BladderScan
verathon

The impact of cleaning and disinfecting on medical device plastics

In hospital environments, a medical device such as an ultrasound bladder scanner is constantly exposed to pathogens. This occurs whenever there is contact between the patient and parts of the device, such as the ultrasound probe. Normal use of the device can also transfer pathogens easily to other surfaces, such as the device's touch screen.
To reduce the occurrence of healthcare-associated infections (HCAIs), hospitals are constantly strengthening their disinfection protocols. In recent years, many hospitals have chosen to use more aggressive cleaning agents and disinfect their devices more often. This can have harmful effects on the plastic housings of the device, causing them to crack, break or degrade. This can lead to equipment failures and result in unexpected downtime.

To counteract the long-term impact of cleaning agents, many medical device manufacturers choose to design their products with specialised plastic formulas that are resistant to chemical degradation. For example, the design of the Verathon® BladderScan i10™ system uses a custom-blended chemically resistant plastic to protect all critical electronic components of the probe, display console and printer.

In recent years, consumer devices such as tablets and smartphones have made their way onto the hospital floor. These devices are typically designed with consumer-grade plastics that are less tolerant of hospital disinfection protocols. And even some medical device manufacturers choose to use commercial-grade plastics, which can place users in the position of choosing between reduced equipment life or compromise to their disinfection standards.

Comparison of plastic materials: A case study

To illustrate the difference between materials, Verathon characterised two different types of plastics, exposing them to repeated cleaning and disinfecting cycles in order to simulate typical in-hospital use. Sets of reference samples for each plastic material were tested side-by-side. An independent lab then performed a fractographic evaluation of the plastics after the testing was completed. The two materials tested were:

1. Polycarbonate
2. Custom-blended plastic used in Verathon BladderScan i10

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The design of the Verathon® BladderScan i10™ system uses a custom-blended chemically resistant plastic to protect all critical electronic components of the probe, display console and printer.

Each set of plastic was repeatedly exposed to Metrex Cavicide1, a fast-kill (one minute kill time) hospital disinfectant. The active ingredients in this disinfectant are:

Didecyldimethylammonium chloride…..... 0.76%
Ethanol…….. 7.50%
Isopropanol…… 15.00%

Source: Metrex™ Cavicide1™, Technical Bulletin, EPA Reg No 46781-12

Lab testing with hospital disinfectant

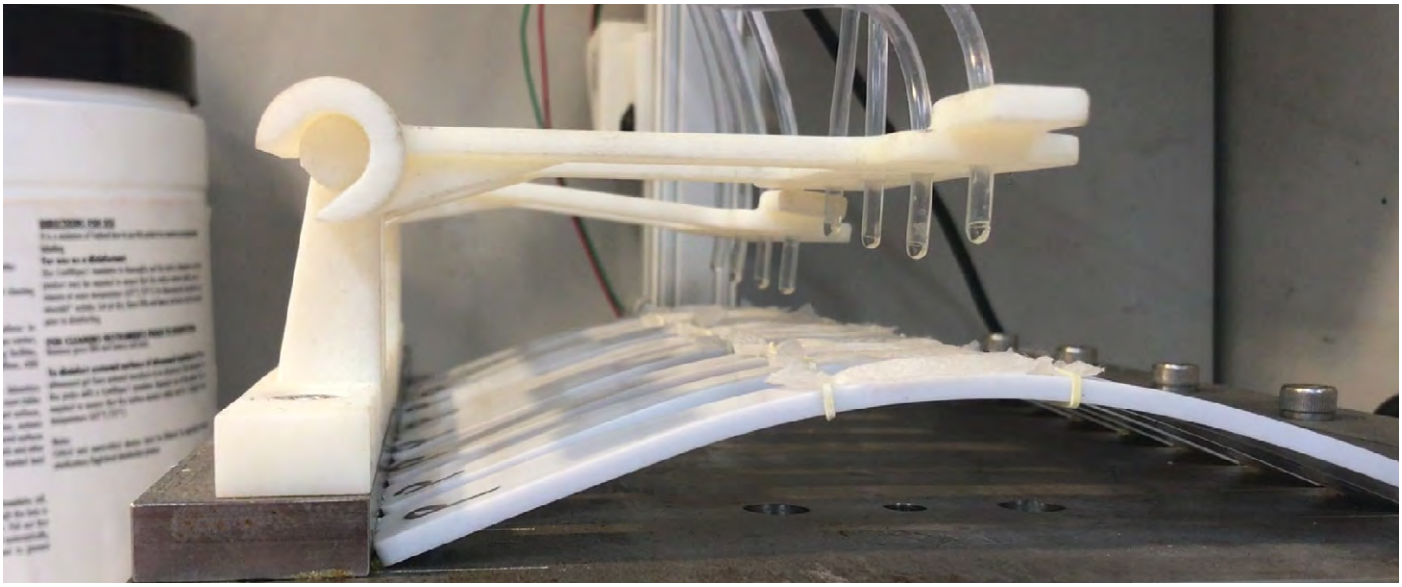


Figure 1. Hospital disinfecting agent being dripped onto plastic samples in the test fixture, simulating exposure to wet exposure time (kill time) and air-drying time.

