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# **Users and commercial sponsors**

## **Overview of the Nanosonics AuditProTM system**

### What is the Nanosonics AuditProTM system?

Nanosonics AuditProTM is a workflow compliance management system. It provides facilities and their broader organizations the ability to track infection control compliance across all ultrasound procedures in all departments ensuring that staff have appropriately disinfected ultrasound probes according to standard operating procedures and the Spaulding classification1.

1. Spaulding EH (1968). Chemical disinfection of medical and surgical materials. Disinfection, sterilization, and preservation. Lawrence C, Block SS. Philadelphia (PA), Lea & Febiger: 517-531.

### What problem does the Nanosonics AuditProTM system solve?

Infection prevention is more important today than ever before, and standardization and compliance has become a fundamental driver of infection prevention. Nanosonics AuditPro standardises infection control to best practice across your organisation.

The Nanosonics AuditProTM system can help to alleviate this burden by automatically linking infection control workflow events to patient procedures. This real-time intelligence on procedure classification, probe utilization, operators, and reprocessing events is communicated through informative management dashboards, summaries and tables at facility and organization levels.

### How does the Nanosonics AuditProTM system work?

The Nanosonics AuditProTM system intelligently combines the infection control workflow decisions made by the clinician, with the infection control process, including the trophon®2 HLD cycle data from embedded AcuTrace® technology with the patient procedure record ID obtained using the incorporated 3D mobile scanner. It then presents this information in the reporting application for fast secure access anywhere within your facility.

### What is included as a part of the Nanosonics AuditProTM system?

Nanosonics AuditProTM is comprised of Mobile Scanning Device (a Wi-Fi enabled device and docking station), a mobile application (pre-installed on the device along with mobile device management software) and software subscription to browser-based management dashboards.

### How does the Nanosonics AuditProTM system allow me visibility of ultrasound infection control across my department and facility?

The digital solution comprises a Mobile Scanning Device for ultrasound users, a subscription to browser-based management dashboards, and digitized logbooks. The sophisticated software combines procedure and disinfection records, including HLD cycle records from the trophon2 device.

It interrogates the data captured through the workflow to create non-compliance notifications to allow for rapid risk assessment and corrective action and intuitive information-rich dashboards to provide infection prevention practice insights. This real-time intelligence on procedure classification, probe utilization, operators, reprocessing events, linked to an individual patient record ID is communicated through informative management dashboards, summaries, tables and reports at facility and organization levels.

### What information can the Nanosonics AuditProTM system provide to me?

The Nanosonics AuditProTM system generates the following dashboards:

* **Facility** – Real-time intelligence and insight on the success of your facility's ultrasound infection prevention practices through email notifications and informative dashboards that display by date, Spaulding classification and department.
* **Ultrasound probes –** Visualize, understand and improve ultrasound asset utilization with dashboards that stratify digitally registered assets by Spaulding classification, departmental location or probe type.
* **Operator** – Quickly identify operators who may be infrequent  trophon®2 users to identify training opportunities or visualize trophon2 infection control efforts, with dashboards that can be viewed by department, operator activity or trophon2 cycle counts.
* **Digitized logbook -** Logbook records are available for view by registered users, with trophon2 cycle data automatically recorded without the need for additional operator paper-based recording. In addition, the data is displayed in a format that can be easily searched and filtered by any captured data point empowering you be generate informative insights.

### How many users of the dashboards can my facility have?

There is no limit to the number of users that can have access to the facility dashboards. Further, users can be classified as administrators, editors or view only to provide access and authority to different groups of users as required.

### What types of notifications are provided by the Nanosonics AuditProTM system?

In the browser-based application, you can access the notifications from the facility dashboard. There are two types of notifications:

* **System notification** – System health checks that let you know if the devices are out off sync, off-line due to network changes at your facility and other causes. The system notification relates to an unexpected incident that impacts the functionalities of the Nanosonics AuditProTM system to support standardization, data accuracy and access to your data in real-time
* **Procedure notification** - The procedure notification relates to a potential non-compliant event that may require documentation, risk assessment and management. Procedure notifications support continuous compliance monitoring to help you identify retraining needs or workflow optimisation opportunities to ensure best patient care.

