PillCam™ Genius SB Capsule Endoscopy Kit

User Manual

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Given Imaging Inc.

Note

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

Rx ONLY

CE 0123

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Preface

Using this guide

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

Intended audience

This guide is intended for medical professionals who perform PillCam Genius SB capsule endoscopy procedures. The PillCam Genius SB capsule endoscopy system is only available to patients by prescription.

Conventions

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 unsafe for MR use.

Chapter 1

Overview

About PillCam Genius SB capsule endoscopy system

The PillCam Genius SB capsule endoscopy procedure enables minimally invasive visualization of the gastrointestinal tract using an ingestible capsule. The PillCam Genius

SB capsule captures images that are later presented to the health care provider for review and interpretation.

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

- One PillCam Genius SB capsule
- One PillCam Genius link device

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. The PillCam Genius SB capsule is propelled by natural peristalsis until excreted.

Each PillCam Genius SB capsule contains a miniature color camera with LEDs, batteries, a transmitter, and an antenna to transmit the acquired images. All of these are encapsulated in a 26.2 mm long and 11.4 mm wide ingestible capsule made of biocompatible plastic.

PillCam Genius link device

The PillCam Genius link device is a single-use device that is worn by the patient throughout the PillCam Genius SB capsule endoscopy procedure. The PillCam Genius link device's electronic parts include a battery, antennas, a CPU, and memory storage. The PillCam Genius link device also has an adhesive layer that attaches to the skin of the patient's abdomen. At the end of the procedure, the PillCam Genius link device is removed and returned to the clinic.

The PillCam Genius link device performs the following functions:

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

Chapter 2

Indications, contraindications, warnings, cautions

PillCam Genius SB capsule endoscopy kit

Indications for use

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

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.
- 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.

Note

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

For remote procedures, where the patient sets up the PillCam Genius link device and ingests the PillCam Genius SB capsule 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 PillCam Genius SB 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

PillCam Genius SB capsule

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

PillCam Genius link device

The PillCam Genius link device is intended for storing images received from the PillCam Genius SB capsule, sending commands to the PillCam Genius SB capsule, and providing notifications for the user while adhered to the patient’s body.

Intended target population

Adult patients as per the product indications. This device has not been tested for use in the pediatric population.

Intended users

1. Trained healthcare providers.
2. Patients while under the supervision of a trained health care provider.

Adverse events

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

Additional adverse events can include skin reactions to the PillCam Genius link device adhesive.

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.
- 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 should not apply any lotion or cream to their abdominal skin at least 12 hours before procedure time.
- The patient's skin must be clean, dry, and intact before applying the PillCam Genius link device. Skin should be washed with soap as close as possible to the procedure time.
- When swallowing the PillCam Genius SB capsule, there is a possibility of choking on the PillCam Genius SB 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 the PillCam Genius SB 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 Genius SB capsule endoscopy procedures to be in the same vicinity as each other. Patients should be at least 3 meters apart.
- After applying the PillCam Genius link device, the patient should avoid any physical activity or sport that involves sweating, bending, stooping, or any movement that may impact the adherence of the PillCam Genius link device.
- Do not shower or bathe while wearing the PillCam Genius link device.
- Patients must not remove the PillCam Genius link device until the device has turned off and no LED light is on, or until instructed by the health care provider.
- If excretion of the PillCam Genius SB 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.
- The PillCam Genius SB capsule should not be swallowed by patients where a concern for aspiration of the capsule exists (for example, 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 PillCam Genius SB capsule directly in the duodenum. Placement of the PillCam Genius SB 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 Genius SB 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.
- 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.
- A negative or normal result obtained via evaluation by the PillCam Genius SB capsule endoscopy does not exclude the presence of pathology and if symptoms persist, further evaluation should be performed.

PillCam Genius SB capsule endoscopy packaging and kit warnings

- Follow all storage and transportation guidelines on the package label.
- Store all PillCam Genius SB capsule endoscopy kits in a safe place, out of the reach of children and infants.
- The PillCam Genius SB capsule and PillCam Genius link device are single-use, disposable devices. Reuse or any other misuse of the PillCam Genius SB capsule endoscopy kit components may result in cross-contamination and possibly an incomplete or short study.

