



C-Scan[®] System

User Reference Manual

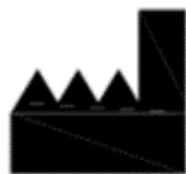
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Revision History

Document Number	Revision Number	Description	Revision Date
DOC000300	01	Initial release.	TBD
	0.92	Draft 2	28 March 2016
	0.93	Draft 3	12 April 2016
	0.94	Draft 4	9 Aug. 2016
	0.978	Draft 4 – IFU, Environ. Specs., Updated View section, beeps, screws	19 Nov. 2016
	01	Manuf. Declaration, Specifications, Troubleshooting	5 Dec. 2016
	02	No CE mark, Instead 'For clinical use only', no ingestion if pairing fails, View not in patient's zone, C-Scan® System (no 'imaging')	03 Jan. 2017
	03	Check-Cap address updated on front page	2017, Feb 28
	04	Updating the range of BMI criteria	2017, Mar 09
	05	View work station: updated display and interpretation flow chart	2017, June 5 th
	06	Limitation of procedure duration to 100 hours	2017, June 29
	07	Clarification on required actions in case of capsule retention and additional information for operating the C-Scan View. New EU Authorized Representative Revised disclaimer	2017, Aug. 30
	08	Add CE mark Revision of warnings, indication, risks and notes, following the response from the NB	2017, Nov. 12
	09	Activation by a pin in the batteries' compartment. Minor revisions of cautions and warnings Updated operation and GUI for the C-Scan View	2018 Jan 31
	10	Additional statements according to FCC guidelines	2018 July 19

1 Using This Guide

1.1 Purpose

This document describes the *C-Scan® System*. It is intended for Physicians, Nurses or Clinic Technicians who must manage a *C-Scan®* procedure. It includes information about:

- Indications, Contraindications, Warnings, Cautions
- Planning and Performing a C-Scan® Capsule Procedure
- Using C-Scan® View to Create the C-Scan® Reconstructed Colon Display
- Reviewing and Interpreting the C-Scan® 2D/3D
- Creating a C-Scan® System Report

1.2 Abbreviations, Acronyms, and Definitions

Definition/Acronym	Description
BIT	Built-In Test
BMI	Body Mass Index
CD	Compact Disc
CMT	Compton Scattering
EV	Expert Viewer
FIT	Fecal Immunochemical Test
IFU	Instructions for Use
mSv	Milli Sievert (X-ray dose units)
RF	Radio Frequency
SCA	Scan Control Algorithm
USB	Universal Serial Bus
XRF	X-ray Fluorescence

1.3 Conventions

Note	A note provides clarification, extra information, or refers to related material.
Caution	A Caution warns about possible damage to equipment.
Warning	A Warning warns about possible harm to person.
Contraindications	Specific situations in which the device and procedure should not be used because it may be harmful to the person

2 **Indications, Contraindications, Warnings, Cautions**

2.1 **Intended Use**

Check-Cap's *C-Scan*[®] *System*'s indication for use is as follows:

The *C-Scan*[®] *System* is intended to provide structural information on the endoluminal surface of the colon. It may be used to screen for suspicious findings in the colon.

Under this intended use, the *C-Scan*[®] *System* fits into the CRC screening paradigm as follows:

- A patient with a positive *C-Scan*[®] *System* test would be referred for optical colonoscopy.
- A patient with a negative *C-Scan*[®] *System* examination would be tracked in the following years

2.1 **Intended Users, Patients and Environments (e.g. home use, outside)**

The screening procedure is indicated for use by trained physician, familiar with all of the *C-Scan*[®] *System* operating procedures.

The *C-Scan* system is intended to examine people in the age of 18 years and older

Following the *C-Scan*[®] *Cap* ingestion and attaching of the *C-Scan*[®] *Track* to his back, the patient precedes with his/hers daily activities.

2.2 **Contraindications**

This screening procedure is indicated for use by average risk, asymptomatic population.

Contraindications for the *C-Scan*[®] procedure include:

- Not for use in pediatric populations (under 18 years)
- Patients with known or suspected GI related symptoms, complaints, or GI diseases such as:
 - ✓ Disorders of swallowing or difficulties with ingesting medications in tablets or capsules
 - ✓ Patients, where a concern for aspiration of the capsule exists (for example, due to cognitive or neurological deficits or a history of aspiration)
- Diffused diseases such as Ulcerative Colitis, Crohn's, or diverticulosis that might cause bowel strictures (per physician discretion)

- Patients with:
 - ✓ Dysphagia
 - ✓ IBD
 - ✓ Chronic constipation
 - ✓ Known motility disorder
 - ✓ Mega colon
 - ✓ Strictures and obstructions in the GI tract
 - ✓ Fistulas
 - ✓ Bowel hernia

- Subject with any condition believed to have an increased risk for capsule retention such as intestinal tumors, radiation enteritis, and incomplete colonoscopies due to obstructions or NSAID enteropathy, as determined by physician discretion
- Patients with positive result in FIT (blood in stool)
- Pregnant or nursing women. Women at child bearing age should use contraceptives during the procedure.
- Patients who underwent lower abdominal surgery in the past that might cause bowel strictures leading to capsule retention (per physician discretion)
- Patients with known delayed gastric emptying
- Patients with cardiac pacemakers
- Patients with advanced cancer or other life threatening diseases or conditions
- Morbid Obesity (BMI > 40) or very low BMI < 22
- Nuclear imaging procedure or any other medical procedure involved with radioactive isotopes within the past four (4) weeks
- A patient in course of radiotherapy
- Sensitivity to the Iodine contrast or severe kidney failure
- Patient with any known condition that precludes compliance with device instructions

2.3 Potential Adverse Events

Use of this device may have potential adverse events:

- Aspiration of the capsule
- Delayed or no excretion of the capsule
- Obstruction, perforation, and mucosal injury or bleeding

Note: There is a low risk of capsule retention, in the GI tract, for more than 300 hours. In some instances, intervention is required to remove the capsule. Intervention, based on the physician's decision and imaging of the capsule's location, may include: use of laxatives, fibers, removal by colonoscopy, or surgery.

2.4 Warnings

There is some risk in any medical examination or procedure. The information provided here is not replacing the need to consult with physicians regarding the proper diagnosis and course of treatment.

Indications, Contraindications, Warnings, Cautions

The following conditions may present a danger to the patient:

- Results obtained by the *C-Scan® System* do not exclude the presence of pathology and if symptoms persist, further evaluation should be performed.
- If the patient has had prior abdominal or pelvic surgery, or if intestinal fistulas, strictures, or stenoses are suspected, the physician should verify that the patient GI tract can tolerate an object the size of the *C-Scan® Capsule*.
- Physician should read the entire manual before using the system for the first time. A complete understanding of the technical principles, clinical applications, and risks associated with the *C-Scan® System* is required before using this product.
- To keep the patient from being exposed to unforeseen risks during passage of the *C-Scan® Cap*, provide the patient with a copy of the Instructions for Use and make sure the patient thoroughly understands the procedure.
- If there is any doubt about the integrity of the *C-Scan® Cap* or *C-Scan® Track* (*C-Scan® Kit*), for example, a broken seal on the outer box or on the inner capsule box, the Kit should be returned to its box and it should not be used until consulting with an authorized Check-Cap representative.
- The *C-Scan® Cap* and *C-Scan® Track* are for single use only.
- Do not use the *C-Scan® Cap* after its expiration date.
- Do not ingest the *C-Scan® Cap* if it was accidentally dropped on the floor. Consult with the authorized Check-Cap representative.
- Only one *C-Scan® Cap* should be ingested at a time and only after confirmation that no other *C-Scan® Cap* or ingestible diagnostic devices remain in the patient's body.
- Instruct the patient not to bite the *C-Scan® Cap* prior or during swallowing.
- The *C-Scan® Cap* should be ingested only after the synchronization test with the *C-Scan® Track* has been successfully completed (audible feedback).
- Instruct the patient to contact the physician immediately if, after ingesting the *C-Scan® Cap*, there is any abdominal pain, nausea, or vomiting.
- Instruct the patient to wear the *C-Scan® Track* throughout the procedure.
- Instruct the patient to stay with 2 hours driving distance throughout the procedure.
- Activities Not Allowed During the Procedure
 - ✓ Full-body immersion in water
 - ✓ Active sport
- CT or MRI machines. (Unless it is a medical emergency. Be sure to notify the medical team about the capsule and Track)
- Do not connect the cable between the *C-Scan® Track* and the *C-Scan® View* while the system is still attached to the patient's back.
- Store the *C-Scan® Cap* within the Kit box in a safe place, out of the reach of children and infants before ingesting and after excretion.
- When swallowing the *C-Scan® Cap* there is the 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 physician supervising the ingestion should act immediately to alleviate the condition.
- If a child has accidentally swallowed the *C-Scan® Cap*, seek immediate medical attention.



Indications, Contraindications, Warnings, Cautions

- A *C-Scan*[®] *Cap* should be ingested only in the presence of authorized medical personnel.
- Patients should carry with them the IFU and adhere to the instructions listed there.
- Undergoing an MRI while the *C-Scan*[®] *Cap* is inside the patient's body may result in serious damage to the intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of the *C-Scan*[®] *Cap*, the physician should be contacted for evaluation and possible abdominal X-ray before undergoing an MRI examination.
- The *C-Scan*[®] *Cap* and *C-Scan*[®] *Track* should only be stored in the original packaging before and after the procedure.
- Final diagnosis based on the *C-Scan*[®] *View* reconstruction should be made only by GI physicians who are trained in *C-Scan*[®] *System* operation.
- The capsule contains low levels of radioactivity and should therefore be disposed of according to local codes and regulations. The patients should be instructed that it should not, under any circumstance, be thrown into the trash.
- If the battery in the *Track* leaks and one of the ingredients gets into the eyes, do not rub them. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the chemical remains. Seek medical attention
- The *C-Scan*[®] *Track* is a delicate electronic device which should be protected from mechanical damage

Note

In order to avoid conditions that might impair the examinations, the subject should adhere to the instructions listed in the diary. The clinical team should verify that all required data is clearly registered in the diary when returned at the end of the procedure.

2.5 Cautions

The following conditions may damage the equipment or the procedure:

- Only trained personnel, familiar with all of the *C-Scan*[®] *System* operating procedures should use the system.
- Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment".
- 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..
- Do not immerse the *C-Scan*[®] *Track* in water or seawater. It can be damaged,
- Do not recharge the battery. It is not designed for recharging.
- Do not pierce the battery, or the *C-Scan*[®] *Track* with the battery installed, The battery may become damaged and deformed,
- Do not use or subject *the C-Scan*[®] *Track* to intense sunlight or hot temperatures such as in a car in hot weather. Its guaranteed performance will be lost and/or its service life will be shortened.
- The use of accessories, batteries, and cables other than those supplied or approved by Check Cap as replacement parts for *C-Scan*[®] *Track* components, may damage the system and void the warranty.

Indications, Contraindications, Warnings, Cautions

- RF communications equipment can affect the *C-Scan*[®] *Cap* and the *C-Scan*[®] *Track*.
- Use the system only with components purchased from or approved by Check-Cap Ltd. Use of other components may damage the system and void the warranty.
- During installation of the *C-Scan*[®] *View*, be sure to inspect the integrity of the power cables.

2.6 Benefits and Risks—C-Scan[®] System

2.6.1 Benefits

The following are advantages of the *C-Scan*[®] System as compared to other modalities:

- No colon preparation
- No diet or food restrictions
- No drugs
- Non-invasive
- No pain or discomfort
- No hospitalization
- No sedation
- Examination while patient continues normal daily routine
- After the patient swallows the *C-Scan*[®] *Cap*, data is transmitted wirelessly as the capsule passes through the digestive system. The data is captured and stored in the *C-Scan*[®] *Track* recorder worn by the patient; immediately after the procedure is complete the data can be downloaded to the *C-Scan*[®] *View* and reviewed by a physician.

2.6.2 Risks

- The *C-Scan*[®] procedure is not for everyone. *C-Scan*[®] *Cap* capsules are contraindicated in patients with known or suspected gastrointestinal obstruction, strictures or fistulas, in patients with cardiac pacemakers or other implantable electro medical devices, and in patients with swallowing disorders.
- There is a low risk of capsule retention, i.e., no excretion of the capsule after more than 300 hours. In some instances, intervention is required to remove the capsule. Intervention, based on the physician's decision and imaging of the capsule's location, may include: use of laxatives, fibers, removal by colonoscopy, or surgery.
- In patients with unsuspected strictures of the GI tract, the *C-Scan*[®] *Cap* can potentially cause intestinal obstruction resulting in the need for hospitalization and surgery.
- There is a low risk from the X-Ray radiation emitted from the capsule. The typical body dose is ~0.06 mSv (which is of the order of magnitude of the dose caused by a chest X-ray examination). During the majority of the time that the capsule is within the patient's system, radiation is not actively delivered to the patient. In total, the radiation exposure time (scan time) is up to 40 minutes of the typical 48-72 hours total transit time in the GI tract from ingestion to excretion.



Indications, Contraindications, Warnings, Cautions

- During capsule ingestion, there is a low risk of aspirating the capsule. All capsule procedures should be ordered by a trained physician, who must be present during the ingestion to ensure a smooth start to the procedure.
- The stickers placed on the back are made from biocompatible materials. After removal from the skin, once the test is completed, all marks should disappear within 24-48 hours. If redness or skin irritation remains after 48 hours, contact the clinic.
- Patients are instructed to ingest small amounts of iodine-based contrast material on a daily basis. Patients with kidney failure or sensitivity to iodine should refrain from the *C-Scan*[®] procedure.
- All medical procedures carry some risk. Information in this user manual should not be used as a substitute for consulting with your physician about diagnosis and treatment.

2.7 Accuracy of the Imaging Performance

C-Scan[®]-*Cap* imaging bench tests indicate the lower visibility limit at 5mm features. The probability of identifying a 10mm feature while moving at 5mm/sec is higher than 95%, when requiring visibility level greater than 3 (SNR) at standard imaging conditions: 30mm colon diameter and 3% Iodine concentration.

These metrics were measured at lab conditions on phantoms.

3 Welcome to the C-Scan® System

3.1 What is the C-Scan® System?

The C-Scan® System is an innovative, disposable, medical device that enables a patient friendly, painless, private, and accurate procedure for colorectal cancer screening. The system is designed to create a reconstructed three-dimensional image of the interior of the colon to enable detection of clinically significant suspicious findings with a high degree of sensitivity.

3.2 The C-Scan® System Process

The C-Scan® capsule is ingested by the patient and propelled by natural motility through the gastrointestinal tract and excreted naturally

The C-Scan® System procedure consists of the following steps:

- Preparing the patient and the system for the ingestion of the capsule
- Performing the capsule procedure
- Data download and 2D/3D images generation
- Review and interpretation by physician
- Preparation of a medical report and recommendation
- Patients should complete the daily diary throughout the procedure. The diary should be reviewed for completeness by the team in the clinic upon return of the C-Scan® Kit to the clinic

Note: The movement of the capsule throughout the GI tract is driven by the natural peristalsis of the bowel. Hence, the total transit time and the dynamics of the capsule propulsion are unpredictable and may substantially vary between patients.

3.3 C-Scan® System Components

The C-Scan® system is composed of:

- C-Scan® Cap

An ingestible capsule enabling intra-colon feature visualization, based on a radioactive source and an array of detectors.

- C-Scan® Track

An external Capsule Positioning System (CPS) that communicates with the C-Scan® Cap, and saves all procedure data. The C-Scan® Track attaches to the patient's back via adhesive skin patches.

- Algorithms

Uses these subsystems to calculate the C-Scan® Cap position (using electromagnetic signals generated within the C-Scan® Cap and the C-Scan®

Track), identifies C-Scan® Cap movements in the colon and correspondingly initiates C-Scan® Cap scans using a dedicated Scan Control Algorithm (SCA).

- C-Scan® View

A PC based Workstation that enables procedure data download from the C-Scan® Track, managing of patients' information, 2D and 3D colon imaging, report generation and printout, and storage/reload of procedure data to and from a CD.

A conceptual block-diagram of the system is shown in Figure 1.

Figure 1: C-Scan® System Key Components



3.4 C-Scan® Cap

Figure 2: C-Scan® Cap



The capsule is designed to be ingested without any cleansing of the colon and travels through the GI tract naturally, while the patient continues eating normally. The technology is based on a low dose radioactive sealed source embedded in the capsule, which emits X-rays through a rotating collimator circumferentially. The capsule's outer surface incorporates detectors, which are designed to collect the backscattered photons within the X-ray energy spectrum. To increase the contrast of the colon's walls and to differentiate them from its content, it is essential to increase the stool's contrast by ingesting regularly a small volume of radio-opaque material (Telebrix, Omnipaque, or equivalent) during the days of the procedure.

The capsule is designed to start scanning (rotating like helical CT) only when the capsule is propelled along the colon. While stationary (which is most of the time) the capsule is set at an idle mode and the radiation is blocked by the concealment mechanism. The transit time of the capsule in the colon may vary typically from 24-100 hours, depending on the personal bowel activity of the patient. The capsules are powered by internal batteries and are designed to operate up to 100 hours.

The capsule is excreted naturally and the patient is notified accordingly.

Welcome to the C-Scan® System

Caution: The C-Scan® Cap capsule transmits data to the C-Scan® Track at a specific frequency of 433.5 MHz \pm 127 KHz. Occasionally, interference from external devices transmitting in the same bandwidth may occur and consequently interrupt or limit the effective performance of the 2-way C-Scan® Cap - C-Scan® Track transmission.

Following are possible scenarios:

- Cellular telephones
- Car or house alarm: These systems operate with momentary transmissions. Depending on the proximity of the car or house alarm transmitter to the ingested capsule, there may be a momentary interference that is not likely to damage the data capture.
- Police/Fire station radio equipment: These systems may operate with a more extended transmission duration. Depending on the proximity of the car or house alarm transmitter to the ingested capsule, this may cause longer duration interference, possibly causing gaps in the data.

3.5 Handling the C-Scan® Cap

The C-Scan® Kit package is designed to ensure a 7cm radiation safety distance from the X-ray source. The capsule should remain in its sealed box in the C-Scan® Kit box until ingestion by the patient. This renders it safe for handling, with no special equipment or precautions necessary.

Since the collimator and concealment mechanism are in the idle state when the capsule is removed from the packaging, it remains safe to handle. Once ingested by the patient, the collimator switches to active (open) mode only when the system senses effective movement in the bowel. The typical calculated radiation effective dose of the C-Scan® Cap in active mode during the procedure is 0.06 mSv (calculated for a procedure of 72 hours with 30 min of active scanning).