Users with the correct privileges can enable an automatic email for the procedure notifications.

### How will the Nanosonics AuditProTM system support me during surveys?

The Nanosonics AuditProTM system has been built with survey requirements as a major input into the design. The system allows for fast traceability searches of patient related procedures, by a unique patient identifier to quickly provide printable survey ready reports. Additionally, it can provide surveysupport through the digitized logbook. In the logbook, electronic records are available to view at any time by registered users and trophon®2 HLD cycle data is automatically recorded without additional operator paper-based recording. The data is displayed in a format that can be easily searched and filtered by any captured data point.

### Who are the stakeholders relevant to the Nanosonics AuditProTM system?

The main stakeholders for the Nanosonics AuditProTM system include, but are not limited to; ultrasound users (e.g., sonographers, clinicians), infection preventionists, department heads (e.g., radiology, OB-GYN), risk or compliance officers and other support departments (e.g., IT or Biomed departments). Nanosonics AuditPro can provide data lead insights into infection control practices, probe asset utilization management and risk to help you in decision making and management reporting.

### For which organizations is the Nanosonics AuditProTM system relevant?

The Nanosonics AuditProTM system has been designed to support a variety of organization types including hospital systems, individual hospitals, multi-clinic organisations and small practices. For example, an admin can set up an organization defined as a group of facilities (site locations), and facilities can further be broken down into customisable departments and even rooms. This permits users to have simple facility setups for clinics or sites, or create organizations to emulate integrated delivery networks (IDNs).

### Does the Nanosonics AuditProTM system have FDA or regulatory approval?

Nanosonics AuditProTM is classified as a 'medical device data system', which is a Class 1 Medical Device exempt from FDA filing. Although exempt, Nanosonics AuditPro has undergone complete design control, verification and validation testing, and thorough documentation to support the product design.

1. Does the Nanosonics AuditProTM system meet EMF standards?

Yes. The Nanosonics AuditProTM system complies with the following standards:

* IEC 60601-1-2:2014 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
* AS/NZS CISPR 32:2015 Electromagnetic compatibility of multimedia equipment - emission requirements
* EN 301 489-1 Electromagnetic Compatibility and Radio Spectrum Matters (erm); Electromagnetic Compatibility (emc) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements
* EN 301 489-3 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz
* EN 301 489-17 Electromagnetic Compatibility and Radio Spectrum Matters (erm); Electromagnetic Compatibility (emc) Standard for Radio Equipment; Part 17: Specific Conditions for 2,4 ghz Wideband Transmission Systems, 5 ghz High Performance Rlan Equipment and 5,8 ghz Broadband Data Transmitting Systems

## **The Nanosonics AuditProTM system workflow**

### For which types of ultrasound probes and procedures can the Nanosonics AuditProTM be used?

The Nanosonics AuditProTM system can capture all ultrasound probes and procedures as mandated by the facility's own standard operating procedures (SOPs), including all probes classified as non-critical, semi-critical and critical according to the Spaulding classification1.

1. Spaulding EH (1968). Chemical disinfection of medical and surgical materials. Disinfection, sterilization, and preservation. Lawrence C, Block SS. Philadelphia (PA), Lea & Febiger: 517-531.

### Why should we capture all procedure data?

Ultrasound procedures are performed throughout healthcare facilities and all of these probes require disinfection to varying degrees to minimize the risk of cross contamination between patients. Applying some level of traceability to all clinical activities may help to address potential healthcare associated infection risk within the clinical setting. Currently, National standards and evidence-based guidelines in the US require that facilities have detailed reprocessing compliance documentation records for semi-critical and critical procedures, as classified by the Spaulding classification.1-3

The Nanosonics AuditProTM system provides an opportunity to generate a wealth of data by the infection prevention information that is captured at point of care. As such, facilities may also choose to trace non-critical probes to be able to generate a more complete data set encapsulating all procedures, generating a richer repository of information and supporting stadardisation of best practice infection prevention practices..

