

The Medtronic logo is displayed in a bold, white, sans-serif font in the top left corner. The background of the entire page is a dark blue gradient with a pattern of glowing, curved lines in shades of blue and red, creating a sense of motion and technology.

PillCam™ cloud reader software

Picture the power of the cloud

The PillCam™ cloud reader software is designed to support the PillCam™ capsule endoscopy platform.

The cloud reader is an ideal solution for clinicians looking for flexible reading options – removing the need to be at a workstation. The software provides a secure platform for uploading PillCam™ capsule endoscopy studies to a cloud-based environment for remote reading, treatment recommendations, and report creation. This enables an efficient and secure way for you to read your studies when and where is most convenient for you.^{1,2,†}

[†]PillCam™ cloud reader is only compatible with PillCam™ SB capsule endoscopy studies.

The software provides a secure platform for uploading PillCam™ capsule endoscopy studies to a convenient, cloud based environment. This allows clinicians to remotely view the study, document treatment recommendations, and create their subsequent report.^{1,2}

PillCam™ cloud reader study flow^{1,3}:

1. A patient study is downloaded from the Data Recorder to the PillCam™ SW v9 workstation and is stored on a designated local computer drive or network drive.
2. The study is uploaded to the cloud by the PillCam™ Synchronization Agent.
3. Authorized users can access the study using the cloud reader HCP application (a web-based application), review the study, and create a report.
4. The synchronization agent continuously synchronizes studies, findings, and reports between the cloud and the local drive.
5. Studies, findings, and reports generated are available for review both on the local PillCam™ SW v9 and the cloud reader HCP application.

Medtronic PillCam™ Cloud Reader Software

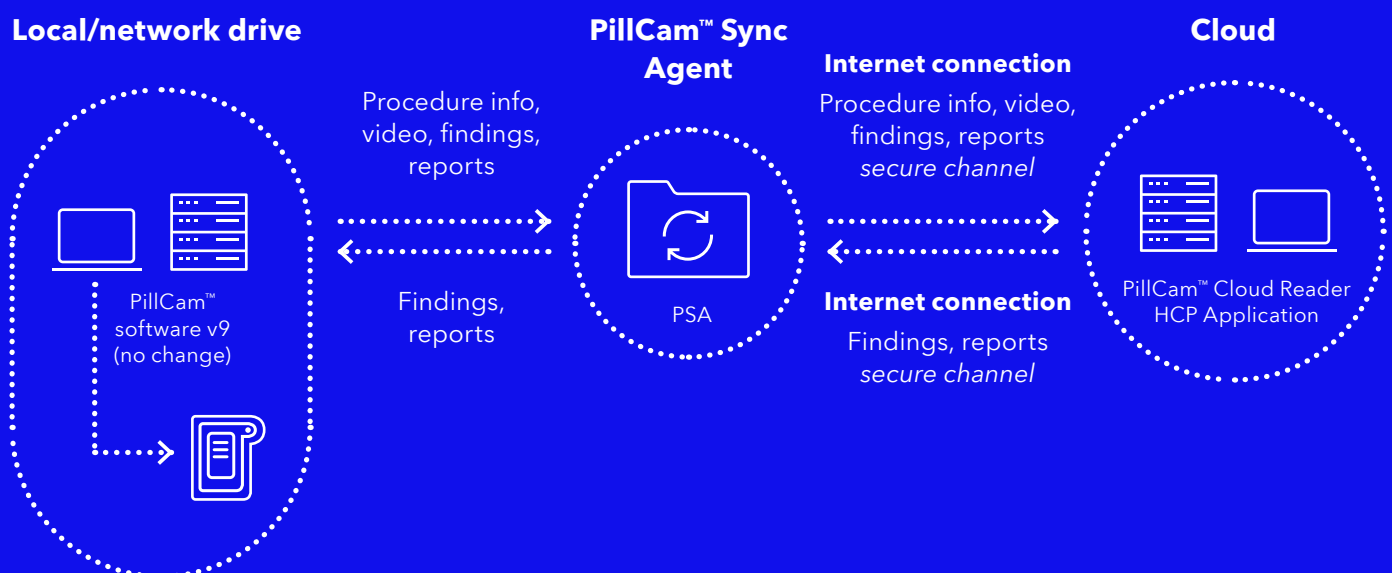
Procedures

Pending review (18) Completed (8) All (26)

