# Hypernova Chronos is leading the way in Ultrasound High Level Disinfection

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Date: March 2023
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# Germitec Hypernova Chronos UVC HLD System

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# Germitec's Chronos Technology

## The following Technology is not yet Approved by the FDA

Germitec and the Hypernova Chronos is:

- A UVC based technology for the Disinfection of Ultrasound Probes
- Available in Europe, Canada, Australia, etc.
- Germitec's technology is under evaluation by the FDA under a DE NOVO classification
- Germitec's USA operations are based in San Diego, County
    - Focus Group Opportunities will be available in the coming weeks!!!!

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# Overview of the Technology

De Novo Classification means that no “previous technology” similar in application has been approved by the FDA prior to the Germitec Submission

- Other UVC application products such as “Hospital Room Disinfection” systems are regulated by the EPA (Environmental Protection Agency) and are held to different disinfection standards than HLD (High Level Disinfection Standards), typically measured in log reduction, ie 6 Log, 5 Log, etc.

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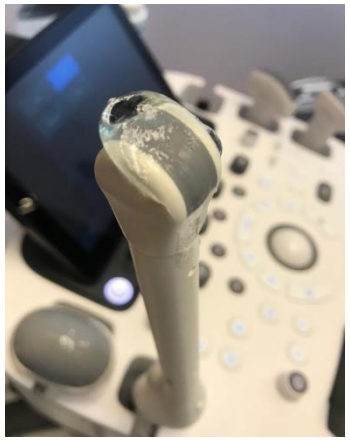
# Cross-Infection risks in ultrasound

## Reducing ultrasound probe cross-infection risk can aid in reducing HAIs

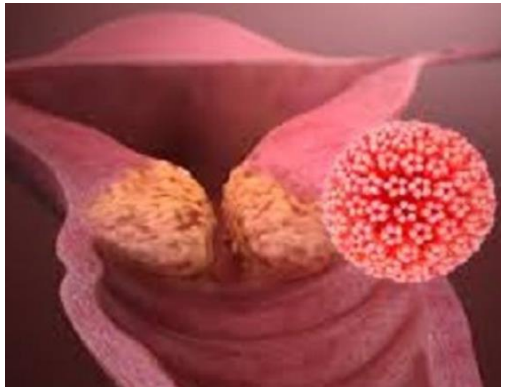


Patients are **41%** more likely to have positive bacterial cultures **30 days after** a transvaginal scan where probes were low level disinfected and **26%** (HR=1.26) more likely to be **prescribed antibiotics.**[1]

Up to **17%** of ultrasound probes were found to be contaminated with human DNA and HPV DNA after disinfection with low level wipes.[2]

Up to **13% of condoms** and **5% of commercial** covers have tears pre and post-transvaginal ultrasound examinations.[6-9]

Research shows that virtually all cervical cancers (**more than 99%**) are caused by high-risk HPV.[3-4]



More than **80%** of probe handles that were not disinfected had residual pathogens including MRSA.[5]

