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# Customer Information Notice: CIN105

# trophon®2 IT Security FAQ

## Contents





*CIN105 v7.0 | Approval Date: March 2023 | Valid until: March 2026 | F-643*
*Please contact your local Nanosonics representative should you require any additional information regarding this Customer Information Notice.*

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| Definitions and Acronyms | |
|---|---|
| **HIPAA** | Refers to the **H**ealth **I**nsurance **P**ortability and **A**ccountability **A**ct of 1996, in particular the portion of the Act known as Administrative Simplification (Subpart F) dealing with the privacy of individually identifiable health information. |
| **BAA** | Business Associate Agreement is a contract between a HIPAA covered entity and a HIPAA business associate (BA). The contract protects personal health information (PHI) in accordance with HIPAA guidelines. |
| **PHI** | Protected Health Information is information that is a subset of health information, including demographic information, and:<br>1. Is created or received by a health-care provider, health plan, employer or health-care clearinghouse; and<br>2. Relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and<br>a. That identifies the individual; or<br>b. There is a reasonable basis to believe the information can be used to identify the individual. |
| **Privacy/Security Officer** | The person in the Facility who is the designated point of contact for HIPAA-related issues and whose position includes oversight of training related to HIPAA. |
| **IP** | Internet Protocol (IP) obtains the address of where the data is required to be sent. |
| **TCP** | Transmission Control protocol (TCP) is responsible for data being delivered to the specified IP. TCP Port 8443 is the protocol enables two hosts to establish a connection and exchange streams of data. |
| **TLS** | Transport Layer Security (TLS) is a cryptographic protocol that provides end-to-end security of data sent between applications over the Internet. |
| **X. 509 Certificate** | A digital certificate that uses the widely accepted international X. 509 public key infrastructure (PKI) standard to verify that a public key belongs to the user, computer or service identity contained within the certificate. |
| **AES** | Advanced Encryption Standard (AES) is a symmetric block cipher chosen by the U.S Government to protect classified information and is implemented in software and hardware. The number is in relation to the key length (i.e. AES 256 means that the key length is 256bits). |



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| Nanosonics IT Risk Assessment FAQ | |
|---|---|
| **Details** | |
| **Company:** | Nanosonics Ltd. |
| **Product/Device/System name:** | trophon2 |
| **Product/Device/System name functionality description:** | The trophon2 device is a stand-alone high-level disinfection medical device with embedded software. There are no other related software or other components that need to be installed or configured for the device to operate. |
| **Is the device FDA approved?** | Yes, the device is FDA-cleared. |
| **Operating System** | |
| **What type of Operating System does the device use?** | It uses a custom embedded Linux Yocto – Dunfell operating system |
| **What type of security features does the Operating System utilize?** | The Operating System security features utilize:<br>• Firewall<br>• USB Connections Monitoring<br>• Activity Audit Logs<br>• CD/USB boot disabled |
| **Connectivity** | |
| **Is the device networked?** | System does not require to be networked, can utilize wired networking (LAN) for customer to integrate device onto own network. |
| **Is the device able to connect to other systems?** | Yes, the device is able to be connected to the customers electronic medical record (eMR) system.<br>Yes, the device is able to connect to the local network time server to synchronize its date and time. |
| **Is the device able to be remotely serviced?** | No, the device cannot be remotely serviced for the purpose of a software upgrade. |
| **What are the ports and protocols required for communications?** | Port 8443: TCP https for S&M and 3rd party connection<br>Port 53: UDP domain name resolution<br>Port 123: UDP NTP default port for local date and time server |
| **Software** | |
| **Current Software Version** | 1.6 |
| **What type of patching/update support does the device receive?** | The device receives:<br>• Manual updates by service<br>• Part of corrective maintenance |
| **Does the device support any anti-virus/malware software?** | No, the device does not support any anti-virus/malware software. |



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| | |
|---|---|
| **Does the software follow any standards, practices or tests?** | Yes, the devices software follows:<br>• IEC 62304 Ed 1.1 (link)<br>• Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Document issued on: May 11, 2005 (link)<br>• Secure by design practices<br>• Source code review and testing<br>• Application penetration testing |
| **Data & Data Management** | |
| **What type of data is created, processed, stored, or received by the system or application?** | Data about the disinfection cycles completed by trophon2 (time, date, operator, probe, reprocessing data). |
| **Where is the application/data being processed or stored?** | Data about the disinfection cycles completed by trophon2 are stored in the device and accessible (read-only) via a thermal printer (trophon Printer), download to USB Drive, or via a network connection. |
| **Is data transmitted over a private or public network?** | Data is accessible (read-only) to 3rd party applications over the network. Security is provided via user-level authentication with TLS and X.509 certificates. |
| **What type of data is transferred?** | Data about the disinfection cycles completed by trophon2 (time, date, operator, probe, reprocessing data). |
| **Does the device display, transmit, or maintain private data (including electronic Protected Health Information ["ePHI"])?** | The device maintains PII which includes the Operator Name, however it does not store PHI. |
| **Storage & Accounts** | |
| **Does the device/application require a server or workstation?** | No, the device does not require a server or workstation |
| **Does the device require any authentication, AD security or password polices?** | No, the device does not require any authentication, AD security or password policies. |
| **Does the device have an auto-log off period of inactivity?** | No, the device does not have an auto-log off period for inactivity |