To simulate prolonged exposure of plastics to hospital cleaning and disinfecting, eight (8) samples of each material were prepared in the same manner. The samples were placed in a fixture with tension applied across an arc to induce mechanical stress on the plastic. The hospital disinfecting agent was applied to the plastic material using a drip test fixture. Timing between drips during testing was set according to the chemical-specific evaporation time to simulate cycling between wet exposure time (kill time) and air-drying time. Test cycles were repeated to simulate the total number of cleanings expected over the device's lifetime.

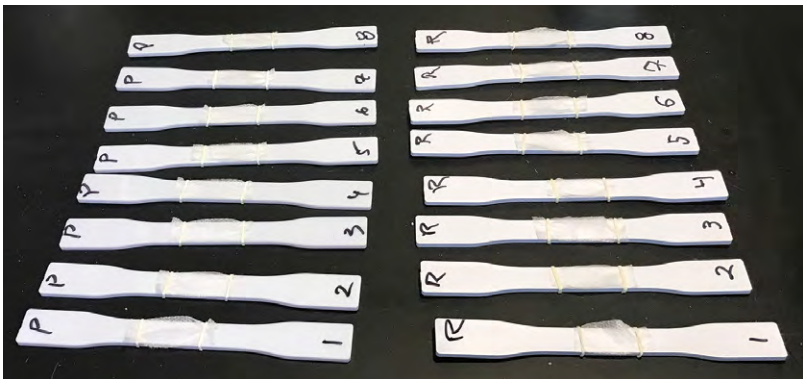
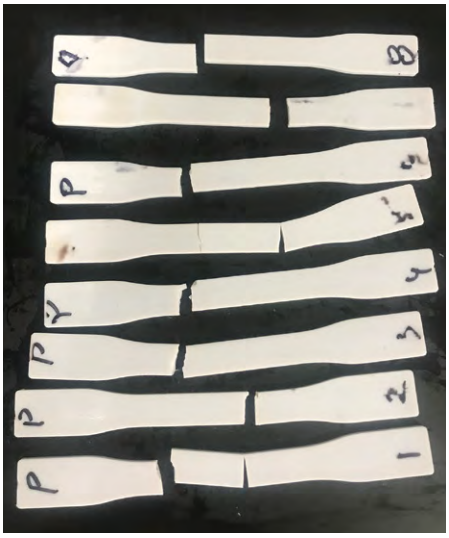


Figure 2. Raw sample stock of two materials prior to testing:
(Left) Polycarbonate
(Right) Custom-blended plastic used in Verathon BladderScan i10

Visible test results

The difference in chemical resistance could be easily observed at the end of test cycle. All eight (8) samples of the polycarbonate material showed catastrophic damage and were cracked. In contrast, all samples of the custom-blended plastic used in the Verathon® BladderScan i10™ system survived the test with no visible cracking or failures.

Polycarbonate



BladderScan i10™ Custom Blend

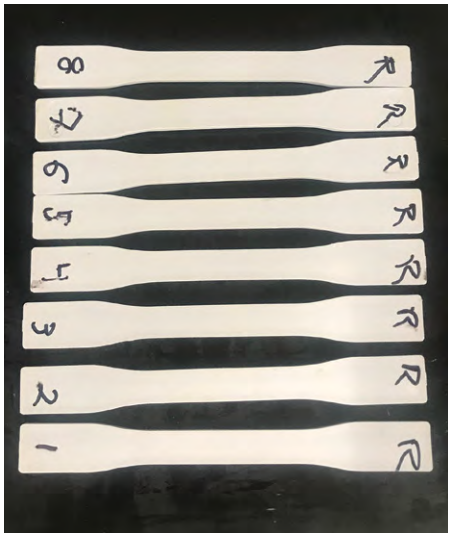


Figure 3. (Left)
At the end of the test, 100% of the polycarbonate samples were broken with catastrophic cracking.

Figure 4. (Right)
No visible damage was observed to the samples of BladderScan i10 custom-blend plastic.

