

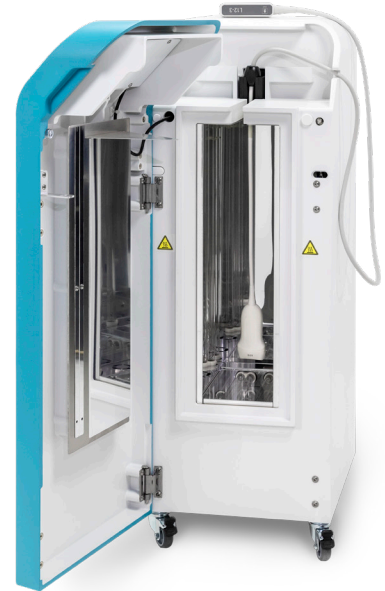
## FACT SHEET

# UV-C HLD compatibility with ultrasound probe materials

The utilisation of plastics has gained popularity in medical device assembly because of their strength, weight, cost savings, aesthetics and performance properties.

Medical Grade Polymers are commonly used to manufacture and assemble surgical instruments, catheters, endoscopes, ultrasound probes and other medical devices.

These medical-grade polymers are designed specifically for use in medical applications that enables the medical devices to be capable of withstanding and resistance to repeated cycles of ethylene oxide (EtO), radiation (UV-C), chemical sterilants and autoclaving.<sup>1</sup>








## Germitec UV-C High Level Disinfection Systems

**Hypernova Chronos** is dedicated to high level disinfection of external, transvaginal (TV), and transrectal (TR) probes, while **Antigermix E1** (AE1) is designed for disinfection of transesophageal (TEE/TOE) probes. Both Hypernova Chronos and Antigermix enable an ultrafast UV-C HLD process: around 90 seconds for external and endocavity (TV/TR) probes, 180 seconds for TEE/TOE probes.

**Germitec conducts various tests in collaboration with probe manufacturers to ensure probe compatibility is achieved:**

- Tests in laboratories on probes or on materials provided by manufacturers
- Tests in laboratories on materials representative of those used in the probes
- Field observations of probes in real use
- Documentary studies

## Germitec's probe compatibility testing process:

Step 1	Step 2	Step 3	Step 4	Step 5
Germitec and the probe manufacturer agree on the required test protocol to be conducted.	The probe manufacturer provides probe samples and/or additional material to be tested in the Hypernova Chronos or AEI.	Germitec runs the test protocol on the probes and checks during the 4000+ cycle process the probe material performance.	Germitec provides a documentary study with the returned probes. In addition, the probe manufacturer conducts fields observations of the probe(s) in real use.	Probe manufacturer adds the Hypernova Chronos or AEI to their probe disinfection approval list.
				

In some probes, UV-C can cause slight discolouration of the housing and the cable. However, slight discolouration does not affect the performance of the ultrasound probe and these changes can be minimised by proper cleaning prior to each UV-C cycle. Cleaning of the device is a necessary part of the decontamination process.

In comparison, **chemical disinfectants are also known to cause discolouration** to the surface of ultrasound probes. For example, **Cidex OPA IFU states signs of surface discolouration** can occur after 7 days or more.<sup>2</sup> Butterfly iQ states in its 'Compatible Cleaning and Disinfection' approved product list that **hydrogen peroxide system can result in premature cosmetic wear** of the device.<sup>3</sup>

## Collaborative Probe Compatibility Program Provides Confidence

**Over 1,000 probes from all major manufacturers have been tested, approved and endorsed for use with Hypernova Chronos and AEI.**

Probes listed in Germitec's Ultrasound Probe Compatibility List have shown **UV-C to be non-corrosive to the sensitive medical-grade polymers** found on ultrasound probes and their probe cables. This is why the length of probe cables can also be high level disinfected within Hypernova Chronos and AEI.

To ensure ongoing compatibility with a growing range of ultrasound probes, Germitec's Ultrasound Probe Compatibility List is regularly updated. **4.1 Lt: Suderinami gamintojai**



**References:** 1. Adhering Medical Grade: Polymers <https://www.masterbond.com/medical-grade-polymers> 2. <https://www.hopkinsmedicine.org/hse/forms/cidexopa/opainstruction.pdf> 3. <https://support.butterflynetwork.com/hc/en-us/articles/360040976672> GER0090-GL-FLY-V04