

QUICK REFERENCE GUIDE

Reading a PillCam™ COLON 2 capsule study in PillCam™ software v9.0E

Medtronic

Software basics: Home screen

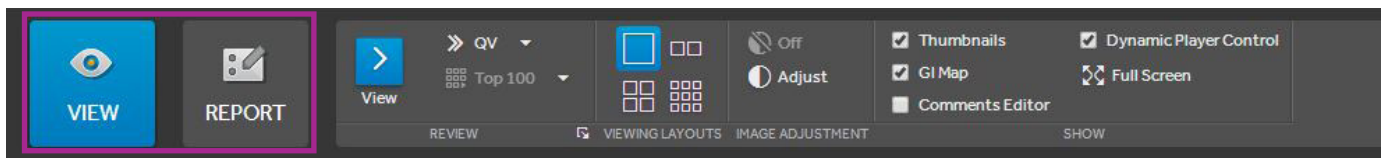
1. Open PillCam™ software version 9.0E from the home screen and enter your Windows login information, a software specific login username or password is not required, click on **View Study**.



To open a video, click on **Study Manager, Open Video, or Recent Videos**

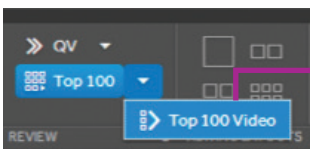
New toolbar

2. The new PillCam™ software v9.0E ribbon has two tabs: **View** and **Report**.

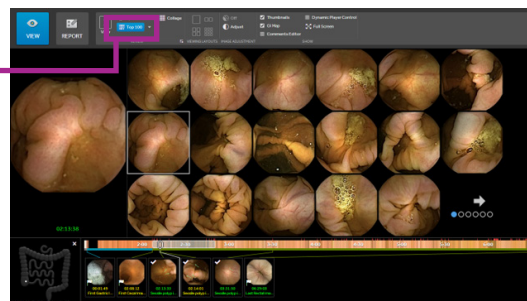


New feature: Top 100

3. The **Top 100** provides a preview of the 100 most clinically relevant images in a PillCam™ COLON capsule study, focused on frames that most likely contain ulcers, bleeding, or polyps.*



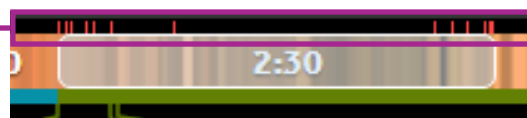
Images can be displayed as a short video



Images can be displayed as a page view

Scroll to see the rest of images

Red marks above the time bar show the Top 100 images



The GI regions are colored in a narrow strip below the time/color bar according to selected landmarks. The colon region color is green.

*Note: Top 100 feature is not intended to detect pathology in lieu of a physician and should not be used as a substitute for reviewing the entire video.

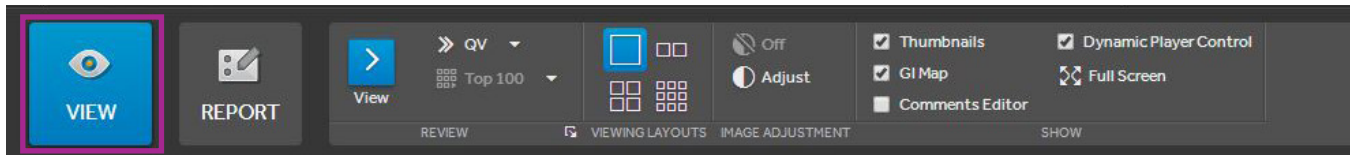
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View screen

The **View Screen** is for full study review, including segmentation of the colon in the GI Map.



Segmentation and the GI Map

To segment the colon, create thumbnails for the first cecal image, hepatic flexure, splenic flexure, and the last rectal image. Right click and select the image to identify your thumbnail.

Localization of the capsule is only an estimate. Use of reader defined landmarks may improve this tool. Discretion should be used when relying on the capsule progress indicator and localization tools to make diagnostic or treatment decisions.

Suggested landmarks

The **Suggested Landmarks** feature is available for procedures utilizing the sensor array. The feature provides suggested images of the hepatic and splenic flexure and is enabled once the first cecal image is marked.

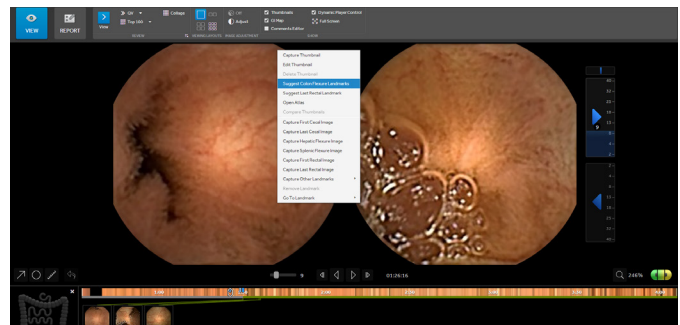
Right click and select the suggested colon flexure landmarks.

