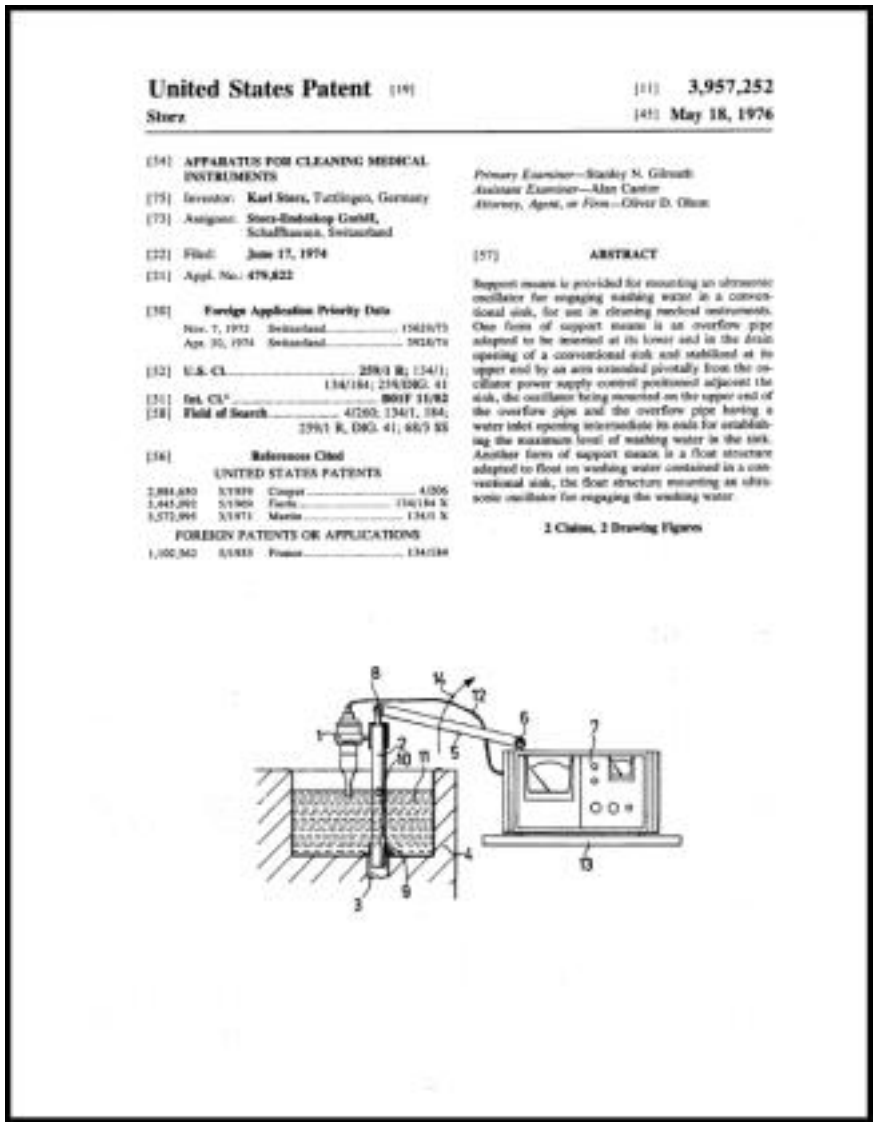
Leave instruments bioburden free, & ready for the next processing step

Why clean with an Ultrasonic?

Complex instruments are difficult to penetrate

- Box locks
- Drill sleeves
- Flexible reamers
- Graspers
- Cannula
- Robotic tools