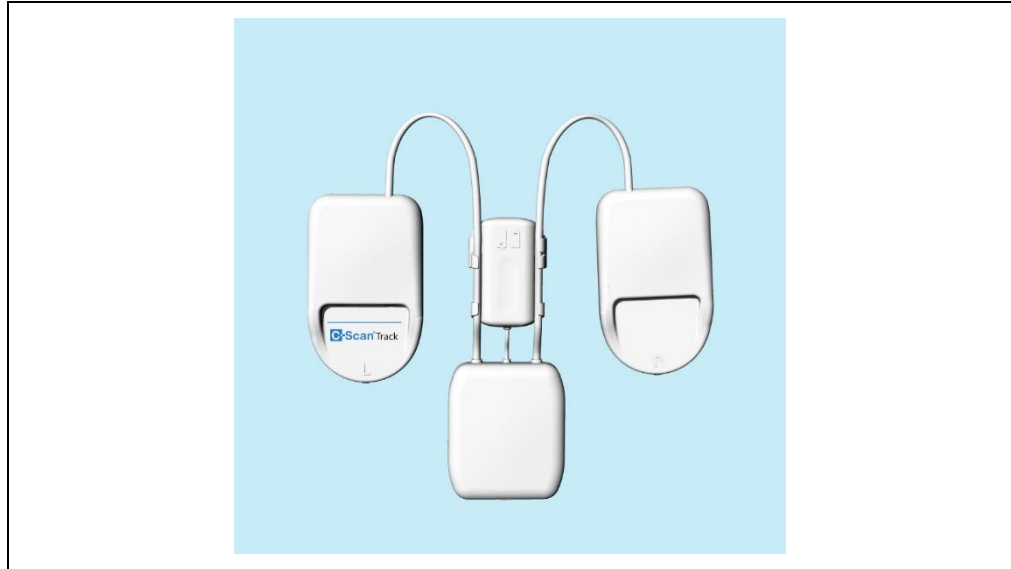
To avoid accidental activation of the capsule while in its box, please observe the following:

- Keep the C-Scan® Cap in its box until use.
- Store the C-Scan® Cap only in the packaging supplied with the product.
- Do not use a C-Scan® Cap if the packaging is damaged.
- Keep the C-Scan® Cap package away from strong magnetic fields (such as MRI devices).

3.6 C-Scan® Track

For full directions on using the *C-Scan® Track*, see Chapter 5: Planning and Performing a C-Scan® Capsule Procedure.

Figure 3: *C-Scan® Track*



The *C-Scan® Track* is an external device that tracks the *C-Scan® Cap* position, sends commands to the *C-Scan® Cap*, receives and stores imaging data sent by the *C-Scan® Cap*, and interfaces at the end of the procedure with the *C-Scan® View*.

The *C-Scan® Track* is a miniaturized and advanced subsystem consisting of the following units:

- *C-Scan® Cap* Positioning System - a localization device aimed to track and record the position and orientation of the *C-Scan® Cap*, enabling intra-colon mapping for the purpose of colon surface imaging
- Data Recorder - a computerized recording device aimed to capture *C-Scan® Cap*'s data (imaging, etc.), through RF communication during its transition in the GI tract to a non-volatile memory, and enable data retrieval through a communication line following procedure completion.
- Processing Unit – an embedded device aimed to control localization and recording functions while running an embedded Scan Control Algorithm through which the *C-Scan® Cap*'s scan mechanism is operated.
- User Interface Unit – Status indicators
- USB Interface Unit – Data retrieval from *C-Scan® Track*, for the purpose of clinical data upload to *C-Scan® View*, production testing, and serviceability.

The *C-Scan® Track* attaches to the patient's lower back.

3.7 C-Scan® View

The *C-Scan® View* is a dedicated PC-based workstation that imports procedure data from the *C-Scan® Track*, manages patient information, displays the 2D and 3D colon imaging, and generates a procedure report and a results CD.

The *C-Scan® View* main functions are:

- Load and display procedure information and data
- Images Review - enables the user to view the "colon" 2D/3D reconstruction
- Produce procedure's review report
- Store and view procedure results on a CD

Note: In the current system configuration, the *C-Scan® View* is not connected to the Hospital Information System nor to the internet. There is no transfer of patient data or demographics to or from the *C-Scan® View*.

The user (nurse/technician/physician) would use the *C-Scan® View* as follows:

- Log in to the *C-Scan® View*
- Connect the *C-Scan® Track* to the *C-Scan® View* using the supplied USB cable
- Start a new procedure:
 - Enter procedure's information, according to clinic/hospital records. Once a procedure is created, *C-Scan® View* processing is carried out automatically, including data loading, parsing (raw data processing), and reconstruction.
 - View the results in the graphics window
 - Review and search for clinical findings that need further intervention
 - Create a summary report and print it
 - Create a procedure results CD, which can be later loaded and viewed in any Check-Cap *C-Scan® View*

4 C-Scan® View Installation Guide

Note: System operation requires a dedicated space with:

- a table (at least 160cm X 70cm)
- a chair
- 3 power connections, compatible for use in the US or Europe
- Be sure to locate the C-Scan® View outside the patient zone (ingestion room)

The following instructions describe how to install the *C-Scan® View* PC sub-system.

Open the PC package and remove the Accessory Package, which contains the keyboard, mouse, and cables. See Figure 4 and Figure 5.

Figure 4: PC Package – with Accessory Package



Figure 5: PC Package – with Accessory Package Removed



Remove the PC from the package.

Remove the power cable from the Accessory Package and connect it to the PC. See Figure 6, Figure 7: , and Figure 8: .

Connect the other end of the power cable to the power outlet.

C-Scan® View Installation Guide

Figure 6: Accessory Package



Figure 7: PC Connection to Power 1

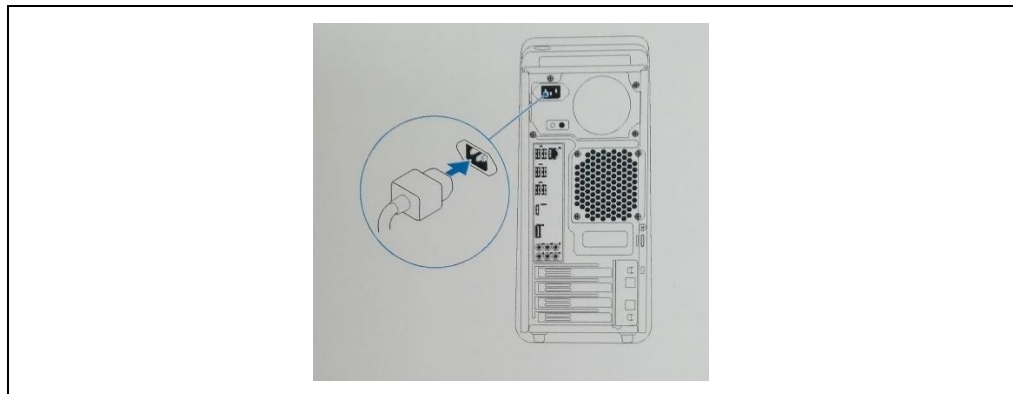


Figure 8: PC Connection to Power 2



Remove the mouse from the Accessory Package.

Figure 9: Mouse



Connect the mouse to any of the USB ports on the rear of the PC, as shown in Figure 10.

Figure 10: USB Ports



Remove the keyboard from the Accessory Package.
 Connect the keyboard to any of the USB ports on the rear of the PC, as shown in Figure 10.
 Prepare the monitor for operation, according to the monitor user manual provided in the monitor package.
 Open the monitor package.
 Remove the monitor from the package, as shown in Figure 11 and Figure 12.

Figure 11: Monitor Unpacking Instructions 1

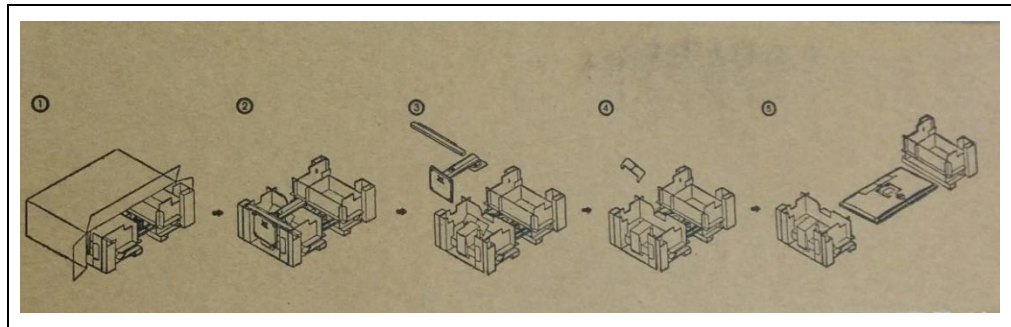
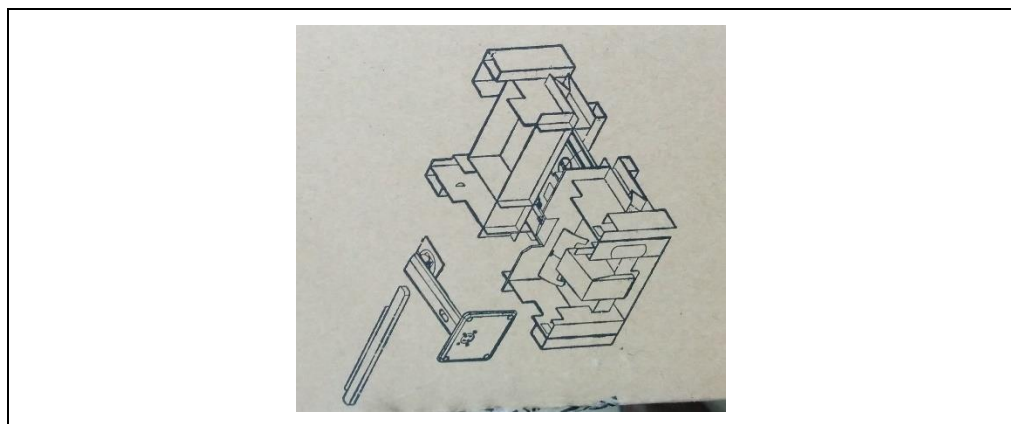


Figure 12: Monitor Unpacking Instructions 2



Remove the DVI cable and the monitor power cable from the Accessory Package, as shown in Figure 13 and Figure 14.

Figure 13: DVI Cable



Figure 14: Monitor Power Cable



Connect the DVI cable to the DVI connector on the monitor and to the DVI connector on the PC.
 Connect the monitor power cable to the power connector on the monitor and to the power outlet. See Figure 15 and Figure 16.

Figure 15: Monitor Connections

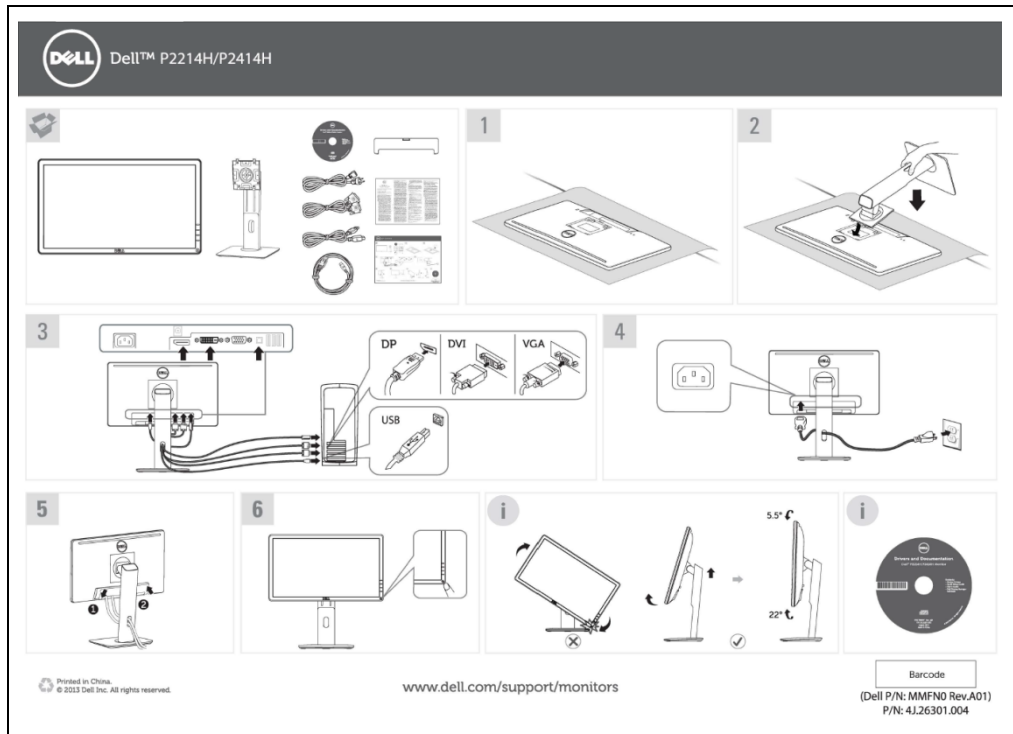


Figure 16: Monitor DVI Connection to PC

Prepare the printer for operation according to the printer user manual provided in the printer package.

Connect the printer power cable to the printer power connector and then to the power outlet.

Press the start button to turn on the printer.

Open the printer cover as shown in Figure 17 and insert the ink cartridges in the proper order. Close the printer cover.

Add paper as shown in Figure 18.

Figure 17: Printer

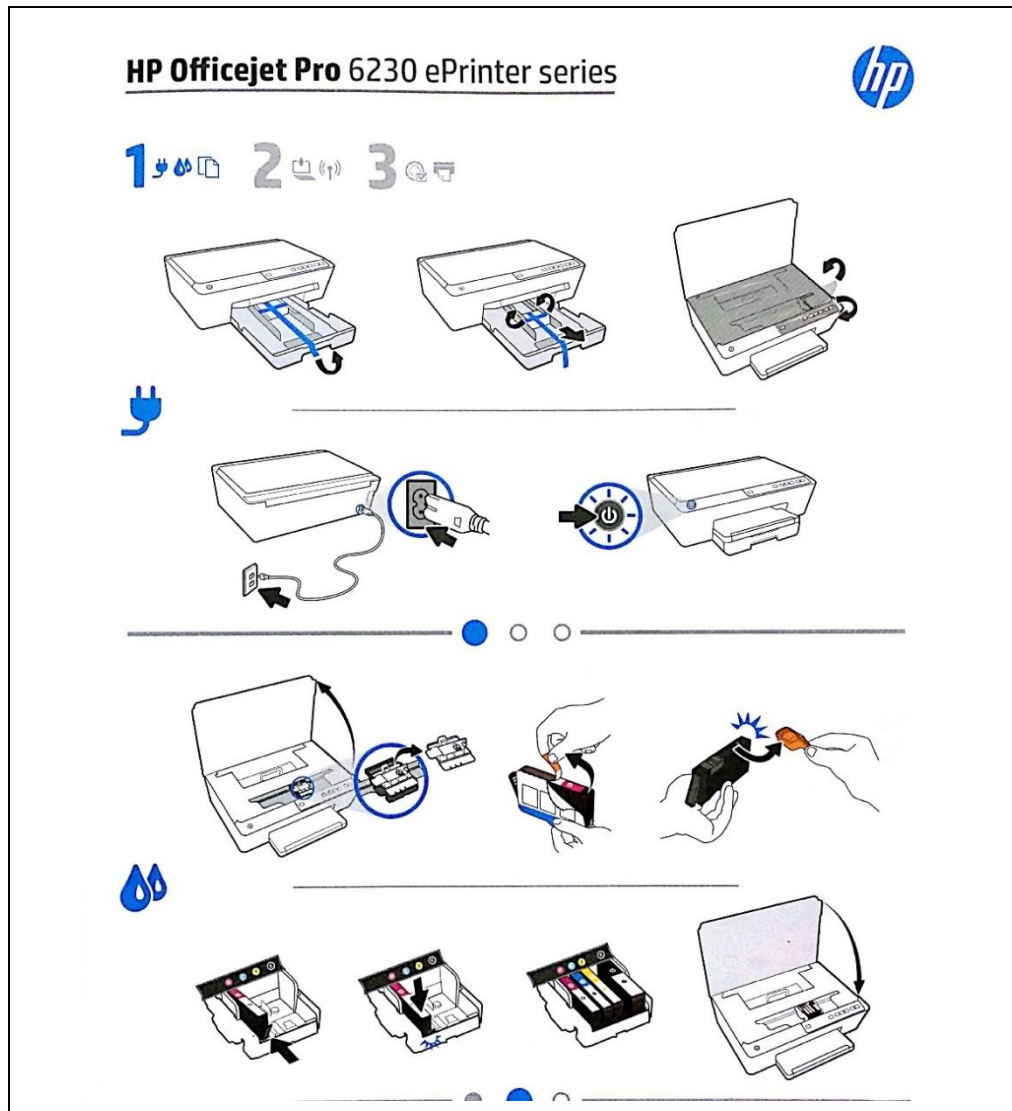
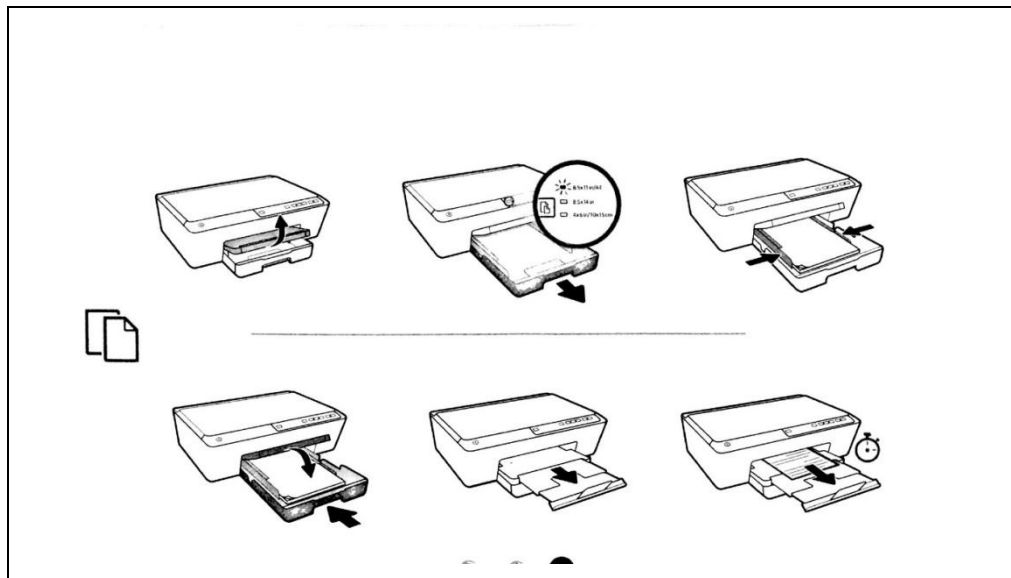


Figure 18: Printer (cont.)