Thumbnails will appear with “? hepatic image” and “? splenic flexure”. Click on the hepatic flexure image, then right click and select the hepatic flexure label.

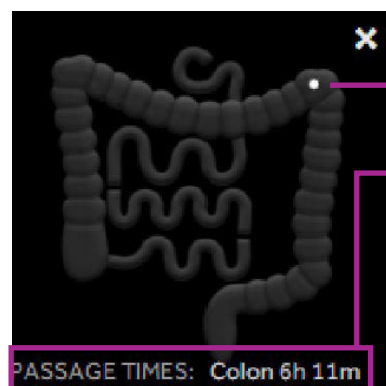
Repeat sequence with the splenic flexure image.

To identify a landmark without using the suggested landmarks feature: find your landmark image, right click over the image and select your label from the drop down list.

Once segmentation is complete, the GI Map is displayed along with the colon passage time.



Tip: Right click to see options for image selection.



Estimated capsule progress displayed as a dot on the map

Passage time for the colon is automatically calculated

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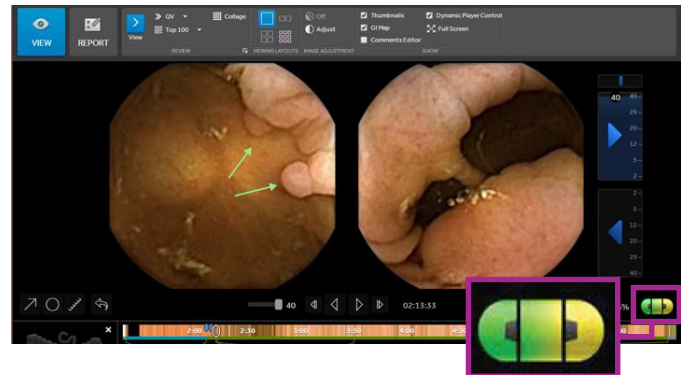
Step 1: preview

Objective:

Segment your colon by identifying your landmarks, while obtaining a quick overview of the video.

Method:

1. Set **QuickView** mode. ** 
2. Set double-head viewing (green & yellow) and read at the fastest speed you feel comfortable.
3. Identify the first cecal images, and then create a thumbnail of the hepatic flexure, splenic flexure, and capture the last rectal image.




**Note: QuickView is not intended to detect pathology in lieu of a physician and should not be used as a substitute for reviewing the entire video. Review of both QV and CQV is required for full video review.

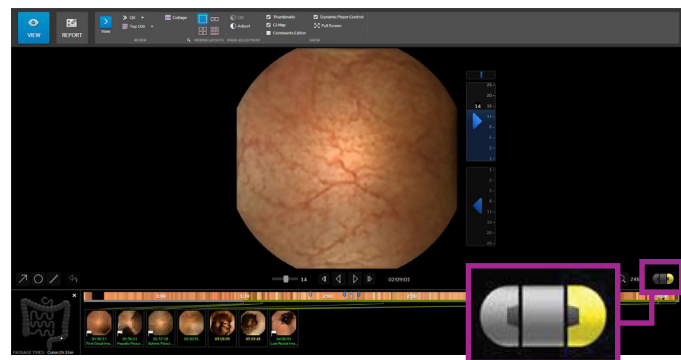
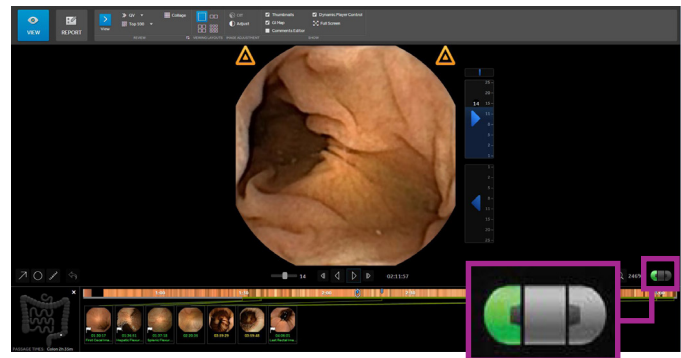
Step 2: review

Objective:

Review video, capturing thumbnails of suspected findings (cruise and capture).

Method:

1. Set **Standard View** mode 
2. Set single-head viewing, green capsule head, and read at a comfortable speed (8 fps is a good starting point).
3. Read from first cecal image to last rectal image with green capsule head capturing thumbnails of suspected findings along the way.
4. Reduce reading speed or scroll manually frame-by-frame when viewing complex anatomy or with rapid capsule movement, being on the lookout for single-frame findings.
5. When end of the video is reached, return to first cecal image.
6. Set to yellow capsule head and again read from the first cecal image to the last rectal image.



