Given Imaging Inc.

PillCam™ Genius Endoscopy System

v1.0

User Manual

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Note
Changes or modifications not expressly approved by Given Imaging could void authority to operate the PillCam Genius endoscopy system.

Rx ONLY

CE 0123

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Using this guide

Intended audience

This guide is intended for medical professionals who perform PillCam Genius SB capsule endoscopy procedures.

Conventions

Screen elements, such as menus, button names, and screen names are in bold as follows: **PillCam Genius recorder.**

A Note is a piece of information or a remark that receives emphasis and appears as follows:

Note
Installing the PillCam Genius Sync Agent requires local administrator permissions.

A Caution warns about possible damage to equipment and appears as follows:

Caution
Make sure that there is no other PillCam Genius SB capsule or other diagnostic capsule in the patient's gastrointestinal tract.

A Warning warns about possible harm to people and appears as follows:

Warning
PillCam Genius SB capsules are MR unsafe.

Chapter 1

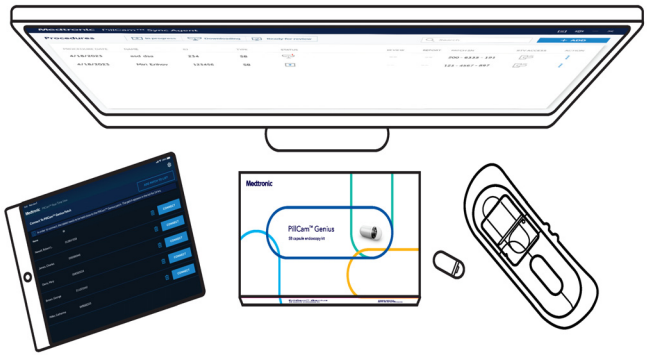
Overview

About PillCam Genius SB capsule endoscopy

The PillCam Genius SB capsule endoscopy procedure is a process that enables minimally invasive visualization of the gastrointestinal tract using an ingestible capsule. The capsule captures images that are later presented to the health care provider for review and interpretation.

The PillCam Genius SB capsule endoscopy system consists of the following components:

- PillCam Genius SB capsule endoscopy kit, which includes:
  - One PillCam Genius SB capsule
  - One PillCam Genius recorder
- PillCam Genius Sync Agent
- PillCam Genius Real-Time View application



Note
Use the following link to access the electronic user manual: https://manuals.medtronic.com/

System components

PillCam Genius SB capsule

The PillCam Genius SB capsules are ingestible imaging capsules which acquire images while moving through the patient's gastrointestinal tract. Each PillCam Genius SB capsule contains a miniature

color camera with LEDs, batteries, a transmitter, and an antenna to transmit the acquired images. The capsule is propelled by natural peristalsis until excreted.

PillCam Genius recorder

The PillCam Genius recorder is a single-use device that is worn by the patient throughout the PillCam Genius procedure. The recorder includes an adhesive layer that attaches to the skin of the patient's abdomen. At the end of the procedure, the recorder is removed and returned to the clinic.

The recorder performs the following functions:

- Receives and stores images from the PillCam SB Genius capsule.
- Transfers images to the PC and the Real-Time View application.

PillCam Genius Sync Agent

The PillCam Genius Sync Agent is used by the healthcare provider to setup and manage PillCam Genius endoscopy procedures and transfer data from the recorder to the PC for video creation.

If the PillCam Genius Sync Agent is connected to the cloud, it will synchronize between local folders containing PillCam procedure data and the data stored in the cloud.

PillCam Genius Real-Time View application

The PillCam Genius Real-Time View (RTV) application allows the healthcare provider to view real-time images from the capsule for a short period of time during the procedure to estimate the location of the capsule in the gastrointestinal tract.

Chapter 2

Indications, contraindications, warnings, cautions

PillCam Genius SB capsule

Indications for use

The PillCam Genius SB capsule is intended for visualization of the small bowel mucosa.

- It may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy.

The PillCam Genius SB capsule may be used as a tool in the detection of abnormalities of the small bowel and is intended for use in adults 21 years and older.

Contraindications

The PillCam Genius SB capsules are contraindicated for use under the following conditions:

- In patients with known or suspected gastrointestinal obstruction, strictures, or fistulas based on the clinical picture or pre-procedure testing and profile.
- In patients with cardiac pacemakers or other implanted electromedical devices.
- In patients with dysphagia or other swallowing disorders.

Note

The PillCam Genius SB capsule may be deployed by using transendoscopic delivery in patients who are either unable to ingest the capsule or are known to have slow gastric emptying time. Placement into the duodenum is recommended to prevent the patient from vomiting the capsule.

- In patients with allergies or other known contraindications to the medications and preparation agents used in the procedure as described in the relevant instructions for use.

For remote procedures, where the patient conducts the procedure at home during a telehealth visit, the following conditions are also contraindicated:

- In patients with swallowing disorders, including those patients with history of aspiration or difficulty swallowing medications.

- In patients with cognitive or physical disabilities that may impact the safety of swallowing the capsule.
- In patients with neurological or muscular disorders that may affect swallowing, such as a history of stroke, or an acute central nervous system (CNS) injury.

Intended purpose

Intended target population

Patients from 21 years of age as per the product indications.

Intended user

Trained healthcare providers.

Adverse events

Potential adverse events associated with the use of this device may include delayed or no excretion of the capsule, aspiration, obstruction, perforation, and mucosal injury or bleeding. In some instances, intervention is required to remove the capsule.

Warnings

Procedure warnings

- A thorough understanding of the technical principles, clinical applications, and risks associated with the PillCam Genius SB capsule endoscopy system is necessary before using this product. Read the entire manual before using the system for the first time.
- To prevent the patient from being exposed to unforeseen risks during passage of the PillCam Genius SB capsule, make sure the patient thoroughly understands the procedure. Provide the patient with a copy of the Patient Instructions.
- Do not use any PillCam Genius kit 18 months after the manufacturing date on the packaging label. Operating times will be shorter the longer the kit remains unused. 12 months of storage will give 11.5 hours of operating time. 18 months will give 10.5 hours of operating time.
- If the PillCam capsule and recorder have been activated but not used within 10 minutes, they should be returned to their packaging to preserve the battery. Ensure that both the capsule and recorder LED lights are off. If, after returning the capsule to the packaging the capsule is still blinking, rotate the capsule in the box such that the text is facing up.
- Ensure the recorder LED is blinking green and capsule LED is blinking white before the patient ingests the capsule.