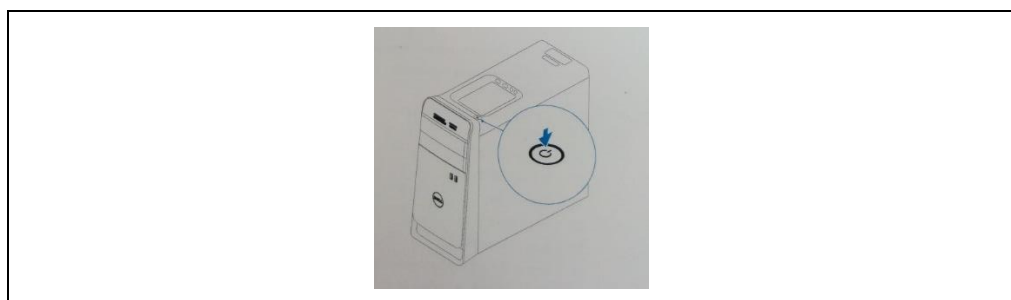
Connect the printer USB cable to the USB port on the printer (see Figure 19) and to any of the USB ports on the rear of the PC.

Figure 19: Printer Connection



Turn on the PC by pressing the power button (see Figure 20). Make sure printer and screen are on.

Figure 20: Power-on Button



Note: The work station is intended to be operated in an office setting similar to standard PC operation:

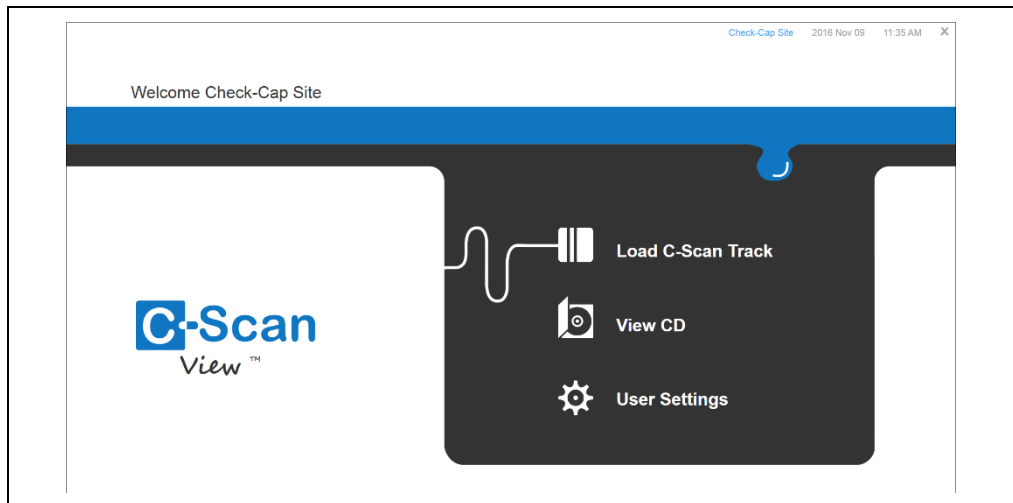
- Office desk - height 70-75 cm
- PC display - at eye level
- Keyboard & Mouse – on table top
- Printer - easily accessible by operator
- Annual maintenance needs to be performed in order to clean the hard drive and replace USB cable once every year

Figure 21: Fully Installed System



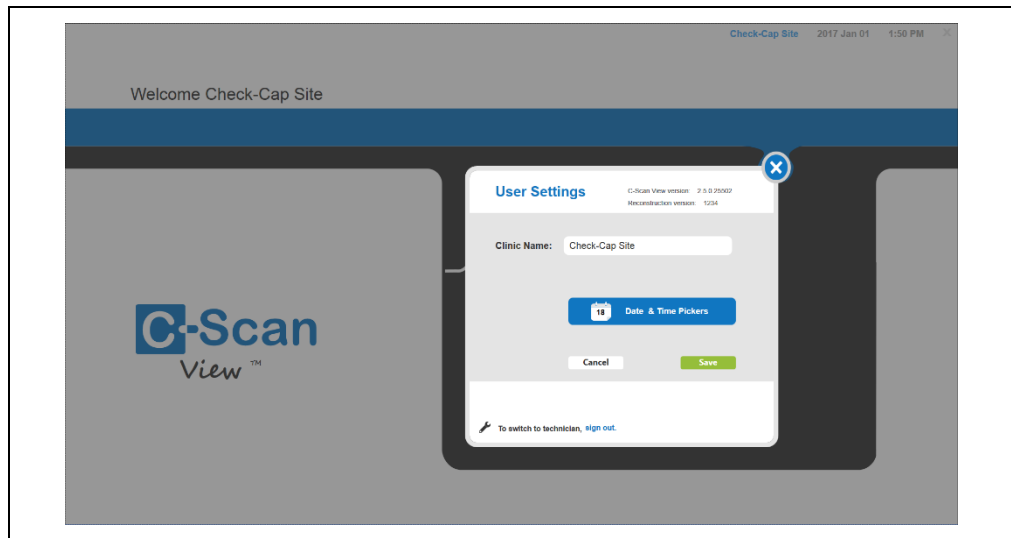
Upon system boot, the Welcome screen is displayed.

Figure 21: Welcome Screen



Click **User Settings** on the Welcome screen to open the User Settings window. The User Settings dialog opens, as seen in Figure 22. Edit the clinic name, time zone, date, and time, for use within the C-Scan® View application, with the User Settings dialog.

Figure 22: User Settings



Edit the Clinic Name.
 Change the date and time (click the Date & Time Picker icon). The Windows Date and Time window opens.
 Click Save to save all changes and to return to the Welcome screen. Click Cancel to discard the changes and to return to the Welcome screen.

5 Planning and Performing a C-Scan® Capsule Procedure

This section describes the steps for planning and performing a capsule procedure using the *C-Scan® System*. It includes the following information:

- Physician’s Preliminary Meeting with the Patient
 - Day of Procedure Meeting with the Patient
 - Ingesting the Capsule
 -
 - Review with the patient the content of the Bag and related documents.
- Discharge the patient.

- During the Procedure
- End of Procedure
- Post-procedure

Note: This document uses the terms physician and nurse or technician to identify the various tasks performed during a *C-Scan®* procedure. Tasks marked for Physician must be performed by a physician trained by Check-Cap. Tasks marked for Technician may be performed by a nurse, technician, physician’s assistant, or by the physician, depending on the particular clinic’s protocol.

5.1 Physician’s Preliminary Meeting with the Patient

Before scheduling a *C-Scan®* procedure and ordering the *C-Scan® System*, the physician should determine if the patient is a candidate for the procedure. The *C-Scan® System* is intended to provide structural information on colonic suspicious findings, lesions and masses.

The Check-Cap *C-Scan® System* is indicated for providing structural information on colonic suspicious findings, lesions and masses.

Under this indication for use, the *C-Scan® System* would fit into the CRC screening paradigm as follows:

- A patient with a positive *C-Scan® System* test would be referred for optical colonoscopy
- A patient with a negative *C-Scan® System* examination would be followed in the coming years as per the current standard of care in patients following CT Colonography

Importantly, imaging with the *C-Scan® System* is performed without bowel preparation, use of sedatives and/or anesthesia, or an invasive procedure with its associated risks and, all considerations when a patient is referred for optical colonoscopy.

Planning and Performing a C-Scan® Capsule Procedure

5.1.1 Guidelines for Determining Patient Suitability for the C-Scan® Procedure

This procedure is indicated for use by average risk asymptomatic population. These guidelines are designed to assist the physician in deciding whether to proceed with the C-Scan® procedure for any patient.

Note: The physician is ultimately responsible for making this decision. It should be made in accordance with these guidelines, clinic policy, and good medical practice.

To determine whether the patient should undergo the capsule procedure with the C-Scan® System, verify that no contraindications apply to the patient:

- The C-Scan® System is not for use in pediatric populations.
- The C-Scan® System is designed for use with subject's age of 18 and older.
- Patients with any known GI related symptoms complaints or GI diseases should not undergo this procedure. Symptoms may include (this list is not comprehensive and the physician should use his/her own judgement):
 - Chronic gastrointestinal bleeding
 - Diarrhea that does not resolve
 - Known or suspected intestinal obstruction, strictures or fistulas
 - Diffused diseases such as Ulcerative Colitis, Crone's, or diverticulosis
 - Swallowing disorders or difficulty ingesting medications in tablets or capsules
 - GI surgery within the past three (3) months
 - Bowel hernia
 - Abdominal surgery that might have caused bowel adhesions and strictures (physicians' decision)
- The C-Scan® System should not be administered to a patient with the following medical conditions:
 - A patient who underwent a nuclear imaging procedure or any other medical procedure involved with radioactive isotopes within the past four (4) weeks
 - A patient in a course of radiotherapy
 - A patient who uses an implanted or portable electro-mechanical device
 - Patients with cancer or other life threatening diseases or conditions
 - Pregnant women (to be verified by test in case of doubt)
 - Morbid Obesity (BMI > 40) or BMI < 22
 - Drug abuse or alcoholism
 - Patient's bowel movements are irregular: less than 2 -3 bowel movements /week
 - Patients with known cardiovascular and pulmonary diseases that limit their daily activities or are classified as life threatening
- Patients who work in an area with a high electromagnetic field should not be examined by the capsule.
- Patients allergic to the contrast agent. Contact Check-Cap for possible substitute contrast agents.

5.1.2 Planning the Procedure with the Patient

The physician should discuss all aspects of the procedure with the patient, including:

- Providing instructions to the patient regarding the preparations prior to ingestion.

Note: This information is also provided to the patient in the Patient Log, which includes tracking of the bowel movement 5-7 days prior to ingestions.



Planning and Performing a C-Scan® Capsule Procedure

- Discussing with the patient how to prepare for the procedure:
 - Skip breakfast on the morning of the procedure so that the stomach is empty. Coffee or tea or juice is permitted.
 - Take all medications as normal
 - Consult with the patient regarding the potential impact of concomitant routine drugs
 - Wear a loose fitting shirt. Women should not wear a dress, as the back must be exposed to attach the C-Scan® Track.
 - Familiarize the patient with all allowed activities, as indicated in Section 5.2.1.1 Activities Allowed by Patient.
 - Plan the daily activities during the procedure, avoiding those activities indicated in Section 5.2.1.2 Activities to be avoided by Patient
- Set the day and time for ingestion
- Verify that all accessories are in stock. See Chapter 12: Information for User for a list of accessories.

5.1.3 Order the C-Scan® System

See Chapter 9: Ordering the C-Scan® System for directions.

5.2 Day of Procedure Meeting with the Patient

5.2.1 Physician's Pre-procedure Meeting

On the day of the procedure, before administering the C-Scan® Cap capsule, the physician should discuss the examination with the patient, obtain the patient's approval, and have the patient sign the clinic's Informed Consent Form [ICF], (For clinical study only, not required for normal use of the device).

Prepare all the accessories and consumables in the patient's bag

Review all the steps involved in the procedure:

- Attaching the C-Scan® Track (described in Section 5.2.2: Preparing the Patient for the Procedure)
- Instruct the patient what to expect before, during, and after the procedure.
 - If the patient experiences any abdominal pain, nausea, or vomiting after ingesting the C-Scan® Cap capsule, the patient should immediately inform the medical staff.
 - If, within 4 days after capsule ingestion the capsule is not excreted, the patient should contact the physician.
 - If, within 2 days after capsule excretion, the patient experiences any post-procedure abdominal pain, vomiting, or other unexplained symptoms, the patient should contact the physician for evaluation.
- Instruct the patient if one of the adhesive stickers detaches from the patient's body to clean and dry the area and affix a new sticker from the C-Scan® Kit.
- Instruct the patient if the C-Scan® Track detaches from its sticker to reattach it to the sticker. The C-Scan® Track will restart recording once it is reattached.

5.2.1.1 Activities Allowed by Patient

The following activities are allowed before and during the procedure:

Planning and Performing a C-Scan® Capsule Procedure

- Eating normally before and after ingesting the capsule, except for skipping breakfast on the first day of the procedure.
- Continuing the daily routine: work, sleep, driving/riding in car or use of public transportation, sit, stand, walk
- Taking a shower (leaving the Recorder attached to the back)

5.2.1.2 Activities to be avoided by Patient

After ingesting the capsule and until its excretion the patient should avoid the following activities:

- Taking a bath, swimming, or hot tub (Jacuzzi)
- Active sport such as jogging, physical exercise in the gym, sauna, any ball-games, skiing, bicycle ride etc.
- Flights, boat trips, or long train travels
- CT or MRI procedures (unless it is an emergency, then be sure to notify the medical team about the capsule and Track).

5.2.1.3 Actions required to be taken by Patient

The patient must take the following actions through the entire procedure:

- Comply with the instructions given by the physician regarding the consumption of contrast material, fibers, or other food supplements.
- Ingest the contrast agent periodically as indicated. The contrast medium used in this procedure is water soluble Iodine (such as Telebrix or Omnipaque).
- Read the IFU before the ingestion and during the procedure. Keep it with you until the end of the procedure
- Keep the C-Scan® Track attached to the body at all times.
- Consult with the clinic with any medical or operational question or concern.
- Adhere to the limitations on activities as listed in Section 5.2.1.2 Activities to be avoided by Patient (and detailed in the IFU).
- Respond to the 'end of procedure' indication from the system by collecting the capsule from the stool and removing the C-Scan® Track from the back and placing it in the designated container.
- Return the C-Scan® Track to the clinic as early as possible.
- Be sure to collect and return all unused supplies
- Notify the clinic if no 'end of procedure' indication was received after 100 hours (4 days) post ingestion.
- Notify the clinic immediately if an error message was received from the C-Scan® Track.

Note: The capsule will send a special signal in case of a concealment malfunction (high radiation) in order to notify the patient and medical team.

- Notice bowel habits. Consult the clinic in case of major changes (constipation or diarrhea).
- Patient should call the clinic if there are any questions or doubts.



5.2.2 Preparing the Patient for the Procedure

Warning: All medical staff (technicians, nurses, physicians) administering the *C-Scan® System* must complete a basic training by Check-Cap before performing a procedure.

5.2.2.1 Verify that the Equipment is Available (Technician)

Before the patient arrives for the procedure, verify that the following equipment and accessories are available:

- *C-Scan® Kit* (as supplied by Check-Cap on a per patient basis), that contains:
 - *C-Scan® Cap* capsule (in a sealed box)
 - *C-Scan® Track* recorder with two AA Batteries installed
 - *C-Scan® Track* stickers (package of six)
 - *C-Scan® Instructions for Use (IFU)*
 - Patient Diary
 - A tool for tightening the screws
- *C-Scan® Track* Location Template (supplied by Check-Cap)
- The following items are purchased locally by the clinic and stocked for numerous procedures:
 - Water and drinking cup
 - Patient Bag with consumables (purchased by the clinic, according to Check-Cap recommendation):
 - Fiber Supplement
 - Contrast Agent
 - Stool Collection Device (5-7 units)
 - FIT Kit (For clinical study only, not required for normal use of the device)
 - Gloves
 - Plastic Tongs
 - Sealable Plastic Bags
 - Alcohol Wipes

Verify that the patient's informed consent is on file.

5.2.2.2 Physician's Procedure Meeting

1. Review the IFU with patient and repeat the highlights.

C-Scan® System: Instructions for Use (IFU)

Explain to the patient how to use the contrast material and the fiber supplement. One portion of each should be taken three times a day – morning, noon, and evening. They do not have to be taken in conjunction with meals. Explain to the patient to continue to take all medications as normal. Explain to the patient how to retrieve the capsule upon excretion. The patient should use a Stool Collection Device to collect each bowel movement. Even in cases that the *C-Scan® Track* does not indicate capsule excretion, the feces should be sifted for the capsule before dumping it in the toilet and flushing. Use the instructions in the kit for exact directions as to its use.

If the *C-Scan® Track* indicates that the *C-Scan® Cap* has been excreted, use the gloves and plastic tongs to retrieve the capsule. Clean the capsule under

Planning and Performing a C-Scan® Capsule Procedure

running water and place in the sealable plastic bag. Replace the bag and capsule in the *C-Scan® Kit* box and return it to the clinic.

Explain to the patient how to make entries in the Patient Diary.

5.2.2.3 Preparing the C-Scan® System for the Procedure (Technician)

1. Open the *C-Scan® Kit* cover. Verify that the seal is still intact. If the box has been opened, discontinue the procedure and contact Check-Cap for further directions.

Caution: Do not remove any components from the package at this time.

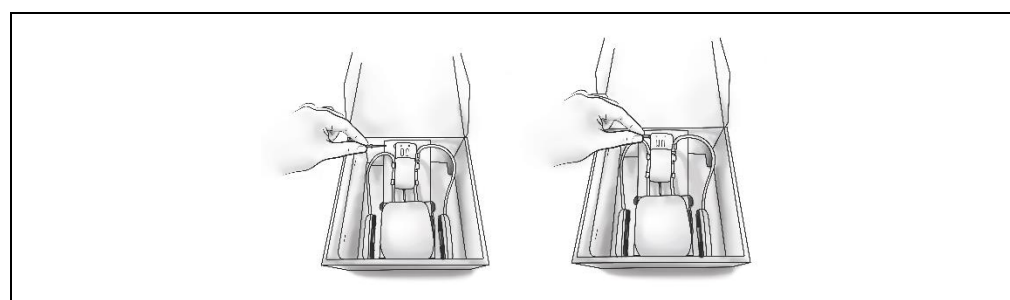
Figure 23: *C-Scan® Kit*



Take out the IFU and hand it to the patient.

Pull out the pin from the cover of the batteries' compartment to activate the Track. A beep is heard within 1 minute and the green LEDs will start blinking.

Figure 24: Activating the C-Scan Track



This activation initiates pairing of the capsule and the recorder. Pairing is performed before the *C-Scan® Cap* ingestion, and includes tuning of the *C-Scan® Track* to the specific *C-Scan® Cap*.

Once paired, the recorder will work only with this capsule. The system tests the communication between the capsule and the recorder and indicates success with an audible beep. A sequence of 5 repeated short beeps and blinking green lights on the *C-Scan® Track*.

