

Medtronic

PillCam™ cloud reader software

Picture the
power of PillCam™



Flexible, seamless, and secure access to your PillCam™ studies†

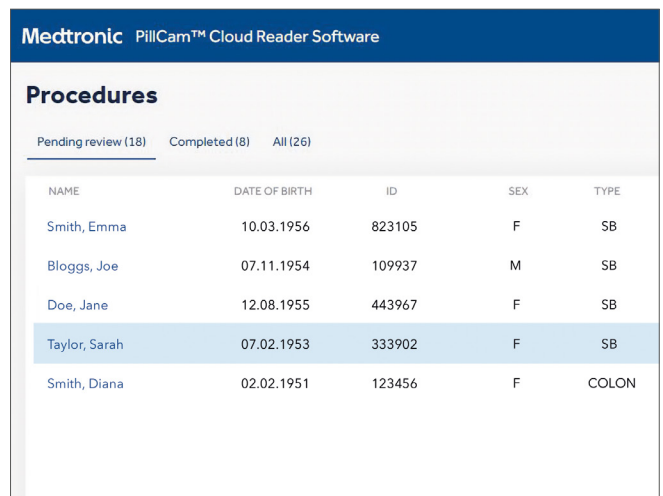
The cloud reader is an ideal solution for clinicians looking for flexible reading options – **removing the need to be at a workstation.** The software provides a secure platform for uploading PillCam™ capsule endoscopy studies to a cloud-based environment for remote reading, treatment recommendations, and report creation. This enables an efficient and secure way for you to read your studies when and where is most convenient for you.¹⁻⁵

How it works

The PillCam™ cloud reader is a Software as a Service (SaaS) that leverages an AWS cloud platform,‡ and can be accessed using a web browser by any authorized and registered user with an internet connection. The software includes¹⁻³:

- **PillCam™ cloud reader software** - a web-based application that includes viewer software enabling review and analysis of PillCam™ capsule procedure data as well as capsule endoscopy report generation⁵
- **PillCam™ sync agent** - a local software that works in the background to maintain synchronization of procedure data between the local folders and the cloud⁵

PillCam™ cloud reader software is an optional part of the PillCam™ capsule endoscopy system and supports the PillCam™ SB 3 and PillCam™ Colon 2.²



The screenshot shows the Medtronic PillCam™ Cloud Reader Software interface. At the top, there is a header with the Medtronic logo and the text "PillCam™ Cloud Reader Software". Below the header, the word "Procedures" is displayed. Underneath, there are three tabs: "Pending review (18)", "Completed (8)", and "All (26)". The "All (26)" tab is selected. Below the tabs is a table with the following columns: NAME, DATE OF BIRTH, ID, SEX, and TYPE. The table contains five rows of data:

NAME	DATE OF BIRTH	ID	SEX	TYPE
Smith, Emma	10.03.1956	823105	F	SB
Bloggs, Joe	07.11.1954	109937	M	SB
Doe, Jane	12.08.1955	443967	F	SB
Taylor, Sarah	07.02.1953	333902	F	SB
Smith, Diana	02.02.1951	123456	F	COLON

Note: This is a screenshot of the PillCam™ cloud reader procedures screen. Names shown are not actual patients and shown for demonstration purposes only.

†PillCam™ cloud reader is only compatible with PillCam™ SB 3 capsule endoscopy studies.