1. Spaulding EH (1968). Chemical disinfection of medical and surgical materials. Disinfection, sterilization, and preservation. Lawrence C, Block SS. Philadelphia (PA), Lea & Febiger: 517-531.

2. AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities.

3. Association of periOperative Registered Nurses (AORN). High-Level Disinfection. AORN Guidelines for periOp-erative practice. Online: AORN, Inc; 2018.

### Does the Nanosonics AuditProTM system help my organization meet guidelines requirements in the United States?

The Spaulding classification is the Federally adopted framework used to determine the level of disinfection or sterilization required for reusable medical devices. This risk-based system is dependent on the patient tissue the medical device may contact during use.1 This fundamental framework forms the basis of U.S. regulations, Federal guidelines (e.g., CDC, FDA) and National Standards (AAMI).2-5 As such, it forms the default disinfection requirements for the Nanosonics AuditProTM system.

National Standards and evidence-based guidelines also require that your facility tracks semi-critical and critical medical devices, including ultrasound probes.5,6 Nanosonics AuditPro makes it possible to trace ultrasound probes used in non-critical, semi-critical and critical applications, categorized according to the Spaulding classification.

1. Spaulding EH (1968). Chemical disinfection of medical and surgical materials. Disinfection, sterilization, and preservation. Lawrence C, Block SS. Philadelphia (PA), Lea & Febiger: 517-531.

2. Code of Federal Regulations: 21 CFR 880.6885 (revised April 1, 2019). Title 21 Chapter 1 – Food and Drug Administration Department of Health and Human Services; Subchapter H-Medical Devices sec. 880.6885 Liquid chemical sterilants/high level disinfectants. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=880.6885>

3. Centers for Disease Control and Prevention (CDC). Guidelines for Disinfection and Sterilization in Healthcare Facilities. 2008

4. Food and Drug Administration (FDA). Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. 2019.

5. AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities.

6. Association of periOperative Registered Nurses (AORN). High-Level Disinfection. AORN Guidelines for periOp-erative practice. Online: AORN, Inc; 2018.

### How can the Nanosonics AuditProTM system improve patient care?

The Nanosonics AuditProTM system uniquely sits with the ultrasound console and user at the point of care, enabling them to incorporate infection control considerations as a part of their everyday patient care. The continuous reprocessing compliance education is built seamlessly into the workflow and helps clinicians deliver best practice infection prevention patient care every time. The workflow requires users to qualify procedures against the Spaulding classification1 for disinfection requirements, delivering standardized infection prevention practices across your entire facility.

Spaulding EH (1968). Chemical disinfection of medical and surgical materials. Disinfection, sterilization, and preservation. Lawrence C, Block SS. Philadelphia (PA), Lea & Febiger: 517-531.

### How will the Nanosonics AuditProTM system fit into my workflow?

The Nanosonics AuditProTM system can be used in a variety of workflows depending on facility requirements. Nanosonics AuditPro does not affect the HLD workflow with trophon®2, it replaces the manual or paper-based documentation step for clinicians. During the workflow, the clinician logs the procedure using the Mobile Scanning Device where they are prompted to confirm the level of disinfection or sterilization before the procedure.

### How does the Nanosonics AuditProTM system affect clinical workflow?

The Nanosonics AuditProTM system replaces the manual or paper-based documentation step for clinicians, which may occur before or after the procedure is performed at the point of patient care.

### How will the Nanosonics AuditProTM impact the clinical workflow and patient throughput efficiencies?

The Nanosonics AuditProTM system has been designed to drive workflow efficiency. It has been tested with ultrasound users and Infection Prevention practitioners and was found to support efficient clinical workflow practices. Front line staff and clinicians using Nanosonics AuditPro in useability studies have said the following:

‘With Nanosonics AuditPro I don’t need to worry about staff not doing the right thing anymore and come survey time I know I won’t need to search paper-based systems hoping that I can find information that demonstrates a patient has not been exposed to cross contamination due to poor staff compliance.’

