

HIPAA Statement

Sectra PACS

Sectra PACS, Version 22.1, March 2020



SECTRA

Knowledge and passion

Contents

1	HIPAA statement	1
---	-----------------------	---

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

Product	Sectra Workstation
Product Code	101
Model	IDS7
Version	22.1
UDI	(01)07350092810210(8012)22.1
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.

Disclaimer

Sectra AB is not responsible for problems caused by changes in the operating characteristics of the computer hardware or operating system, which are made after the delivery of the software, or for problems that occur as a result of the use of Sectra software in conjunction with non-Sectra software other than the software explicitly covered in this documentation. For a complete description of warranty, refer to the End User License Agreement supplied with the Sectra product.

Trademark and Patent Disclaimer

Sectra, Sectra Imtec and the Sectra logotype, are registered trademarks of Sectra AB. FIMAG and Image Exchange Portal are registered trademarks of Burnbank Systems Ltd in the UK. IDS7, Sectra BizTrack, Sectra CloudFlex, Sectra DoseTrack, Sectra IEP, Sectra Image Central, Sectra Image Lab, Sectra LiteView, Sectra UniView, Sectra One Connect, Sectra Open Archive, Sectra VNA, Sectra UserInfluence, and WISE are trademarks of Sectra Imaging IT Solutions AB. Sectra Preop Online and Sectra OneScreen are trademarks of Sectra AB. RxEye is a registered trademark of RxEye AB.

Windows is a registered trademark of Microsoft Corporation in the United States and other countries. *Mac*, *Safari*, and *iPad* are registered trademarks of Apple Inc. in the United States and other countries. All other names/products by ® or ™ are registered trademarks of the respective manufacturer.

The intellectual property of Sectra includes a number of patents, for full information refer to: <https://sectra.com/medical/about-sectra/patents/>

Copyright and Legal Statement

© Sectra AB, Sweden, 2020

All rights are reserved. Reproduction or transmission in whole or part, in any form or by any means, electronic, mechanical or otherwise, is prohibited without written consent of the copyright owner.

Copyrights and all other proprietary rights in any software and related documentation ("Software") made available to you rest exclusively with Sectra AB. No title or ownership in the Software is conferred to you. Use of the Software is subject to the end user license conditions as are available on request.

To the maximum extent permitted by law, you shall not decompile and/or reverse engineer the software or any part thereof.

Sectra AB
Teknikringen 20
SE-58330 Linköping
Sweden
Phone: +46 13 23 52 00
E-mail: info.medical@sectra.com

SECTRA

Knowledge and passion