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# Know when to HLD

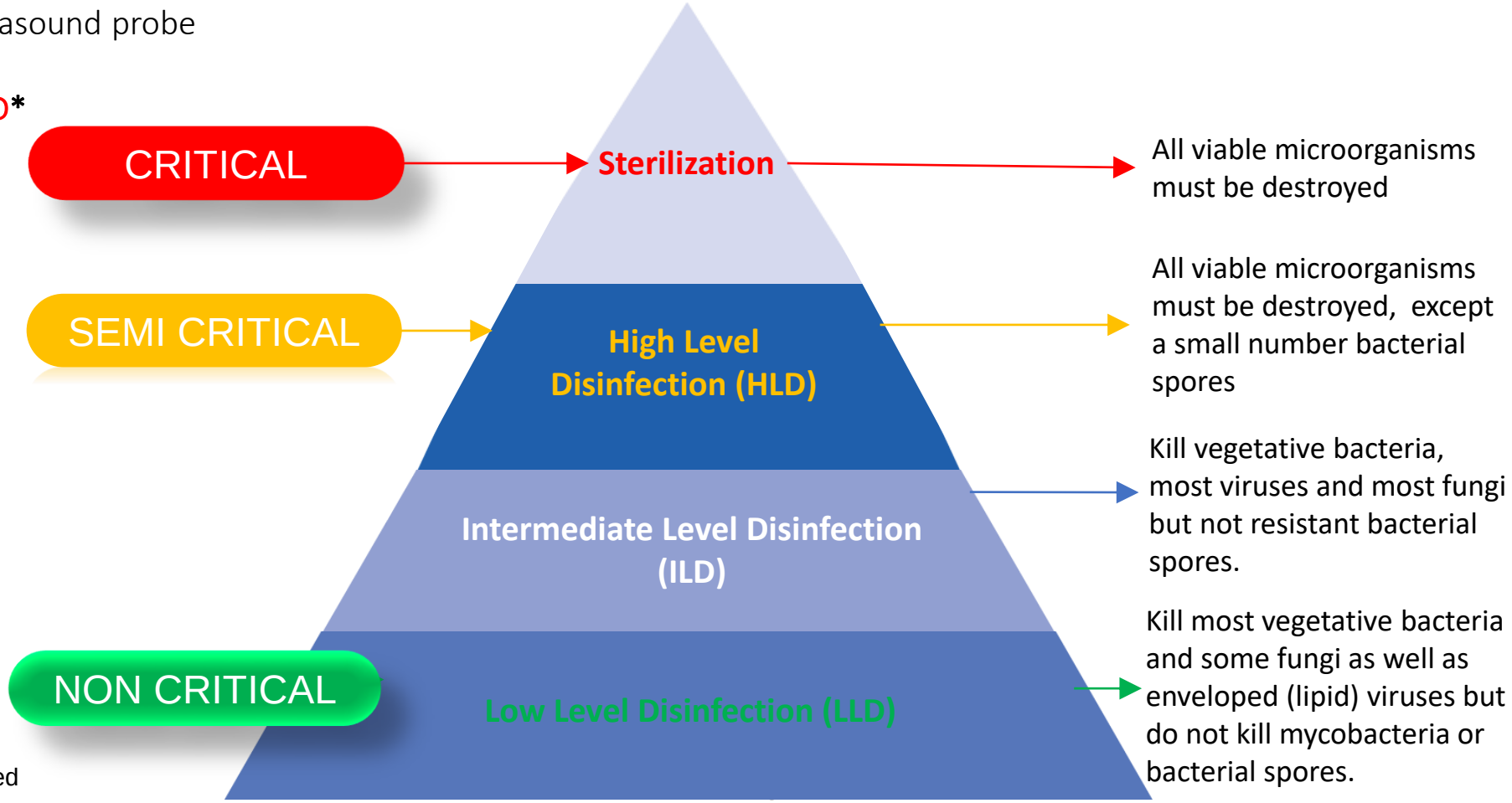
## Defining Disinfection Levels

**Under the Spaulding classification** the ultrasound probe is classified into:

- critical probe = Sterilisation or HLD*
- semi-critical probe = HLD
- non-critical probe = LLD