- Do not use any PillCam Genius SB capsule endoscopy kit after its expiration date.

PillCam Genius SB capsule warnings

- If the seal on the PillCam Genius SB capsule packaging is broken, the PillCam Genius SB capsule endoscopy kit needs to be replaced.
- 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 SB capsule endoscopy kit and replace both the PillCam Genius SB capsule and the PillCam Genius link device.
- If a child has accidentally swallowed any unused or spent PillCam Genius SB capsule, seek medical attention.
- A PillCam Genius SB capsule should be ingested only in the observation of authorized medical personnel.
- Avoid touching the PillCam Genius SB capsule camera dome at all times and especially when removing the capsule from the capsule packaging.
- Instruct the patient to avoid biting the PillCam Genius SB capsule prior to swallowing.
- Instruct the patient to not wear lipstick or lip balm prior to ingesting the PillCam Genius SB capsule.

PillCam Genius link device warnings

- Check the PillCam Genius link device for visual defects such as tears or cracks. Do not use the PillCam Genius link device if any visual defects are noted.
- If the PillCam Genius link device protective case sealing is damaged, the PillCam Genius SB capsule endoscopy kit needs to be replaced.
- Do not touch the adhesive areas of the PillCam Genius link device.
- Improper placement of the PillCam Genius link device may result in loss of images.
- Do not allow the PillCam Genius link device to get wet. Immediately wipe the PillCam Genius link device with a dry cloth if it does get wet.
- Do not connect the PillCam Genius link device to a computer or other external power source while the device is on the patient’s body.
- The USB connector cover on the PillCam Genius link device should remain closed while the device is on the patient’s body.
- In rare cases, materials in the PillCam Genius link device could lead to skin injury or irritation including allergic reactions, burning sensations, desquamation, or peeling of the skin. Remove the PillCam Genius link device in the event of continuous skin irritation.
- The patient should immediately remove the PillCam Genius link device if the device heats up and causes discomfort.
- Remove the PillCam Genius link device before cardiac defibrillation.

Cybersecurity and privacy warnings

The PillCam Genius SB capsule endoscopy 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 PillCam Genius SB capsule endoscopy 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 PillCam Genius SB capsule endoscopy 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 PillCam Genius SB capsule endoscopy kit home to conduct the procedure remotely under a telehealth visit, the health care provider should scan the QR code first at the clinic. The patient does not have to worry about broken seals.

Security

Medtronic maintains an extensive set of methodologies to secure the PillCam Genius SB capsule endoscopy system both on the application level and the infrastructure level.

Protecting information is critically important to Medtronic. Medtronic has established strong processes, technologies, and expertise to safeguard and protect its information and systems, the information of its business partners, and most importantly, the privacy and safety of the patients and healthcare providers that use Medtronic's products.

Global Security and Privacy Offices

The Global Security Office and the Global Privacy Office are enterprise-wide security and privacy teams at Medtronic that work across the entire organization. The Global Security and Global Privacy offices provide broad security and privacy expertise, governance, and oversight for product security issues, in addition to guiding and enforcing security and privacy policies across Medtronic's organizational units.

The Global Security and Global Privacy offices within Medtronic ensure customer data is only shared at the minimum amount necessary, and ensure data is only stored in secure locations using secure methods.

Alongside top security experts and strict governance, Medtronic's Global Security and Global Privacy offices maintain a high standard of security and privacy by using up-to-date methodologies, data, and security tools.

Furthermore, Medtronic embeds subject-matter security and privacy experts within each operating unit, including the endoscopy unit that developed the PillCam Genius SB system. Product security and privacy practices are executed by subject-matter experts within Medtronic businesses and are supported by an enterprise-wide, cross-functional team. This enables Medtronic to embed security and privacy considerations into the entire product life cycle.

Lastly, Medtronic's Enterprise Quality organization further ensures product security and privacy using rigorous quality processes.