History

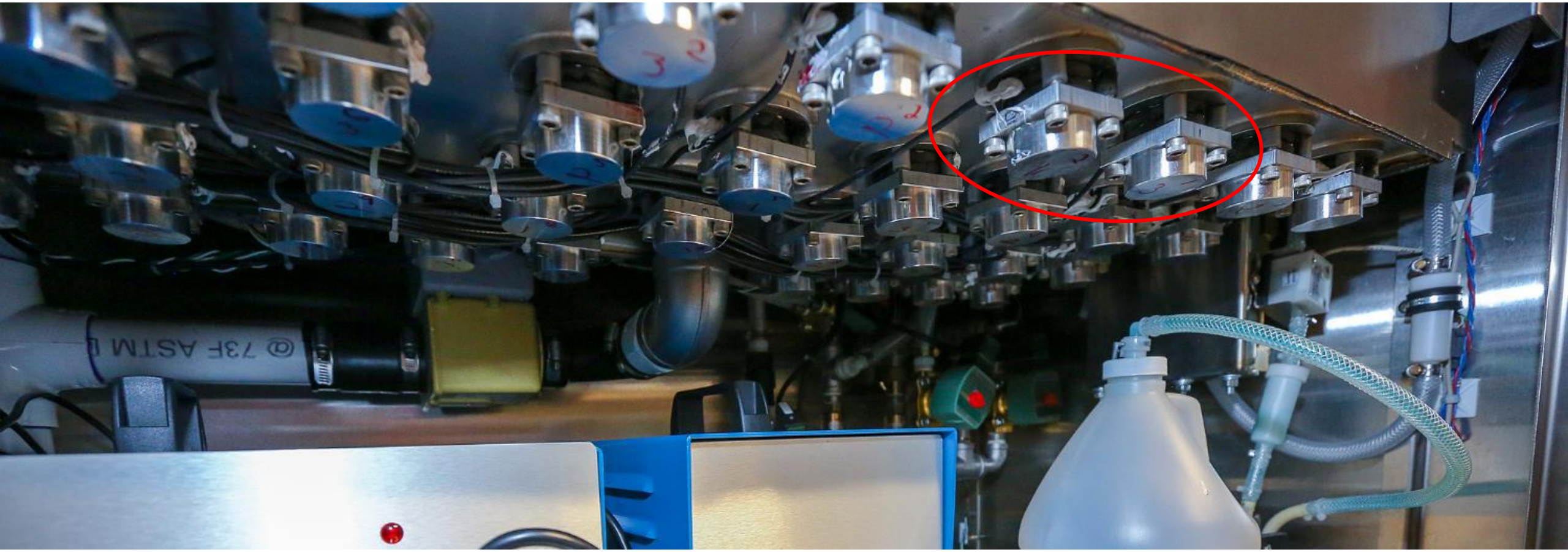


United States Patent [19]
Storz
[11] 3,957,252
[45] May 18, 1976

[54] APPARATUS FOR CLEANING MEDICAL INSTRUMENTS
[75] Inventor: Karl Storz, Tuttlingen, Germany
[73] Assignee: Storz-Endoskop GmbH, Schaffhausen, Switzerland
[22] Filed: June 17, 1974
[21] Appl. No.: 479,822
[30] Foreign Application Priority Data
Nov. 7, 1973 Switzerland 15619/73
Apr. 30, 1974 Switzerland 5928/74
[52] U.S. Cl. ..... 259/1 R; 134/1; 134/184; 259/DIG. 41
[51] Int. Cl.² B01F 11/02
[58] Field of Search ..... 4/260; 134/1, 184; 259/1 R, DIG. 41; 68/5 SS
[56] References Cited
UNITED STATES PATENTS
FOREIGN PATENTS OR APPLICATIONS
Primary Examiner—Stanley N. Gilreath
Assistant Examiner—Alan Cantor
Attorney, Agent, or Firm—Oliver D. Olson
[57] ABSTRACT
2 Claims, 2 Drawing Figures

- Early 1930's - General effect first observed in an RCA test lab
- 1954 – Recognized as a cleaning method by Bendix & others
- 1965 – Becomes the standard for circuit board cleaning ("the RCA clean")
- Mid-1960's - First medical washing applications

How The Technology Works



Key component: **P**ie**Z**oelectric **T**ransducer (PZT)

- Electronic energy pulses vibrate the PZT's, which emit ultrasound energy
- Ultrasonic energy enters tank water and forms pressure waves

How The Technology Works

Tiny vacuum voids (bubbles) created

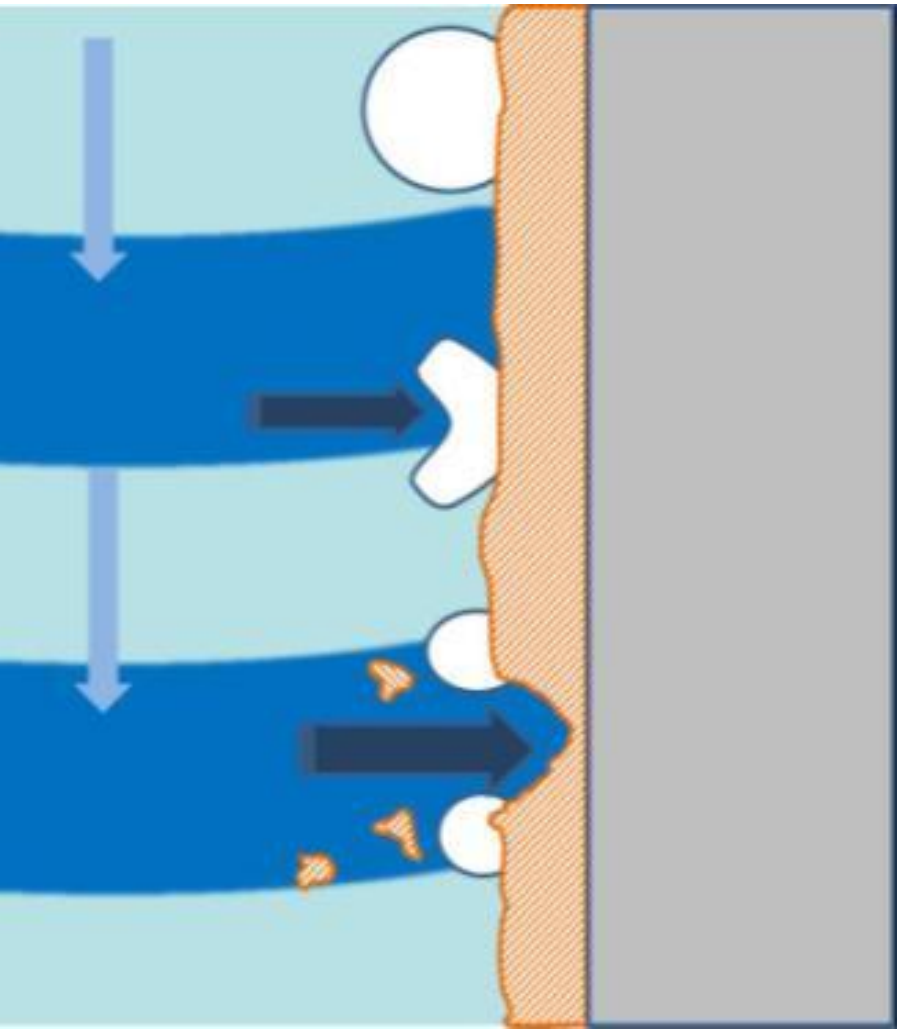
Bubbles implode

Resulting jets create extreme small-scale effects:

- 20,000 PSI pressure
- 5,000K temperature

Effect is called Cavitation

What does “Cavitation” do?



Creates a powerful effect that blasts off heavy soil

- Shear forces, as bubbles collapse, rip particulates off surfaces
- Ultra = beyond, Sonic = sound. Sound beyond what you can hear
- High frequency (>40khz) = smaller bubbles & fine detail cleaning
- Electronics parts, hard disk drives, optics
- Low frequency(40khz) = larger bubbles & more “scrubbing” power
- Medical instruments, automotive parts

Effect isn’t vibration-based, it’s all about the cavitation

Where else have we seen Sonics?