If pairing fails, it is indicated by a **longer series of Beeps** (5 sec.). Please contact Check-Cap for possible actions. The physician should not allow the patient to ingest the capsule following 'pairing fails' notification



Planning and Performing a C-Scan® Capsule Procedure

Remove the *C-Scan® Track* and stickers from the *C-Scan® Kit* box. To attach the Recorder to the patient, you will need the following equipment:

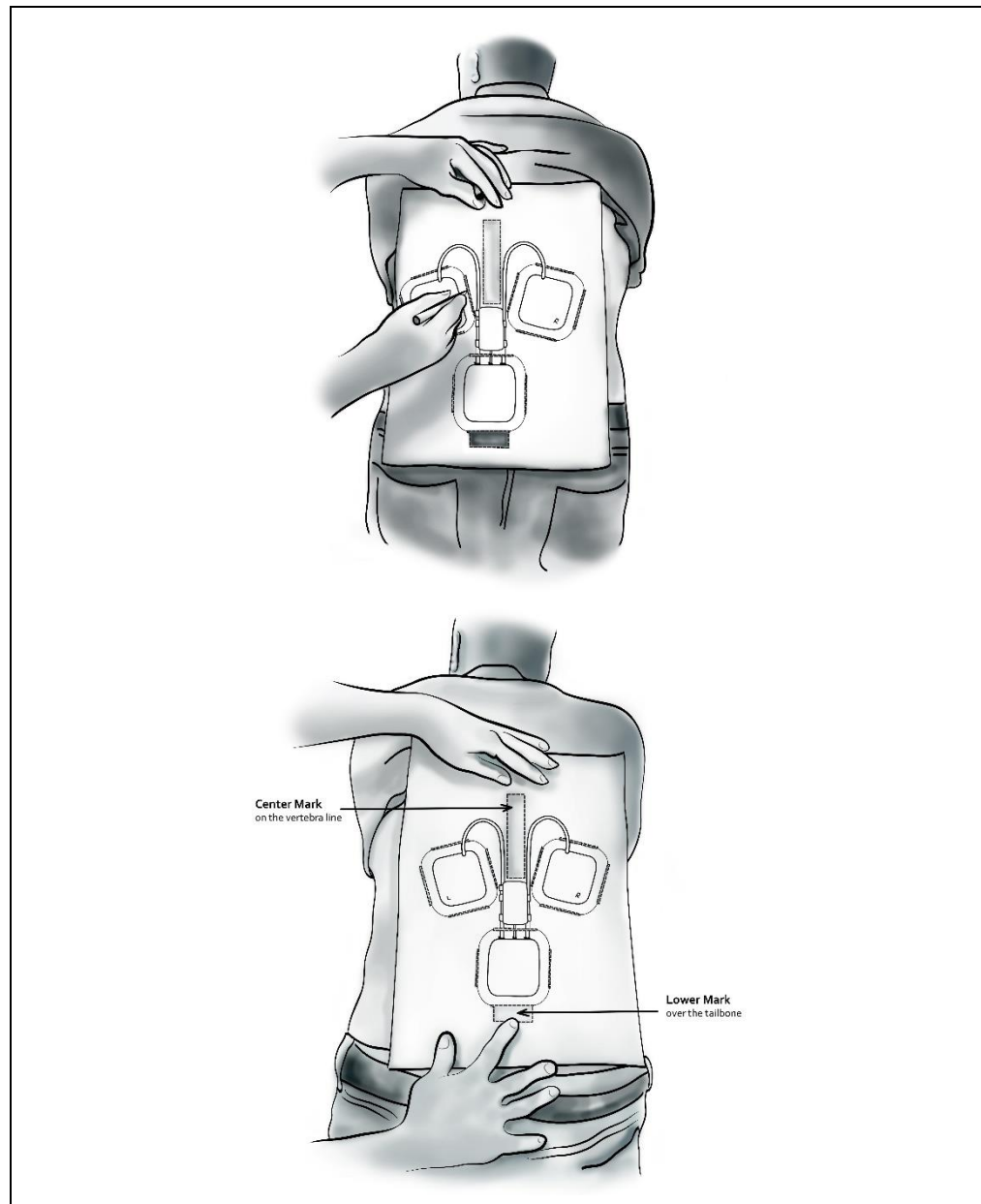
- *C-Scan® Track*
- *C-Scan® Track* Location Template
- *C-Scan® Track* stickers
- Razor and alcohol (not supplied), to shave the area of the sensors on the back

Note: The *C-Scan® Track* stickers must be applied directly to smooth skin for proper adhesion. Make sure there are no obstructions, such as hair. If needed, shave the area where the *C-Scan® Track* is to be attached.

- Remove overcoat, jacket, etc.
- Open the belt buckle and button of the trousers. Slightly lower the trousers.
- Pull up the shirt and expose the lower back.
- Place the *C-Scan® Track* Location Template on the patient's back and use a marker to mark the area where the *C-Scan® Track* should be attached.
 - Keep the center mark on the vertebra line.
 - Place the lower mark just above the bottom over the tailbone.

Planning and Performing a C-Scan® Capsule Procedure

Figure 25: Placing the Location Template

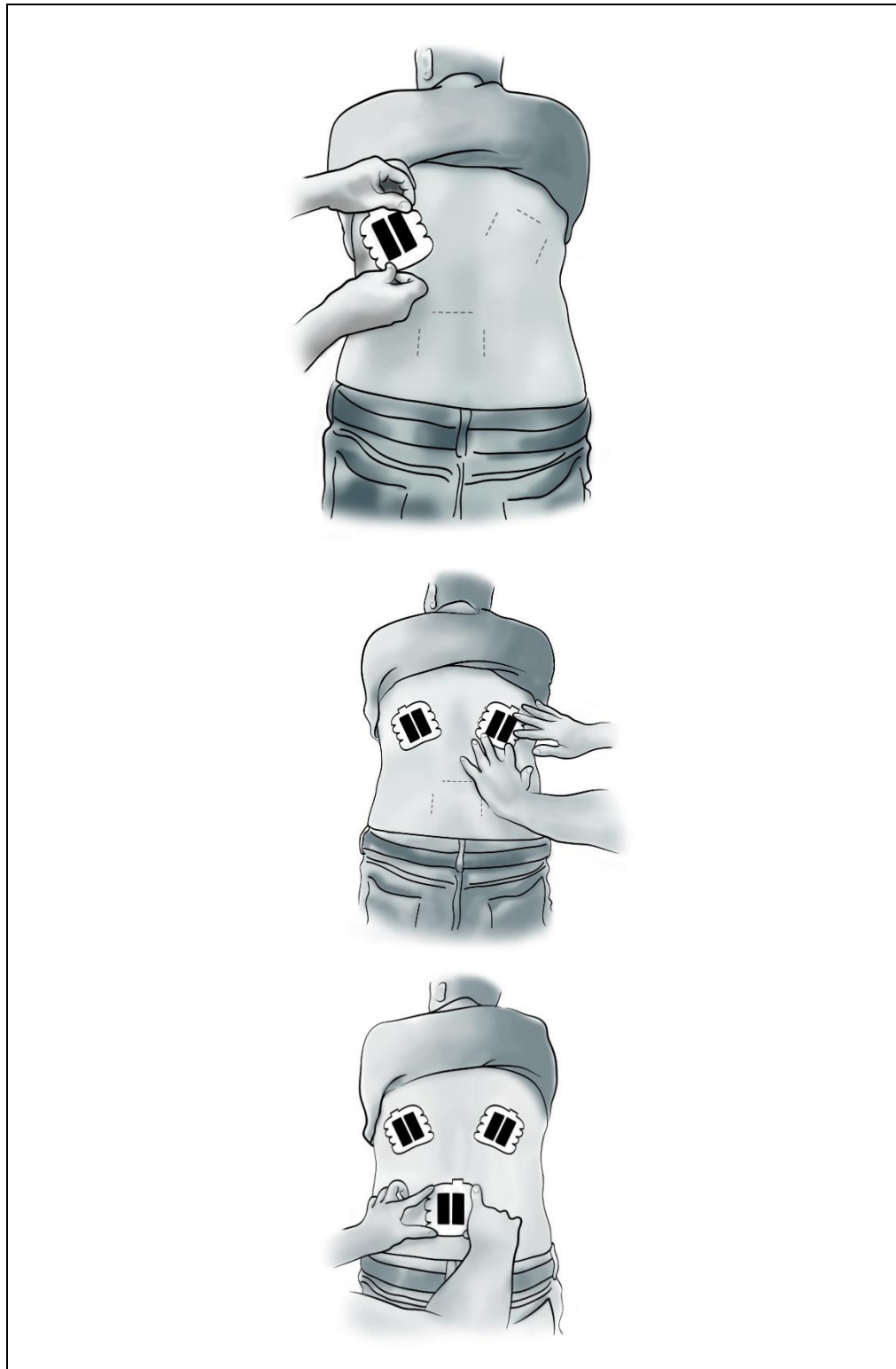


Remove the template.

Note: There are two size stickers. The smaller ones are used to affix the two top individual sensors, and the larger one to affix the bottom sensor/recorder unit.

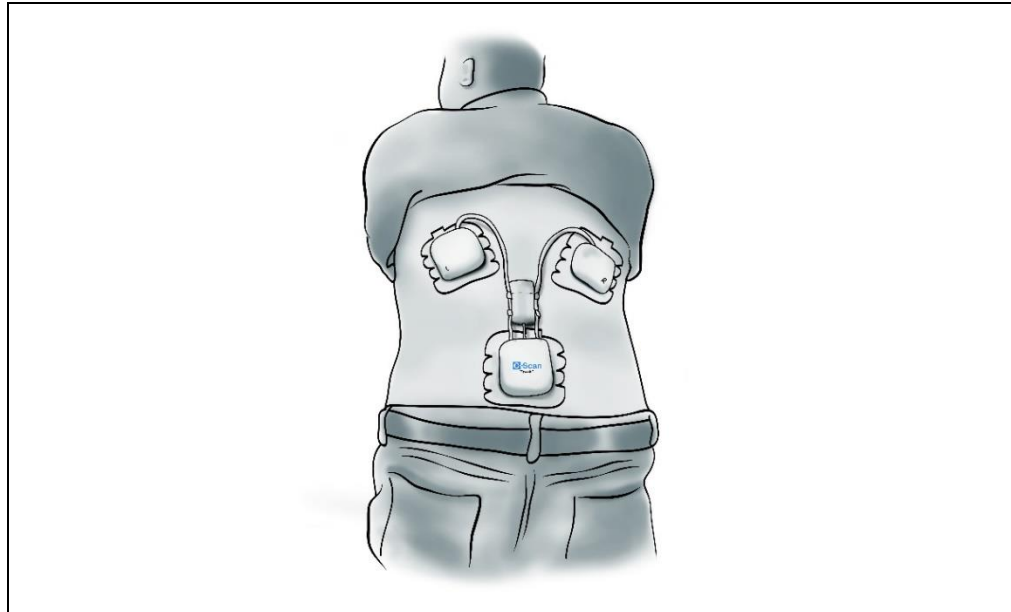
Have the patient slightly bend forward at a 45 degree angle. This helps ensure a strong adhesion during patient motion. Clean the area with alcohol. Remove the backing from a sticker and affix it to the patient's skin just above the buttocks according to the mark previously made. Repeat the same for the remaining two upper stickers.

Figure 26: Affixing the Stickers



Attach the lower recorder unit to the lower patch by pressing the unit so that the hook and loop fasteners engage.
 Attach the two upper units, left and right to the upper patches, press firmly to assure optimal fit.

Figure 27: Attaching the C-Scan® Track to the Patient's Back



Note the patient and procedure details in the clinic log for capsule procedures and in the patient's diary.

Let the patient get dressed and make sure that the patient is comfortable. Ensure there are no alarms from the C-Scan® Track recorders attached to the back.

Verify that the patient has the contact details in case of queries or any malfunction.

5.3 Ingesting the Capsule

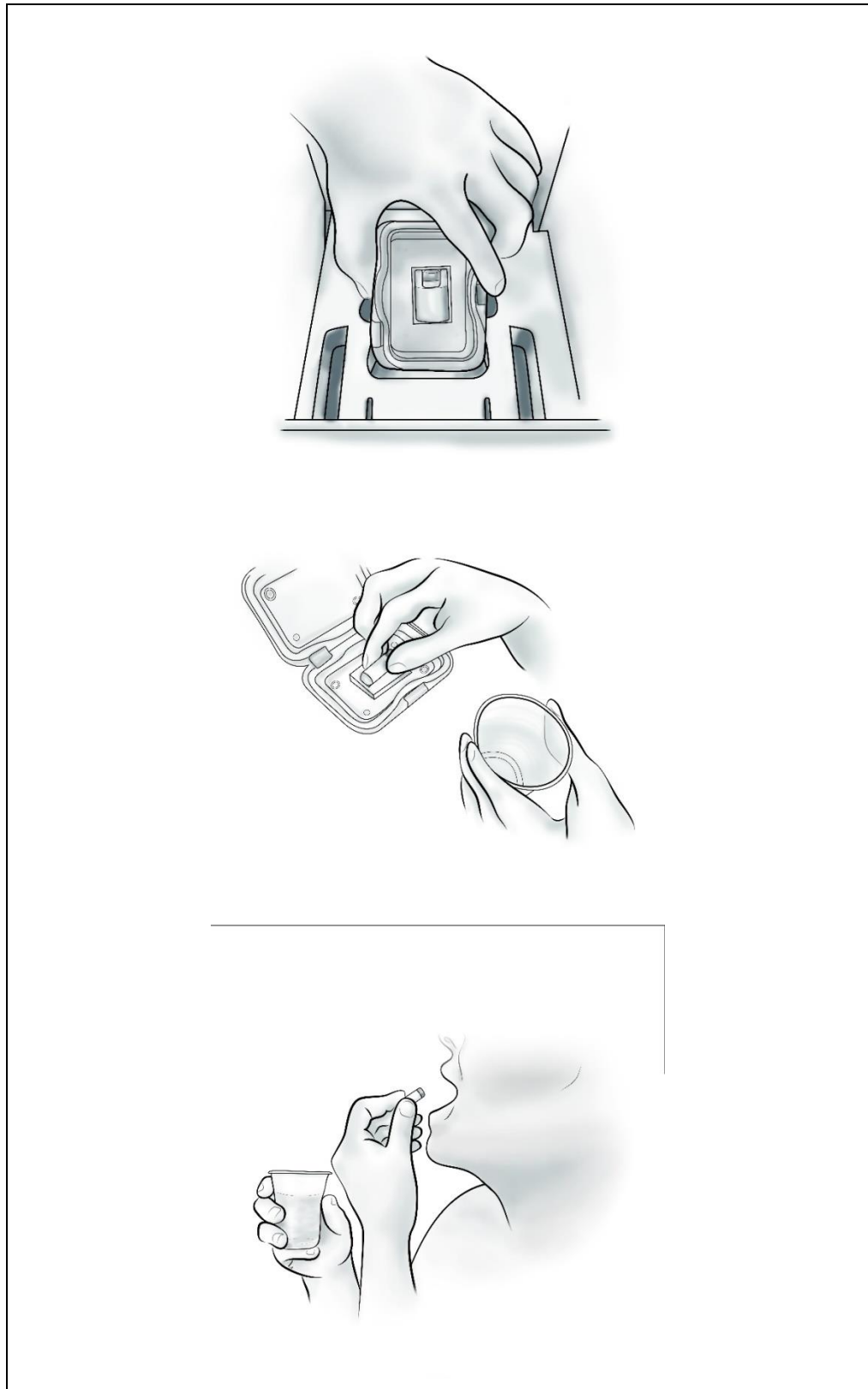
Fill a cup with contrast agent diluted with water and place it next to the patient. Hand the C-Scan® Cap sealed box to the patient. Verify that the seal is still intact. The patient should open the box by removing the "Remove before ingestion" label on the side of the box. **Note:** If the box has been opened, discontinue the procedure and contact Check-Cap for further directions.

The patient must open the box by releasing the blue clasp downward (preferably above a table) and remove the capsule. Make sure the patient does not squeeze the capsule.

Be sure to keep the box above a table or similar work top, to prevent accidentally dropping the capsule on the floor. If it falls – it must not be ingested

Explain to the patient that the capsule must not be bitten or held between the teeth, but rather it must be placed on the tongue until it is ingested.

Figure 28: Patient Taking the Capsule



Planning and Performing a C-Scan® Capsule Procedure

Have the patient swallow the capsule with some water (with contrast agent) and witness the smooth ingestion of the capsule.

Ask the patient to wait 5-10 minutes before leaving.

Verify that there have been no malfunction alarms from the *C-Scan® Track*.

Remember that there is no indication of normal operation, except for the absence of alarms.

Hand the patient the Patient Bag and the empty *C-Scan® Kit* box.

Review with the patient the content of the Bag and related documents.

Discharge the patient.

5.4 During the Procedure

The patient should do the following during the procedure:

- Take the contrast agent and the fiber supplement as directed. Record each intake in the patient log.
- List all meals in the patient log.
- List all bowel movements in the patient log. Use a Stool Collection Device with each bowel movement. Use the instructions in the kit for exact directions as to its use.
- Carry a Stool Collection Device with you when you leave the house (to work etc.). Be sure to take the Kit box with you to store the retrieved capsule in it.

The clinic team (technician and/or physician) should contact the patient every 1-2 days to ensure adherence to procedure instructions. Enter each contact into clinic's patient record.

Note: The clinic team (technician and/or physician) should contact the patient ~100 hours after ingestion, in case the capsule has not been excreted and collected already. They should discuss with the patient the possibility of lost capsule (in the toilet) and consider inviting the patient to the clinic for abdominal X-Ray to assure it is already out of the body. In some instances, intervention is required to remove the capsule. Intervention, based on the physician's decision and imaging of the capsule's location, may include: use of laxatives, fibers, removal by colonoscopy, or by surgery.

5.5 End of Procedure

The procedure concludes upon excretion of the *C-Scan® Cap*. When the capsule is excreted, the *C-Scan® Track* indicates the end of the procedure with a series of 4 short beeps.

When the *C-Scan® Track* indicates that the *C-Scan® Cap* has been excreted, use the gloves and plastic tongs to retrieve the capsule. Clean the capsule under running water and place in the sealable plastic bag. Replace the bag and capsule in the *C-Scan® Kit* box and return it to the clinic.

Note : If the Kit box is not with you, be sure to wrap the capsule with any soft padding to protect the delicate medical device and place the bag with the capsule in an alternative container of the same size as the Kit box.

Keep the container away from the body. Do not put the capsule in your pockets.

Figure 29: Placing Capsule in Sealable Plastic Bag



Record the end of the procedure in the Patient Log.

5.6 Post-procedure

5.6.1 Patient Post-procedure Actions

1. Place the retrieved *C-Scan® Cap* capsule in the sealable plastic bag, seal the bag, put it in the capsule box and then in the capsule box holder in the Procedure Box.

Remove the *C-Scan® Track* from the stickers.

Replace the *C-Scan® Track* in the original *C-Scan® Kit* box. Do not remove the batteries.

Remove the stickers from the back and discard them.

Place the completed Patient Diary in the Patient Bag.

Replace all unused vials of contrast agent and fibers in the Patient Bag.

Return the *C-Scan® Kit* and the Patient Bag to the clinic (in person or by messenger).

5.6.2 Technician Post-procedure Actions

1. Receive the *C-Scan® Kit* and Patient Bag from the patient.

Remove the *C-Scan® Track* from the box, verify the ID number and procedure details.

Leave the *C-Scan® Cap* in the box. It will be disposed of later, together with the *C-Scan® Track*, according to local codes & guidelines. See Section 9.2: Returning the *C-Scan® Cap* for instruction.

Review the completed patient diary and verify patient adherence to the instructions. Pay special attention to the notes on the contrast material.

Connect the *C-Scan® Track* to the *C-Scan® View* workstation for data download, using the supplied USB cable. (See Chapter 6 for directions on creating the *C-Scan®* reconstructed 3D display).



Planning and Performing a C-Scan® Capsule Procedure

Note: The download and reconstruction process is typically completed in 60 minutes or less.

Verify that the *C-Scan® Cap* is in the *C-Scan® Kit* box.

5.6.3 Physician Post-procedure Actions

2. Review the patient clinical data in all optional modes of presentation. See chapter 7 for a complete description of using the *C-Scan® View* program. Search for clinical findings, add annotations and interpretation. Prepare a clinical report.