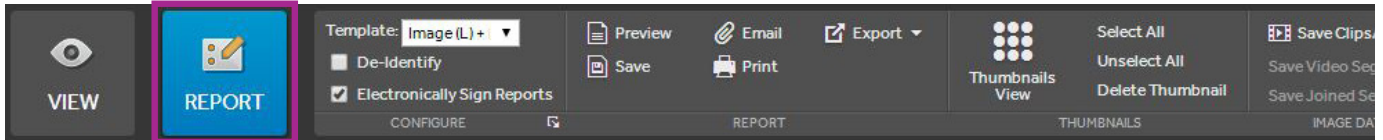
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Report screen

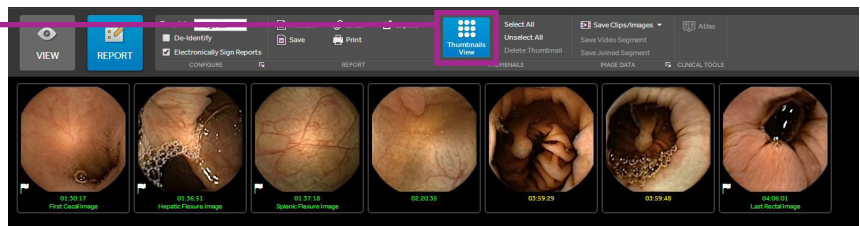
Choose **Report** icon to create a report.



Key features

Select **Thumbnails View** to review all thumbnails or choose **Select All** to include all thumbnails into the report.

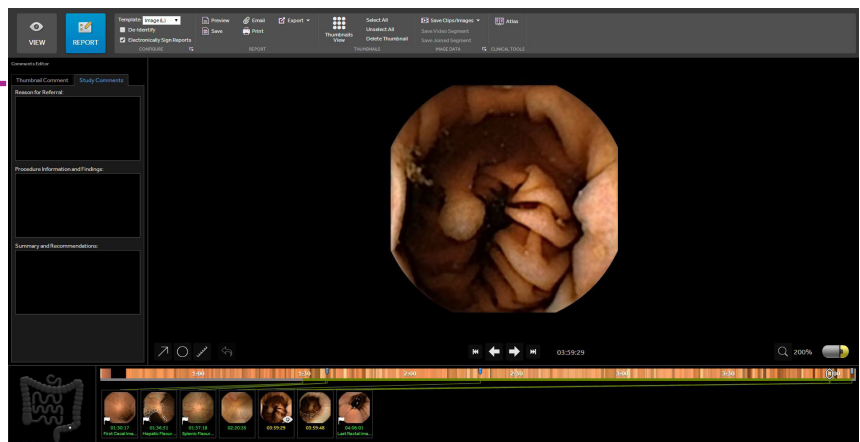
Select thumbnails for inclusion on report



Enter:

- Procedure information
- Findings
- Summary
- Recommendations

Preview report then save.



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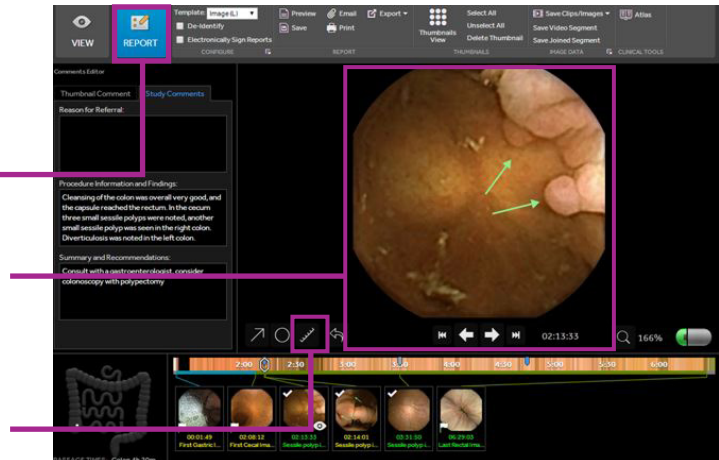
Step 3: analysis and report

Objective:

Analyzing captured findings and completing the study report.

Method:

1. Select **Report**.
2. Click on the thumbnail of suspected findings and scroll back-and-forth to view suspected findings from multiple angles and perspectives.
3. Click the ruler to enable the **Polyp Size Estimation Tool**. When using the polyp size estimation tool, locate the image of the polyp that shows the maximum polyp surface area.[†]
4. Enter comments for the reason for the referral, findings, and a patient summary.



† Note: The polyp size estimation measurement is only an estimate. Use discretion when making diagnostic or treatment decisions.

Tips:[‡]

- When possible, do not conclude findings based on a single image; scroll to additional images
- Use blood vessels and vascular pattern in decision-making
- Beware of folds mimicking polyps
- Beware of bubbles mimicking polyps and polyps appearing as bubbles
- Pay special attention to the cecum as the ileocecal valve can mimic a polyp

[‡] These tips do not replace proper training.

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™ COLON 2 capsule include capsule retention, aspiration, skin irritation, perforation, obstruction, mucosal injury, and bleeding. The risks associated with colon preparation are allergies or other known contraindications to any preparation agents or medications used for the PillCam™ COLON 2 regimen, according to laxative medication labeling and per physician discretion. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. After ingesting the PillCam™ COLON 2 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. The safety of the PillCam™ COLON 2 capsule has not been established in patients below the age of 18.

Please refer to the product user manual or medtronic.com/gi for detailed information.