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|---|---|
| **Does the device have any access controls?** | No, the device does not require authorization to operate (e.g. Password controls).<br>When enabled, the device does have access controls via RFID to run disinfection cycles. Details are programmed on RFID chips and information programmed to the card/tag is at the discretion of the hospital/site. |
| **What account types are used on the device?** | The device does not utilize any generic or default/guest accounts |
| **How are these account types managed?** | These account types are not required to be managed as they are not utilized on the device |
| **Access** | |
| **Does the device support any User, Vendor or Privileged access?** | No, the device does not support any User, Vendor or Privileged access. |
| **Does the device allow remote User or Vendor access?** | No, the device does not provide remote access to the User or the Vendor. |
| **Auditing & Logging** | |
| **Is there any audit logging of data activity on the device?** | Yes, the device has logging capabilities with references to READ, WRITE, UPDATE, VIEW and PRINT actions.<br>*Note:<br>READ - will read the data on the text file stored<br>WRITE - will write new data to a text file<br>UPDATE - will write on a previously saved text file stored<br>VIEW – will only show specified data, not all of the data (i.e. trophon2 “Last Cycle” View will display only date, time, operator, etc.)<br>PRINT – will print the data saved to that text file |
| **What type of information does the audit log include?** | The information captured is:<br>• Operator name<br>• Medical instrument name & serial number<br>• Date<br>• Time<br>• Action (View and print)<br>• Data type (text) |
| **Can the data be exported from the device?** | Yes, the data can be exported from the device. It can export it as a CSV file. |
| **Encryption** | |
| **Is data encrypted in transit?** | Yes, using TLS 1.2 |
| **Is sensitive data encrypted at rest/storage** | No |



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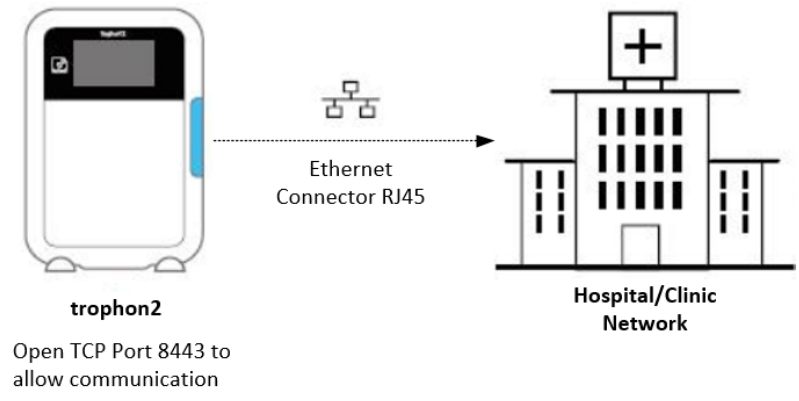
| | |
|---|---|
| **Are backups encrypted?** | No |
| **Other Devices** | |
| **Does the device require any additional devices (i.e. tablets, smartphones, laptops etc.)?** | No the device does not require any additional devices to be managed. |
| **Data Backup and Disaster Recovery** | |
| **Does the device create any backups of the data?** | No the device does not automatically create any backups of the data. The data is saved and stored internally on the device and can be retrieved via USB download. The data can also be retrieved by the service team via service and maintenance software. |
| **How frequently does the device create these backup?** | The device does not create backups. |
| **Does the device have a disaster recovery service?** | No the device does not have a disaster recover service. |
| **3rd Party Applications/Software** | |
| **Is all software and code inventoried?** | Yes all software and code is inventoried. This is done in the risk assessment under SOUP Items (Software Of Unknown Provenance) |
| **Do you have formal processes in place for tracking and managing the use of open source code?** | Yes, this is declared and analyzed in the risk assessment under SOUP Items (Software Of Unknown Provenance) |
| **What 3rd party software does the device use?** | Linux – Operating System<br>Qt Framework – Display<br>Apache Derby – Database<br>Java – Application<br>Spring, Eclipse – Web service<br>Google GRPC – for remote procedure calls. |
| **What uses does the 3rd party software have?** | The 3rd party software is restricted to Service. |
| **System Diagram** | |
|  | |



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| HIPAA | |
|---|---|
| **Is there an active BAA?** | No, the device does not require to be under the HIPAA legislation as it does not used, create, stored, transmit, access, view, or disclose any PHI. |
| **Is PHI being disclosed to you (vendor) other than in the capacity as member of the customer?** | No, the device does not require to be under the HIPAA legislation as it does not used, create, stored, transmit, access, view, or disclose any PHI. |
| **Is there a Privacy/Security Officer designated?** | No, the device does not require to be under the HIPAA legislation as it does not used, create, stored, transmit, access, view, or disclose any PHI. |
| **Do you have policies and procedures in place to ensure the physical and technical safegaurding of PHI?** | No, the device does not require to be under the HIPAA legislation as it does not used, create, stored, transmit, access, view, or disclose any PHI. |

The trophon family includes trophon® EPR and trophon®2 devices which share the same core technology of 'sonically activated' hydrogen peroxide.





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