The Global Security and Global Privacy offices with the Enterprise Quality organization provide a holistic product security, privacy governance, and oversight which allows for the establishment of policies and procedures that apply across Medtronic's wide range of products and geographies, including the PillCam Genius SB capsule endoscopy system.

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 SB capsule endoscopy kit 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 Genius SB 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 SB capsule endoscopy kit and its components need special precautions regarding Electromagnetic Compatibility (EMC) to avoid loss of image transfer resulting in video gaps. The PillCam Genius SB capsule 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 27.
- 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 SB capsule endoscopy system.
- Keep the PillCam Genius SB capsule endoscopy system away from electrical equipment while in use.

Cautions

- Make sure that only trained personnel, familiar with all of the PillCam Genius SB capsule endoscopy system operating procedures, supervise the use of the system at the clinic or during a telehealth visit.
- 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.
- If the PillCam Genius SB capsule and PillCam Genius link device have been activated but not used within 15 minutes, they should be returned to their packaging to preserve the battery. Ensure that both the PillCam Genius SB capsule and PillCam Genius link device LED lights are off. If after returning the PillCam Genius SB capsule to the packaging, the capsule is still blinking, rotate the capsule in the packaging such that the text is facing up.
- Ensure the PillCam Genius link device LED is blinking green and PillCam Genius SB capsule LED is blinking white before the patient ingests the capsule.
- Occasionally, some images may be lost due to radio interference (for example, from amateur radio transmitter, MRI, etc.). On rare occasions this may result in the need to repeat the capsule endoscopy procedure. In this case, the health care provider should

advise the patient to stay within the premises of the clinic during the capsule endoscopy procedure 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.
- Patients should return the PillCam Genius link device to the clinic and healthcare providers should dispose of the device according to the applicable local regulations.

Benefits and risks—PillCam Genius SB capsule endoscopy

Benefits

- After the patient swallows the PillCam Genius SB 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 link device worn by the patient. After the procedure is complete, the images are downloaded to a workstation, 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 Genius SB capsule endoscopy offers a simple, safe and non-invasive alternative to traditional imaging procedures.

Risks

- Capsule endoscopy 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 include history of subacute small bowel obstruction, small bowel tumors, Crohn’s disease, history of small bowel resection, abdominopelvic radiation therapy, and chronic use of NSAID [1,2]. Systematic reviews identified the overall risk of retention for capsule endoscopy to be 1.4%. The risk of retention for obscure bleeding was estimated to be 1.2%, for suspected Crohn's disease 2.6%, for established Crohn's 4%, and for neoplastic lesions the rate of retention was 2.1% as compared to healthy volunteers [3]. Over the past two decades, due to improved patient selection, and use of patency capsule, the risk of capsule retention was reduced to below 1% [2].
- There is an extremely rare risk of capsule aspiration while patients are attempting to swallow a PillCam Genius SB capsule or patency capsule [2].
- The PillCam Genius SB capsule may be administered by using transendoscopic delivery in patients who are either unable to ingest the capsule, or are known to have slow gastric emptying time. If using transendoscopic delivery, potential complications include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, hypertension, respiratory arrest, and cardiac arrhythmia or arrest due to the transendoscopic procedure.
- There is a low risk of skin irritation from the PillCam Genius link device adhesive.

- PillCam Genius SB capsules are contraindicated in patients with cardiac pacemakers or other implantable electro-medical devices. There is a potential risk of arrhythmia or interference to other medical systems in the event of using the PillCam Genius SB capsules in such patients.
- A patient with known or suspected delayed gastric emptying (whether disease related or drug induced) could be at increased risk for incomplete PillCam Genius SB capsule endoscopy procedure of the small bowel.

References

[1] Pennazio, Marco, et al. "Small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders: European Society of Gastrointestinal Endoscopy (ESGE) Guideline–Update 2022." Endoscopy 55.01 (2023): 58-95.

[2] Cortegoso Valdivia, Pablo, et al. "Indications, detection, completion and retention rates of capsule endoscopy in two decades of use: a systematic review and meta-analysis." Diagnostics 12.5 (2022): 1105.