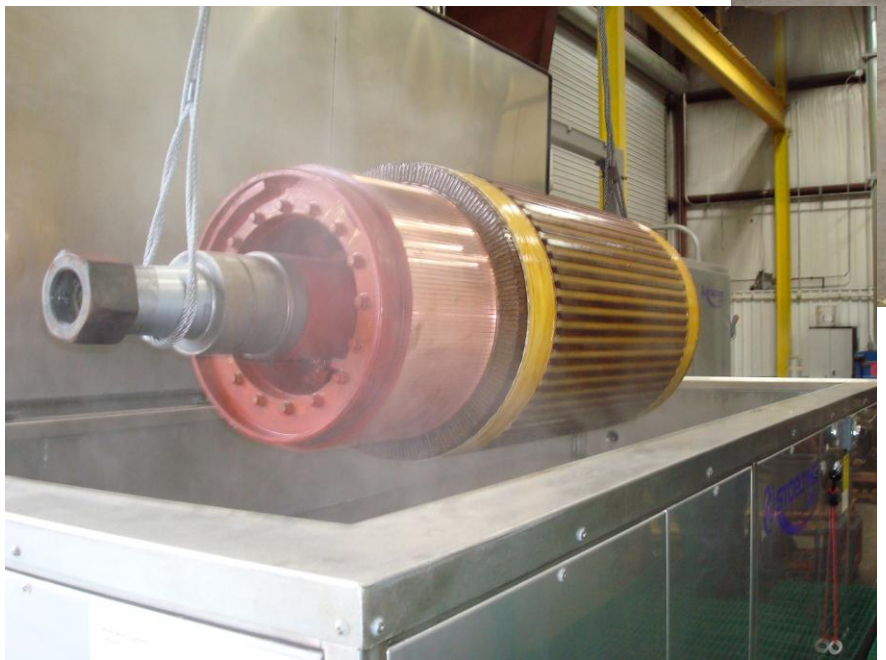
Other Applications

Penetrates crevices

- Anywhere liquid can reach
- Areas inaccessible by pressure alone

Many uses

- Automotive parts
- Electroplating
- Pharmaceutical production
- Electronics components
- Optics
- And (of course), Healthcare



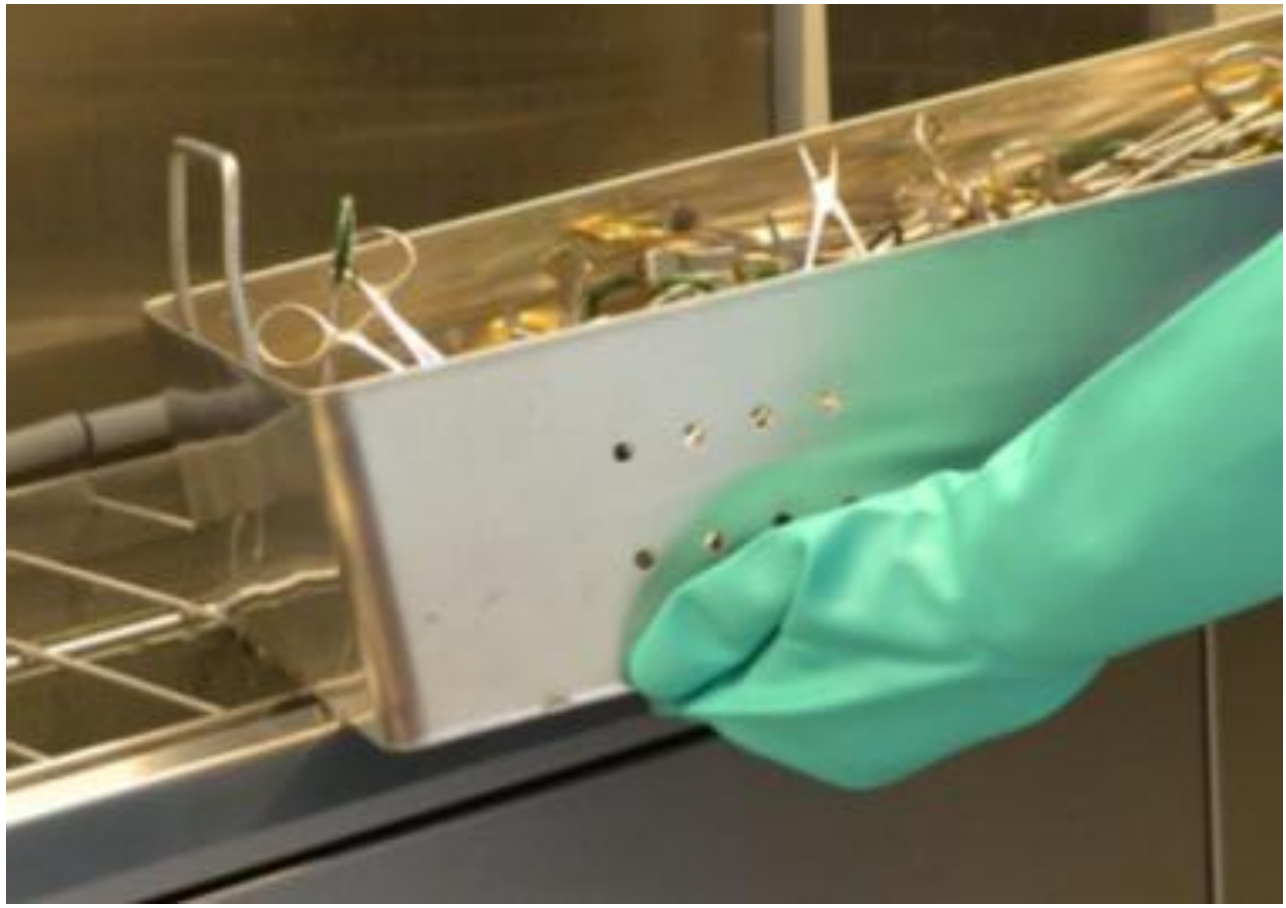
To Sonic…or not to Sonic

Which instruments can I clean this way?