- When swallowing the capsule, there is a possibility of choking on the capsule. If the patient exhibits any symptoms and/or clinical signs of choking (labored breathing, wheezing, involuntary coughing, etc.), the recommended first-aid procedure should be followed.
- Instruct the patient to contact the health care provider immediately if, after ingesting any PillCam capsule, there is any abdominal pain, nausea, or vomiting.
- Only one PillCam Genius SB capsule should be ingested at a time and only after confirmation that no other PillCam capsules or ingestible diagnostic devices remain in the patient's body.
- If, contrary to instructions, a patient ingests more than one PillCam Genius SB capsule, instruct the patient to immediately contact the health care provider.
- Do not allow multiple patients undergoing PillCam endoscopy procedures to be in the same vicinity as each other. Patients should be at least 3 meters apart.
- After applying the recorder, the patient should avoid any physical activity or sport that involves sweating, bending, stooping, or any movement that may impact the adherence of the recorder.
- If excretion of the capsule from the patient has not been positively verified, and the patient develops unexplained post-procedure abdominal pain, vomiting, or other symptoms of obstruction, they should contact the physician for evaluation and possible abdominal X-ray examination.
- Occasionally, some images may be lost due to radio interference (e.g., from amateur radio transmitter, MRI, etc.). On rare occasions this may result in the need to repeat the capsule procedure. In this case, the health care provider should advise the patient to stay within the premises of the clinic during the capsule endoscopy to prevent this problem from recurring.
- In a small number of cases, a PillCam Genius SB capsule may not image the entire small bowel due to variation in patient GI motility.
- The capsule should not be swallowed by patients where a concern for aspiration of the capsule exists (e.g. due to cognitive or neurological deficits or a history of aspiration). In these patients it is recommended a capsule endoscopic delivery system is used to place the capsule directly in the duodenum. Placement of the capsule in the duodenum will decrease the risk of aspiration of the device (by vomiting) and gastric retention.
- If intestinal fistulas, strictures, or stenoses are suspected, or the patient has had prior abdominal or pelvic surgery, the health care provider should consider performing an examination to ascertain patency for an object the size of the PillCam capsule.
- In patients with unsuspected strictures of the gastrointestinal tract, any PillCam capsule can potentially cause intestinal obstruction resulting in the need for hospitalization and surgery.
- A patient with known or suspected delayed gastric emptying (whether disease related or drug induced) could be at increased risk for incomplete PillCam capsule endoscopy of the small bowel.
- The safety of this device in pregnant women has not been established.
- The safety of this device in patients with significant gastrointestinal diverticular disease is unknown.
- Remove the recorder before cardiac defibrillation.
- A negative or normal result obtained by the PillCam Genius SB capsule does not exclude the presence of pathology and if symptoms persist, further evaluation should be performed.

Packaging and kit warnings

- Follow all storage and transportation guidelines on the package label.

- Store all kits in a safe place, out of the reach of children and infants.

Capsule warnings

- If there is reasonable doubt concerning the integrity of the PillCam Genius SB capsule due to dropping, biting, or any other event, use a different PillCam Genius kit and replace both the capsule and the recorder.
- If a child has accidentally swallowed any unused or spent PillCam capsule, seek medical attention.
- A PillCam Genius SB capsule should be ingested only in the observation of authorized medical personnel.
- Instruct the patient to avoid biting the capsule prior to swallowing.
- Instruct the patient to not wear lipstick or lip balm prior to ingesting the capsule.

Recorder warnings

- Check the recorder for visual defects such as tears or cracks. Do not use the recorder if any visual defects are noted.
- Ensure the patient is wearing loose-fitting, opaque, two-piece clothing and not wearing a belt.
- Ensure the patient does not have any known allergies to adhesive bandages.
- The patient's skin must be clean, dry, and intact before applying the recorder. Skin should be washed with regular soap as close as possible to the procedure time.
- The patient should not apply any lotion or cream to their skin at least 12 hours before procedure time.
- Do not touch the adhesive areas of the recorder.
- Improper placement of the recorder may result in loss of images.
- Do not allow the recorder to get wet. Immediately wipe the recorder with a dry cloth if it does get wet.
- Do not connect the recorder to a computer or other external power source while the recorder is on the patient's body.
- The USB connector cover on the recorder should be closed while the recorder is on the patient's body.
- In rare cases, materials in the recorder could lead to skin injury or irritation including allergic reactions, burning sensations, desquamation, or peeling of the skin. Remove the recorder in the event of continuous skin irritation.
- The patient should immediately remove the recorder if the recorder heats up and causes discomfort.
- Patients should return the recorder to the clinic and healthcare providers should dispose of the recorder according to the applicable local regulations.

Cybersecurity and privacy warnings

The PillCam Genius kit has 2 seals on the package. Opening the first seal on the front of the package will show the QR code. The second seal will open the kit. Before the health care provider scans the

QR code, they must ensure that the first seal is not broken. They should not use the kit if the seal is broken. Once they confirm it is not broken, they can break the seal and scan the QR code.

If the patient is taking the kit home to conduct the procedure remotely under a telehealth visit, the health care provider must scan the QR code first at the clinic. The patient does not have to worry about broken seals.

Electromagnetic compatibility warnings

- After ingesting the PillCam Genius SB capsule and until it is excreted, the patient should not be near any source of powerful electromagnetic fields, such as one created near an MRI device.
- Keep the magnets in the PillCam Genius packaging away from implants such as pacemakers, defibrillators, nerve stimulators, and other devices that could be affected by proximity to a DC magnetic field.
- Undergoing an MRI while the PillCam Genius SB capsule is inside the patient's body may result in serious damage to their intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of any PillCam capsule from their body, they should contact the health care provider for evaluation and possible abdominal X-ray before undergoing an MRI examination.
- The PillCam Genius endoscopy system and its components need special precautions regarding Electromagnetic Compatibility (EMC) to avoid loss of image transfer resulting in video gaps. The PillCam Genius endoscopy system needs to be installed and put into service according to the Electromagnetic Compatibility (EMC) information provided in *Guidance and manufacturer's declaration* on page 49.
- The use of any accessory other than those specified may result in increased emissions or decreased immunity of the PillCam capsule.
- The PillCam Genius endoscopy system may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- Portable and mobile RF communications equipment can affect the PillCam Genius endoscopy system.
- Keep the PillCam Genius endoscopy system away from electrical equipment while in use.

Cautions

- Make sure that only trained personnel, familiar with all of the PillCam Genius endoscopy system operating procedures, use the system.
- Endoscopic capsule placement requires skill and experience in endoscopic esophageal intubation with an accessory device seated at the distal tip of the endoscope. Use of the device is not recommended if the clinician lacks the required experience and proficiency.

Benefits and risks—PillCam capsule endoscopy

Benefits

- PillCam capsule endoscopy is the most widely used patient-friendly tool for visualization of the GI tract.

- After the patient swallows the PillCam capsule, images and data are transmitted wirelessly as the capsule passes through the digestive system. The images are captured and stored in the PillCam Genius recorder worn by the patient. After the procedure is complete, the images are downloaded to a PC, compiled into a study, and reviewed by a health care provider.
- The procedure does not require sedation, intubation, bowel insufflation or radiation.
- Patients may continue with their normal daily activities during the procedure with some limitations.
- PillCam capsule endoscopy offers a simple, safe and non-invasive alternative to traditional imaging procedures.

Risks

- PillCam capsules are contraindicated in patients with known or suspected gastrointestinal obstruction, strictures or fistulas, in patients with cardiac pacemakers or other implantable electromedical devices and in patients with swallowing disorders.
- Capsule retention has been reported in less than two percent of all capsule endoscopy and patency procedures. Capsule retention is defined as having a capsule remain in the digestive tract for more than two weeks.
- Causes of retention cited in the literature include: NSAID strictures, Crohn's disease, small bowel tumors, intestinal adhesions, ulcerations, and radiation enteritis. Summaries in published literature identify the overall risk of retention for capsule endoscopy to be 1.4%. The risk of retention for obscure bleeding is estimated to be 1.2%, for suspected Crohn's disease to be 2.6%, for known Crohn's the risk is higher at 5% and for neoplastic lesions the rate of retention is 2.1% as compared to healthy volunteers [1]. To verify passage of the capsule from the GI tract, an abdominal X-ray may be obtained at the discretion of the health care provider. The capsule can be removed using medical, endoscopic or surgical intervention.
- There is an extremely rare risk of capsule aspiration while patients are attempting to swallow a PillCam capsule or patency capsule.