[3] Liao, Zhuan, et al. "Indications and detection, completion, and retention rates of small-bowel capsule endoscopy: a systematic review." Gastrointestinal endoscopy 71.2 (2010): 280-286.

Essential performance

PillCam Genius SB 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.

Intended use environments

The PillCam Genius SB capsule endoscopy system is intended for use in the following environments:

- Non-health care environments such as homes, residences, nursing homes, and hotels.
- Outdoor environments such as on streets, sidewalks, and parks.
- Vehicles such as cars, buses, and trains. However, acceptable vehicles do not include emergency medical services, such as ambulances, or passenger aircraft.
- Transportation stations such as train and bus stations.
- Professional health care facilities such as physician offices, clinics, and hospitals.

Warning

The PillCam Genius SB capsule endoscopy system cannot be used near high-frequency (HF) surgical equipment or outside of an RF shielded room of an ME system for magnetic resonance imaging.

Warning

Use of this equipment adjacent to, or stacked with other equipment, should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Chapter 3

General procedure overview

Note
Any serious incident that may occur in relation to the device should be reported to the manufacturer and necessary regulatory authority, if in the European Union, the competent authority of the member state, in which the user or patient is established.

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 and any known allergies.
3. At least the day before the procedure, the health care provider should provide the patient with a copy of the Patient 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. On the day of the procedure, remove the PillCam Genius link device from the PillCam Genius package. Ensure the PillCam Genius link device's green LED light is on and constant, and apply the PillCam Genius link device. Refer to "Applying the PillCam Genius link device instructions" on page 13 for the device application instructions.
6. Remove the PillCam Genius SB capsule from the capsule packaging to activate the capsule. Ensure both the PillCam Genius link device and the PillCam Genius SB capsule lights are blinking. The patient should ingest the PillCam Genius SB capsule under the supervision of a health care provider with as much water as needed. Refer to "PillCam Genius SB capsule guidelines" on page 16 for guidelines on PillCam Genius SB capsule ingestion.
7. Before allowing the patient to leave the clinic or ending the telehealth visit for PillCam Genius link device application and PillCam Genius SB capsule ingestion, inform the patient the blinking green LED on the PillCam Genius link device indicates that the procedure is ongoing.
8. Inform the patient that at the end of the procedure, the PillCam Genius link device LED light will turn off and they can remove and return the device to the clinic. Refer to "PillCam Genius link device removal, return, and disposal" on page 18 for more instructions.

Chapter 4

PillCam Genius SB capsule endoscopy procedure

Note
For remote procedures: opening of the PillCam Genius SB capsule endoscopy kit, placement of the PillCam Genius link device, 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 PillCam Genius link device placement and PillCam Genius SB capsule ingestion.

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

PillCam Genius link device

Before the PillCam Genius link device is applied to the patient's abdomen, read all general and safety guidelines in "Indications, contraindications, warnings, cautions" on page 2.

Note
It is recommended for the healthcare provider to add a new procedure to the PillCam Genius Sync Agent before applying the PillCam Genius link device to the patient. The healthcare provider should input the QR code and encryption key information at this step.

Before application:

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

Before applying the PillCam Genius link device, 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 link device instructions

Removing the PillCam Genius link device from its packaging:

1. Place the PillCam Genius SB capsule endoscopy kit on a clean, flat surface.
2. Open the package and remove the PillCam Genius link device protective case.

Note

- Do not use sharp objects to open the PillCam Genius SB capsule endoscopy kit protective case.
- Do not throw away the packaging until the patient applies the PillCam Genius link device and ingests the PillCam Genius SB capsule.

3. Place the PillCam Genius link device 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 PillCam Genius link device from the protective case, refer to Figure 1.

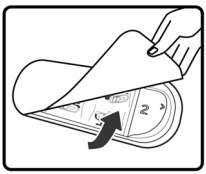


Figure 1. Opening the package

5. After removing the PillCam Genius link device from the protective case, note the device LED appears constant green. Place the PillCam Genius link device next to the protective case. Refer to Figure 2 for the location of the PillCam Genius link device LED light.