Note: Review of the reconstructed images and interpretations should typically be completed in 10-15 minutes (by trained physicians).

6 Using C-Scan® View to Create the C-Scan® Reconstructed Colon Display

C-Scan® View is a proprietary application that reconstructs the raw data from the C-Scan® Track to a viewable format for review and analysis by the physician. It is installed by Check-Cap on a PC supplied by Check-Cap.

Caution: The C-Scan® View workstation is designed to be used only with the C-Scan® System. Connecting any other devices or peripherals not defined in this document can cause it to malfunction.

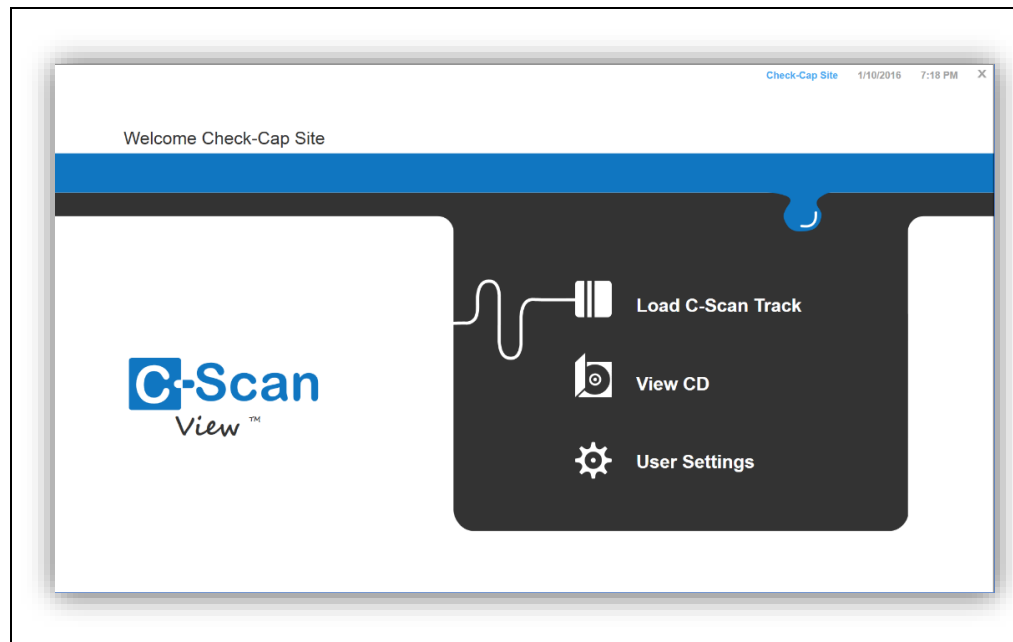
C-Scan® View imports procedure data from the C-Scan® Track, displays the 2D/3D colon reconstruction, and generates a procedure report and a results CD.

The C-Scan® View is comprised of the following components:

- PC with CD R/W drive and USB port
- Monitor, Keyboard, Mouse
- Printer

Upon system boot, the Welcome screen is displayed:

Figure 30: C-Scan® View Welcome Screen



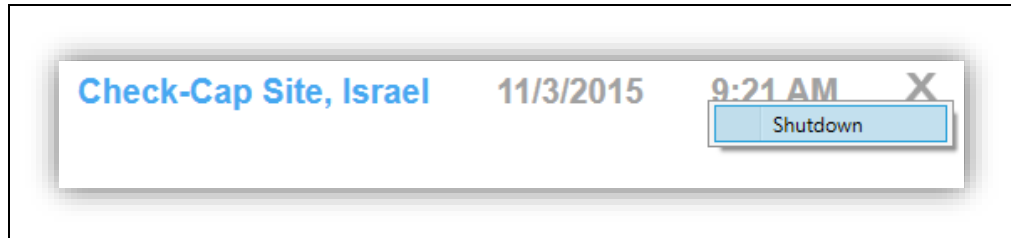
The user can:

- Load data from a C-Scan® Track
- Review a previous procedure saved on a CD
- Change settings

Using C-Scan® View to Create the C-Scan® Reconstructed Colon Display

- Click the X to close the Welcome screen. This opens the **Shutdown** button. Click **Shutdown** to shut down the PC.

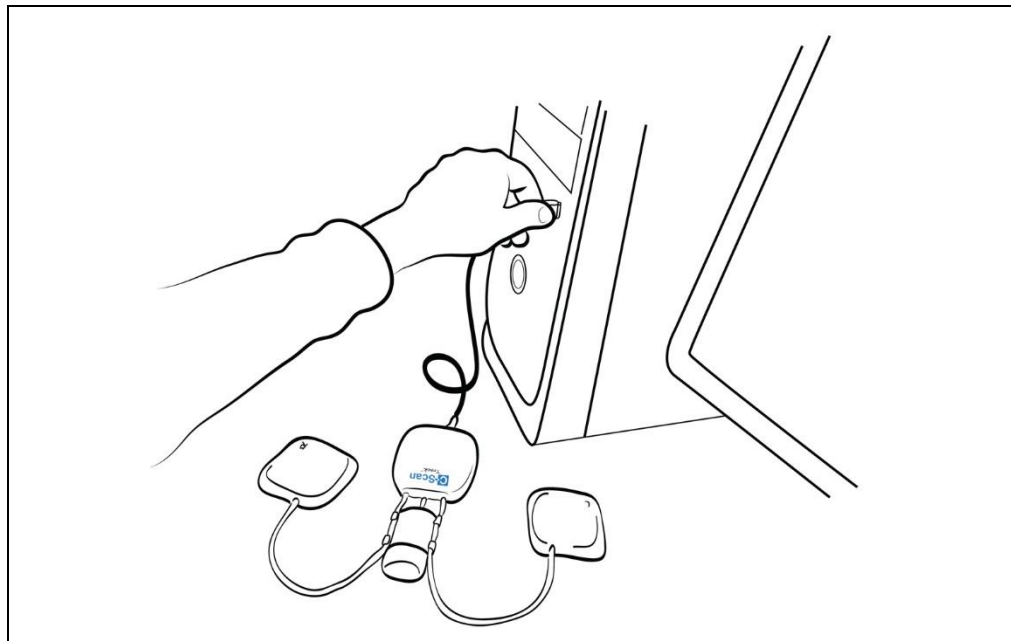
Figure 31: Shutdown



6.1 C-Scan® Track Download

To download the procedure data into the *C-Scan® View* and start a new procedure analysis session, connect a *C-Scan® Track* (only one) to the *C-Scan® View* using the included USB cable, and click **Load C-Scan® Track** on the Welcome screen.

Figure 32: Connecting the C-Scan® Track to the C-Scan® View



Once a *C-Scan® Track* is connected and **Load C-Scan® Track** is clicked, the *C-Scan® View* starts a new procedure process.

If **Load C-Scan® Track** is clicked and the download fails for any reason, the *C-Scan® View* displays the following notification: "Failed to connect to C-Scan® Track. Please check C-Scan® Track connection". Check the *C-Scan® Track* connection to the PC and click **OK** to close the message and return to the Welcome screen.

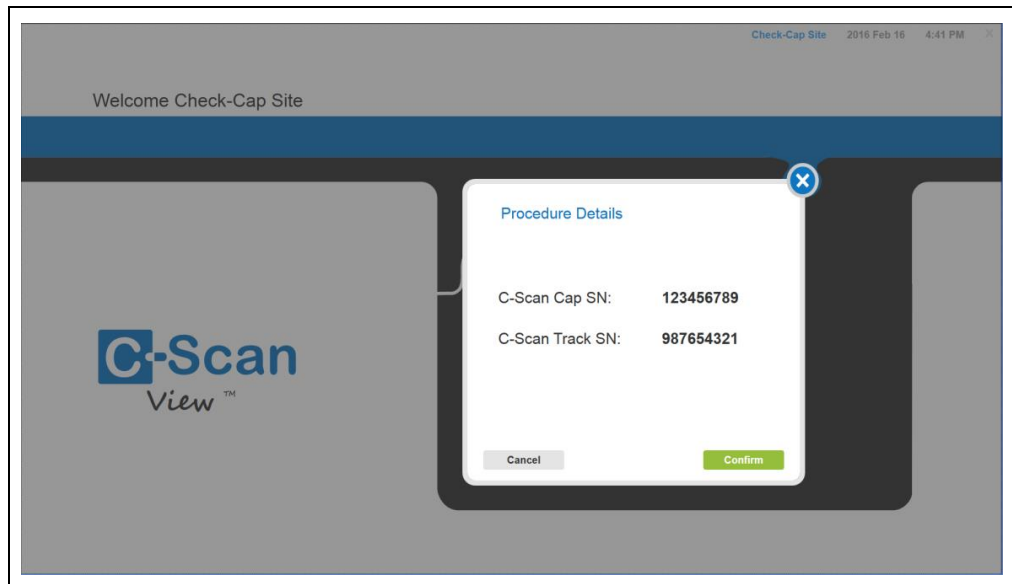
Figure 33: C-Scan® Track Failure to Connect Error Message



6.2 Loading and Processing C-Scan® Track Data

After successfully connecting a C-Scan® Track and clicking **Load C-Scan® Track**, the Procedure Details window opens.

Figure 34: Procedure Details Window

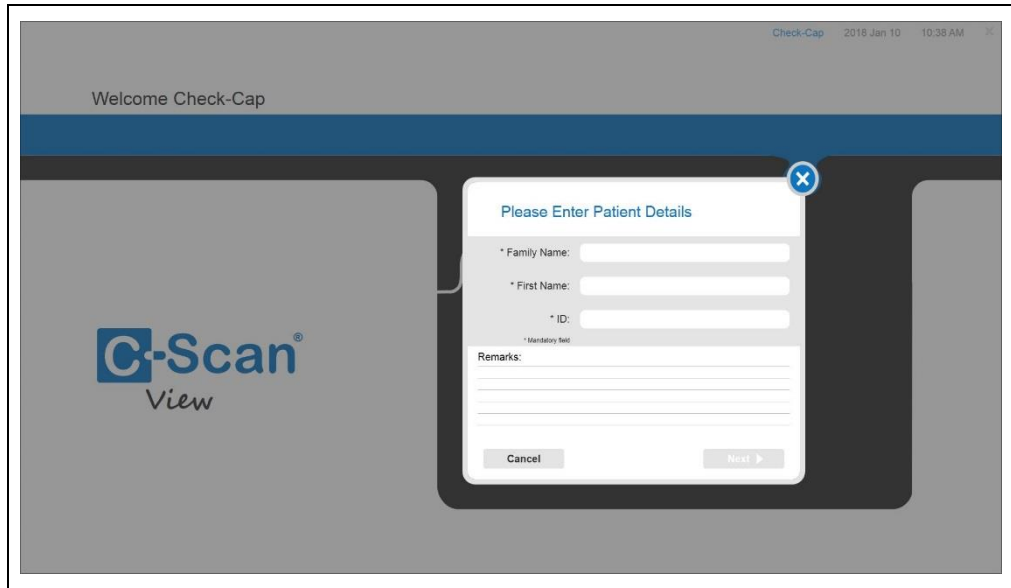


Verify that the C-Scan® Cap Serial Number and the C-Scan® Track Serial Number match those actually used. Click **Confirm** to open the Patient Details window.

If the information on the screen is incorrect, click **Cancel** to close the window and return to the Welcome screen. Connect the C-Scan® Track with the correct serial number to the C-Scan® View and continue the download.

Using C-Scan® View to Create the C-Scan® Reconstructed Colon Display

Figure 35: Patient Details Window



Enter the patient details:

- Enter the Family Name (maximum of 20 characters).
- Enter the First Name (maximum of 20 characters).
- Assign an ID (e.g., patient ID or birthdate), or copy the ID from the Clinic/Hospital record for cross-reference purposes (maximum of 20 characters).
- Enter any remarks (maximum of 1000 characters).

To save the patient data, click **Next**. The Processing Data screen opens and shows the progress of the download and reconstruction.

Press **Cancel** to close the window and return to the Welcome screen. A confirmation message opens:

Figure 36: Patient Details Cancel Message

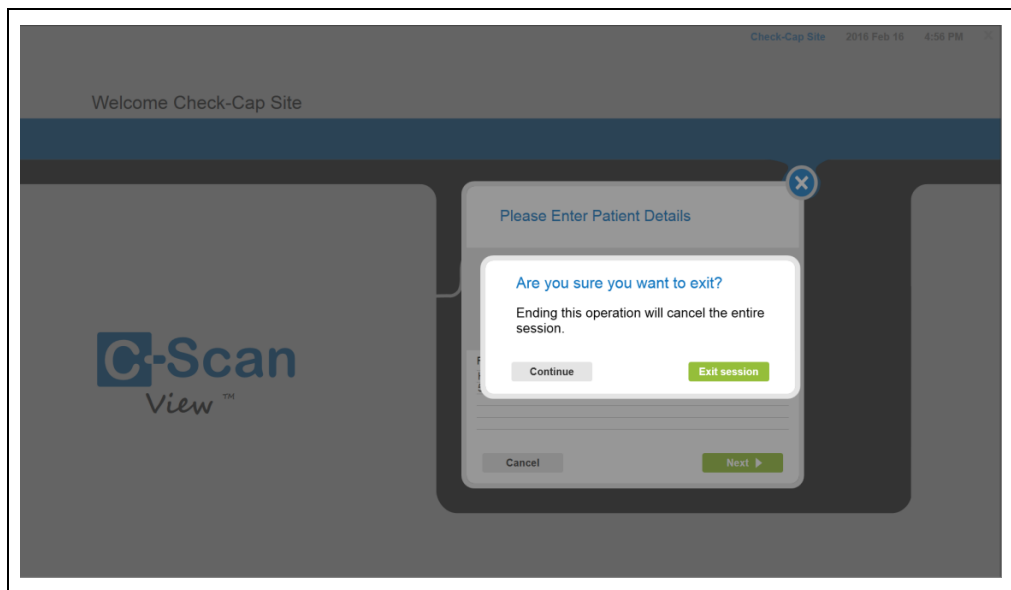
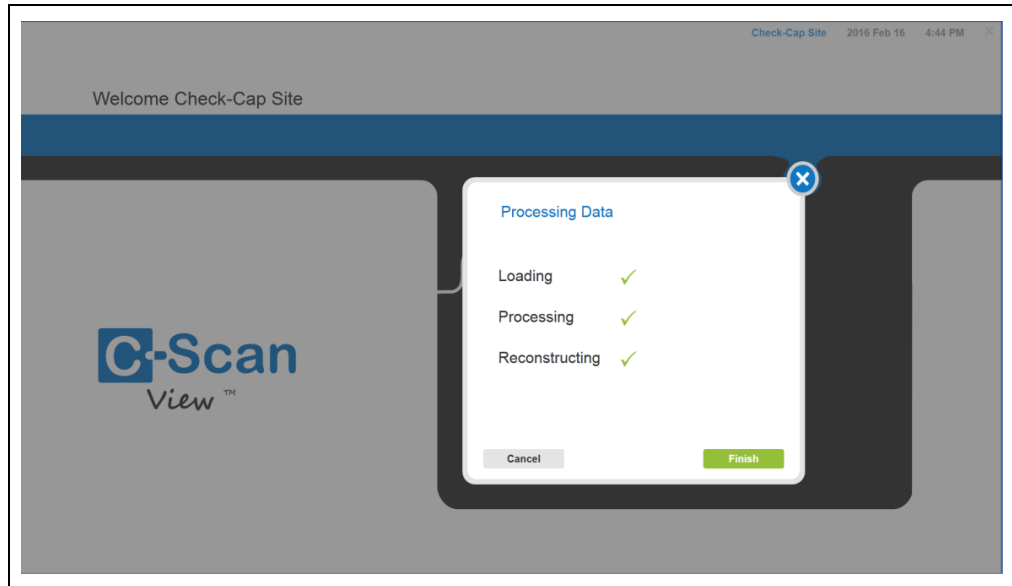


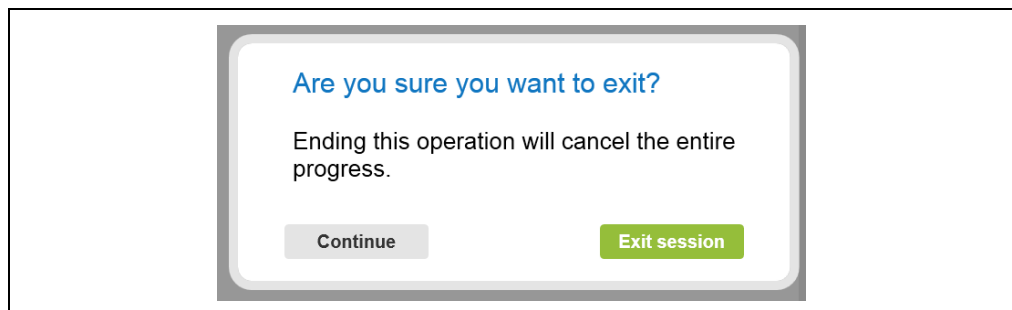
Figure 37: Processing Data Screen



Upon successful completion, all three stages show a check-mark. Click **Finish** to complete the processing and begin reviewing the 3D Reconstruction.

If a stage failed, a red X appears next to the failed action and the notification "Invalid data" is displayed. Click **Cancel** to cancel the processing and return to the Welcome screen. A confirmation message opens:

Figure 38: Cancel Message



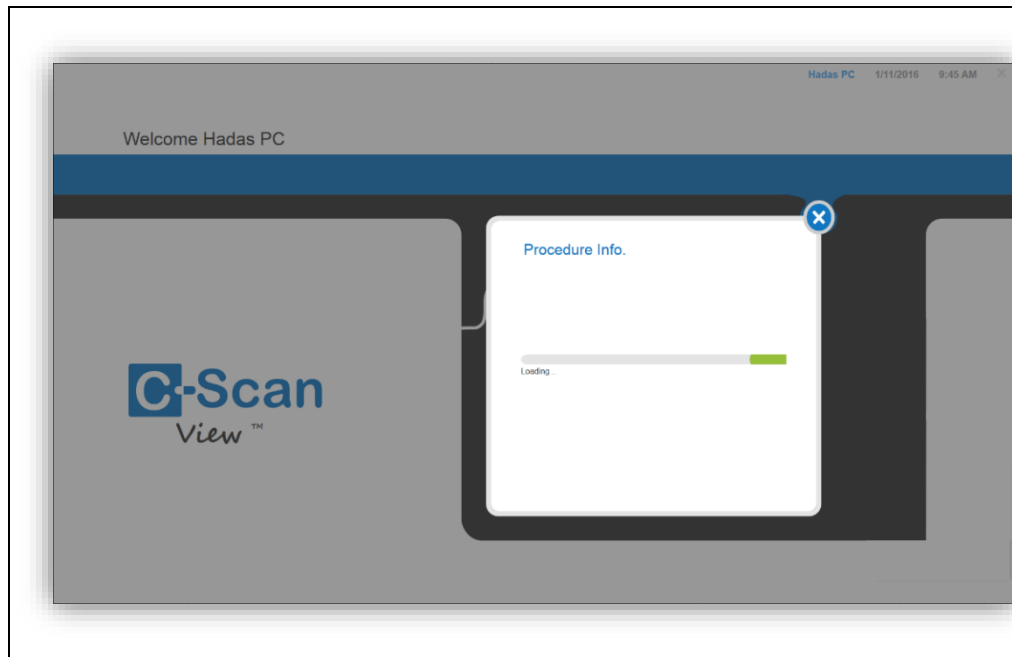
Press **Exit Session** to close the window and return to the Welcome screen. Press **Continue** to continue the session and advance to the Processing Data window.