‘So easy to look at reports and notice problems rather than flicking through the logbook.’

### Can the Nanosonics AuditProTM system alert my clinicians if a probe is not reprocessed appropriately for the procedure, they are about to undertake?

Nanosonics AuditProTM is not designed alert clinicians if a probe has not been reprocessed appropriately before the procedure they are about to undertake. Clinicians should rely upon their facility standard operating procedures to be able to identify the level reprocessing of the probe (e.g., terminal barrier for sterilization, or trophon® clean probe cover and trophon printer label for high level disinfection).

### Can the Nanosonics AuditProTM system track probe sterilization?

Yes. The Nanosonics AuditProTM system allows for entry of a sterilization ID if the probe has undergone sterilization as part of the reprocessing workflow.

### How does the Nanosonics AuditProTM system replace logbooks and paper-based systems?

The Nanosonics AuditProTM system comprises a Mobile Scanning Device for ultrasound users and a subscription to browser-based management dashboards, including digitized logbooks. The sophisticated software automatically combines procedure and disinfection records, including HLD cycle records from trophon2, and links to a unique patient procedure identifier captured through the 3D barcode scanner on the Mobile Scanning Device, creating traceability from the reprocessing record to the patient record by virtue of a unique patient procedure identifier (e.g., accession number).

### What are the main benefits of the Nanosonics AuditProTM system over paper-based methods?

Traceability can be completed manually (e.g., logbooks), or by incorporating digitization (e.g., RFID scanning and electronic records). Traceability completed using manual method such as logbooks may be prone to risk such as losing files or logbooks, incomplete or inaccurate information by the operator, violation of privacy legislation when the information is not stored securely ultimately contributing to potential time wasted organizing documentation ahead of a survey.

Digitization, through the Nanosonics AuditProTM system, can help to ensure that information capture and labelling is standardized across the entire ultrasound probe reprocessing workflow (e.g., using RFID technology and printers). This can help reduce manual administrative burden, the risk of operator error and incomplete record keeping. The AAMI National standard recommends digitization for this reason:

“Digitization of the process will allow quick access to load information, thus facilitating a quick response. In addition, this documentation provides evidence of a department’s quality control program. Electronic records of process monitoring results, including specific load item identification are recommended because of their better legibility, accuracy, traceability, security and data integrity.”

1. AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities. Page 47.

### How is the Nanosonics AuditProTM system different to other track and traceability systems currently available?

Current digital traceability systems are limited as they may require transportation of the probe to a central reprocessing department for infection control workflow and documentation. This can significantly impact clinical workflow and implementation of infection control processes by users and required asset investment and utilization. The Nanosonics AuditProTM system uniquely sits a point of care with the user and ultrasound console allowing users to capture infection prevention documentation at point of use.

## **Implementation of the Nanosonics AuditProTM system**

### How difficult is implementation, and what additional resources will be required?

The implementation of the Nanosonics AuditProTM is straightforward. The system implementation lead at your facility can self-register the system using the included instructions. In most circumstances your IT team will need to provide simple support. Nanosonics has developed the Implementation Success guide to support customers through each step and of course the product is supported by Nanosonics Customer Service.

### What level of IT is support required to implement the Nanosonics AuditProTM system in the facility?

The Nanosonics AuditProTM system has been designed to be a 'turnkey' solution that permits clinical staff to set up the system in their facilities with minimal support from the IT department.

### Do I need a trophon®2 for the Nanosonics AuditProTM system to function correctly?

The Nanosonics AuditProTM system is designed to call HLD cycle data from trophon®2 devices with software version 1.3 or later.

### How does the Nanosonics AuditProTM system connect with my trophon®2 device/s?

trophon®2 devices can connect to a facility network through an ethernet cable and port. Alternatively, a wireless bridge can be used to support connectivity. The Mobile Scanning Device(s) connect via Wi-Fi.

### How does it connect if there is no Ethernet port to connect my trophon2 device to?

An alternate method requiring a wireless bridge is possible to allow trophon®2 devices to be connected to the facility network. Please consult your IT department regarding the use of wireless bridges within your organization.