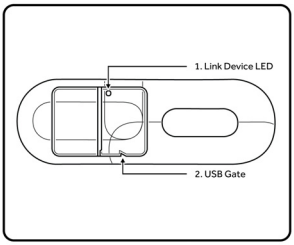


Figure 2. PillCam Genius link device LED and USB gate

Note

Do not remove the PillCam Genius SB capsule yet.

Applying the PillCam Genius link device:

Note

For remote procedures, the health care provider must have direct visualization of PillCam Genius link device placement and PillCam Genius SB capsule ingestion.

Note

Before applying the PillCam Genius link device, identify the following:

- Tabs on the rear (tabs 1-3) and front side of the PillCam Genius link device (tabs 4-7).
- Location of the LED light on the PillCam Genius link device. During the procedure, the PillCam Genius link device provides notifications including LED indications, vibrations, and sounds.

Warning

Improper placement of the PillCam Genius link device may result in loss of images. Refer to the instructions for correct placement of the PillCam Genius link device.

Warning

Do not touch the adhesive areas of the PillCam Genius link device.

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 PillCam Genius link device facing the healthcare provider, remove tab 1 from the rear of the device by gently pulling it down and to the left as shown in Figure 3.

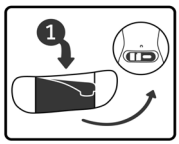


Figure 3. Remove tab #1 and apply PillCam Genius link device to body

3. Holding the PillCam Genius link device in the areas of tab 2 and 3, turn the device so the adhesive area is facing the patient's body.
4. Position the PillCam Genius link device such that the curved area at the top of the device is about 1 finger width below the navel.
5. Gently press the PillCam Genius link device 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.

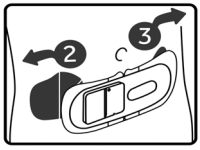


Figure 4. Remove tabs 2 and 3

Note

One hand should always be holding the PillCam Genius link device gently to the skin while the other hand removes the tabs.

7. With one hand, gently remove tab 4 on the front of the PillCam Genius link device. At the same time, use the other hand to smooth the adhesive to the skin. Repeat with tab 5.

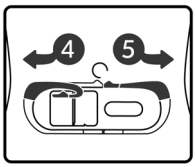


Figure 5. Remove tabs 4 and 5

8. Repeat step 7 with tabs 6 and 7.

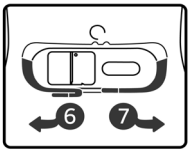


Figure 6. Remove tabs 6 and 7

Note

If, after applying the PillCam Genius link device, it detaches from the body the patient should:

- Avoid touching the adhesive areas.
- Attempt to re-apply the PillCam Genius link device in its original position.

Warning

- Immediately remove the PillCam Genius link device if the device heats up and causes discomfort.
- In rare cases, materials in the PillCam Genius link device could lead to skin injury or irritation including allergic reactions, burning sensations, desquamation, or peeling of the skin. Remove the PillCam Genius link device in the event of continuous skin irritation.
- Do not shower or bathe while wearing the PillCam Genius link device.
- After applying the PillCam Genius link device, the patient should avoid any physical activity or sport that involves sweating, bending, or stooping.
- Patients must not remove the PillCam Genius link device until the device has turned off and no LED light is on, or until instructed by the health care provider.

Note

The PillCam Genius link device will automatically shut down if it reaches the maximum temperature of 43 °C (109.4 °F).

PillCam Genius SB capsule guidelines

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

Note

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

- Keep the capsule in its package 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 package away from strong magnetic fields such as MRI devices.
- Keep metal objects away from the lid of the capsule package.

Note

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

PillCam Genius SB capsule ingestion

The PillCam Genius SB capsule is activated when it is removed from the capsule package. 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 15 minutes, or if the capsule is suspected to be defective, return the capsule and the PillCam Genius link device to the original packaging.
- Visually inspect the PillCam Genius SB capsule for defects or dirt before ingestion.
- Follow appropriate hygiene standards to ensure hands are clean before handling the PillCam Genius SB capsule.