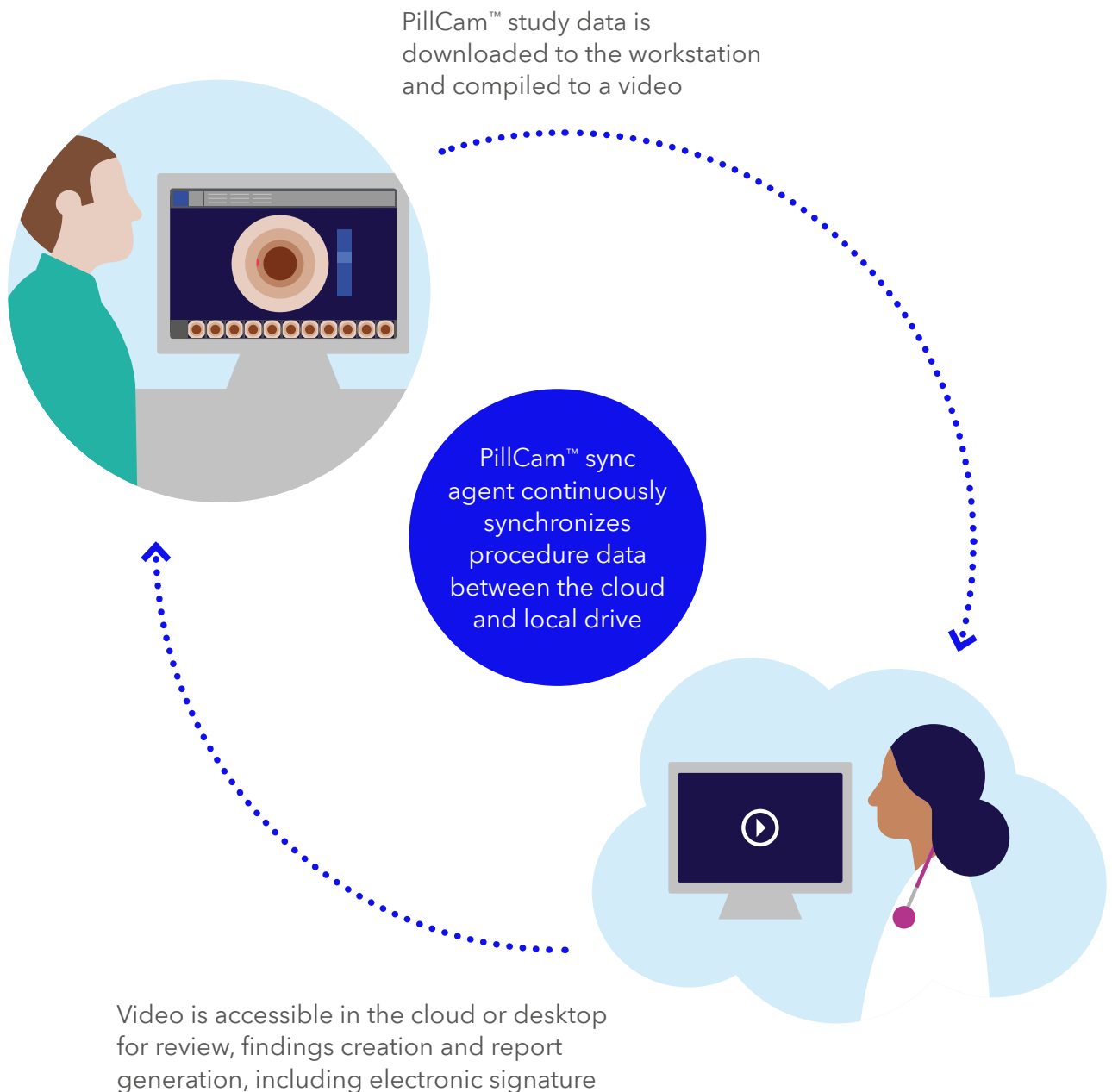
‡Compatible with Google Chrome, MS Edge, and Safari.

Benefits of PillCam™ cloud reader software include¹⁻³:

- Viewing and interpreting studies can be performed anywhere, at any time
- Manage study access locally
- May increase a physician's capacity to read studies by removing the need to read at a designated workstation
- Compatible with both PC and Mac computers
- Procedure data is automatically removed from the cloud 30 days after initial upload

Note: user bandwidth requirements are comparable to major entertainment streaming services

Designed with simplicity in mind^{4,5}



Secure-by-design^{1-3,6}

- PillCam™ cloud reader software follows global security and privacy guidance and requirements†
- Only authenticated, registered users can login and can only access data from their allowed site
- Procedure data – including study details, findings and reports – are stored in the cloud for 30 days, after which they only remain on the local drive
- Registration, usage, and final report electronic signature require dual-factor authentication as an added level of security
- Reports can be de-identified on an as-needed basis



Data in transit

PillCam™ cloud reader utilizes AWS, which uses secure tunneling communications web-based HTTPS over SSL.



Data at rest

Data at rest protection is employed using data encryption algorithms.

User management³

PillCam™ cloud reader software supports three user roles:

- **Clinic administrator** – full clinic administrative rights, including adding and removing users and updating roles
- **Physician** – full read and report creation permissions, including electronic signature
- **Nurse** – designed to facilitate pre-reading by qualified staff

†Includes FDA and EU MDR regulation, CIA Triad model, NIST security framework, OSWAP methodologies, GDPR guidelines and HIPAA guidelines.

References

1. Based on internal test report #RE00443754 REV01, PillCam™ Cloud Reader Software - HCP application verification report
2. Based on internal test report #RE00443760 REV01, PillCam™ Cloud Reader Software - HCP Cloud Verification Report
3. Based on internal test report #RE00444307 v1.0, PillCam™ Cloud Reader - Product Security Summary
4. Based on internal test report #RE00443758 REV01, PillCam™ Cloud Reader Software - PSA Application Verification Report
5. PillCam™ Cloud Reader software user manual. March 2023
6. Based on internal test report #RE00412130 v1.0, PillCam™ Cloud Reader Architecture Design Chart

This material is only intended for distribution in Europe. Indications, claims, and intended use may be different in other regions.

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

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