### How does the Nanosonics AuditProTM system connect with the cloud application?

Nanosonics AuditPro Mobile Scanning Device is a healthcare grade, android-based device and is Wi-Fi enabled for point of care use which can be disinfected also.

### How does the Mobile Scanning Device connect if there is no Wi-Fi in the clinical room?

If wireless connectivity is lost, the Mobile Scanning Device may still be used. If there is no network connection, data is temporarily stored on the device, un-synced procedures will be displayed as a yellow notification banner. When the network is restored, the data is automatically uploaded, and the procedure data is transferred from the device.

### Do I need special training to be able to use the Nanosonics AuditProTM system?

Nanosonics provides two different levels of training for Nanosonics AuditPro. First, Nanosonics AuditProTM self-learning activities that are available at the Nanosonics Training Academy (<https://www.nanosonicsacademy.com/>). Second, additional training is available as an in-service that can be organized through Nanosonics clinical application specialist team.

### What additional support is required for my clinical team, and who will provide this?

Nanosonics provides two different levels of training for the Nanosonics AuditProTM system. First, Nanosonics AuditPro self-learning activities that are available at the Nanosonics Training Academy (<https://www.nanosonicsacademy.com/>). Second, additional training is available as an in-service that can be organized through Nanosonics clinical application specialist team.

### What IT support does the Nanosonics AuditProTM system require to connect with my trophon®2 device(s)?

The Nanosonics AuditProTM system is **not** an IT integration project. The system has been designed to allow customers to self-register and complete set-up in as little as 20 minutes. In some facilities the assistance of IT staff may be require to allocate static IP addresses and provide Wi-Fi details. The trophon®2 device and mobile scanning device communicate via publicly available ports using SSL security authentication.

### Does the Nanosonics AuditProTM system integrate with other information technology systems in healthcare?

The current release of Nanosonics AuditPro does not integrate with other electronic medical records (EMR) or information technology systems in healthcare.

### Can the Mobile Scanning Device be reprocessed?

Nanosonics AuditPro Mobile Scanning Device is a healthcare grade 'Honeywell EDA51-HC', and all surfaces can be wiped until visibly clean by an approved method specified by the manufacturer’s instructions and set out within the eIFU.

## **The Nanosonics AuditProTM system and cybersecurity**

### How is my patient data protected?

The Nanosonics AuditProTM system is engineered to protect and keep data secure. On the Mobile Scanning Device, mobile device management software is used to ensure security is maintained and secure sockets layer (SSL) certification is used to authenticate data transfers and ensure the data remains encrypted during transit and when in rest. Nanosonics will maintain the security of the device platform and applications with regular software releases and security patch updates as required.

**Additional internal cybersecurity standards - Mobile Application**

* AAMI TIR57:2016 Principles For Medical Device Security - Risk Management

**Additional cybersecurity standards – Amazon Web Services (AWS) infrastructure**

AWS has robust controls in place to maintain security and compliance in the cloud. AWS Compliance certifications and attestations are assessed by a third-party, independent auditor and result in a certification, audit report, or attestation of compliance. AWS claims compliance with the following non-exhaustive list of standards:

* CSA – Cloud Security Alliance Controls
* ISO 9001 – Global Quality Standard
* ISO 27001 – Security Management Controls
* ISO 27017 – Cloud Specific Controls
* ISO 27018 – Personal Data Protection

For more information please visit <https://aws.amazon.com/compliance/programs/>.

### Does the Nanosonics AuditProTM system use or store PHI?

No. The Health Insurance Portability and Accountability Act (HIPAA) protects certain health and medical information that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual (PHI). Whilst Nanosonics AuditPro collects and patient procedure ID information including accession numbers and medical record numbers (MRNs) where the clinician follows the instructions for use (eIFU), what is collected is not capable of identifying any particular patient.

Further the data sets that Nanosonics holds does not provide Nanosonics with the capability to identify any individual patient via the information collected through the Nanosonics AuditProTM system. Accordingly, the Nanosonics AuditPro system does not collect, use or store PHI and HIPAA compliance is not required.

