

HIPAA Statement

Sectra PACS

Sectra PACS, Version 21.1, February 2019



SECTRA

Knowledge and passion

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1 HIPAA statement

The US Congress passed the Health Insurance Portability and Accountability Act (HIPAA) in 1996, which became effective starting from 1997. The Administrative Simplification provision of HIPAA was developed to reduce the costs and administrative burdens of health care by making it possible to replace manual transactions on paper with standardized electronic transactions. The Administration Simplification provisions of HIPAA also address the security and privacy of health data. Sectra has implemented the provisions into our software solutions to provide means for health care providers to comply with the HIPAA regulations.

This provision of the law required the Department of Health and Human Services (DHHS) to develop standards (also called rules or regulations) for the maintenance and transmission of these transactions. These standards were developed to:

- Improve the efficiency and effectiveness of the health care system by standardizing the interchange of electronic data for the specified transactions
- Protect the security and confidentiality of electronic health information

Sectra enables our customers to implement HIPAA-compliant security features due to our proactive product development. Specifically, Sectra PACS allows our customers to enable the following features, policies and restrictions:

- The ability to implement and administer strong passwords
- The ability to ensure integrity, authenticity and confidentiality of communication between Sectra PACS components
- The ability to audit user activity
- The ability to restrict user access to a specific selection of medical information
- The ability to prevent unauthorized access to images in the Sectra Workstation's local cache by means of encryption
- The ability to anonymize images that are displayed or exported by the Sectra Workstation
- The ability to ensure high availability, which is maintained by the overall system design, its deployment and through system monitoring with Sectra Monitoring Server

Sectra PACS software enables functionality, which when properly configured and implemented, allows Sectra PACS customers to be fully compliant with all pertinent aspects of HIPAA. Sectra PACS endorses the security standards raised by HIPAA and we are committed to enabling our customers to protect patient privacy. Privacy and security are essential components of our software solutions.

For more information about how Sectra PACS deals with HIPAA issues, please see www.sectra.com/medical or contact info.medical@sectra.com to receive the *Sectra HIPAA white paper*.

LABEL

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| Product | Sectra Workstation |
| Model | IDS7 |
| Version | 21.1 |
| UDI | (01)07350092810166(8012)21.1 |
| Manufacturer | Sectra AB Teknikringen 20 SE-58330 Linköping Sweden www.sectra.com |
| Contact | https://sectra.com/medical/about-sectra/contact/ |



Regulatory Clearance Statement

The quality system of Sectra AB [Sectra] conforms to ISO 9001, ISO 13485 and ISO 27001. All Sectra medical devices have obtained regulatory clearance for those markets where Sectra sells and deploys its devices, e.g. EEA, USA, Canada, Australia. For further regulatory information, please contact Sectra.

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