**Spaulding Classification is determined by:**

1. Ultrasound probe contacting the Patient's procedure site
2. Level of cross-infection risk.



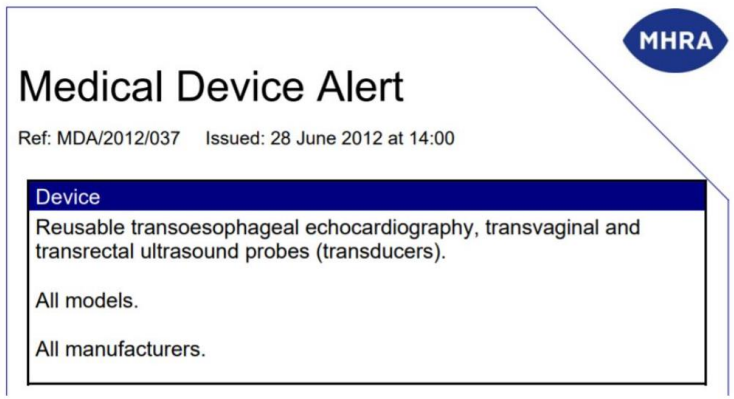

* if not possible can be high level disinfected and placed inside a sterile cover to prevent the contamination of a sterile filed[1-3]

# Issues with Chemical Disinfectants

## Manual disinfection risk

Manual soak (soaking bulk liquid disinfectants) method risk.

- Safety threat to patients as **steps** in the cleaning and disinfection process can be **missed and lack of compliance**.
- Risk of exposure to **dangerous chemicals**
- Global disinfection guidelines are favouring automation
- Manufacturer's instructions are beginning to move away from manual HLD as an option.[1-2]




There have been numerous cases of **cross infection risks to patients due** to manual ultrasound probe reprocessing:

- Patient contacting hepatitis C virus after transrectal prostate biopsy as part of an individual screening for prostate cancer.
- Patient contracting hepatitis B linked to improper ultrasound transducer disinfection that led to a fatality.[3-4]

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# Issues with Chemical Disinfectants

## Skin and respiratory problems

A **substantial number of studies** have shown that Ortho-phthalaldehyde (OPA) and glutaraldehyde (GTA) anaphylaxis, can pose severe health and safety risks for patients and clinical staff.

Exposure to these chemicals can cause **skin reactivity, dermatitis, respiratory problems and systemic antibody** production. It now appears that the health issues of OPA exposed to health care workers are comparable to that of glutaraldehyde, suggesting that it may not be a safe alternative. [1-7]

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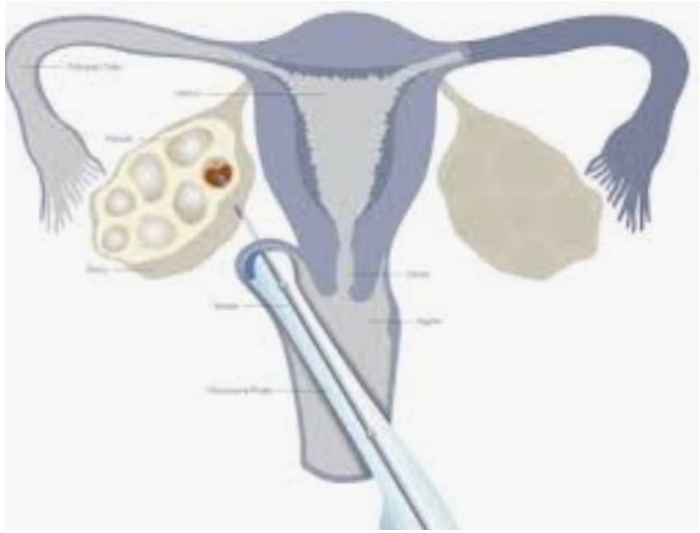
# IVF success rate in mind!

## Exposure to toxicity residuals can impact oocyte retrieval

**The risk of exposure to** toxicity residuals can impact oocyte retrieval, embryo transfer and other IVF applications during pelvis ultrasound probe procedures.[1-9]



Study Research Impact on integrity on cellular membrane, metabolic activity or cell growth. The liquid toxicity of disinfecting agents were classified into three main groups according to their relative toxicity:

1. **Mild** (TC(50) > 1 mM, including phenol, **hydrogen peroxide (30% w/v),** and formaldehyde (37% w/v),);
2. **Moderate** (1mM > TC(50) > 0.1 mM, Sodium hypochlorite (4% w/v),); and
3. **Severe** (TC(50) < 0.1 mM, glutaraldehyde (50% w/v), cupric ascorbate, and peracetic acid (32% w/v),) toxicity.