### Is Nanosonics required to be HIPAA compliant?

No. The Health Insurance Portability and Accountability Act (HIPAA) protects certain health and medical information that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual (PHI). Given that the Nanosonics AuditProTM system does not collect, use or store PHI, HIPAA compliance is not required.

However, even though compliance with HIPAA is not required, Nanosonics is going beyond its legal obligations and has already taken steps to become HIPAA compliant by putting systems and procedures in place to achieve compliance operationally. Additionally, Nanosonics AuditPro system has been designed to meet HIPAA compliance standards.

Nanosonics strives to protect your personal data and privacy. Nanosonics takes all necessary precautions to keep data safe and secure and comply with all obligations under other data privacy and data protection laws to the extent they are applicable to us and our products and services. Our privacy statement is available on our corporate website.

### Where is my data stored, and how is my data managed?

The Nanosonics AuditProTM system is engineered to protect data. Data collected as part of the Nanosonics AuditPro system is securely stored in multi-zone, HIPAA and GDPR compliant AWS server facilities in US East 1, North Virginia and US West 1, North California (DR).

Data captured by trophon®2 and the Nanosonics AuditPro Mobile Scanning Device resides in your facility until it is transmitted to the Nanosonics AuditPro cloud application. The procedure data is deleted from the mobile application as soon as it has been successfully transmitted to the cloud database. The unique patient identifier is anonymized in the cloud application and can only be completely reviewed by an authorized facility user. This information is available to authorized staff through the comprehensive dashboards accessible to the Nanosonics AuditPro cloud application and is stored securely in the Nanosonics AuditPro system.

For more information about how your data is managed, please refer to the Nanosonics Privacy Policy <https://www.nanosonics.com/policies/privacy/>.

### What happens with my data at the end of my subscription?

Following the end of the subscription period, the data will be provided to all customers. Customers also have the option of subscribing to view-only access to the system for a nominal fee. If the data is not requested and view-only data subscription is not purchased, Nanosonics will keep information for three years before permanently destroying the data.

## **Purchasing Nanosonics AuditProTM for your organization**

### How much does the Nanosonics AuditProTM system cost?

The Nanosonics AuditProTM system has been designed to be a flexible system to meet the needs of a large variety of customer types and workflow scenarios. There are various purchase models available for Nanosonics AuditPro to match these varied solutions. Please contact your local Nanosonics representative for further information and personalized quotes.

### How many Nanosonics AuditProTM Mobile Scanning Devices do I need?

The Nanosonics AuditProTM system uniquely sits with the ultrasound user and console at the point of care, enabling clinicians to incorporate infection control considerations as part of their everyday care. The system is flexible to adapted to meet a variety of facility workflow needs.

### What is my organization's financial commitment?

The Nanosonics AudtProTM system is available on a 5-year contract term.

### What is the duration of my subscription?

Nanosonics will maintain the device and application software as part of the product with a 5-year lifecycle. Following this period, customers may opt to renew their subscription.

### How or where can I buy the Nanosonics AuditProTM system?

Please contact your local Nanosonics representative for further information and personalized quotes.

### What is the warranty of the hardware provided?

The device has one year warranty. Nanosonics Customer Support will manage customer device failures. In the event of a lost device or complete device failure, Nanosonics will ship a new device at a cost to the customer, priced at spare part pricing. If the failed device has failed under warranty conditions, the invoice will be credited to the customer.

### How can I protect against theft, loss, and damage of Nanosonics AuditProTM Mobile Scanning Devices within my facility?

The Mobile Scanning Device(s) can be secured to their use location, ideally the ultrasound console, using a number of tethering devices that are available on the open market. The device has two separate loops available to connect such tethering devices.

### What impact does the Nanosonics AuditProTM system have on the environment?

The Nanosonics AuditProTM can reduce the consumption of paper-based compliance note books and the required secure storage of this material. Nanosonics offers a complete end-of-life device recycling program at no charge to all customers where the components are recycled.