References:

[1] Liao et al., Indications and detection, completion, and retention rates of small-bowel capsule endoscopy: a systematic review, Gastrointestinal Endoscopy, 2010; 71:280-286

Essential performance

PillCam Genius Small Bowel endoscopy system provides images for visualization of the small bowel mucosa. It allows a trained operator to identify any significant defects in the provision of the images.

Chapter 3

Installing and setting up

Installing PillCam Genius Sync Agent

The PillCam Genius Sync Agent application is installed at the desktop computer hosting PillCam desktop software v9.7 and above.

During installation:

- Define the folder where the PillCam Genius Sync Agent will be installed.
- Define the folder where the PillCam Genius SB videos will be created.

> **Note**
> If using the PillCam Cloud Reader software, choose the folder that will sync with the cloud.

- Enter the user name and password of a service account with read/write access to the folders listed previously.

It is recommend to prepare this information prior to installation.

PillCam Cloud Reader software users

To download the PillCam Genius Sync Agent application:

1. In the top-right corner of the **Procedures** page, click the currently logged-in user name.
2. Select **Manage your account**.
3. Under **My Account**, select **PillCam Genius Sync Agent**.
4. Click the **Download** button to download the software.

To install the PillCam Genius Sync Agent application:

> **Note**
> Installing the PillCam Genius Sync Agent requires local administrator permissions.

1. Double-click the downloaded executable file to start the installation.
2. Follow the on-screen instructions to install the application. After installation, the PillCam Genius Sync Agent icon appears in the Windows notification area.
3. To open the PillCam Genius Sync Agent, click the icon.

When using the PillCam Genius Sync Agent for the first time, a prompt will appear to log in. Click **GO TO LOGIN** and use the Cloud Reader clinic administrator credentials. The clinic administrator will have to verify their identity with an authentication code sent to their email or mobile phone.

Users not using PillCam Cloud Reader software

Procedure still needed

Real-Time View application

Real-Time View is available to download from the following QR code:

Note
Real-Time View application is only available on iOS devices.

Chapter 4

General procedure overview

1. The health care provider should consider performing radiologic imaging or using a patency capsule before utilizing a PillCam Genius SB capsule in patients who are suspected to suffer from fistulae or strictures.
2. The health care provider should check with the patient regarding the use of any prescription medication.
3. At least the day before the procedure, the health care provider should provide the patient with a copy of the Patient Instructions, refer to *Patient Instructions* on page 26 for more instructions.
4. The health care provider should place the patient on a liquid diet starting after lunch the day before the capsule endoscopy. From 10 p.m. the evening before the capsule endoscopy, the patient should stop eating or drinking except for necessary medication with a sip of water.
5. Add a new procedure to the PillCam Genius Sync Agent anytime before applying the recorder, refer to *Adding a New Genius SB Procedure in PillCam Genius Sync Agent* on page 19.
6. On the day of the procedure, remove the recorder from the PillCam Genius package. Ensure the recorder's green LED light is on and constant. Apply the recorder. Refer to *Applying the PillCam Genius recorder:* on page 16 for recorder application instructions.
7. Remove the PillCam Genius SB capsule from the capsule box to activate the capsule. Ensure both the recorder and the capsule lights are blinking. The patient should ingest the capsule under the supervision of a health care provider with as much water as needed. Refer to *PillCam Genius SB capsule guidelines* on page 18 for guidelines on capsule ingestion.
8. The health care provider can view the live images from the endoscopy procedure using the Real-Time View application. Refer to *Real-Time View application* on page 31 for more instructions.
9. Before allowing the patient to leave the clinic, inform the patient the blinking green LED on the recorder indicates that the procedure is ongoing.
10. Inform the patient that at the end of the procedure, the recorder LED light will turn off and they can remove and return the recorder to the clinic. Refer to *Recorder removal, return, and disposal* on page 20 for more instructions.
11. The healthcare provider can then download the procedure data from the recorder. Refer to *Downloading data from the patch* on page 20 for more instructions.

Chapter 5

PillCam Genius procedure

Note
For remote procedures: the placement of the PillCam Genius recorder and ingestion of the PillCam Genius SB capsule must be done under a health care provider's direction via a telehealth visit. The health care provider must have direct visualization of recorder placement and capsule ingestion.

Note
It is recommended to open only one PillCam Genius kit at a time in the same room to avoid signal interference between the kits.

PillCam Genius recorder

Before applying the PillCam Genius recorder to the patient's abdomen, read all general and safety guidelines in *Indications, contraindications, warnings, cautions* on page 5.

Before application:

Warning
- Make sure that the skin is clean, dry, and intact. Skin should be washed with regular soap as close as possible to the procedure.
- Do not apply any lotion or cream to the skin at least 12 hours before procedure time.
- Check the recorder for visual defects such as tears or cracks. Do not use the recorder if any visual defects are noted.

Before applying the recorder, make sure:

- The patient is wearing loose-fitting, two-piece clothing that is dark or opaque, and not wearing a belt.
- The patient's skin is uninjured and not red or irritated.

Applying the PillCam Genius recorder instructions

Removing the PillCam Genius recorder from its packaging:

1. Place the PillCam Genius SB capsule endoscopy kit on a clean, flat surface.

2. Open the package and remove the recorder protective case.

Note
- Do not use sharp objects to open the PillCam Genius protective case.
- Do not throw away the packaging until the patient applies the recorder and ingests the capsule.

3. Place the recorder protective case on a surface with the sealing layer facing up.
4. Gently pull the sealing foil in the direction of the arrow to open the package. Remove the patch from the protective case.
5. After removing the recorder from the protective case, note the recorder LED appears constant green. Place the recorder next to the recorder protective case. Refer to the figure below for the location of the recorder LED light.

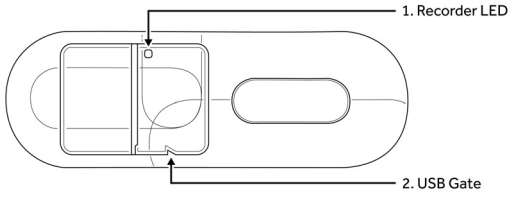
Note
Do not remove the capsule yet.

Applying the PillCam Genius recorder:

Note
Before applying the recorder, identify the following:
- Pull tabs on the rear (tabs #1-3) and front side of the recorder (tabs #4-7).
- Location of the LED light on the recorder. During the procedure, the recorder provides notifications including LED indications, vibrations, and sounds.

Warning
Improper placement of the recorder may result in loss of images. Refer to the instructions for correct placement of the recorder.

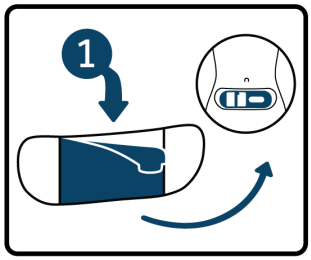
Note
Do not touch the adhesive areas of the recorder.