1. Place the package on a flat surface as shown in Figure 7. Tear the sealing tab on top of the PillCam Genius SB capsule package to open the capsule package lid.

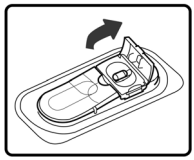


Figure 7. Open the PillCam Genius SB capsule package lid

2. Opening the PillCam Genius SB capsule package lid causes the PillCam Genius SB capsule LED to blink white.

3. Instruct the patient to gently hold the white area of the PillCam Genius SB capsule with two fingers, and carefully lift the capsule out of the package. Do not touch the transparent dome.

4. Ensure the PillCam Genius link device LED is blinking green and PillCam Genius SB capsule LED is blinking white.

5. Instruct the patient to swallow the PillCam Genius SB capsule with a sip of water. The ingestion procedure may take several minutes.

Note

After the ingestion of the PillCam Genius SB capsule, the patient should avoid direct exposure to bright sunlight.

Multiple procedures

When performing more than one PillCam Genius SB capsule endoscopy procedure in the same clinic, perform only one PillCam Genius SB capsule ingestion at a time with no other

active PillCam Genius SB capsule endoscopy kits present in the room to prevent signal interference with other procedures.

Warning
Do not allow multiple patients undergoing PillCam capsule endoscopy procedures to be in the same vicinity as each other. Patients should be at least 3 meters (9 feet) apart.

Monitoring procedure progress

PillCam Genius link device notifications and LED meaning

LED color	Attribute	Meaning
Green	Constant	The PillCam Genius link device is working. The procedure has not yet started.
Green	Blinking	The PillCam Genius link device is working. The procedure has started and the PillCam Genius link device and PillCam Genius SB capsule are paired.
Blue	Blinking	The PillCam Genius link device is transferring data to a workstation or tablet device.
Blue	Constant	Data transfer to the workstation is complete. The user can disconnect the PillCam Genius link device from the workstation and dispose of it.
Off	Off	The procedure is complete and the PillCam Genius link device can be removed from the patient's body.

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

PillCam Genius link device removal, return, and disposal

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

Removing the PillCam Genius link device

To remove the PillCam Genius link device, use one hand to gently pull one of the device edges toward the center of the PillCam Genius link device as shown in Figure 8. With the other hand, press down on the exposed skin to help separate the skin from the adhesive area.

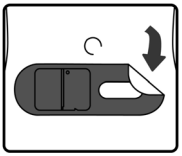


Figure 8. Removing the PillCam Genius link device

Returning the PillCam Genius link device

If the patient is not present at the clinic when removing the PillCam Genius link device, they will need to return the device to the clinic.

1. After removing the PillCam Genius link device, fold the device in half by folding the adhesive area of one side of the device onto the adhesive area of the other side of the device.

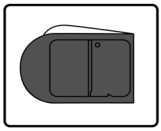


Figure 9. Folding the PillCam Genius link device

2. Insert the folded PillCam Genius link device into the plastic bag provided with the PillCam Genius SB capsule endoscopy kit.

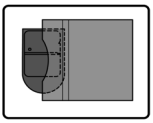


Figure 10. Insert folded PillCam Genius link device into plastic bag

3. Insert the plastic bag containing the PillCam Genius link device into the envelope provided with the PillCam Genius SB capsule endoscopy kit. Return the envelope to the clinic.

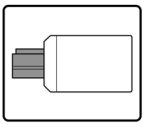


Figure 11. Insert plastic bag into envelope

Disposing of the PillCam Genius link device

After downloading data from the PillCam Genius link device, dispose of the device according to the applicable local regulations for electrical equipment disposal in the area.