Magnifying the analysis

The failed polycarbonate test samples were further analysed by The Madison Group, an independent consulting group specialising in plastics engineering. They performed a fractographic evaluation of the failed samples under various magnifications using a scanning electron micrograph.[1] The following selected figures illustrate the degradation that occurred to the polycarbonate material from the simulated exposure to hospital disinfection.

These figures from Sample 4 of the failed polycarbonate illustrate the plastic becoming brittle with repeated chemical exposure, until it eventually cracks under mechanical stress.

Figure 5.
Top view of broken polycarbonate (Sample 4); 10x magnification.

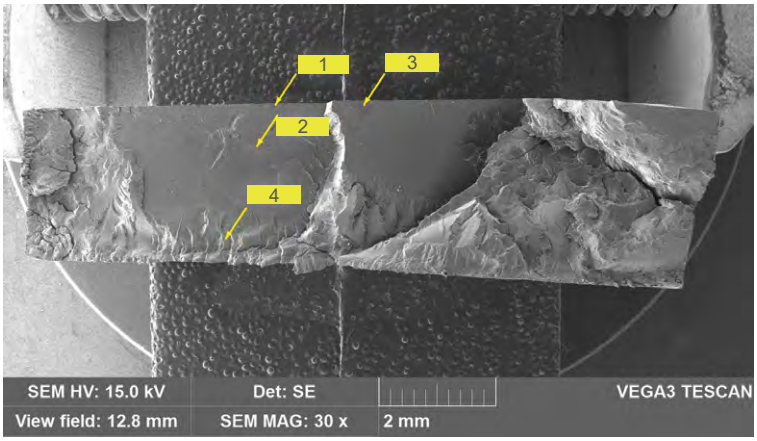


Figure 6.
Cross-section detail of fracture surface (Sample 4). 30x magnification with markers identifying damage areas 1–4.

The Madison Group reported:

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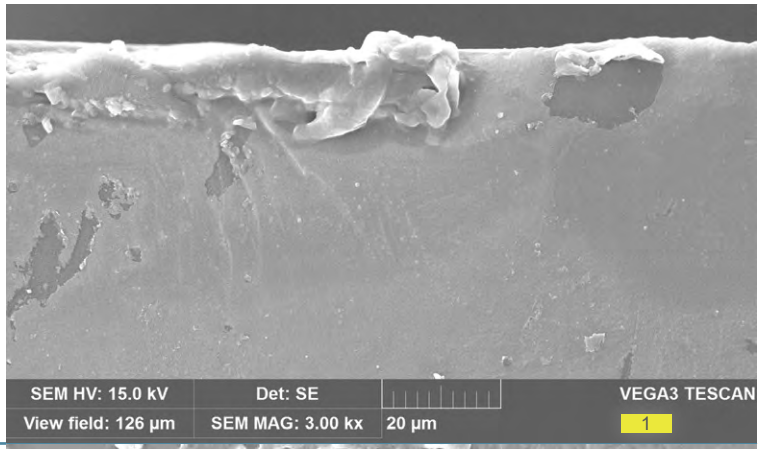
The Polycarbonate samples exhibited catastrophic transverse fractures. The observed fracture features were indicative of a slow crack initiation and growth mechanism, transitioning into more rapid crack extension for final overload...

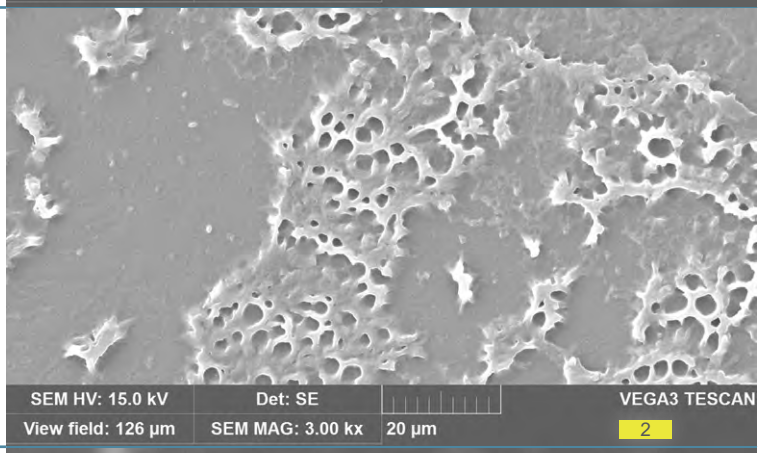
...The visual and microscopic examinations of the samples designated as [BladderScan i10 custom-blended plastic] did not reveal signs of cracking or other surface modifications.