Trophon **hydrogen peroxide (80ml; 35% w/w) is a higher concentration to the chemical tested in the study.**

- At least 1-in-3 sonographers are concerned about the 'risk of exposure to hazardous chemicals', and other potential risks associated with hydrogen peroxide exposure
- 47% of sonographers have personally experienced an adverse event from using the Trophon system most commonly skin burns
- Probes are difficult to dry completely, e.g. in Needle guide grooves lead to chemical burns

# Hypernova Chronos

## Leading the way in High Level Disinfection

### When seconds count Chronos delivers

**SAFE - Reduces Risk**

Chronos is probe friendly and chemical free

**EFFECTIVE - Reduce Infection Risk**

Chronos delivers UV-C HLD to inactivate microorganisms and proven effective through independent Microbicidal efficacy testing

**EFFICIENT - Reduces Cost**

Chronos streamlines clinical workflows with an ultrafast 90 seconds HLD cycle time and automated verification system

**COMPLIANT - Streamline Audits**

Chronos improves audit-readiness and removes paperwork

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# SAFE – Reduce Risk

## Chronos is Probe friendly and chemical free that reduces risk

### Probe friendly

- UV-C HLD energy is probe friendly
- Many leading ultrasound probe manufacturers have approved the use of Chronos
- Extensive probe compatibility testing.
- Easy probe loading and unloading mechanism reduces wear and tear on probe cable

PHILIPS SIEMENS acuson mediwatch ALOKA mindray ATL MEDISON hp SonoSite Canon EDAN SonoScape biosound esaote Interson GE

### Chemical Free

- **Safeguards staff and patients** by avoiding hazardous chemicals, fumes, and spills.
- **No chemical residuals** are left on the probe after disinfection, protecting the operator and patient from chemical burns (hand or face)
- **Environmentally friendly examination room** that is ideal for point of care ultrasound.

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# EFFECTIVE – Reduce Infection Risk

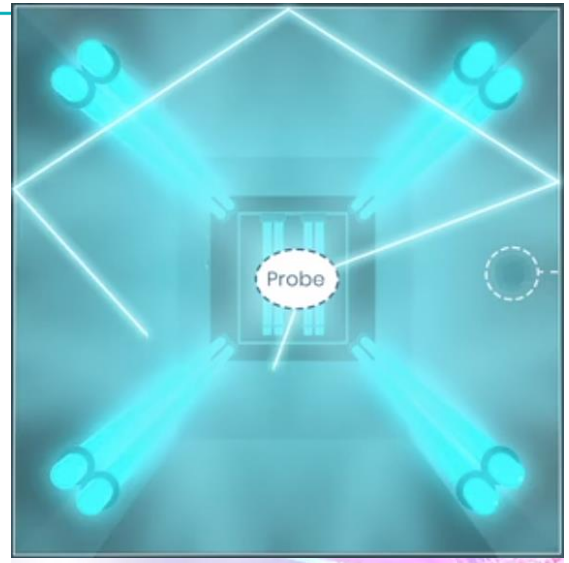
Chronos delivers **UV-C HLD** to inactivate microorganisms and proven effective through **independent Microbicidal Efficacy testing** to **reduce infection risk**

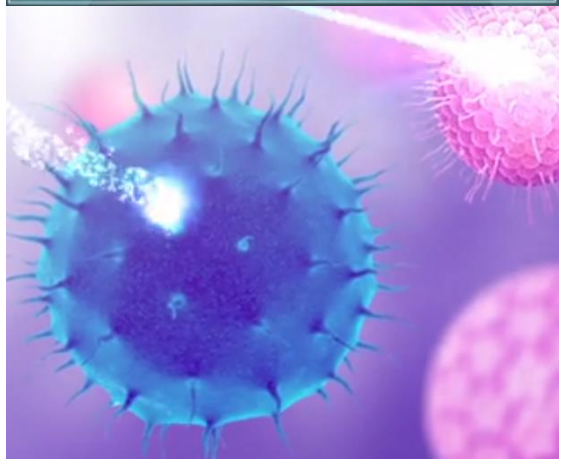
UV-C HLD

Chronos delivers UV-C high level disinfection (HLD) as particles and waves reflected from the chamber walls ensures there is no shadowing on the probe surface.