NAME	DATE OF BIRTH	ID	SEX	TYPE	PROCEDURE DATE
Smith, Emma	10.03.1956	823105	F	SB	04.25.2023
Bloggs, Joe	07.11.1954	109937	M	SB	04.22.2023
Doe, Jane	12.08.1955	443967	F	SB	04.22.2023
Taylor, Sarah	07.02.1953	333902	F	COLON	04.22.2023

Note: This is a screenshot of the PillCam™ cloud reader procedures screen. Not actual patients. Examples provided for demonstration purposes only.

PillCam™ cloud reader workflow²



PillCam™ cloud reader security measures^{1,2,4,5}:

- PillCam™ cloud reader connects to Amazon Web Services utilizing a secure tunneling communications web-based HTTPS over SSL.
- PillCam™ cloud reader is a Medtronic-owned SaaS, based on the AWS platform, designed with security and privacy as top priority, maintaining security measures required for medical data regulations and standards.
- PillCam™ cloud is managed and monitored 24/7 by the Medtronic Global Security Office, an expert unit that leads, governs and approves cybersecurity measures across Medtronic. The PillCam™ cloud is managed and monitored using various advanced cloud security and monitoring tools such as AWS WAF, AWS Shield, Contrast, CloudGuard Dome9, CloudWatch, CloudTrail, and more.
- PillCam™ cloud reader has successfully completed extensive security analysis, penetration testing and risk assessments, carried out by the Medtronic GSO and by a certified 3rd party.
- All data is encrypted in transit and at rest, with patient sensitive data being stored fully encrypted.
- Only registered, authorized users can access procedure data in the cloud. Any related PII / PHI data is owned by the facility account and is available only to relevant roles in the account, based on credentials. Strict privacy measures are in place for user authentication and authorization, including a dedicated software pipeline to handle each request, required MFA, and more.

Note: when a study is uploaded to the cloud, the study still resides on the original C:// or network location.³



PillCam™ cloud reader system requirements

User connections requirements: minimum internet connection required for video display depends on capsule type and viewing speed. It is preferable to connect via a network with at least 5Mb bandwidth (this requirement is like many HD media streaming platforms).

Browser compatibility

Compatible with MS Edge, Google Chrome, and Safari.¹

Install process and requirements³:

Installation is conducted following a teleconference with Medtronic technical support personnel.

1. Complete the PillCam™ cloud reader questionnaire document.
 - This document will be provided after processing the appropriate usage agreement.
 - Please ensure the information on the form is entered digitally.
2. An email will be sent to an account IT representative (identified as account's clinical administrator in the questionnaire), with a link to the PillCam™ cloud reader application.
3. Installation of the PillCam™ sync agent can be performed by the clinic administrator through the cloud reader application.
4. Clinic administrator completes registration to cloud reader software.
5. Clinic administrator logs into cloud reader and downloads the sync agent software.
 - If needed, Medtronic technical support can assist during the sync agent installation.
6. Following installation, the clinic administrator can set up users, set roles, and send registration links.
7. To ensure a successful installation experience, please ensure the following criteria are met:
 - System requirements detailed in this document are met.
 - A system administrator should be available with requisite permissions to download, install, and configure software.
 - An active firewall may prevent communications and access to the cloud environment. If your facility has an established firewall, please ensure an IT representative who works with firewall security is available for the initial call or follow up consultation call as needed.



References

1. Based on internal test report #RE00443754 REV01, PillCam™ Cloud Reader Software – HCP application verification report
2. Based on internal test report #RE00444307 v1.0, PillCam™ cloud reader – Product Security Summary
3. PillCam™ cloud reader software user manual. March 2023
4. Based on internal test report #RE00412130 v1.0, PillCam™ cloud reader Architecture Design Chart
5. Based on internal report # RE00442468, V1.0, PillCam™ cloud reader Software Penetration Testing Report

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Important: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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