6.3 Viewing a 3D Reconstruction from a CD

Place a CD that contains patient procedure analysis results in the CD drive and close the drive. Click **View CD** on the Welcome screen to load the procedure from the CD. The system reads the information and displays the CD Load Progress screen.

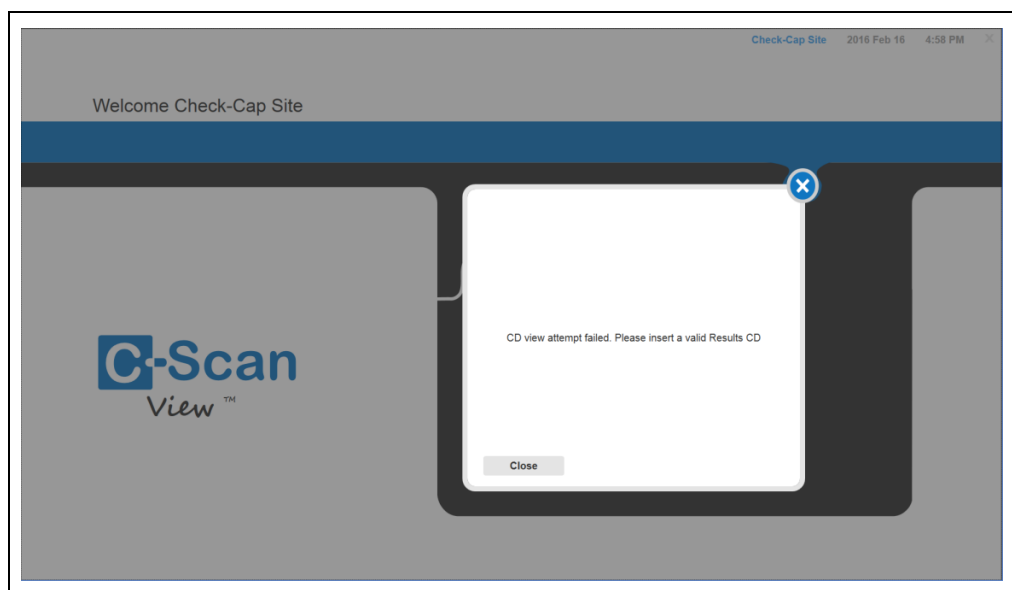
Using C-Scan® View to Create the C-Scan® Reconstructed Colon Display

Figure 39: Load CD Progress Screen



If the CD fails to load, an error message is displayed:

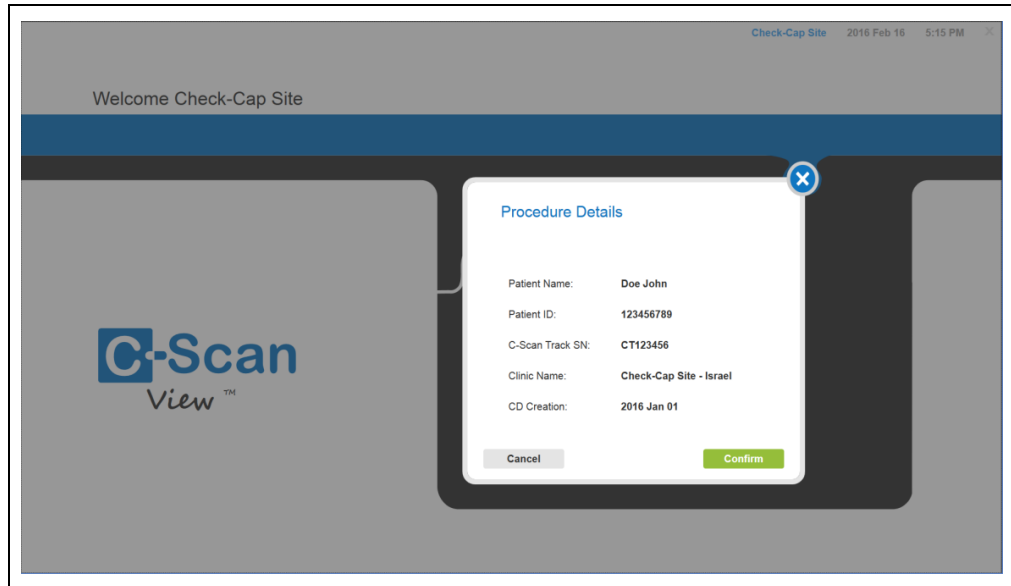
Figure 40: Load CD Failure Screen



Click **Close** to return to the Welcome screen.

When the CD completes loading, the system displays the Procedure Details screen.

Figure 41: Procedure Details Screen



The Procedure Details screen displays the following items:

- Patient full name
- Patient ID
- C-Scan® Track Serial Number
- Clinic name
- CD Creation Date

Click **Confirm** to advance to the Review screen. See Chapter 7 for information on reviewing a 3D Reconstruction.

6.4 Backing Up Data

The user can create a procedure results CD, enabling reviewing the results at another time or on another C-Scan® View. The Report can be viewed on any PC, except for the C-Scan® View, that supports reading PDF files.

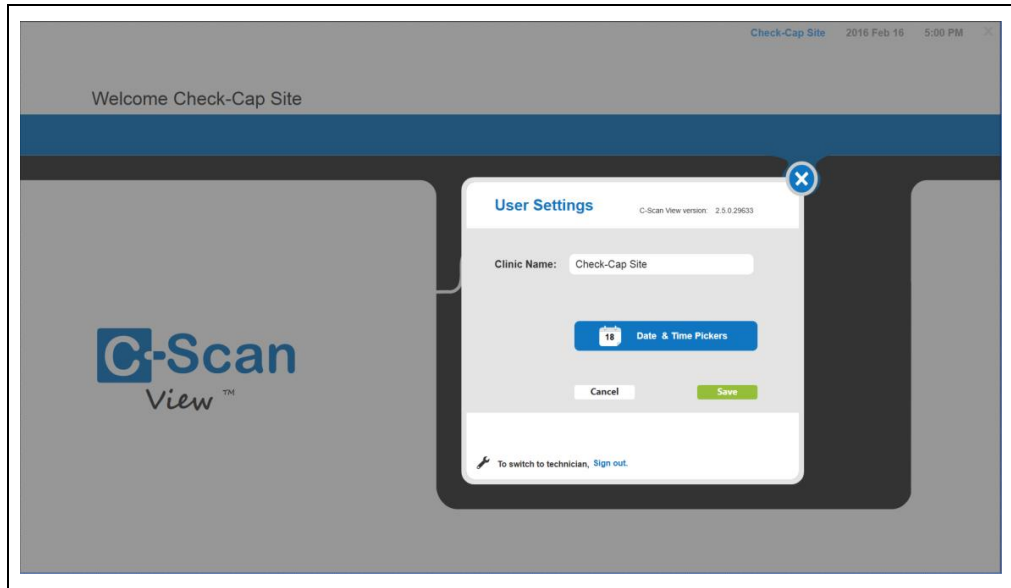
See Section 6.4 for directions for saving procedure results.

6.5 User Settings

Click **User Settings** on the Welcome screen to open the User Settings window.

Using C-Scan® View to Create the C-Scan® Reconstructed Colon Display

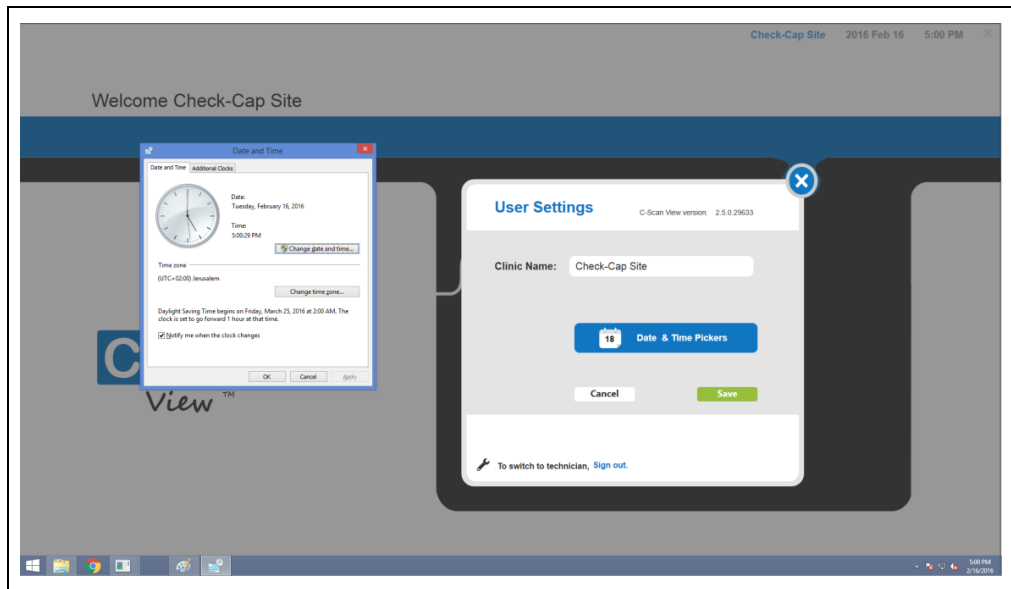
Figure 42: User Settings



All users can use this window to:

- Change the clinic name (maximum 50 characters)
- Change the date and time (click the Date & Time Picker icon). The Windows Date and Time window opens.

Figure 43: Change Date and Time



Click **Save** to save all changes and to return to the Welcome screen. Click **Cancel** to discard the changes and to return to the Welcome screen.

An authorized service technician can sign out from the current user and sign in as a Technician. Click Sign out to open the Password window. Enter an authorized password to log in. The technician can view the system log and access the system BIOS and Windows utilities.

7 Reviewing and Interpreting the C-Scan® 2D/3D Images

Warning: Only a physician trained by Check-Cap in the use of the *C-Scan® View* should review the procedure results.

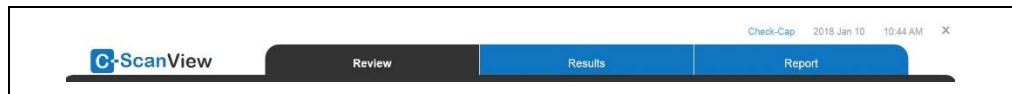
See Chapter 6: Using C-Scan® View to Create the C-Scan® Reconstructed Colon Display for a description of the steps to download the data from the *C-Scan® Track* to the *C-Scan® View*.

Note: The *C-Scan® Cap* large bowel (colon) scan coverage may vary due to variations in patient GI motility.

The movement of the capsule throughout the GI tract is driven by the natural peristalsis of the bowel. Hence, the total transit time and dynamics of the capsule propulsion are unpredictable and may substantially vary between patients.

7.1 Understanding the Navigation Bar

Figure 44: Navigation Bar



The *C-Scan® View* navigation bar contains two tabs:

- Review – Opens the Review screen
- Results - Opens the Results screen
- Report – Opens the Report screen

Select a tab by clicking on it. The selected tab is shown in black.

7.2 Review Screens – General

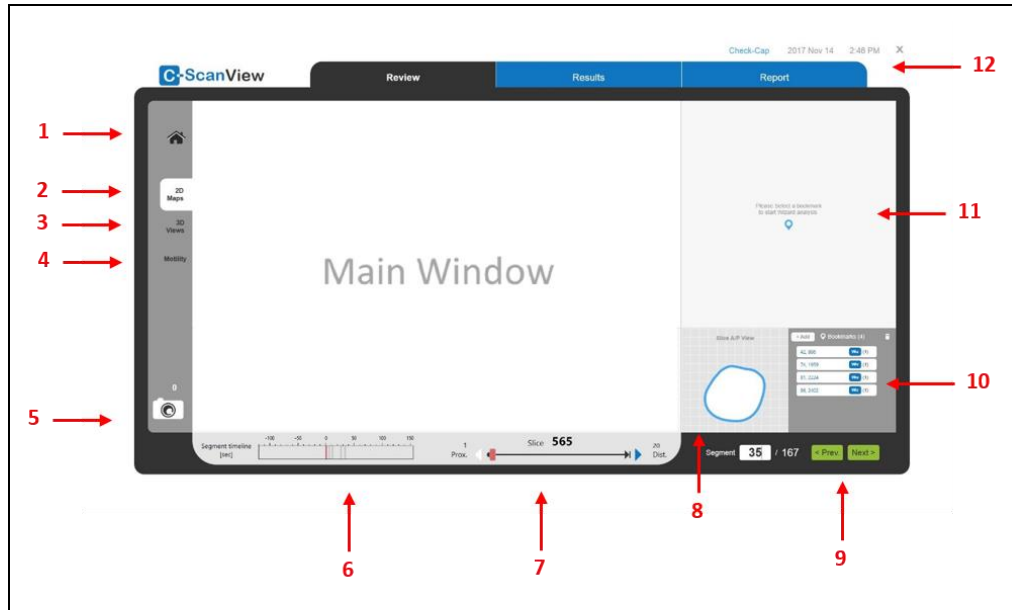
The viewing screen contains:

- Main window—displaying 2D maps, 3D maps, and motility data
- Segment and slice reference and navigation controls
- Help text with guidelines for evaluating suspects

The system also allows the user to take snapshots that are automatically saved in the report section where they can later be edited and a report generated and printed.

Reviewing and Interpreting the C-Scan® 2D/3D Images


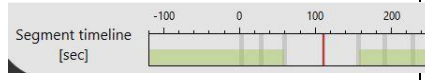
Figure 45: Review Screens-General

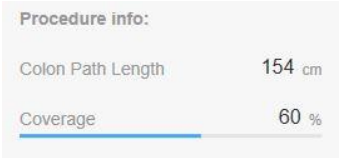



- | | |
|---------------------|-------------------------------|
| 1. Home icon | 7. Slice navigation bar |
| 2. 2D Maps tab | 8. 2D slice display |
| 3. 3D Views tab | 9. Segment navigation control |
| 4. Motility tab | 10. Bookmarks table |
| 5. Snapshot icon | 11. Suspect evaluation wizard |
| 6. Segment timeline | 12. Navigation bar |

The general functionalities of the Review screens are described in Table 1.


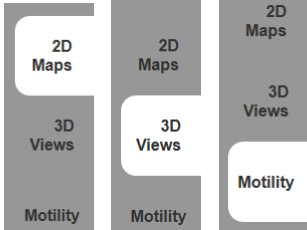
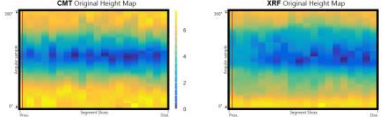






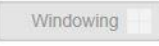

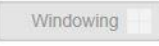

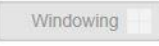







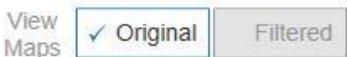
Table 1: Graphics Main Displays and Functionalities

Item	Description	Illustration
Segment and Slice Display		
Segment Control	Displays current segment number out of total number of segments in the procedure. Navigation buttons allow scrolling through segments. Additional navigation buttons are available under the 2D maps	
Segment Timeline	Displays the position of the currently selected slice relative to the other slices in the segment. Segments overlap is indicated.	


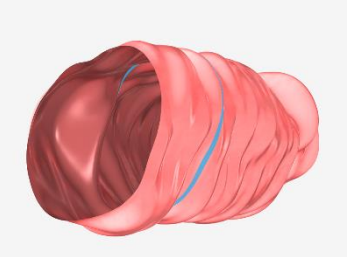

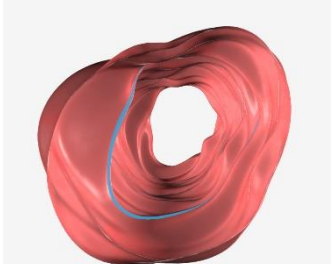

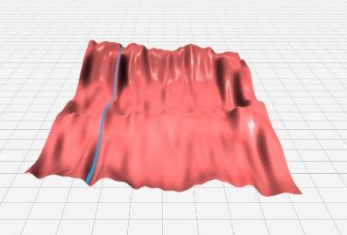
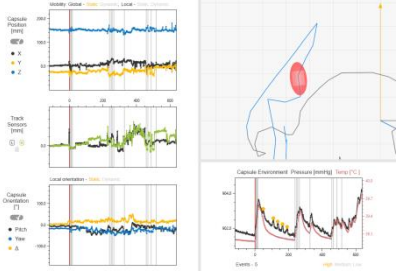
Item	Description	Illustration
Procedure info	<p><u>In the 2D Map view:</u> Colon length and coverage are displayed.</p>	<p>Procedure info:</p> <p>Colon Path Length 154 cm</p> <p>Coverage 60 %</p> 
Segment Info	<p><u>In the 2D Map view:</u></p> <p>Displays the length, duration, and distance to rectum for the selected segment.</p> <p>The Segment Locator displays the approximated model of the scanned colon with the current segment marked.</p> <p>Displays information about the similarity of the CMT and XRF maps.</p> <p>Displays information about the range validity of the CMT and XRF maps.</p> <p>Use this information when filling out the Suspect Evaluation wizard dialog.</p>	<p>Segment info: Segment Locator:</p> <p>Length - 7 mm</p> <p>Duration - 426 sec</p> <p>Distance to Rectum - 0 cm</p> <p>Maps within Range - Both One None</p> <p>Maps Similarity - High Medium Low</p>  <p>Maps Similarity - High Medium Low</p> <p>or</p> <p>Maps Similarity - High Medium Low</p> <p>or</p> <p>Maps Similarity - High Medium Low</p> <p>Maps within Range - Both One None</p> <p>or</p> <p>Maps within Range - Both One None</p> <p>or</p> <p>Maps within Range - Both One None</p>