Each area in the failed Polycarbonate (Sample 4) cross-section was analysed under increased magnification.

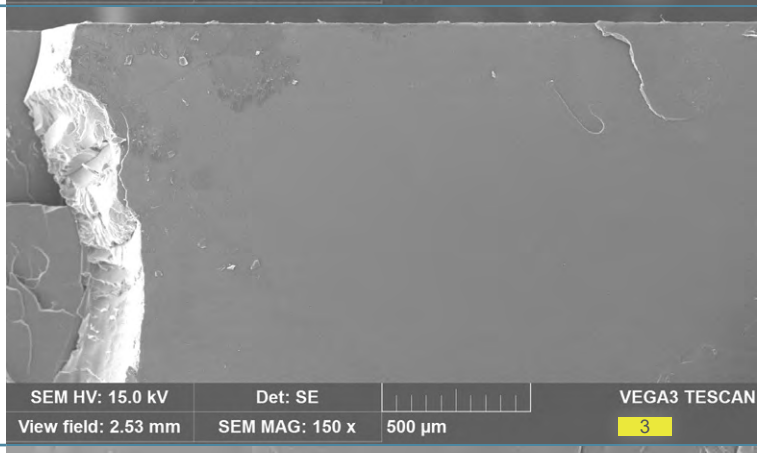
Area 1 is the area of crack initiation, and Area 2 is the adjacent fracture surface. The fracture surface exhibits ridge-like features representing crack unions, indicating the initiation of multiple individual cracks.



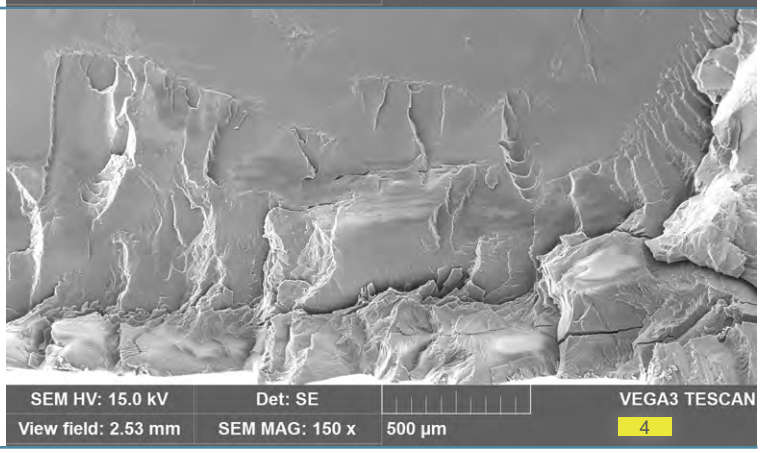
The honeycomb appearance of Area 2 under magnification shows significant signs of chemical interaction with the fracture surface.



Area 3 shows a second location of crack initiation. There are additional signs of crack unions and chemical interaction.



Area 4 is a final fracture zone located on the edge of the sample opposite the origin fracture. The features of Area 4 are characteristic of final mechanical overload. Secondary cracking is also present, indicative of chemical interaction with the plastic material.



The Madison Group further reported:

Overall, the observed features [of the Polycarbonate sample] were indicative of chemically induced failure. The fracture characteristics suggested a mixed mode of environmental stress cracking and molecular degradation.

- A significant amount of evidence was found to indicate environmental stress cracking. Environmental stress cracking (ESC) is a failure mechanism whereby a plastic material cracks due to the contact with an incompatible chemical agent while under tensile stress. It is a solvent-induced failure mode, in which the synergistic effects of the chemical agent and mechanical stresses result in cracking. These features included multiple crack origins and bands of ruptured craze remnants.
- Other features, including a honeycomb morphology, localised delamination and secondary cracking were associated with chemical attack/molecular degradation of the plastic.

Conclusion

Cleaning and disinfecting are a critical infection control requirement in the hospital environment. The lab tests and analysis described here demonstrate the kind of damage that may occur to medical device plastic components with repeated exposure to these chemicals. Some types of plastics like ordinary polycarbonate may crack or break under these hospital conditions, which could lead to equipment downtime that impacts patient care.

Lab testing also demonstrates that the custom-blended plastic used in Verathon® Bladderscan i10™ is resistant to chemical-induced failures. With BladderScan i10 you can be certain that your equipment will be ready when your staff and patients need it.

1. The Madison Group, Report TMG 22-21807-00, “Fractographic Evaluation of Chemically Exposed Samples”, 14 June 2022. Report kept on file at Verathon, 20001 North Creek Parkway, Bothell WA 98011, USA

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