UV-C HLD energy of the photons penetrates the cell walls of microorganisms **destroying them**

- bacteria,
- fungi,
- viruses,
- mycobacteria
- spores, which is



# EFFECTIVE – Reduce Infection Risk

Chronos streamlines clinical **workflows** with an ultrafast 90 seconds HLD cycle time and **automated verification system r**educes cost

## Workflow

Chronos streamlines clinical workflows to maximise patient throughput, whilst maintaining the quality of patient care.

This is achievable through:

- Simple plug and play design that minimising staff interaction and training requirements
- Ultrafast automated 90 seconds cycle time
- Single cycle disinfection of the probe and the cable section
- Mobile device within departments
- Ideal at point of care ultrasound to support quick diagnosis and assessment

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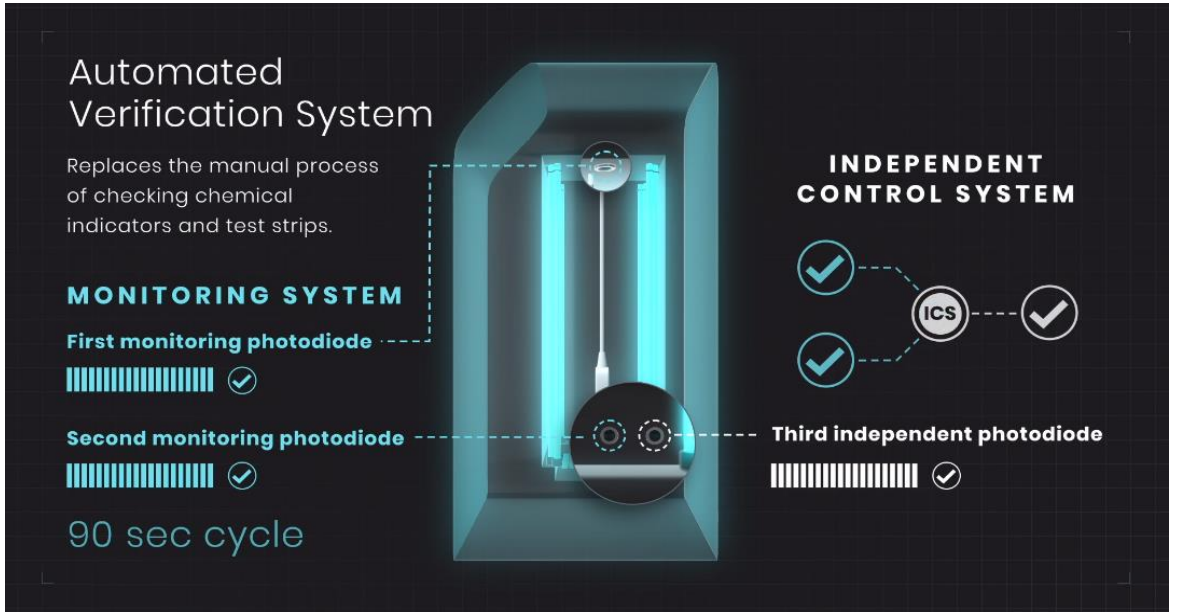
# EFFICIENT – Reduce Cost

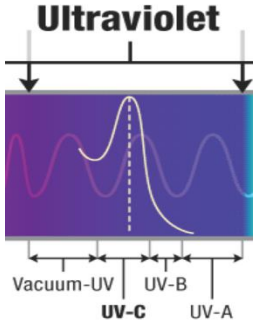
Chronos streamlines clinical **workflows** with an ultrafast 90 seconds HLD cycle time and **automated verification system r**educes cost

The **monitoring system consists of two photodiodes** that continuously measure the UV-C dose to operate the disinfection cycle to ensure High Level Disinfection efficacy is achieved. This takes approximately 90 seconds.