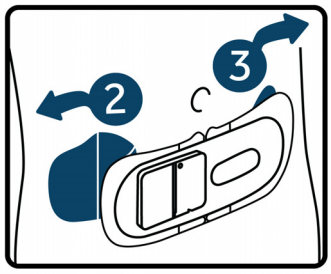
1. Recorder LED
2. USB gate

1. While the patient is standing, instruct the patient to remove or lift their shirt to expose the lower abdominal area.

2. With the rear of the recorder facing the healthcare provider, remove tab #1 from the rear of the recorder by gently pulling it down and to the left.



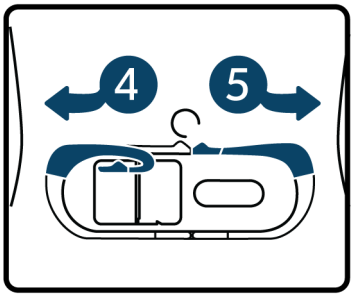
3. Holding the recorder in the areas of tab #2 and #3, turn the recorder so the adhesive area is facing the patient's body.
4. Position the recorder such that the curved area at the top of the recorder is about 1 finger width below the navel.
5. Gently press the recorder against the skin of the abdomen to secure it in place.
6. Remove tab #2 and then tab #3 by gently pulling each tab in the direction of the arrows. Make sure to only pull the gray layer of the tab. Gently press the adhesive area against the skin of the abdomen as each tab is removed to secure it in place.



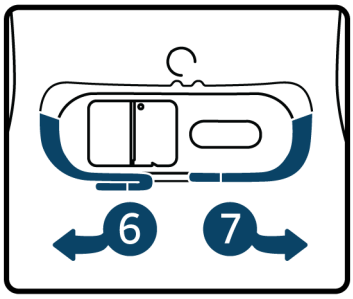
Note

One hand should always be holding the recorder gently to the skin while the other hand removes the tabs.

7. With one hand, gently remove tab #4 on the front of the recorder. At the same time, use the other hand to smooth the adhesive to the skin.



8. Repeat step 8 with each tab #5, 6, and 7.



Note

If, after applying the recorder, it detaches from the body the patient should:

- Avoid touching the adhesive areas.
- Attempt to re-apply the recorder in its original position.
- Contact the clinic for instructions on how to proceed.

Warning

- Immediately remove the recorder if the recorder heats up and causes discomfort.
- In rare cases, materials in the recorder could lead to skin injury or irritation including allergic reactions, burning sensations, desquamation, or peeling of the skin. Remove the recorder in the event of continuous skin irritation.
- Do not shower or bathe while wearing the recorder.
- After applying the recorder, the patient should avoid any physical activity or sport that involves sweating, bending, or stooping.
- Do not allow multiple patients undergoing PillCam endoscopy procedures to be in the same vicinity as each other. Patients should be at least 3 meters apart.
- Patients must not remove the recorder until the recorder has turned off and no LED light is on, or until instructed by the health care provider.

Note

The PillCam Genius recorder will automatically shut down if it reaches 41 °C (105.8 °F).

PillCam Genius SB capsule guidelines

PillCam Genius SB capsules are packaged using a controlled process that ensures the capsule is activated only when needed.

When it is time to ingest the capsule, open the lid of the capsule box to expose the capsule.

Note

To avoid accidental activation, indicated by a blinking LED light, of the PillCam Genius SB capsule while in its box:

- Keep the capsule in its box until it is ready for ingestion.
- Only store capsules in the packaging supplied with the product.
- Do not use a capsule if the packaging or case is damaged.
- Keep the capsule box away from strong magnetic fields such as MRI devices.
- Keep metal objects away from the lid of the capsule box.

Note

The PillCam Genius SB capsule starts capturing images the moment it is removed from the capsule box. Thus, the images of people, their faces, and surroundings could be captured by the capsule.

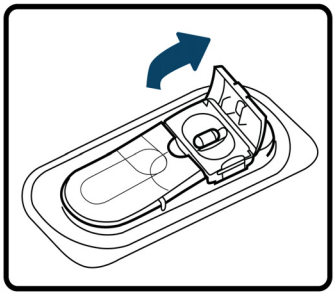
Capsule ingestion

The capsule is activated when it is removed from the capsule box. Capsule ingestion is the process of having the patient swallow the PillCam Genius SB capsule.

Note

- If the patient does not ingest the PillCam Genius SB capsule within 10 minutes, or if the capsule is suspected to be defective, return the capsule and the recorder to the original packaging.
- Visually inspect the capsule for defects or dirt before ingestion.
- Follow appropriate hygiene standards to ensure hands are clean before handling the capsule.

1. Place the package on a flat surface as shown below. Tear the sealing tab to open the capsule box lid.



2. Opening the capsule box lid causes the capsule LED to blink white.
3. Instruct the patient to gently hold the white area of the capsule with 2 fingers, and carefully lift the capsule out of the box. Do not touch the transparent dome.
4. Ensure the recorder LED is blinking green and capsule LED is blinking white.
5. Instruct the patient to swallow the capsule with a sip of water. The ingestion procedure may take several minutes.

Multiple procedures

When performing more than one PillCam Genius SB capsule endoscopy procedure in the same vicinity, follow these guidelines to prevent signal interference with other procedures:

- Perform only one capsule ingestion at a time with no other active PillCam Genius SB capsules present in the room.
- Do not permit patients wearing a PillCam Genius recorder to stand next to other patients with ingested capsules.

Monitoring procedure progress

PillCam Genius recorder notifications and LED meaning

LED color	Attribute	Meaning
Green	Constant	Recorder is working. Procedure has not yet started.
Green	Blinking	Recorder is working. Procedure has started and the recorder and capsule are paired.
Blue	Blinking	Recorder is transferring data to a PC or device.
Blue	Constant	Data transfer to PC is complete. The user can disconnect the recorder from the PC and dispose of it.
Off	Off	Procedure is complete and recorder can be removed.

In addition to changing LED colors signifying a change in recorder status, the recorder will provide an audio and haptic notification. The patient does not have to acknowledge or act on any notifications until the procedure is complete.

Recorder removal, return, and disposal

The recorder LED light will turn off once the procedure is complete. Once the recorder LED light has turned off, the patient may remove the recorder. The recorder does not have to be removed immediately.

Removing the recorder

To remove the recorder, use one hand to gently pull one of the recorder edges toward the center of the recorder. With the other hand, press down on the exposed skin to help separate the skin from the adhesive area.

Returning the recorder

If the patient is not present at the clinic when removing the recorder, they will need to return the recorder to the clinic.

1. After removing the recorder, fold the recorder in half.
2. Insert the folded recorder into the plastic bag provided with the PillCam Genius kit.
3. Insert the plastic bag containing the recorder into the envelope provided with the PillCam Genius kit. Return the envelope to the clinic.

Disposing of the recorder

After downloading data from the recorder, dispose of the PillCam Genius recorder according to the applicable local regulations for electrical equipment disposal in the area. For more information on downloading data from the recorder, refer to *Downloading data from the recorder* on page 28.