- Consult the instrument IFU
- It will indicate if ultrasonic cleaning is needed

Which instruments are best served by sonication?

- The more complex, the better the “fit”
- The less complex, the less added value sonics provide



Avoid the Technology Limitations

Only works in liquid

- Always fully submerge instruments

Is impeded by solid masses

- Avoid solid metal trays
- Don’t use solid/perforated plastic trays
- Best tray type – open-weave wire mesh or heavily perforated metal
- Don’t stack trays

Power Concentration / Density

Power density: transducer power / tank water volume

- Example: 1000W power / 15 gallon tank = 66W/Gal.
- Higher the ratio, the more ultrasonic power is being focused within the tank
- Minimum acceptable is generally defined as 48-50 W/Gal.
- Power output typically fixed, can't "turn it up to 11"
- Sonics with multiple fill levels may have multiple power generators

Recommendation: use only enough water to fully cover instruments

Unit loading

Should you fill the chamber up to the top with instruments?

- Most manufacturers specify a tray capacity which is lower than the max water level
- Overloading often extends cleaning duration
- Overloading creates risk – will this load be clean? Will all instruments be submerged?
- Know the lift weight capacity of the sonic

Water Quality

AAMI TIR34 lists “key water quality factors to consider for ultrasonic cleaning”:

a) Water hardness

b) Water temperature

c) Ionic contaminants (eg. Chlorides & heavy metals)

d) Microbial level

e) Bacterial endotoxins

Two areas of concern

- Unit function (scale deposits)
- Wash quality (all the rest)

Chemistry

Use non-foaming, sonic-indicated, detergent

Maintain water within detergent manufacturer’s specified temperature range

Dose correctly

- Concentration
- Some sonics dose by time, some by flowmeter
- Flowmeter dosing is more accurate

Wash Time

There is no one “standard cycle”

Most cycles specified by instrument manufacturer’s IFU

IFU cycles can range from 8 to 20 minutes

IFU cycles seem to assume minimum loading – heavy cycles may need more time

Degassing

Sonic cavitation much less effective when air is dissolved in water

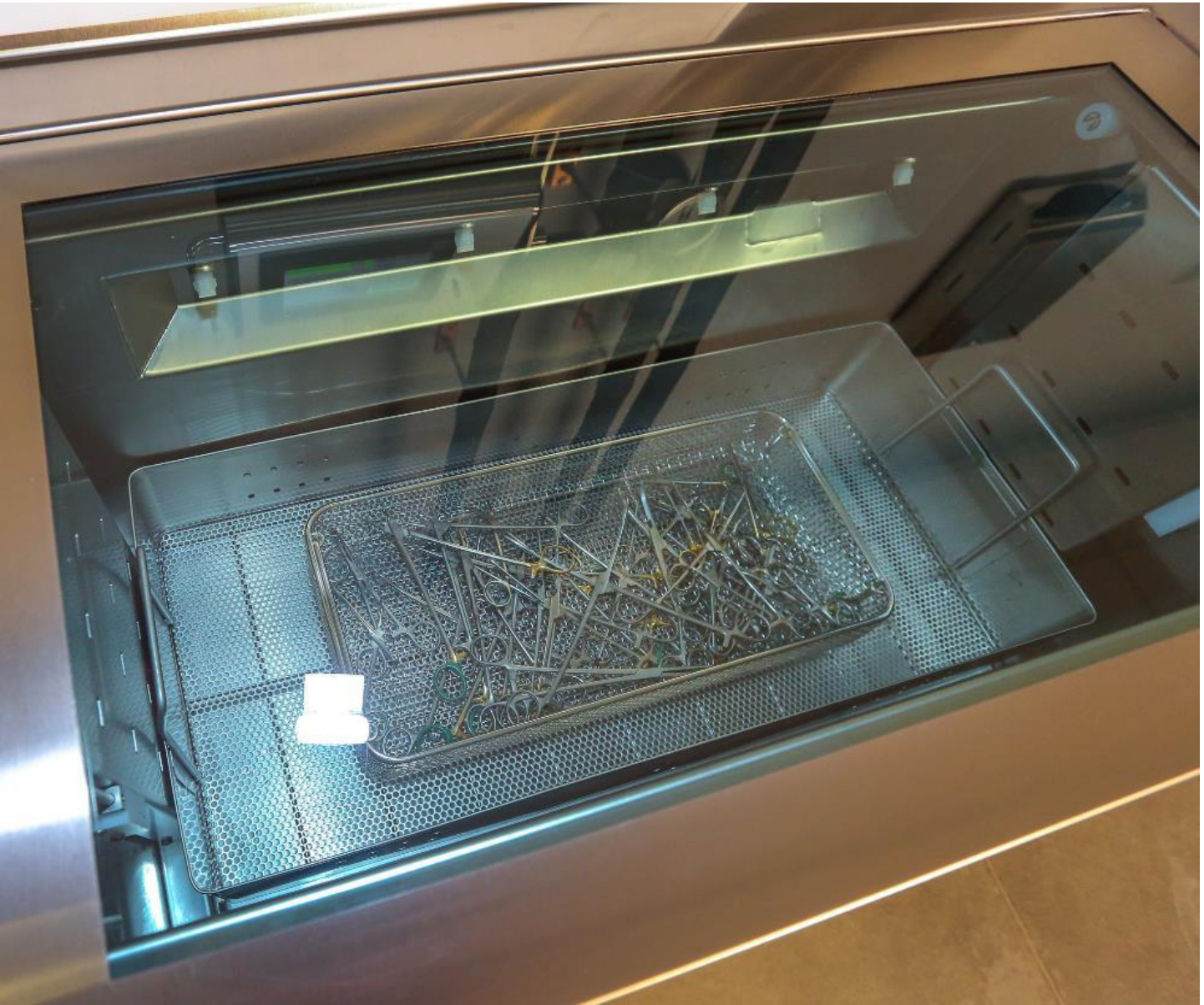
“Degassing” is forcing the dissolved air to to escape the water in the tank

Can be manual (add degas time to cycle time), or automatically programmed into machine

Longer degas when tank is freshly filled

Shorter for additional uses of the same water

Tank Water Quality



How often should tank water be changed?