An **Independent control system validates the disinfection cycle** based on the UV-C dose measurements of a third photodiode, declaring the disinfection cycle completed "CYCLE OK".

The Automated Verification system operates similar to **Parametric Release** providing extra reassurance and saves time in automatically validating every disinfection cycle.

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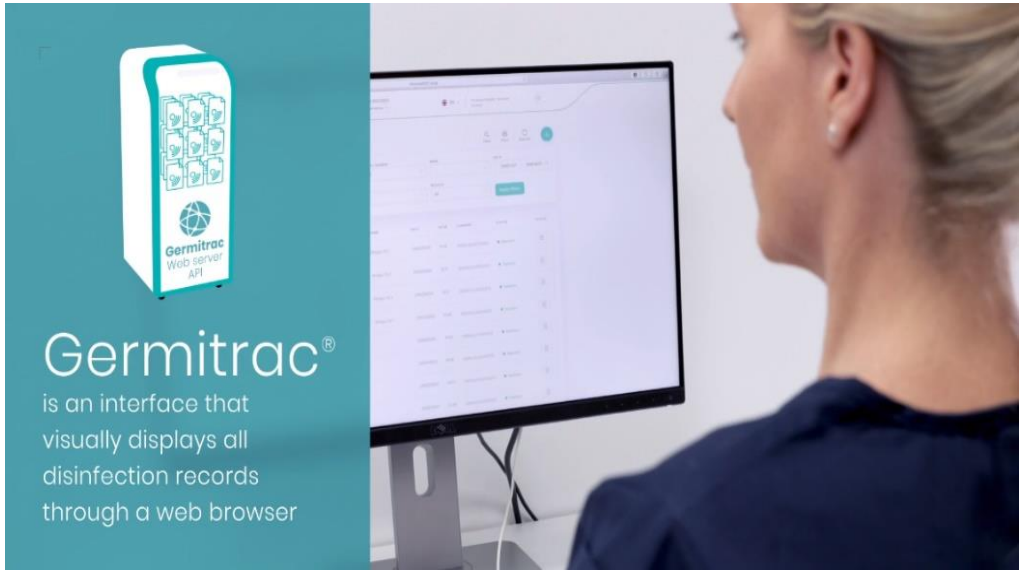
# COMPLIANT - Streamline Audits

Chronos improves **audit-readiness** and removes paperwork to **Streamline Audits**

## Traceability

## Data Access

Germitrac is an interface that visually displays all disinfection records through a web browser

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**Data Access**

Data can be easily accessed via a computer or hospital network linked to the Chronos by an Ethernet cable.