Chapter 6

PillCam Genius Sync Agent

Overview of PillCam Genius Sync Agent

The icon in the Windows notification area indicates the status of the PillCam Genius Sync Agent:


System functioning


Disconnected from cloud (for PillCam Cloud Reader software users)

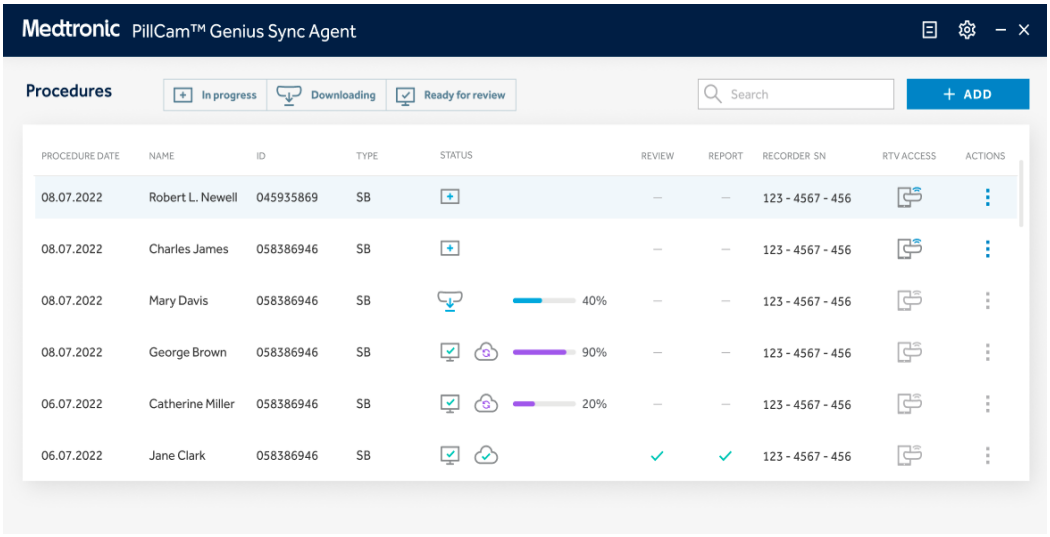

Error in one or more procedures

To open the PillCam Genius Sync Agent, click the icon to display the **Procedures** page.

Use the Windows account user name and password to login.

Procedures page

The PillCam Genius Sync Agent **Procedures** page contains information on all PillCam endoscopy procedures currently in the system. The following is a summary of each feature on the **Procedures** page.



Patient and procedure information

Each procedure will have the procedure date, patient name, ID number, patient sex, and type of PillCam endoscopic procedure being conducted.

Status

The **Status** column displays the status of each procedure, as indicated by the following:

In progress: from creating a new procedure in the PillCam Genius Sync Agent and during the procedure, until connecting the recorder to the PC

Downloading: during data transfer from the recorder to the PC and during video creation

Ready for local review: video is ready for review in PillCam desktop software

Cloud sync: during video upload from the local archive to the cloud (PillCam Cloud Reader software users only)

Ready for cloud review: procedure data synced successfully to the cloud from the local archive; procedure data can be reviewed in the cloud (PillCam Cloud Reader software users only)

Downloading error: there is a problem with either downloading the data from the recorder or creating a video

Cloud sync error: there is a problem uploading the video to the cloud (PillCam Cloud Reader software users only)

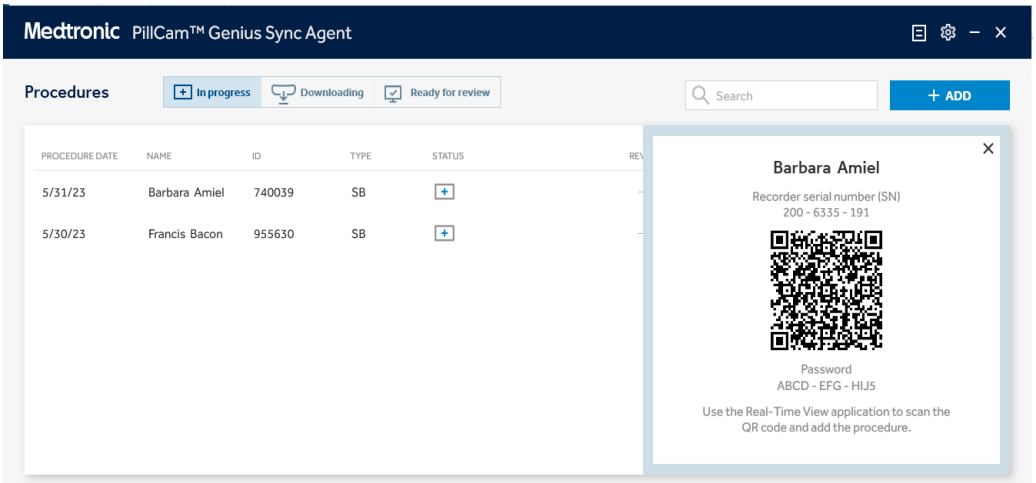
For more information on troubleshooting, refer to *Troubleshooting* on page 35.

Access RTV

The **Access RTV** column contains a procedure-specific QR code that enables access with the Real-Time View application. Click on the icon to view the QR code.

Note

The **Access RTV** icon is enabled only if the Real-Time View application password is entered for the procedure.



Actions

Note
Column actions can only be completed if the password information is entered for the procedure, either by scanning the QR-code or manual entry.

The column actions can be found by clicking the 3 vertical dots to the right of the **Access RTV** column. The column actions allow the user to **Edit** or **Delete** a procedure.

- **Edit:** The procedure can only be edited while the procedure is **In progress.** After downloading the procedure, the procedure details can be edited in the PillCam desktop software v9.7.
- **Delete:** The health care provider can delete a procedure while the procedure is **In progress,** or if an error occurs during **Downloading.**

Note
Deleting a procedure is permanent.

Filter

The healthcare provider can filter procedures by **In progress**, **Downloading**, and **Ready for local review.** The healthcare provider can filter by one option or multiple.

Search

The **Search** function allows the healthcare provider to search procedures by patient name or ID number.

New procedure

The **+ ADD** button allows the health care provider to create new procedures. For more information on creating procedures, refer to *Adding a new PillCam Genius SB procedure in PillCam Genius Sync Agent* on page 26.

Patient Instructions

Print Patient Instructions for the respective PillCam procedure and give them to the patient at least a day before the procedure. To print the instructions, click on the **Patient Instructions** button.

Note
The instructions are provided as a PDF file with editable fields.

Settings menu

To open the Settings menu, click the icon in the top right corner of the main screen.

The **Settings** menu allows performing the following actions:

- Select the software language
- Save the log file
  - The log file includes a list of application events for customer support purposes
  - The Audit file contains all user actions for HIPAA compliance
- View the Privacy Policy
- View the Terms of Use
- View the About screen

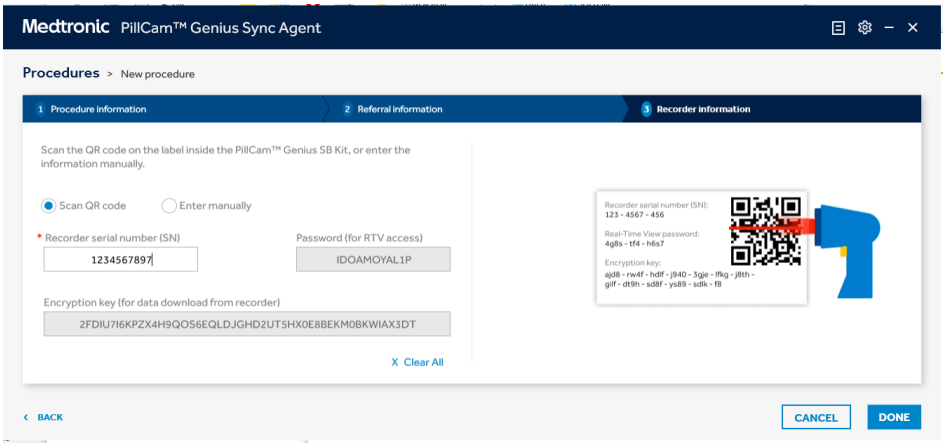
Procedures in PillCam Genius Sync Agent

Note
It is recommended to add a new procedure before applying the PillCam recorder to the patient.