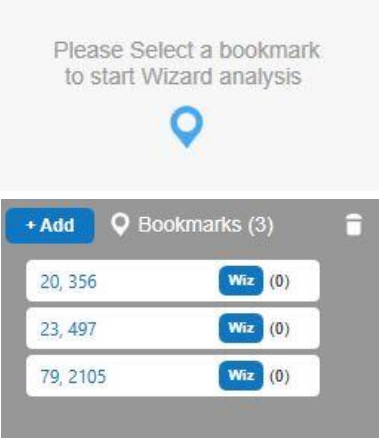
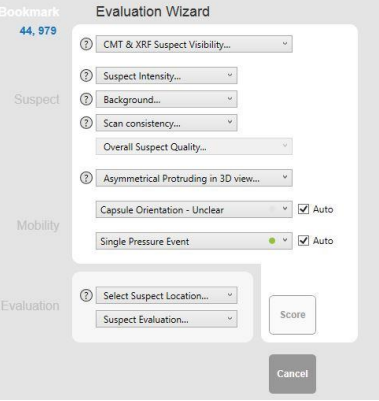
**Reviewing and Interpreting the
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Item	Description	Illustration
Slice Info	<p><u>In the 2D Map view:</u> Displays the number of slices and percentage of time in the same location as the current selected slice.</p> <p>Displays the number of pressure events in current slice (counts events in the entire segment of the current selected slice, including overlap segments).</p> <p><u>In the 2D Map and Motility views:</u> Displays information about local capsule orientation for the current slice (in reference to slices in close proximity). Displays information about local capsule mobility for the current slice (in reference to slices in close proximity). Displays information about global capsule mobility for the current slice (in reference to all slices in the procedure). In slices where the information is uncertain the status cannot be determined. Displays information about pressure events in current slice (counts events in the entire segment containing the capsule, including overlap segments). Use this information when filling out the Suspect Evaluation wizard dialog.</p>	
Slice Navigation Bar	<p>The slide navigation bar enables sliding between slices. The slice selection is synchronized in all views, i.e., in the 2D maps, 3D views, and Motility graphs.</p>	
Slice A/P View	<p><u>2D slice display</u> A 2D cross section of the reconstructed segment, displaying the current slice.</p>	

Item	Description	Illustration		
Bookmarks	Once an ROI marks a region of interest around a suspect in the 2D maps, it can be added as a bookmark. The segment and slice number can be clicked providing quick access to the marked ROI.			
Viewing Modes				
2D, 3D, and Motility Tabs	Use 2D, 3D, and Motility tabs to select display of 2D maps, 3D views, or motility information.			
2D Maps				
2D Height Maps	The 2D height maps represent 2D height of the colon tissue above the surface as seen from the inside by the capsule for CMT and XRF based signals. To the right of each 2D map, a color scale is displayed.			
Region Of Interest (ROI)	Use the ROI button to mark a region of interest around a suspect in the 2D map. The marked ROI is seen in 3D Views as well.	<table border="0" style="width: 100%;"> <tr> <td style="text-align: center;">Disabled </td> <td style="text-align: center;">Enabled </td> </tr> </table>	Disabled 	Enabled 
Disabled 	Enabled 			
Windowing	Use the Windowing button to select a window in the 2D map. The map display changes to adjust the map dynamic range according to the range of the selected window only.	<table border="0" style="width: 100%;"> <tr> <td style="text-align: center;">Disabled </td> <td style="text-align: center;">Enabled </td> </tr> </table>	Disabled 	Enabled 
Disabled 	Enabled 			
Gray	Use the Gray button to change the 2D color scale to grayscale.	<table border="0" style="width: 100%;"> <tr> <td style="text-align: center;">Disabled </td> <td style="text-align: center;">Enabled </td> </tr> </table>	Disabled 	Enabled 
Disabled 	Enabled 			
Original/Filtered Signals for 2D Map Display	To display both the CMT map and the XRF map using filtered signals, click the Filtered tab. To return to maps using original signals, click the Original tab.			

**Reviewing and Interpreting the
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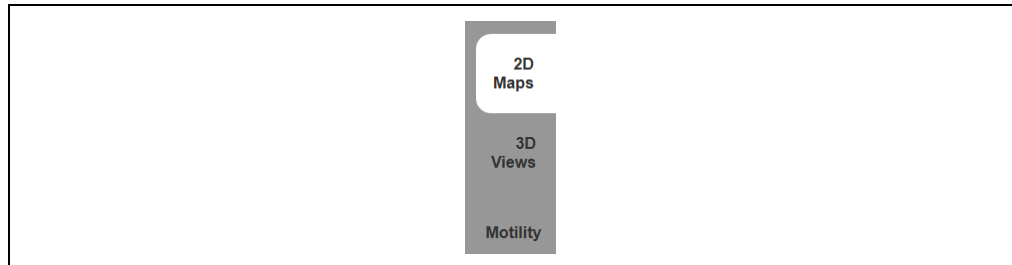
Item	Description	Illustration
3D Views		
 <p>3D Tube Display</p>	<p>3D display of the colon exterior allowing the user to zoom in/out and rotate the tube.</p> <p>Changing slice slider position highlights the selected slice in blue along the colon tube.</p>	
 <p>3D Fly Through Display</p>	<p>3D display of the colon interior allowing the user interactive navigation along the colon longitudinal axis.</p> <p>Changing slice slider position highlights the selected slice in blue along the colon tube.</p>	
 <p>3D Plane Display</p>	<p>A 3D tube "opened to a plane" (fillet).</p> <p>Changing slice slider position highlights the selected slice in blue along the colon "fillet".</p>	
Motility		
<p>Motility Information</p>	<p>Four graphs display information about movement through the segment:</p> <ul style="list-style-type: none"> • Capsule position • Track sensor movement • Capsule orientation • Capsule environment pressure <p>A schematic map shows the capsule position on the approximated colon model</p>	

Item	Description	Illustration
Suspect Evaluation		
Suspect Evaluation wizard dialog	Suspect Evaluation wizard dialog can be initiated by clicking the Wiz button on a chosen bookmark.	
Suspect Evaluation wizard dialog	The Suspect Evaluation wizard is composed of a set of questions, to be answered by the user. Some of the questions are automatically answered by the wizard, relying on automatic slice indicators, averaged on the slices composing the ROI, and the answer can be changed manually. After filling out the form, clicking "score" results in a score between 0 and 1, representing the statistical probability the suspect is a suspicious finding (0 low, 1 high).	

7.3 Action Icons

Action icons are located to the left of the main window.

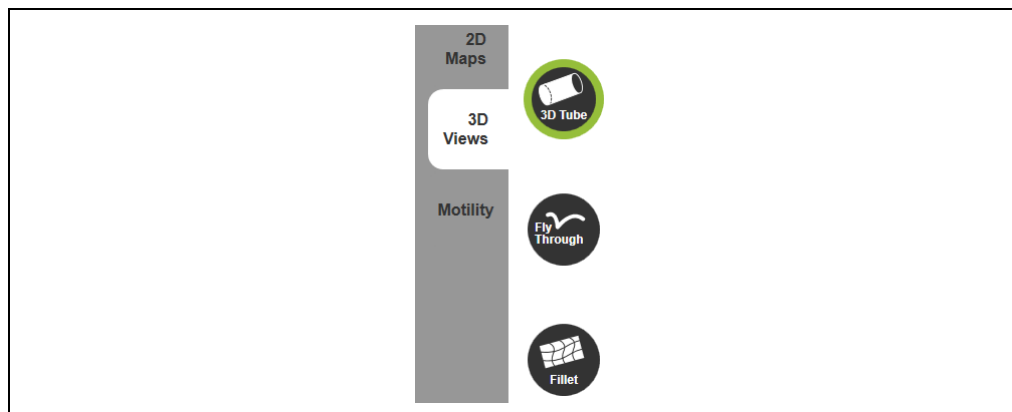
Figure 46: Mode Selection



Use the tab icons to select the view mode:


- 2D maps
- 3D views
- Motility information


Figure 47: 3D View Selection



When selecting 3D Views, three view types are available. To switch to another view, click the corresponding button. The views, described in Section 7.8, are:

- 3D Tube
- 3D Fly Through
- Fillet (Plane)

In case the display in the main window was edited, use the Home icon () to reset the display to its original state.

Use the Snapshot icon () to save an image displayed on the screen. The number of saved images is shown next to the icon. Up to 50 images can be saved.

7.4 Segment Control

Figure 48: Segment Control Bar

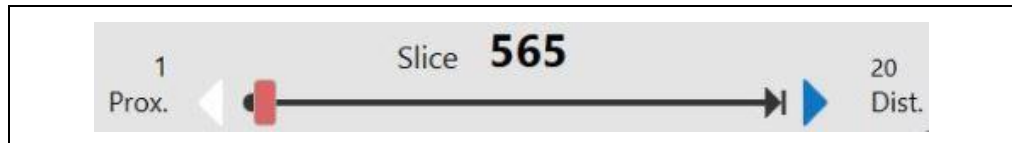


The Segment Control Bar at the bottom of the screen allows the viewer to scroll through the colon segments.

The current segment number and the total number of segments are displayed, as in the example: "Segment 25 of 29". Any segment number within the range of segments can be entered in the text box to enable viewing the corresponding segment.

7.5 Slice Control

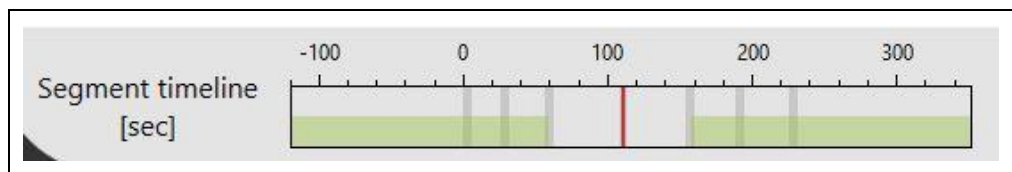
Figure 49: Slice Control Bar



Use the Slice control bar to select a specific slice within the currently selected segment.

7.6 Segment Timeline

Figure 50: Segment Timeline



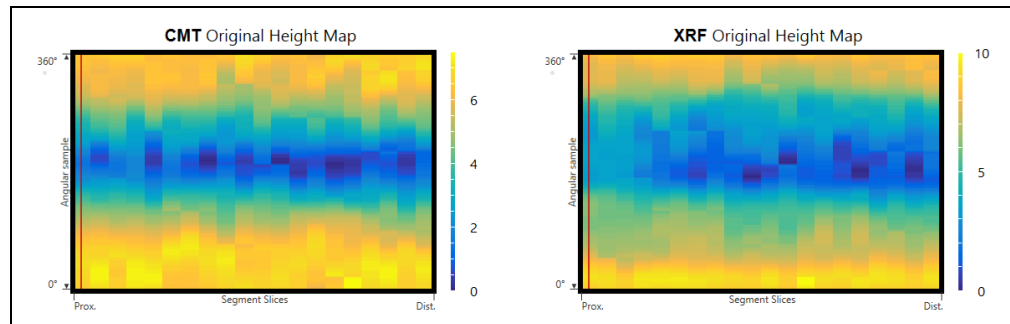
The Segment timeline displays the position of the currently selected slice relative to other slices in the segment. The green portion of the timeline is an overlap that also appears in the neighboring segment. An overlap with the next segment corresponds to a green portion on the right side and an overlap with the previous segment corresponds to a green portion on the left side.

7.7 2D Map Mode

The 2D height maps represent 2D height of the colon tissue above the surface as seen from the inside by the capsule for CMT and XRF based signals.

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Figure 51: CMT and XRF Maps: No Suspect



In Figure 51 the 2D maps show the CMT and XRF data of a segment with no suspicious finding or lesion.

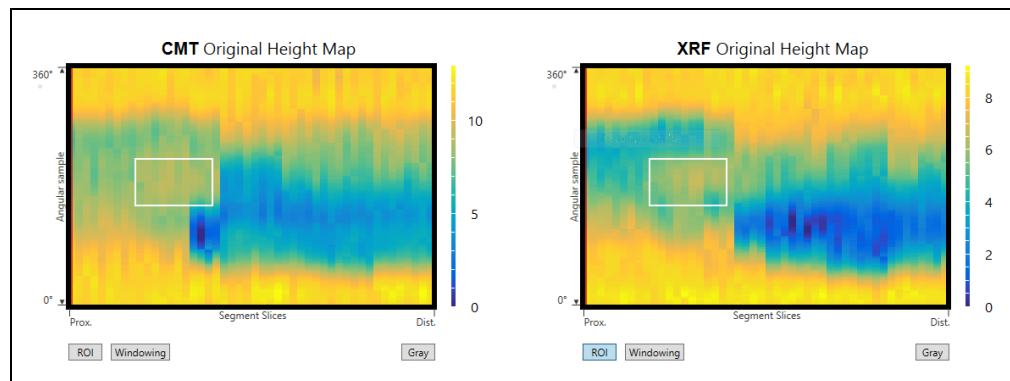
Click a 2D map and use the left and right keyboard arrows to control the slice angular rotation in the 2D maps. Once the angular rotation changes, an indication (a dot mark) will appear next to the angular axis. Click the Home icon to reset the angular change.

Click the Windowing button under a 2D map and select a window in the map to change the dynamic range of the map according to the range of the selected window. Click the Home icon to reset the dynamic range map.

Click the ROI button under either of the maps to mark a region of interest around a suspect region. The ROI is marked in both maps for easy comparison between the maps.

Please refer to DOC001212 C-Scan View Physician training document for more information on interpreting 2D images and identifying suspects

Figure 52: Region of Interest (ROI)



7.8 3D View Mode

7.8.1 3D Tube Mode

3D Tube Mode shows the outside of the colon segment. Select the segment number to be reviewed, or continue reviewing the same segment reviewed in one of the other modes. Click on **Next Segment** to move to the next segment, or **Prev. Segment** to move to the previous segment. The approximate location of the segment is highlighted in blue on the Colon Segment Locator. A particular slice

can be selected using the slice control bar, moving the slider by clicking and holding the mouse pointer on it, and moving the mouse to the desired location.

Use the mouse to control the movement of the colon reconstruction as follows:

- Tube pan is controlled by the right mouse button.
- Tube zoom in/out is controlled by the mouse scroll wheel.
- Tube rotation is controlled by the left mouse button.

7.8.2 Fly Through Mode

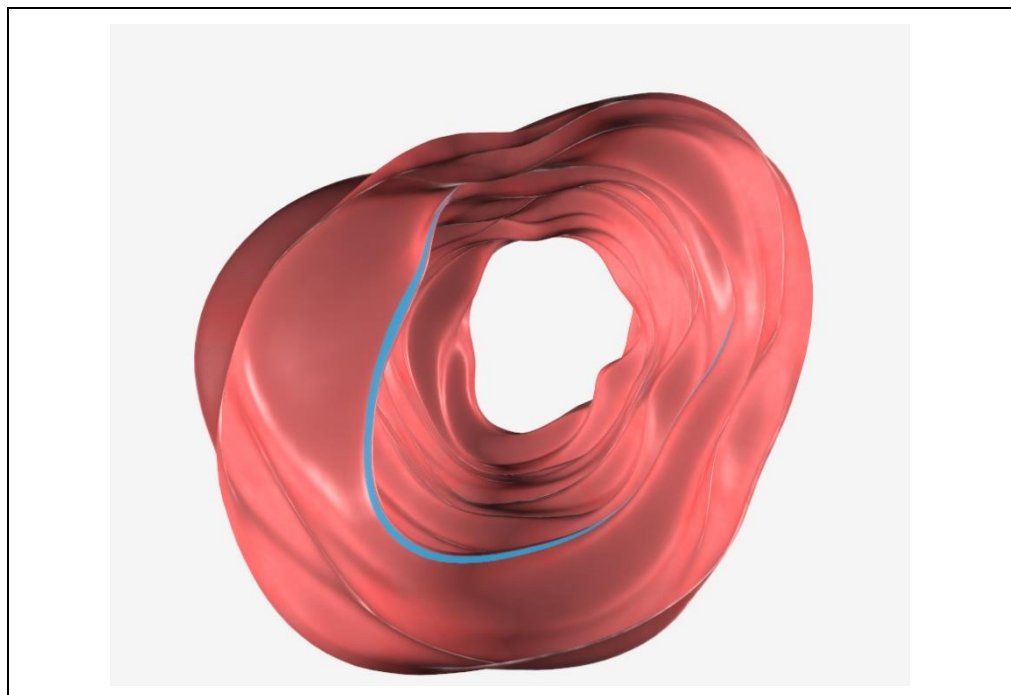
Fly Through Mode shows the inside of the colon. The reconstruction starts with the first segment at the proximal end of the colon. Click on **Next Segment** to move to the next segment, or **Prev. Segment** to move to the previous segment. The approximated location of the segment is highlighted in blue on the Colon Segment Locator. A particular slice can be selected using the slice control bar, moving the slider by clicking and holding the mouse pointer on it, and moving the mouse to the desired location.

Use the mouse to control the movement of the colon reconstruction as follows:

- Fly through movement is controlled by the mouse scroll wheel
- Fly through angle is controlled by the left mouse button.

A segment with a suspicious finding is displayed in Figure 53:

Figure 53: Colon Segment with Suspicious Finding



Click **Next Segment**, or enter a segment number to continue the review.

7.8.3 Fillet Mode

Fillet Mode opens the 3D Tube and shows the inside of colon segment. Select the segment number to be reviewed, or continue reviewing the same segment reviewed in one of the other modes. Click on **Next Segment** to move to the next segment, or **Prev. Segment** to move to the previous segment. The approximate location of the segment is highlighted in blue on the Colon Segment Locator. A particular slice can be selected using the slice control bar, moving the slider by clicking and holding the mouse pointer on it, and moving the mouse to the desired location.

Use the mouse to control the movement of the colon reconstruction as follows:

- Fillet movement along the axis is controlled by the mouse scroll wheel.
- Fillet rotation is controlled by the left mouse button.
- Fillet pan is controlled by the right mouse button.
- Use the left and right keyboard arrows to move the fillet cut line (the fillet rotates around the cut line).
- Use the left and right keyboard arrows to control the slice angular rotation. Click the Home icon to reset the angular change.

7.9 Motility Information

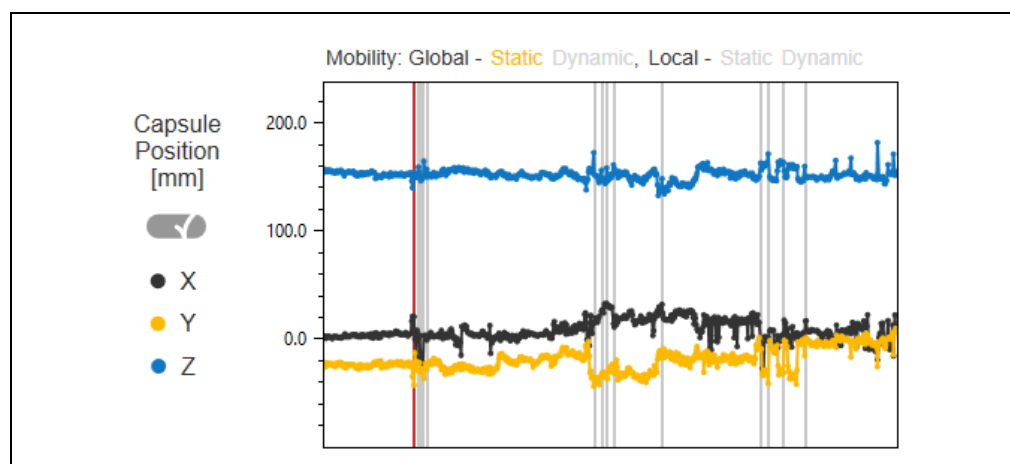
Four graphs display information about movement through the segment. The vertical lines in each graph represent the slices composing the segment.

The Capsule Position graph (Figure 54) shows the X, Y, and Z coordinates of the capsule throughout the segment.