This provides users with numerous functionalities

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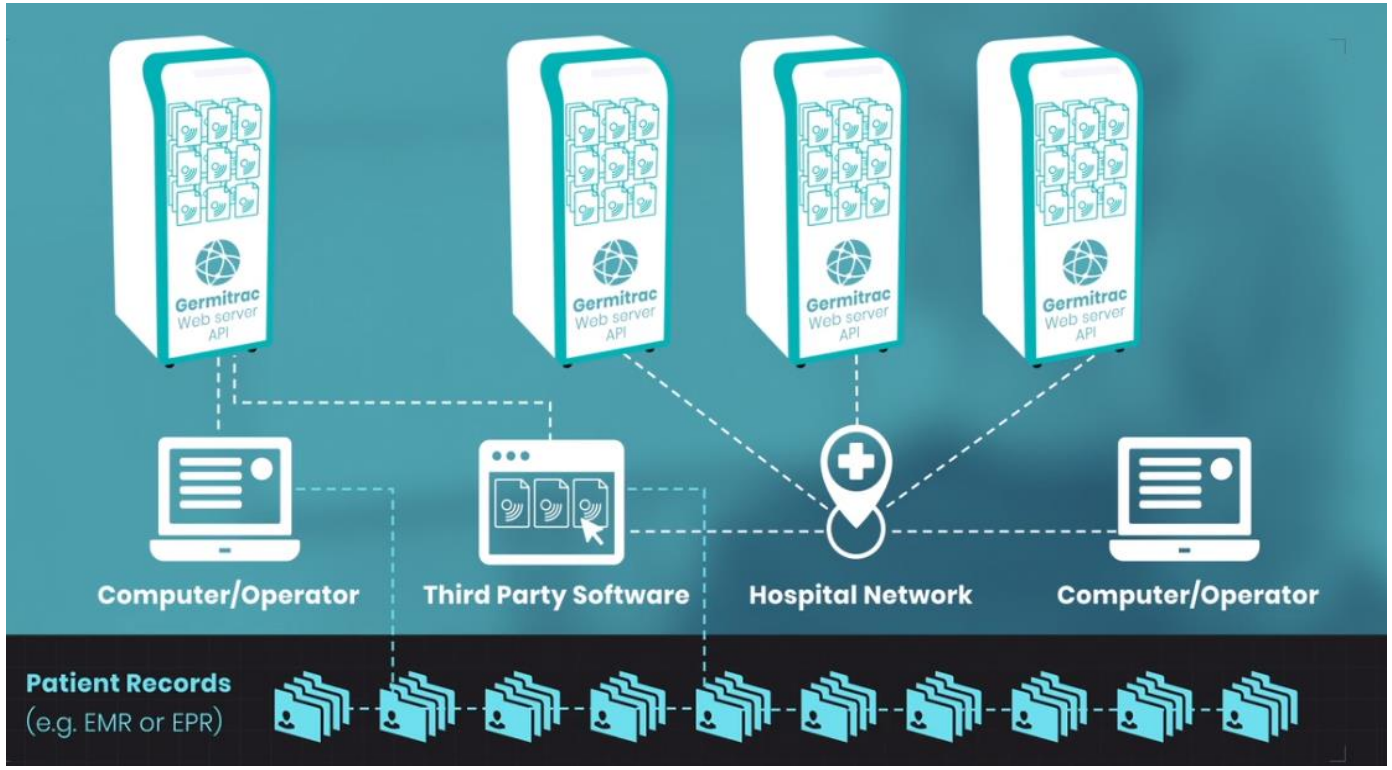
# COMPLIANT - Streamline Audits

Chronos improves **audit-readiness** and removes paperwork to **Streamline Audits**

**Integrated – with the hospital network**
The digital disinfection records can be manually linked to a patient profile.

**Automated through a third-party software** accessing Germitrac API web services to retrieve disinfection data and link it to a patient record, for example **Electronic Medical Records (EMR)** or **Electronic Patient Record (EPR)**