Adding a new PillCam Genius SB procedure in PillCam Genius Sync Agent

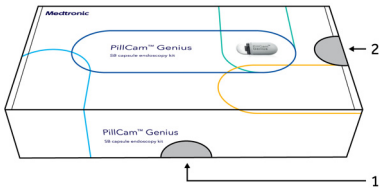
1. To add a new procedure in the **Procedures** window, click **+ ADD.**
2. Fill in the required patient information. Once all mandatory fields with red asterisks are complete, click **Continue.**
3. Select the appropriate options from the drop down menus for referral information and reason for referral. Click **Continue.**
   a. Drop down options are inputted from the PillCam desktop software installed on the PC. The health care provider can also type in the applicable information if not present in the drop down menu options.
   b. The **Reason for Referral** drop down menu options are also inputted from the PillCam desktop software and includes common referral visit reasons. The health care provider may fill out additional information in the **Reason for Referral** text box.

4. Input the recorder information by either scanning the QR code placed on the PillCam Genius kit package using a 2D barcode reader, or by inputting the information manually. Refer to the software and the following note for figures of the packaging and QR code. The password for the Real-Time View application and the encryption key for data download can be filled in later. Save the encryption key for future reference if not inputted at this step. Press **Done** once complete.

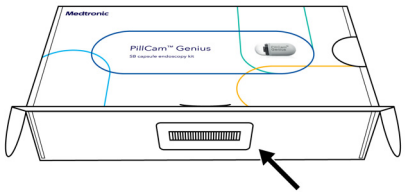


Note

The PillCam Genius SB capsule endoscopy kit is fitted with two seals as shown in the following figures. Opening the first seal, #1 in the figure, will raise the front flap to expose a label with a QR code. This QR code is unique for each kit and will enable decryption of the recorder data upon download. The QR code should not be shared outside of the clinic to ensure protection of patient procedure data. Opening the second seal, #2 in the figure, will fully open the kit. If either of these seals are broken before the planned procedure, the kit should not be used.



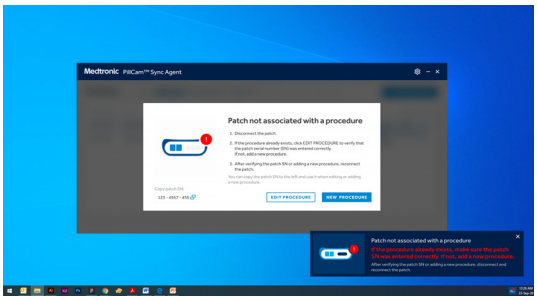
1. Seal 1
2. Seal 2



5. The new procedure is added to the **Procedures** page and shows as **In progress** on the page. The procedure can be executed immediately or at a later date.

Adding a PillCam Genius SB procedure after recorder application

Although it is recommended to add a procedure before the PillCam recorder is applied, the healthcare provider can add a procedure after the recorder is applied. Once the PillCam Genius Sync Agent is connected to a recorder not previously associated with a procedure, the following message will appear:

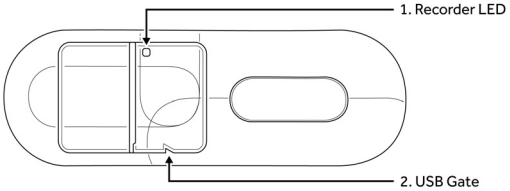


Follow the instructions on-screen to disconnect the recorder and then add a new procedure by selecting **+ ADD**. Refer to *Adding a new PillCam Genius SB procedure in PillCam Genius Sync Agent* on page 26 for more information. After adding a new procedure, the healthcare provider can reconnect to the recorder.

If the healthcare provider did not save the QR code with the Real-Time View application password and encryption key from the packaging of the PillCam Genius kit, please contact customer support to obtain this information. Provide customer support with the recorder serial number that appears in the pop-up message in the previous illustration.

Downloading data from the recorder

1. After the recorder has been removed and returned to the clinic, open the USB gate on the recorder.



1. Recorder LED
2. USB gate

2. Connect the recorder to the computer using a USB-C cord.

3. Data download and video creation will start automatically and the procedure status in the PillCam Genius Sync Agent will change to **Downloading.** During recorder download, the recorder LED light will flash blue.
4. Disconnect the recorder after receiving a notification from the PillCam Genius Sync Agent the video is ready and the recorder can be disconnected. When the recorder is ready to be disconnected, the LED light will be a constant blue.
5. Once the procedure status is **Ready for Review**, the video files can be viewed locally from the PC. Refer to *Status* on page 24 for the applicable status bar icons.
6. If the healthcare provider is using PillCam Cloud Reader software, procedure data will automatically upload to the cloud.
7. Check marks will appear in the **Review** or **Report** columns when the review or report is ready. The procedure stays in the **Procedures** page for 30 days after successful video creation. For PillCam Cloud Reader software users, the procedure stays for 30 days in the cloud after successful video upload.

Chapter 7

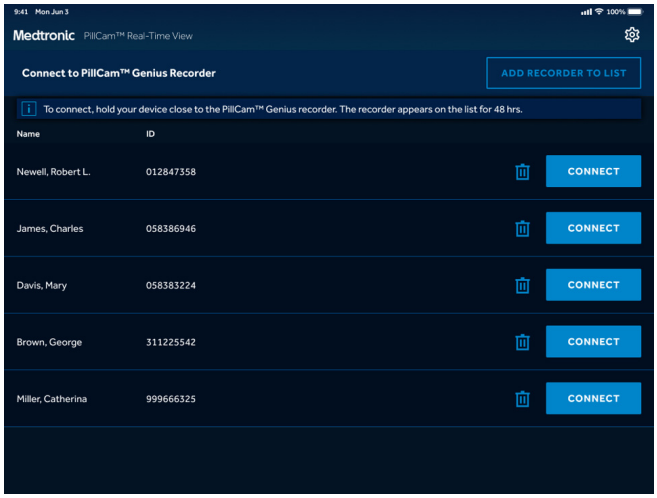
Real-Time View application

Real-Time View application overview

The Real-Time View (RTV) application allows the healthcare provider to see live images during a PillCam Genius procedure to estimate the capsule's location.

Main screen

The main screen of the Real-Time View application shows the recorders that are currently connected to the device. Each procedure will have the patient name and ID number.



Settings menu

To open the Settings menu, click the icon in the top right corner of the main screen.

The **Settings** menu allows performing the following actions:

- Select the software language
- View the Privacy Policy
- View the Terms of Use
- View the About screen

Adding a recorder to the Real-Time View application

On the main screen, click **ADD RECORDER TO LIST**.