AAMI ST79:2017, Section 7.6.4.4.1 d)

"…after each use (a "use" should be defined in the health care facility's policies and procedures):"

Lumen flushing

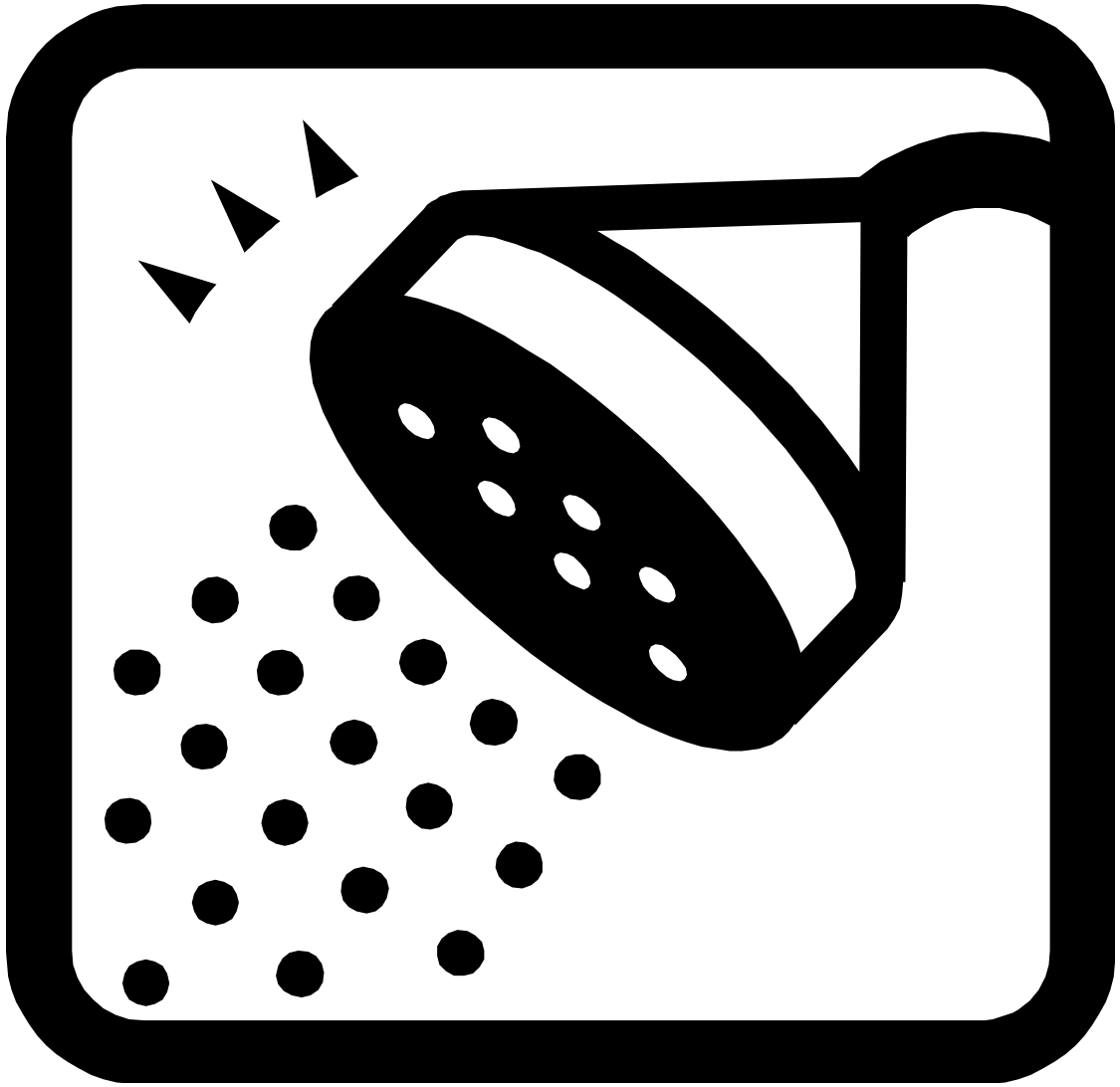
Pushes water through lumens to remove released bioburden

Prevents efficiency-robbing air pockets within lumen

If you’re washing cannulated instruments, you need to have this feature (DaVinci)

Especially effective when used both in wash and rinse cycles

Rinsing



Debris removal – surfaces

- Post-sonic rinsing useful to prevent debris re-deposition & soap build-up

Do you need to rinse?

- Are you bypassing the washer/ disinfector?
- Are you processing lumened instruments?
- Do you have IFU's that specify post-sonic rinse?
- Processing daVinci Endowrists?

If yes to any of these, you may need a sonic with rinse

Purified (DI/RO) Water Rinsing

Do you need to DI rinse?

- Is it specified in the instrument IFU?
- Are your instruments bypassing the washer/disinfector?
- If No to both & the instruments don't have a lumen, then probably not.