Chapter 5

Troubleshooting

PillCam Genius link device troubleshooting

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

Problem	Possible cause	Action
PillCam Genius link device LED light doesn't turn green when taken out of package	Hardware fault	• Replace PillCam Genius SB capsule endoscopy kit • Contact customer support
PillCam Genius link device LED light doesn't blink green when PillCam Genius SB capsule is taken out of package	Hardware fault	• Replace PillCam Genius SB capsule endoscopy kit • Contact customer support
Difficulty removing adhesive tabs from PillCam Genius link device, tabs tear or rip when removing	Misuse or mechanical fault	• Peel off the tabs manually with minimal contact to the adhesive side • Replace PillCam Genius SB capsule endoscopy kit

PillCam Genius SB capsule troubleshooting

Problem	Possible cause	Action
PillCam Genius SB capsule LED light doesn't blink when taken out of package	Hardware fault	• Replace PillCam Genius SB capsule endoscopy kit • Contact customer support

Appendix A

System labeling

Symbol glossary

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

Symbol	Standard reference	Symbol title	Explanatory text
Rx only	21 CFR 801.109	For prescription use only	Indicates this is a prescription device.

	ISO 15223-1, Clause 5.7.7	Medical device	Medical device symbol
	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.
	ISO 15223-1, Clause 5.2.8	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	MDR (EU) 2017/745, Chapter II; Article 20 & Annex	CE Mark	Indicates conformity to European Regulation 2017/745 (MDR) - Chapter II; Article 20 & Annex V
	ISO 15223-1, Clause 5.1.1 EN 980, Clause 5.12	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Clause 5.1.3 EN 980, Clause 5.6	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Clause 5.1.4 EN 980, Clause 5.3	Use by date	Indicates the date after which the medical device is not to be used.
	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.
	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.
	ASTM F2503	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.
	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.
	47 CFR Part 15	Federal Communication Commission Number (FCC ID#)	Complies with United States Radio communication requirements.
	ISO 15223-1 Sec 5.3.8 ISO 7000-2620	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	IEC 60601-1, Table D.1, Symbol 2	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, in compliance to IEC 60529.

	ISO 15223-1 Sec 5.3.9 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.
	N/A	Do not use sharp objects	Indicates not to use sharp objects or box cutters to open the packaging.

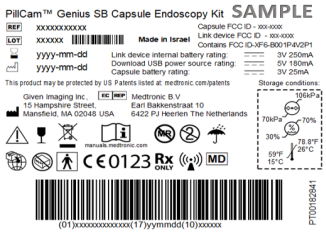
List of standards

1. ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
2. ISO 152231:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer
3. IEC 60601-1: 2005+A1:2012+A2:2020 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
4. ASTM F2503–23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
5. 21 CFR § 801.109 Prescription devices, 2016
6. MDR (EU) 2017/745 Regulation of the European parliament and of the council on medical devices.
7. 47 CFR Part 15 —Radio frequency devices
8. Directive 2012/19/EU, Waste electrical and electronic equipment (WEEE)

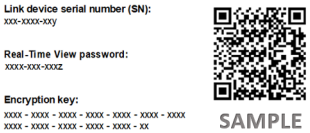
Labels

The following lists the labels attached to the PillCam Genius SB capsule endoscopy kit and protective case.

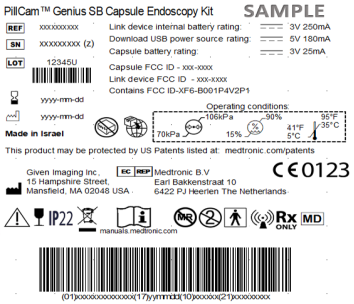
PillCam Genius SB capsule endoscopy kit labeling



QR label



PillCam Genius SB capsule endoscopy protective case labeling



Appendix B

System specifications

The following tables list specifications for the PillCam Genius SB capsule endoscopy kit, PillCam Genius SB capsule, and PillCam Genius link device.