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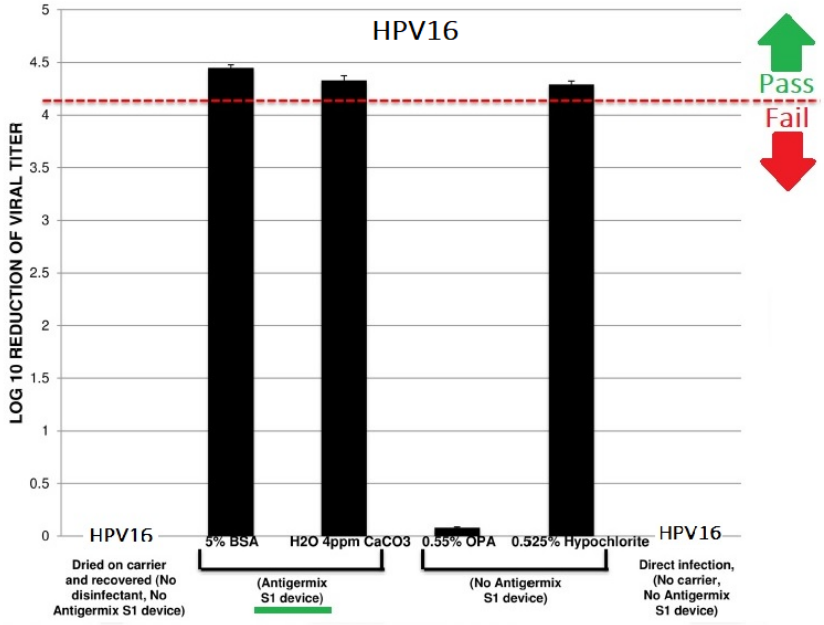
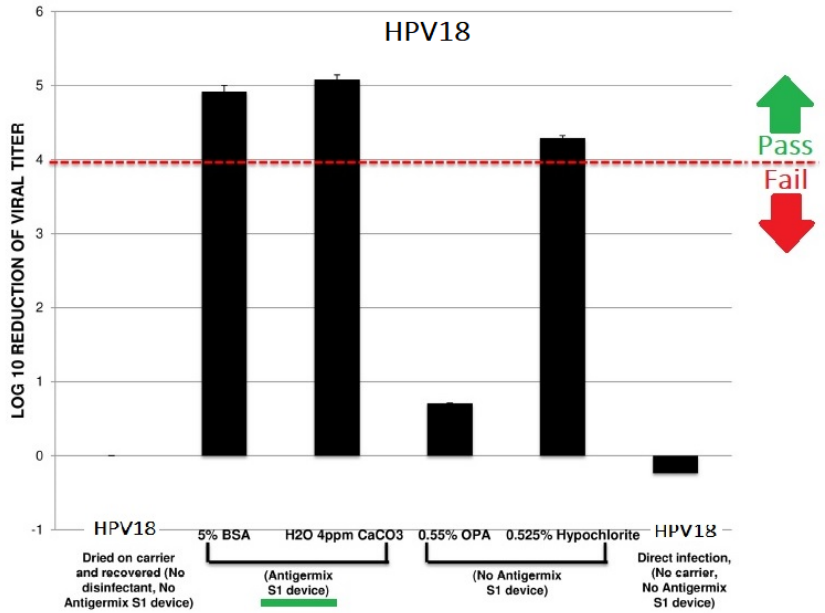
# Human Papillomavirus (HPV)

## HPV research is a major driver in changing clinical practice

Published research papers show ultrasound probes are a potential source of HPV transmission, posing a new challenge for infection prevention.[1&3]

Results suggest that healthcare facilities using endocavitary ultrasound probes need to strongly consider disinfection methods that are effective against HPV - **adopting new technologies such as UV-C HLD.[2]**




UVC radiation as an effective disinfectant method to inactivate human papillomaviruses (**HPV16 and HPV18 )** whereas OPA showed minimal efficacy[1-2]

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# UV-C  High Level Disinfection

## A Green Technology for a Better Tomorrow

Hypernova Chronos provides a unique, patented ‘greener’ High Level Disinfection technology, which removes the use of toxic chemicals in healthcare facilities around the world.

With UV-C light as an alternative disinfection method it is generating an eco-friendly clinical environment and alleviating chemicals being dumped into the environment

- **Soaking** - Each soak station uses 30 litres* of chemicals per annum and disposal of personal protective equipment (gowns and eye glasses)
- **Disinfectant wipes** – Each examination room uses 3,600 wipes annum
- **Storage** – Chemical storage area
- **Utility room** – special ventilation room

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# THANK YOU !