The Real-Time View application password and recorder serial number can be added automatically by scanning the provided QR code, or entered manually.

Refer to *Access RTV* on page 24 for more information on the QR code.

Scanning the QR code

Note
In order to scan the QR code, camera permissions for the Real-Time View application must be enabled.

1. Click **ADD RECORDER TO LIST** from the center or top-right of the screen.
2. Open the PillCam Genius Sync Agent to scan the QR code for the relevant procedure.

Note
Do not scan the QR code from the PillCam Genius kit packaging. Only the QR code from the PillCam Genius Sync Agent will have the relevant information.

3. The recorder and patient information have been added to the list on the Real-Time View application main screen.

Manually adding the recorder

1. Select **ADD RECORDER TO LIST** from the center or top-right of the screen.
2. Select **Enter Information Manually**.
3. Fill out the mandatory fields for the Real-Time View application password and recorder serial number.
4. Fill out the mandatory fields for the patient's full name and ID.
5. The recorder has been added to the list on the Real-Time View application main screen.

Deleting a recorder

To delete a recorder from the recorder list on the Real-Time View application main screen, click the **Trash** icon to the left of the **Connect** button.

Recorders are automatically deleted from the recorder list after 24 hours.

Viewing videos from the recorder

Connecting a recorder to the Real-Time View application

Note
In order to connect the recorder to the Real-Time View application, Bluetooth™* must be enabled on the device.

Note
After connecting a recorder to the Real-Time View application, ensure the connection was made to the correct patient by checking the recorder LED is blinking blue. If the recorder is not blinking blue, the connection was made to a different patient and recorder.

After adding a recorder to the recorder list, the healthcare provider can connect to the recorder by selecting the **Connect** button to the right of the patient name and ID.

The Real-time View application and recorder need to be in the same vicinity to ensure a connection between them. The connection process consists of 3 steps that will be detailed in the Real-Time View application. It may take up to 1 minute for the Bluetooth to make a connection with the recorder.

Using the Real-Time View application during a procedure

Once the recorder is connected, the Real-Time View application screen will appear. The screen will show the patient name, procedure type, and time stamp indicating how much time has elapsed since the capsule was activated.

To pause the video, select the **Pause** button. To play again, press **Play**.

Note
When the real-time viewing session is over, the recorder LED will return from blinking blue to blinking green.

Real-Time View application time limits

The Real-Time View application will only show live images from the recorder for 2 minutes at a time. If the healthcare provider wishes to view longer, they will have reconnect to the recorder each time. In order to preserve the battery life of the recorder during a procedure, the Real-Time View application can only show 30 minutes of live images for each procedure.

Chapter 8

Troubleshooting

PillCam Genius recorder troubleshooting

Note
Use the following email address to contact Medtronic customer support:
rs.gi-usa-technicalsupport@medtronic.com

Problem	Possible Cause	Action
Recorder LED light doesn't turn green when taken out of package	Hardware fault	• Replace kit • Contact customer support
Recorder LED light doesn't blink green when capsule is taken out of package	Hardware fault	• Replace kit • Contact customer support
Difficulty removing adhesive tabs from recorder, tabs tear or rip when removing	Misuse or mechanical fault	• Peel off the tabs manually with minimal contact to the adhesive side • Replace kit
Recorder begins to detach from body	Misuse or oily skin	Apply medical tape (not supplied in kit) to attach recorder to body

PillCam Genius SB capsule troubleshooting

Problem	Possible Cause	Action
Capsule LED light doesn't blink when taken out of package	Hardware fault	• Replace kit • Contact customer support

PillCam Genius Sync Agent troubleshooting

Problem	Possible Cause	Action
Unable to open PillCam Genius Sync Agent	• PillCam Genius Sync Agent service is down • Access permissions	• Restart PC • Contact IT to check credentials • Contact customer support
Unable to log in	• Access permissions	• Contact IT to check user permissions • Contact customer support
Recorder is not recognized by the PillCam Genius Sync Agent	• Hardware fault • PillCam Genius Sync Agent service is down	• Disconnect and reconnect the recorder to the PC • Use a different USB cable • Use a different USB port • Restart the PC • Contact customer support
Unable to save a new procedure or data from the recorder	• Access permissions • PillCam Genius Sync Agent service is down • Insufficient disk space	• Contact IT to check permissions for the folder videos and raw data are saved in • Check available disk space • Contact customer support
Unable to edit or delete a procedure	• Access permissions • PillCam Genius Sync Agent service is down	• Contact IT to check permissions for the folder videos are saved in • Contact customer support
Video creation failed	• System configuration • Access permissions	Contact customer support
Export log fails	• Access permissions • Insufficient disk space	• Contact IT to check user permissions • Check available disk space • Contact customer support

Real-Time View application troubleshooting

Problem	Possible Cause	Action
Camera not working	No camera permission granted	• Grant camera permission manually in **Settings -> PillCam RTV -> Camera** • Add patient information manually

Problem	Possible Cause	Action
Unable to pair with recorder	• Wrong recorder information entered (Bluetooth Serial, Bluetooth password) • No Bluetooth permissions • Hardware fault • Device Bluetooth is off • Device wireless network is off	• Check recorder LED light is flashing green • Remove recorder from list and add again with valid information • Grant Bluetooth permissions manually in **Settings -> PillCam RTV -> Bluetooth** • Turn device Bluetooth on • Turn device wireless network on
Image is displayed, but recorder LED light is still blinking green	Mismatch between different patients and recorders	• Disconnect from current recorder • Select and connect to correct recorder • If problem persists, remove and add valid recorder information
Image screen too dark	Device screen brightness is set too low	Increase device's screen brightness
Connection to recorder failed during step 3	No local network access permission granted	Grant permissions for local network access manually in **Settings -> PillCam RTV -> Local Network**

Appendix A

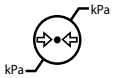
System labeling

System labeling

The following table lists the labels attached to various components of the PillCam Genius SB endoscopy system.

Symbol	Standard reference	Symbol title	Explanatory text
	21 CFR 801.109	For prescription use only	Prescription device
	ISO 15223-1, Clause 5.4.3 ISO 980, Clause 5.18 IEC 60601-1, Table D.1, Symbol 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	MDD 93/42/EEC, Annex XII	CE Mark	To indicate conformity with the provisions of MDD 93/42/EEC Directive.
	ISO 15223-1, Clause 5.1.1 EN 980, Clause 5.12	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC.
	ISO 15223-1, Clause 5.1.3 EN 980, Clause 5.6	Date of manufacture	Indicates the date when the medical device was manufactured.
	MDR (EU) 2017/745, Chapter II, Article 13 (3)	Importer	Indicates the device importer information.
	ISO 15223-1, Clause 5.1.5 EN 980, Clause 5.4	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.1.6 EN 980, Clause 5.10	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.