AAMI TIR-34 2007 implies treated water is a "factor to consider" for automated cleaning sonics, but doesn't explicitly spell this out

Verifying Sonic Function

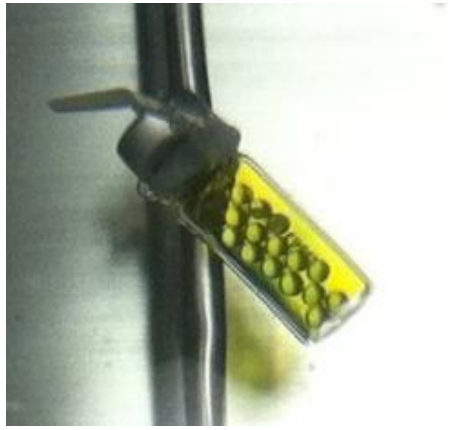
Is my sonic creating cavitation (is it working?)

“Tin Foil” test

- Traditional method, inexpensive
- Proves that transducers are functioning

Pre-packaged vial

- Coated beads that change color in response to sonic energy
- More expensive, yet easier to interpret



AAMI ST79 considers a sonic a “mechanical washer”

- Test daily

Verifying Sonic Cleaning

Is my functioning sonic having the desired effect?

Test coupons

- Backing material, coated with challenge media
- Some use blood & fibrin, others ink dots or other material
- Very similar to washer test coupons
- Make sure that all test surfaces are immersed when in use
- Check with sonic manufacturer for tips/recommendations before using

Resolving Wash Issues

"My instruments aren't exiting the sonic clean", or "I'm failing sonic validation testing"

Check:

- Chemistry concentration & type (tune the power generators)
- Tank water temperature
- Water quality, especially hardness
- Degas time
- Unit overloading
- Lumen flush connected
- Instrument rinse
- Basic sonic function

Adjust / change only one of the above at a time to pinpoint the true cause.

Run a few test loads to double-check cycle settings

Recording Cycle Results

Still uncommon for sonics

Cycle parameter output types

Paper printout

- Traditional approach, found in some older machines
- Difficult interface with electronic record-keeping.

USB

- Easy commercially available storage
- Stand-alone, no automatic link with network resources

Networked

- Seamless connection to instrument-tracking systems

Instrument Drying

Some older sonics offer a dry feature

- Post-sonic drying useful for direct-to-low-temp instruments

Do you need to dry?

- Do you/will you sonic low-temp (H2O2/Ozone) instruments?
- Will those low-temp instruments bypass the washer/disinfector?
- Consider a drying cabinet – more efficient

Disinfection

Some sonics offer a thermal disinfection feature

Do you need to disinfect within the sonic?

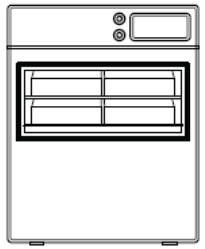
- Are your instruments bypassing the washer/disinfector?

Sonics and daVinci

STEP 14 (optional)

Thermal Disinfection

A



DISINFECT
Perform disinfection per hospital policy and regional guidelines. Thermal disinfection is not a substitute for reprocessing.

