

RFP specifications for longer-lasting medical devices

More stringent disinfecting protocols to combat the rise of superbug threats in medical facilities have made designing durable medical devices challenging.

Minor changes to an RFP can ensure new devices are disinfectant-ready and able to meet the rigors of the hospital environment.

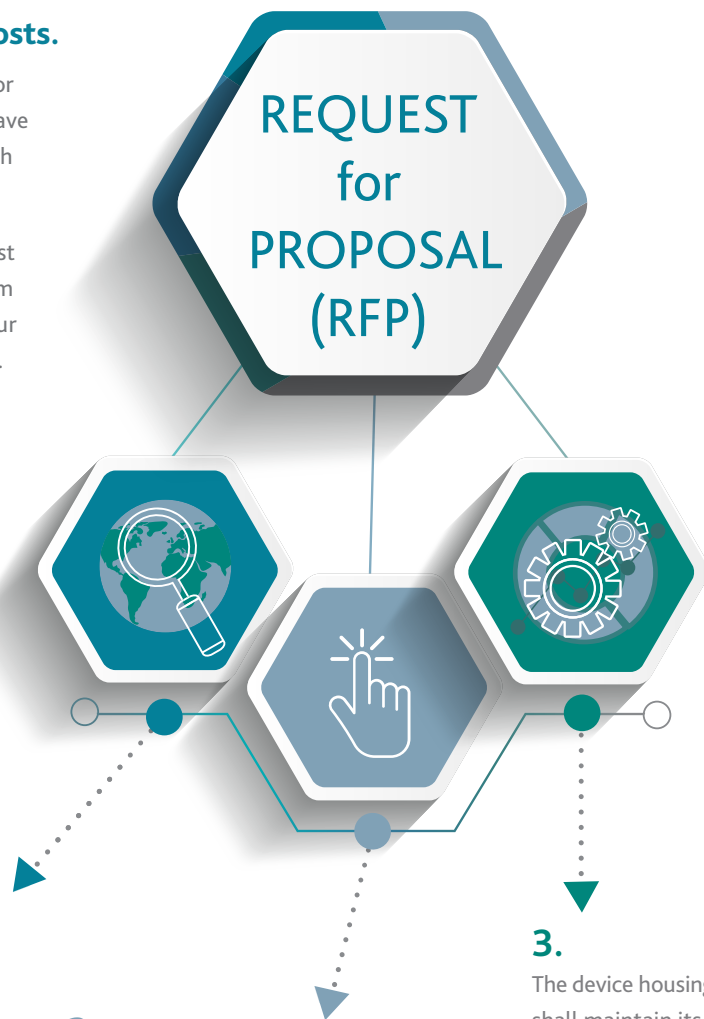
Improve patient safety; lower operating costs.

Consider including content similar to this in your request for proposal (RFP). If your RFP includes these items, you could have access to cleaner, safer, longer-lasting medical devices which would improve patient safety and lower operating costs.

By broadening the number of disinfectants in IFUs across most of the devices in your hospital, it could give you more freedom to purchase the disinfectants you want while improving your chances of having more successful Joint Commission audits.

mindray

The BeneVision N-Series patient monitors by Mindray tackle cleanability and durability with a five-year warranty enabled by Eastman medical polymers.



1.

The device housing and hardware shall be made of materials compatible with a wide range of disinfectants, including bleach, alcohol, quats (quaternary ammonium), and hydrogen peroxide used for cleaning up to (X) times per day throughout the device's expected service life of (X).

2.

The device housing shall not become sticky to the touch after cleaning with the preceding listed types of disinfectants up to (X) times per day throughout the device's expected service life of (X).

3.

The device housing and hardware shall maintain its integrity when bumped into a wall or dropped in the course of normal use throughout the device's expected service life.

Test housing material performance using a simple 4-step test.

Materials	Control (joules)	DISINFECTANTS						
		Diversey Virex® TB (ether, benzyl quat)	Clorox Healthcare® Bleach Germicidal Wipes (germicidal hypochlorite)	Clorox Healthcare® Multi-Surface (IPA quat)	Clorox Healthcare® Hydrogen Peroxide (H ₂ O ₂ cleaner)	PDI Sani-Cloth® AFIII (benzyl quat, DPG ether)	PDI Super Sani-Cloth® (IPA quat)	PDI Sani-Cloth® Plus (IPA benzyl quat)
% RETENTION OF IMPACT ENERGY TO BREAK								
Eastman Tritan™ MX711 copolyester	4.3	75 ± 26	89 ± 1	92 ± 4	95 ± 5	109 ± 3	101 ± 3	114 ± 1
Eastman Tritan™ MX731 copolyester	4.3	65 ± 24	96 ± 5	98 ± 5	99 ± 5	104 ± 2	100 ± 2	116 ± 1
Eastman Tritan™ MXF121 copolyester	4.8	91 ± 1	95 ± 3	90 ± 5	89 ± 1	94 ± 2	87 ± 2	100 ± 1
Eastman MXF221 copolyester	5.2	94 ± 2	95 ± 2	92 ± 3	98 ± 1	93 ± 4	83 ± 1	96 ± 3
PC/PBT	5.3	8 ± 3	98 ± 2	57 ± 45	94 ± 2	9 ± 2	91 ± 8	16 ± 2
PC/polyester	5.5	6 ± 1	6 ± 2	91 ± 12	23 ± 1	5 ± 0	75 ± 28	8 ± 2
PC/ABS 1	6.8	15 ± 1	70 ± 21	84 ± 13	97 ± 2	20 ± 3	16 ± 1	71 ± 22
PC/ABS 2	6.6	Break on jig	102 ± 1	64 ± 21	69 ± 32	6 ± 1	42 ± 37	5 ± 0
PVC	4.5	19 ± 2	19 ± 0	45 ± 36	56 ± 32	46 ± 36	18 ± 2	100 ± 0

% Retention

≥ 80%
 ≥ 60%
 < 60%

Step 1: Select a strain jig to replicate stress in the device. **Step 2:** Place plastic tensile bars on a 1.5% strain jig. **Step 3:** Apply disinfectants to tensile bars and enclose in a plastic bag for 24-hour exposure at room temperature. **Step 4:** The most critical step. Remove tensile bars from the jig and run a reverse side impact test on the exposed and control samples. The percent of impact strength retention shows differences in mechanical integrity of plastics after exposure to disinfectants, giving an indication of how well the plastic will withstand cleaning and the normal rigors of a hospital environment.

For more information and to view the full test, visit eastman.com/medical or email plasticsmedicalteam@eastman.com.

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It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

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