PillCam™ SB 3 system

Patient Check-in

1. Open RAPID™ software v8.3. From the home screen, click on Patient Check-in.

2. A. Click the Recorder Bar to select recorder.
   B. Click Check-In Patient.

3. Enter procedure information and select SB Capsule type. Click Finish.

4. A. Confirm data and check Accept.
   B. Click Finish. PillCam™ recorder 3 is ready for procedure.

*These instructions are for PillCam™ recorder 3 with v28D firmware.
Preparation of Equipment and Patient

5. Place sensors on patient.

For 8-Lead Sensor Array for PillCam™ SB 3 Procedure

A. Place 8-lead sensor array according to Sensor Location Guide for SB Procedures.
B. Place PillCam™ recorder 3 pouch on patient and adjust shoulder and belt straps.

For Sensor Belt

A. Place sensor belt on patient over a single layer of clothing.
B. Place the downlink loop across the patient’s left shoulder and adjust to fit.
C. Place PillCam™ recorder 3 pouch on patient and adjust shoulder and belt straps.

6. A. Remove checked-in PillCam™ recorder 3 from cradle and confirm that it is charged.
B. If screen is off, use any navigation button to turn screen ON. If non-responding, push on/off.
C. Confirm match of patient and procedure data displayed on the LCD screen.

7. A. Connect the sensors to the PillCam recorder 3. A sound will play when the connection is made. If the sensor is not properly connected, the icon will appear on the screen.
B. Insert the PillCam™ recorder 3 into the pouch.
Preparation of Equipment and Patient (cont.)

8. A. Open the PillCam™ SB 3 capsule box and hold it with the blinking capsule close to the sensors on patient’s abdominal area to perform pairing.

B. The white capsule LED on the top of the PillCam™ recorder 3 will blink at the same rate as the capsule. The red unpaired icon on the upper right corner of the LCD will appear.

C. Use the navigation buttons to select the capsule ID on the screen that matches the one on the back of the capsule box.

D. Push the middle navigation button to pair the capsule with the PillCam™ recorder 3. After pairing, the green pairing icon should replace the red pairing icon. The capsule LED on top of the PillCam™ recorder 3 will blink blue at the same frequency as the recording rate.

9. A. Instruct the patient to swallow the capsule with a sip of water. **Patient should never ingest an unpaired capsule or the procedure will fail, resulting in lost data.** The green paired icon must appear on the upper right corner of the LCD before ingestion.

B. After operating in the paired mode for three minutes, the AFR symbol will replace the green paired icon.

C. Provide the patient with procedure instructions.

Instructions During Procedure

Post-ingestion Instructions for Patients

A. During the procedure, keep all sensor elements in place without removing them.

B. At the end of the procedure, the icon is displayed on the LCD.
Instructions During Procedure (cont.)

Real-time Viewing

A. To start Real-time Viewing, press the middle (1), left (2), and right (3) navigation buttons in that order.

B. Capture thumbnails with the right navigation button.

C. To exit Real-time Viewing, press the left navigation button.

Video Download from PillCam™ Recorder 3

10. A. Remove equipment from the patient, disconnect the sensor from recorder and place the PillCam™ recorder 3 into its cradle. Open RAPID™ software v8.3 and click Recorder Download from home screen.

B. Click the Recorder bar to select the recorder.

C. Click the Create Video button.

11. The video creation progress bar indicates time remaining.

A prompt will indicate that the video is complete.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Risk Information: The risks of the PillCam™ SB 3 capsule include capsule retention, aspiration, and skin irritation. Endoscopic placement may present additional risks. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. After ingesting the PillCam™ SB 3 capsule, and until the capsule is excreted, patients should not be near any source of powerful electromagnetic fields, such as one created near an MRI device. Passage of an intact patency capsule does not preclude the presence of an intestinal stricture or other pathology. Please refer to the product user manual or medtronic.com/gi for detailed information.