Symbol	Standard reference	Symbol title	Explanatory text
	ISO 15223-1, Clause 5.1.7 EN 980, Clause 5.5	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1, Clause 5.3.4 EN 980, Clause 5.21	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1, Clause 5.3.7 EN 980, Clause 5.17.3	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Clause 5.4.2 IEC 60601-1, Table D.1, Symbol 28	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1, Clause 5.4.4 EN 980, Clause 5.11 IEC 60601-1, Table D.1, Symbol 10	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	IEC 60601-1, Table D.1, Symbol 20	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	IEC 60601-1, Table D.1, Symbol 4	Direct current	To indicate on the rating plate that the equipment is suitable for direct current only.
	Directive 2012/19/ EU, Annex IX	Separate collection for electrical and electronic equipment	Do not throw in trash. Dispose according to local regulations.
	CAN/CSA-C22.2 No.60601-1-08 ANSI/AAMI ES60601-1:2005 CAN/CSA-C22.2 No.601.1-M90	CSA certification Mark	Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety standards.
	ASTM F2503	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.

Symbol	Standard reference	Symbol title	Explanatory text
	IEC 60601-1-2, Clause 5.1.1	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	NA	Not made with natural rubber latex	Not made with natural rubber latex.
	47 CFR Part 15	Federal Communication Commission Number (FCC ID #)	Complies with United States Radio communication requirements.
	ISO 15223-1 Sec 5 ISO 7000-2620	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	IEC 529 and EN60529	Protection against fluid ingress: Drip-proof	Indicates the IP rating of a device. The values show the protection level against environmental particulate and liquid ingress respectively.
	ISO 15223-1 Sec 5 ISO 7000-2621	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1 Sec 5	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
		Do not use sharp objects	Indicates not to use sharp objects or box cutters to open the packaging.

List of standards

1. ISTA 2A Partial Simulation Performance Tests
2. IEC 60601-1 Electrical safety 2005+AMD1:2012+AMD2:2020 CSV

3. IEC 60601-1-11 Electrical safety in home use 2015+AMD1:2020 CSV
4. IEC 60601-1-2 EMC
5. ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process 2015+AMD1:2020 CSV
6. ISO 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
7. ISO 10993-4 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
8. ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity 2009
9. ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization 2021
10. ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
11. ISO 10993-18 Biological evaluation of medical devices - Part 18: Chemical characterization of materials
12. ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation 2021
13. ISO 22442-1 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk mitigation
14. IEC 60601-1-6 electrical safety Usability 2013+AMD2:2020 CSV
15. EN 62366-1 Usability for medical devices 2015+AMD1:2020 CSV
16. EN 62304 Software life cycle processes 2006+AMD1:2015
17. ISO 14971: 2012 Risk management
18. ISO 14971: 2019 Risk management
19. ISO 15223 – Labeling symbols 2021
20. ISO 20417 – Medical Devices – Information to be supplied by the manufacturer 2021
21. Restricted materials: MDR, REACH, PoP, Proposition 65
22. ISO 13485 2016
23. ISO 13485 2016/AC:2018
24. RED Directive 2014/53/EU, 2014
25. EN 303 520 Short Range Devices (SRD); Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz V1.2.1
26. EN 301 489-1 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements V2.2.3
27. EN 301 489-17 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Boardband Data Transmission Systems V2.3.5
28. EN 300 330 Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU V2.1.1
29. EN 300 328 (for 100 mW) Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the V2.2.2

30. EN 300 440 (for 10 mW) Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range V2.2.1

31. IEC 62311 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz) EU Harmonized version 2008

32. EN 62209 Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Part 2: Procedure to determine the specific Absorption Rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz), 2010 /A1:2019

33. ISO 62209-3 Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Part 3: Vector measurement-based systems (Frequency range of 600 MHz to 6 GHz), 2019

34. Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff, 2013

Kit labeling

The following table lists the labels attached to the PillCam Genius kit.

Protective case labeling

The following table lists the labels attached to the protective case label.

Appendix B

System specifications

PillCam Genius software specifications

PillCam Sync Agent

Properties		Comments
OS	Windows 10 version 21h2 and above; Windows 11	
CPU	Core i3	
RAM	Minimum: 8 GB Recommended: 16 GB	
Disk Space	1 GB for software; 35 GB for video creation storage	After the video is created, disk space used for video creation is cleared. The user can then choose to save the Genius SB raw data (up to 16 GB).
USB	USB 2	
Software prerequisites	PDF reader software such as Adobe	

Real-Time View

Properties	
Supported devices	iOS devices released after September 2021
iOS	Version 15.0 and above
RAM	Minimum resolution: 2266x1488

PillCam Genius kit specifications

The following tables list specifications for the PillCam Genius SB capsule and recorder.

PillCam Genius SB capsule

Properties		
Physical	Dimensions	Length: 26.2 mm Diameter: 11.4 mm
	Weight	3.0 g
	Material	Biocompatible plastic
Optical	Illumination	4 white light emitting diodes
	Number of imaging heads	1
	Field of view	136° (Optical field of view from entrance pupil per FDA method)
	Minimum detectable object	>0.07 mm
Operational	Frame rate	Either 2 or 5.5 fps
	Time to first use from manufacturing date: Operating time	12 months: 11.5 hours 18 months: 10.5 hours
	Chemical safety	Resistant to dissolution in pH=2 to pH=8
	Battery type	Silver oxide, mercury free
	Operating temperature	20–40 °C (68–104 °F)
	Operative relative humidity	0–100% RH
	Operating atmospheric pressure	520-790 mmHg
	Storage temperature	0–26 °C (32–78.8 °F)
	Storage relative humidity	0–85% RH
	Storage atmospheric pressure	520-790 mmHg
	Frequency	435 MHz
	Bandwidth	3.2 MHz @ 2.7 Mbps; 10.0 MHz @ 8.1 Mbps
	Modulation	MSK
Downlink communication	Operating frequency	13.56 MHz
	Receiver bandwidth	±150 MHz

PillCam Genius recorder specifications

Properties		
Reception antenna	Number	2
	Antenna 1 type	Three loop
	Antenna 2 type	Monopole
	Size	Length: 200.3 mm Width: 62.8 mm
	Material	Polyimide
Transmission antenna	Number	1
	Type	Three loop
	Size	Length: 200.3 mm Width: 62.8 mm
	Material	Polyimide
Receiver	Operating frequency	435 MHz
	Bandwidth	<10 MHz
Transmitter	Operating frequency	13.56 MHz
	Bandwidth	300 MHz
	Modulation type	Frequency-linear chip
	Measured emission	<90.5 dB[uV/m] at a distance of 3 meters
Operational	Time to first use from manufacturing date: Operating time	12 months: 11.5 hours 18 months: 10.5 hours
USB	Connector type	Type C
	Cable type	3
Bluetooth	Protocol	4.2
Wireless network	Protocol	802.11 n

Properties		
Physical	Software	Proprietary FW
	Material	Top cover: TPE Foam: EVA Skin adhesive: silicone adhesive on PU carrier
	Recording capacity	16 GB
	Weight	75.0 g
	Size	Length: 240.9 mm Width: 104.8 mm Height 13.0 mm
	Battery type	Lithium Manganese Dioxide (Li-MnO2)
	Battery capacity	2200 mA*H, 3V
	Storage temperature	15-26 °C (59-78.8 °C)
	Storage humidity	30-70%
	Storage pressure	70 kPa-106 kPa
	Operating temperature	5-35 °C (41-95 °F)
	Operating humidity	15-90%
	Operating pressure	70 kPa-106 kPa

Appendix C

Guidance and manufacturer’s declaration

System specifications

Appendix D

World wide radio communication- regulations datasheet

World Wide Radio Compliance, the product is in compliance with applicable regulations and standards.

Brand: PillCam™

Model: Genius

United States compliance

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.