PARAMETER	VALUE
Temperature	185 °F - 199 °F (85 °C - 93 °C)
Time	1 - 5 minutes

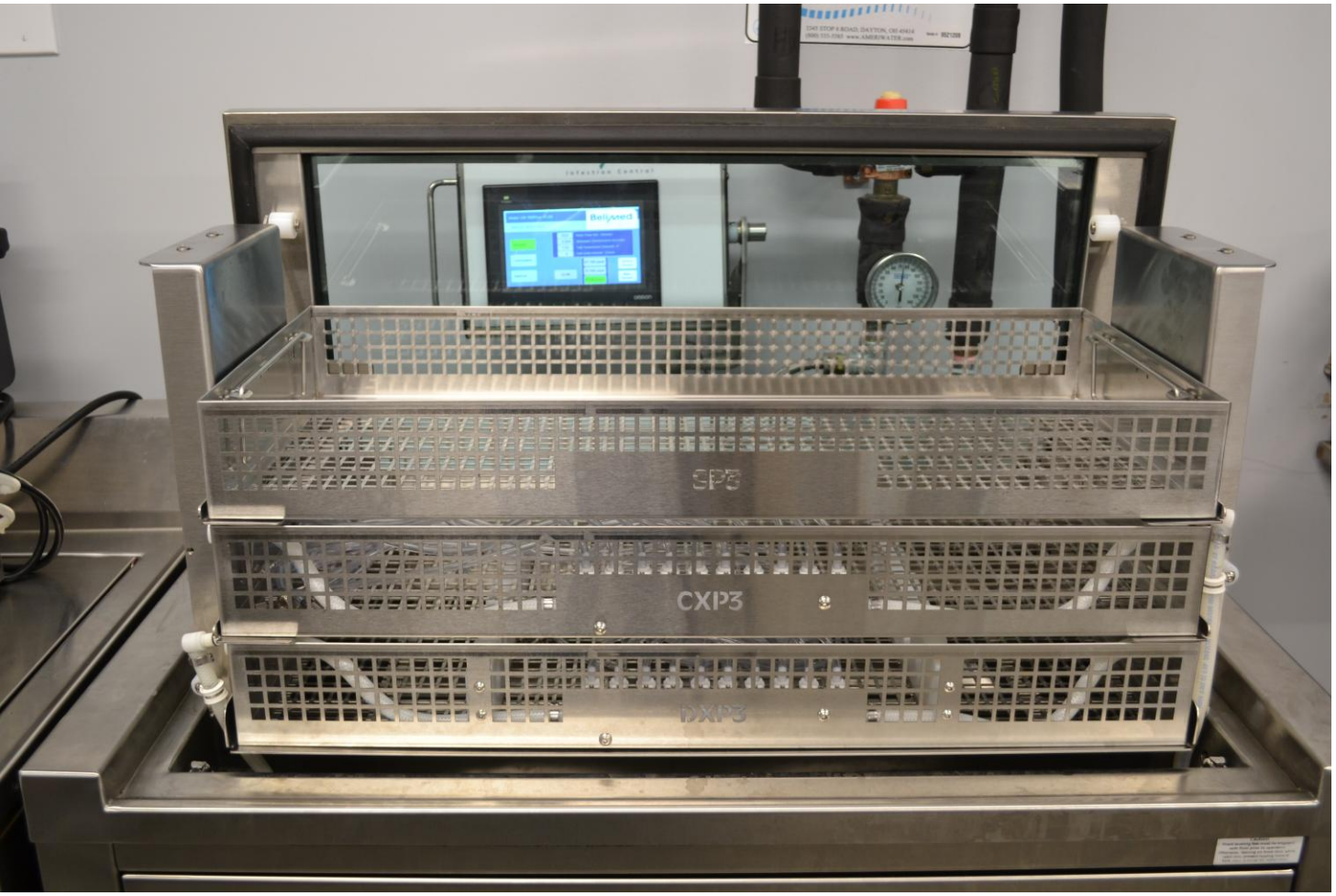
Thermal disinfection is OPTIONAL

Always get latest IFU and for Endowrists from Intuitive's Sterile Reprocessing Support Team (SRS) Rep:

To schedule an In-Service at your hospital, contact
Customer Service at **1.800.876.1310** or e-mail **SRS-Support@intusurg.com**
please provide your Hospital Name, City/State & Contact Information

- Endowrists can be run through a thermal disinfect cycle in the washer, in a basket. ALL previous washing steps MUST be completed per the IFU.
- Time and temp of WD Thermal Disinfect step can be set within the IFU ranges.

Ergonomics



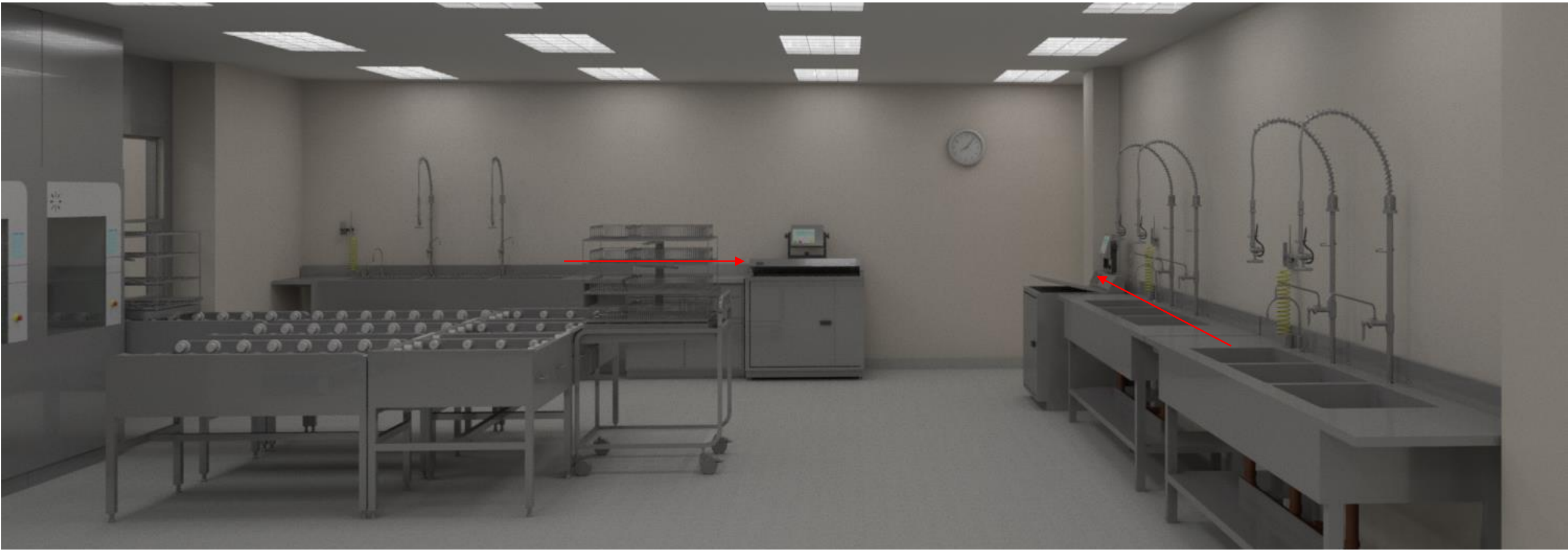
Look for a tray/lid lift function

- Reduces the strain of lifting heavy instrument sets out of a deep chamber

Should I worry about ergonomics & sonics?

- Do your sonics have a chamber that's more than 10" deep (measured from the top work-surface)?
- Are you sonic'ing full, heavy sets?
- If yes to either, then a powered elevator will be a good choice
- Check loading height for ease of use

Balance Workflow between Sinks and Sonic



Where should sonics be in my SPD?