PillCam Genius SB capsule endoscopy kit specifications

Properties		
Storage	Storage temperature	15-26 °C (59.0-78.8 °F)
	Storage atmospheric pressure	520-790 mmHg
	Storage relative humidity	30-70%
Operational	Operating time	11.5 hours
	Shelf-life	Up to 12 months

PillCam Genius SB capsule specifications

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	130° (Method B, per ISO-8600-3) 171° (Method A, at 1.0 mm per ISO-8600-3) 156° (Method A, at 4.5 mm per ISO-8600-3)
	Minimum detectable object	Greater than 0.07 mm
Operational	Frame rate	Either 2 or 5.5 fps
	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
	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 kHz

PillCam Genius link device 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	Up to 10 MHz
Transmitter	Operating frequency	13.56 MHz
	Bandwidth	300 kHz
	Modulation type	Frequency-linear chip
	Measured emission	Up to 90.5 dB[uV/m] at a distance of 3 meters
USB	Connector type	Type C
	Cable type	3
Bluetooth™*	Protocol	4.2
Wireless network	Protocol	802.11 n
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
	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

Warning
Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning
Portable RF communications equipment, including peripherals such as antenna cables and external antennas, should be used no closer than 30 cm (12 inches) to any part of the PillCam Genius SB capsule endoscopy kit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration - electronic emissions

The PillCam Genius SB capsule and PillCam Genius link device are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam Genius SB capsule and PillCam Genius link device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PillCam Genius SB capsule and PillCam Genius link device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PillCam Genius SB capsule and PillCam Genius link device are suitable for use in all establishments, including domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electronic immunity

The PillCam Genius SB capsule and PillCam Genius link device are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam Genius SB capsule and PillCam Genius link device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 5%.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrical fast transient/ burst IEC 61000-4-4	2 kV for power supply lines 1 kV for SIP/SOP lines	Not applicable (battery powered equipment without lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line to line 2 kV line to earth	Not applicable (battery powered equipment without lines)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T for 250/ 300 cycles	Not applicable (battery powered equipment without lines)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electronic immunity for home health and professional health care facility environments with ME equipment and ME systems

The PillCam Genius SB capsule and PillCam Genius link device are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam Genius SB capsule and PillCam Genius link device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Electromagnetic environment - guidance
IEC 61000-4-6 Conducted RF	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz) and amateur bands (1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz)	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz) and amateur bands (1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz) (Applicable for USB cable)

Immunity test	IEC 60601 test level	Electromagnetic environment - guidance
IEC 61000-4-3 Radiated RF	10 V/m 80 MHz to 2.7 GHz	[E] = 10 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	
IEC 61000-4-39 Immunity to magnetic fields in close proximity	8 A/m 30 kHz 65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	8 A/m 30 kHz 65 A/m 134.2 kHz 7.5 A/m 13.56 MHz

Recommended separation distances between portable and mobile RF communications equipment and the PillCam Genius SB capsule

The PillCam Genius SB capsule is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PillCam Genius SB capsule can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PillCam Genius SB capsule as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m] 150 kHz to 80 MHz $d = 1.2\sqrt{p}$	Separation distance according to frequency of transmitter [m] 80 MHz to 800 MHz $d = 1.2\sqrt{p}$	Separation distance according to frequency of transmitter [m] 800 MHz to 2.7 GHz $d = 2.3\sqrt{p}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m] 150 kHz to 80 MHz** $d = 1.2\sqrt{p}$	**Separation distance according to frequency of transmitter [m] 80 MHz to 800 MHz** $d = 1.2\sqrt{p}$	**Separation distance according to frequency of transmitter [m] 800 MHz to 2.7 GHz** $d = 2.3\sqrt{p}$
100	Not applicable	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note: • At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Recommended separation distances between portable and mobile RF communications equipment and the PillCam Genius link device

The PillCam Genius link device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PillCam Genius link device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PillCam Genius link device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m] 150 kHz to 80 MHz** $d = 1.2\sqrt{p}$	**Separation distance according to frequency of transmitter [m] 80 MHz to 800 MHz** $d = 1.2\sqrt{p}$	**Separation distance according to frequency of transmitter [m] 800 MHz to 2.7 GHz** $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note: • At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Declaration of Conformity with Radio and Telecommunications Terminal Equipment Directive

Hereby, Given Imaging, declares that this equipment is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

Appendix D

Worldwide radio communication- regulations datasheet

United States compliance

Brand: PillCam

Model: Genius SB capsule. FCC ID: O8PGSB

Model: Genius Link Device. FCC ID: O8PPATCH

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.

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

Note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help