- As close to the processing sink as possible
- If consistently sonic'ing, long path to the sonic can cost time, and interfere with other SPD staff
- If sonic'ing rarely, walking over to a central sonic is more acceptable

General Upkeep

Keep lid closed when not in use to limit evaporation

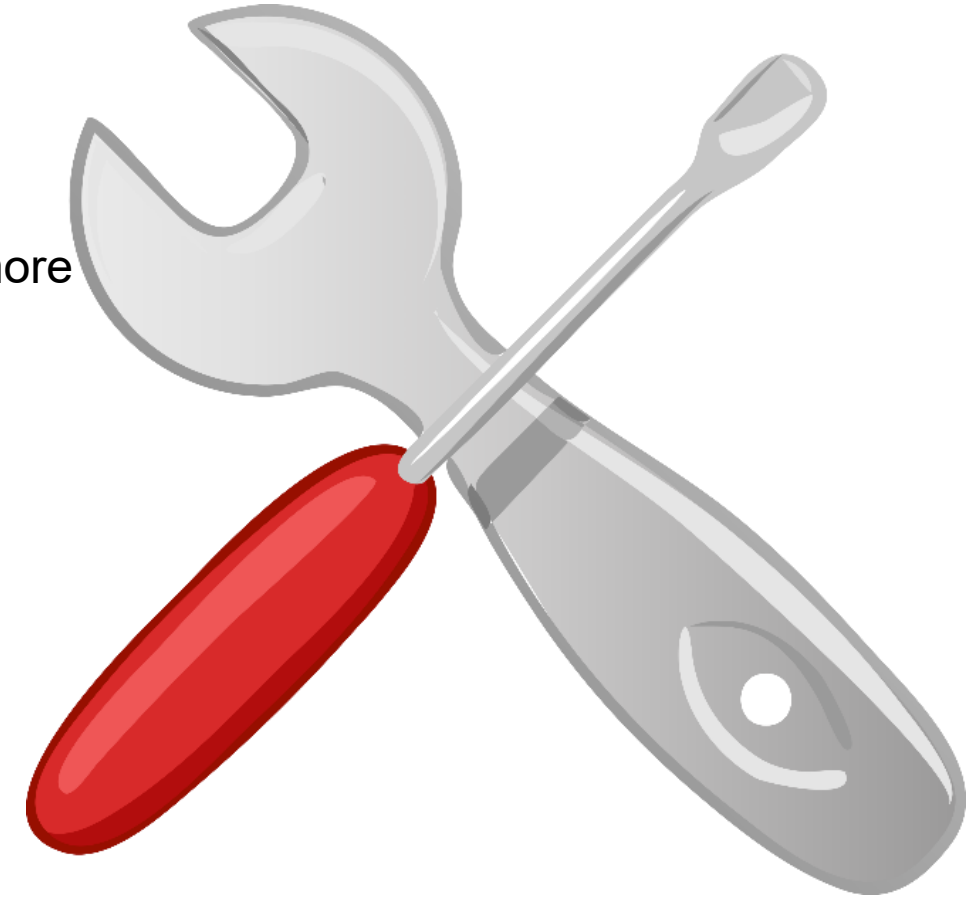
Inspect the detergent reservoir

Clean tank and exterior panels at least once a week

Inspect plumbing & hoses for leaks

Any additional maintenance as called out in the IFU

Major Maintenance Watchouts



Transducers

- Constant vibration can cause failure in epoxy bonds, brazing is more reliable
- Tank bond failure results in loss of function

Mechanicals

- Lid/tray lift mechanisms can wear out over time
- The more complex the mechanism, the more likely it is to fail

Electronics

- Keep water away from displays & controls, particularly if below tank opening

Service support is key

Summary

- Sonics are a powerful and appropriate soil removal tool
- Sonic setup is key to good results
- Reliable tools exist to validate and verify unit function
- There’s no “one-size fits all”; select a sonic based on your expected usage

Questions?

Thank-You for your time today.

Contact

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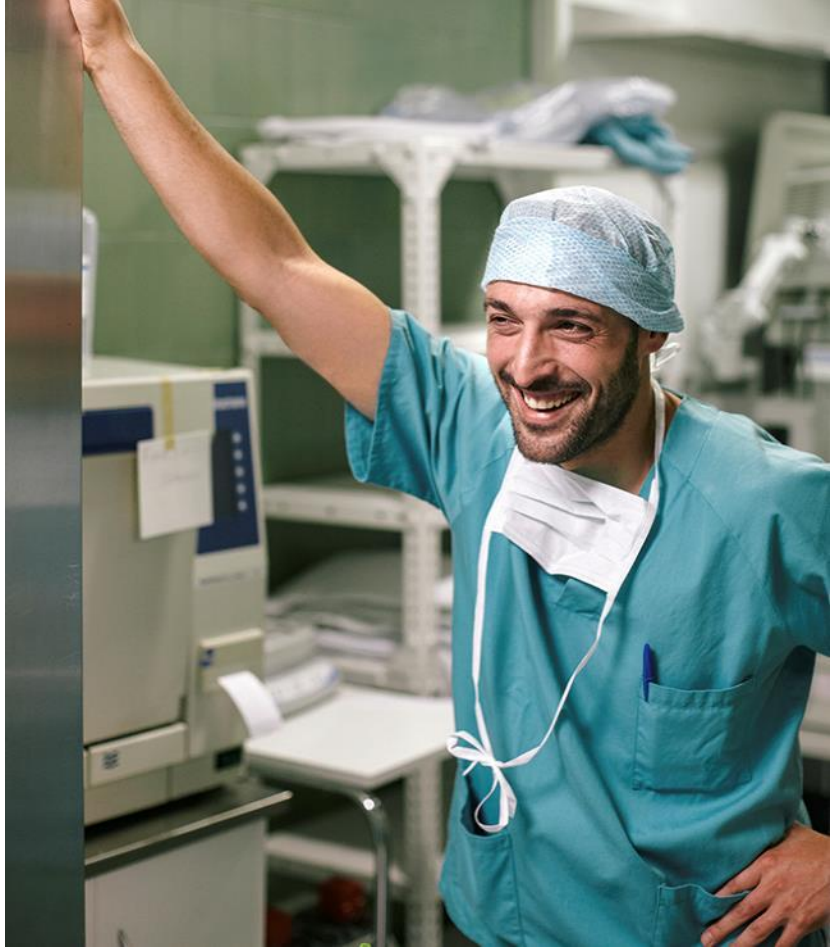

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