The local mobility status is derived from the capsule position, options are static/dynamic. In some cases, the track sensors cause invalid position changes, and then the automatic indicators cannot be determined. "Local mobility" indicator options are both colored in grey in this case.

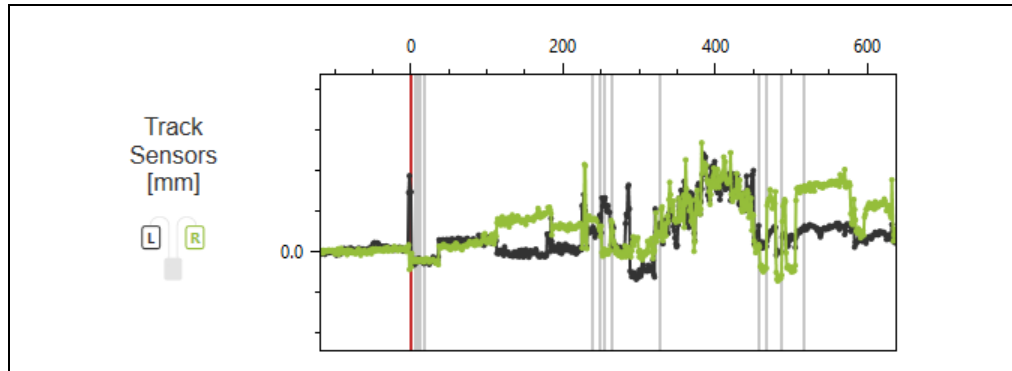
The global mobility status is derived from the number of slices and the time spent in the current slice, options are static/dynamic.

Figure 54: Capsule Position Graph



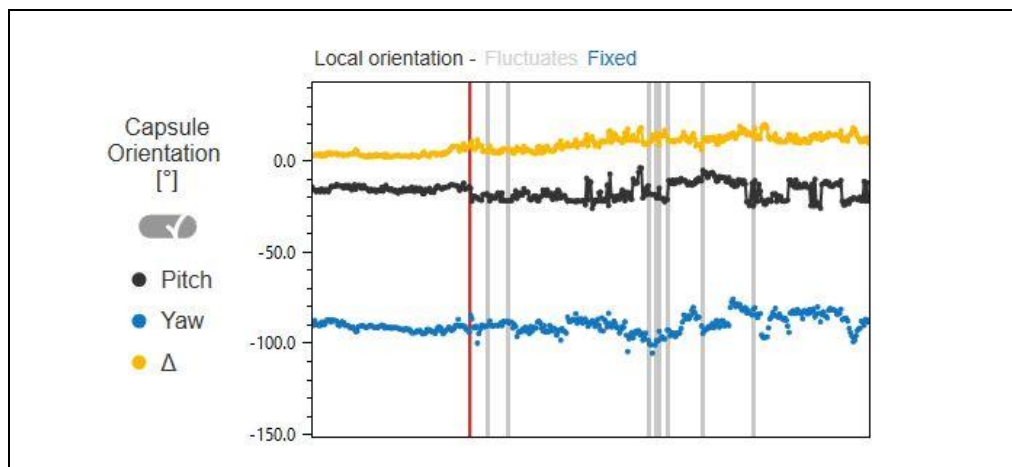
The Track Sensors graph (Figure 55) shows the movement of the left and right sensors of the C-Scan® Track throughout the segment.

Figure 55: Track Sensors Graph



The Capsule Orientation graph (Figure 56) shows the change of the capsule's orientation throughout the segment: pitch, yaw, and Δ (a measurement representing the maximal angular changes of the capsule). Slice status is considered static if $\Delta < 35^\circ$. See examples in Table 4. In some cases, the track sensors cause invalid orientation changes, and then the automatic indicators cannot be determined. "Local orientation" indicator options are both colored in grey in this case.

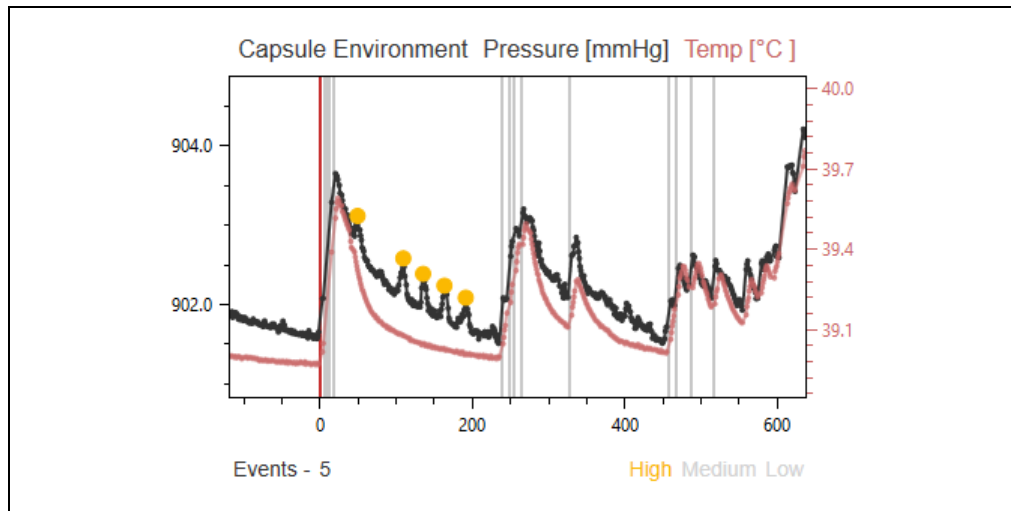
Figure 56: Capsule Orientation Graph



The Capsule Environment graph (Figure 56) shows the changes in pressure and temperature in the capsule environment. Immediately after a slice is captured, a peak in pressure and temperature occurs. Those peaks are not relevant for suspect analysis. Any other peaks in pressure that occur in the segment are marked with an orange ball.

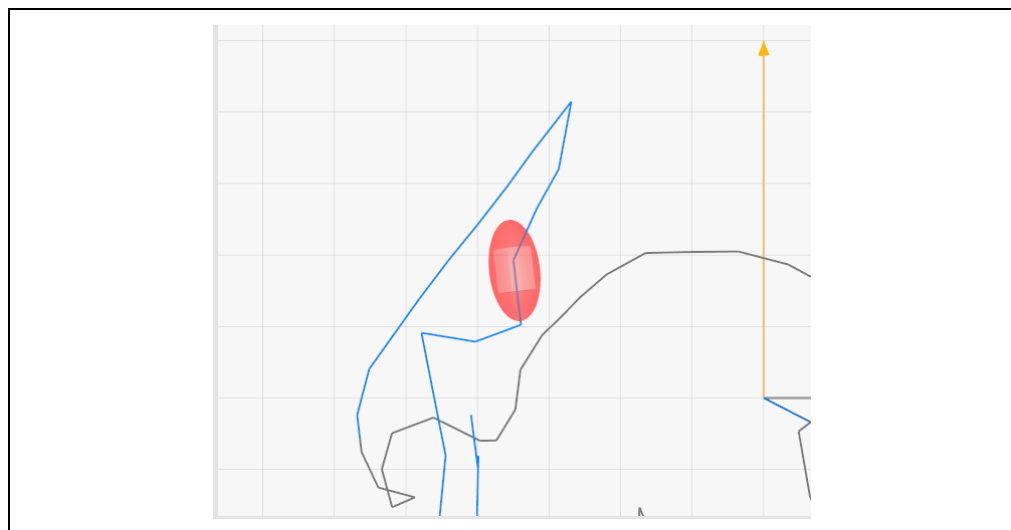
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Figure 57: Capsule Environment Graph



In the top right of the screen, the capsule position on the colon model is shown (Figure 58).

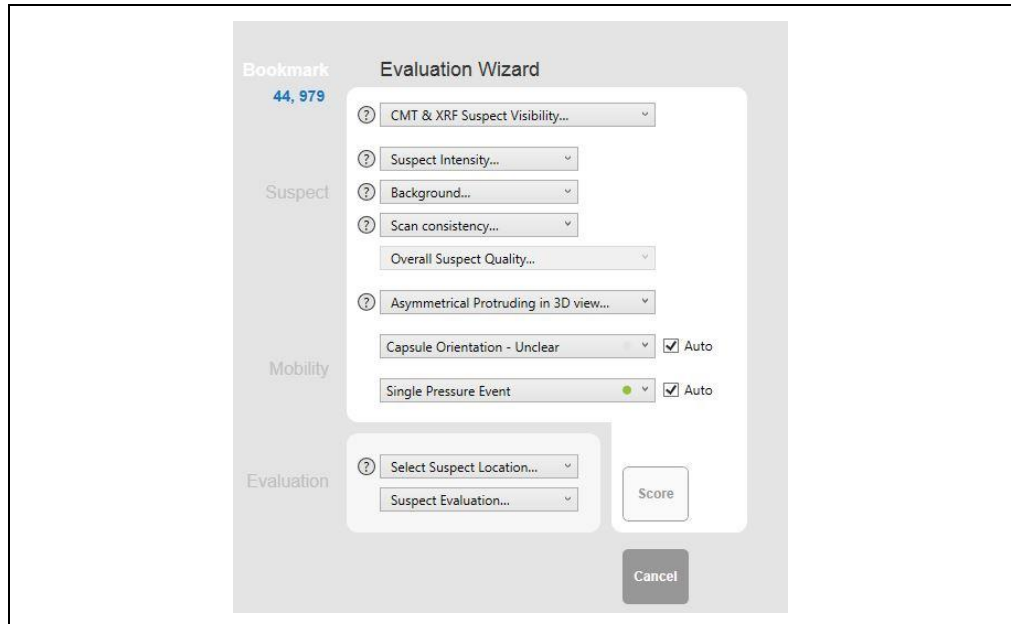
Figure 58: Capsule Position in Colon



7.10 Evaluating Suspects

When a suspect is identified, add it as a bookmark and start the analysis wizard process.

Figure 59: Suspect Analysis Wizard



Answer the questions in the form. When the Evaluate button is clicked, a score (between 0 and 1) is generated. The higher the score, the greater the statistical likelihood of the suspect being a suspicious finding. The analysis wizard algorithm compares the suspect profile, built using the physician answers, to a clinical database, and determines how statistically similar it is to a suspicious finding profile.

Use the suggested score combined with personal evaluation of the suspect to decide whether the finding is suspicious or not. Personal evaluation is based on the suspect reliability and clinical experience.

The questions refer to the suspect's visibility, quality, 3D&2D appearance, and sensors information around the suspect. Every answer can increase / decrease suspect reliability, but no one answer by its own can determine if a suspect is a suspicious finding or not.

There are several indicators related to slice and segment info that support answering some of the questions. These indicators are calculated by the C-Scan View automatically and the automatic answer is chosen in the analysis wizard form. It is possible to change the automatic answer. Make sure that the indicators reflect the actual status correctly (based on experience). If not, answer the question differently.

Indicators status is colored as follows:

- Yellow - more likely to support case of suspicious finding / increases suspect reliability
- Blue - less likely to support case of suspicious finding / decreases suspect reliability
- Green - somewhere between blue and yellow

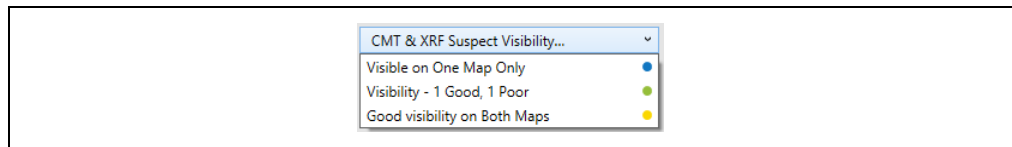
Note, determining if a suspect is a suspicious finding or not requires the full picture, and cannot be determined solely by relying on a single indicator. A

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suspicious finding can include several green/blue indicators and a non-suspicious finding can include several green/yellow indicators.

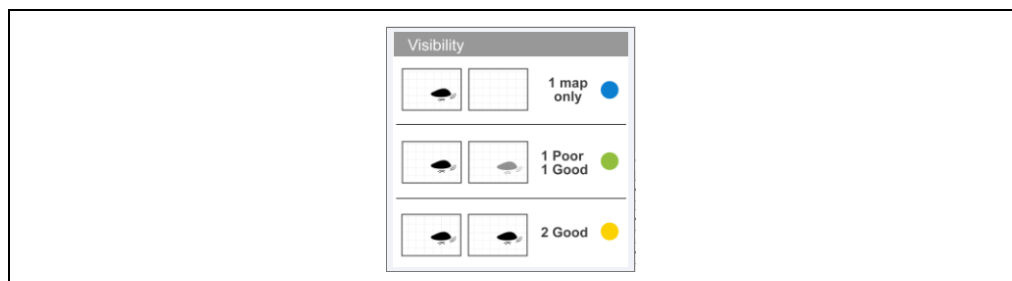
The questions are specified below:

Figure 60: Suspect Visibility



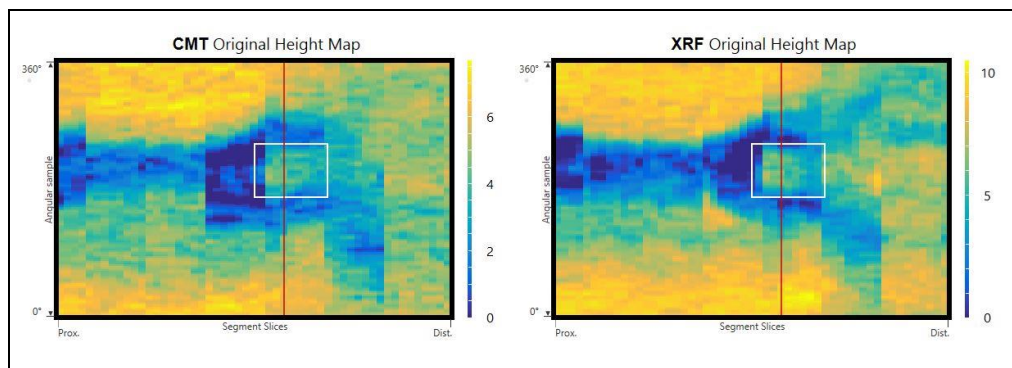
Answer the question about suspect visibility based on your personal assessment (refer to the Help text and diagrams for illustrations, by hovering over the question mark icon). A suspect seen in both maps is more reliable.

Figure 61: Help Text and Diagrams for Suspect Visibility



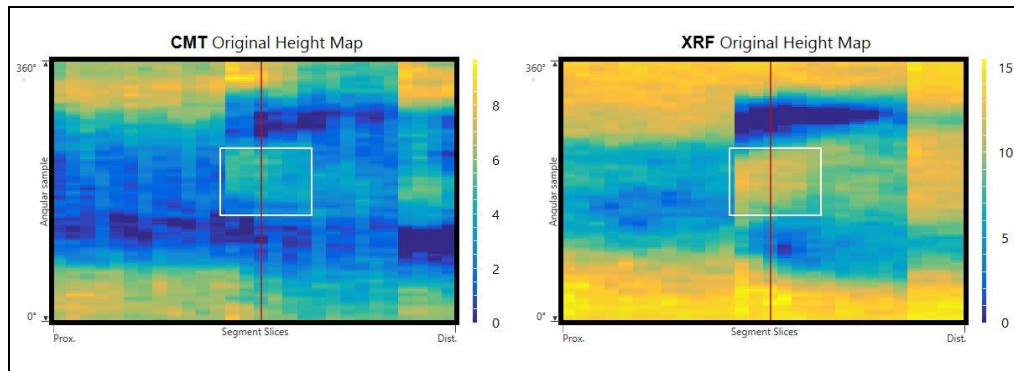
An example of good visibility on both maps is shown in Figure 62

Figure 62: Example of Good Visibility on Both Maps



An example of poor visibility on one map is shown in Figure 63.

Figure 63: Example of a Poor Visibility on One Map (CMT)



An example of a suspect visible on one map only is shown in Figure 64.

Figure 64: Example for Suspect Visible on One Map Only (XRF)

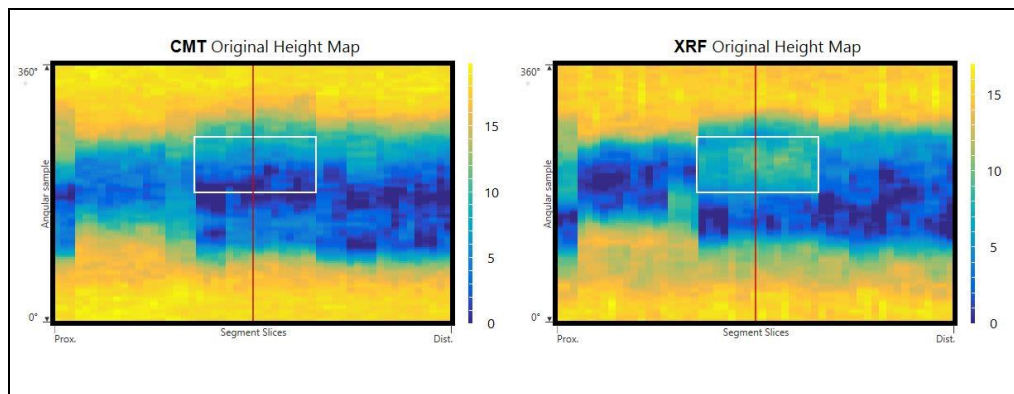
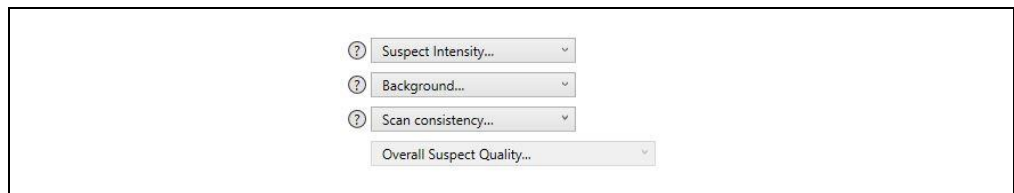
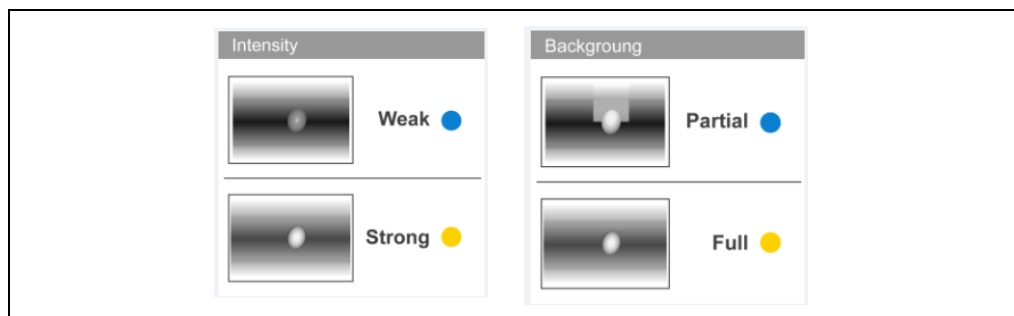


Figure 65: Suspect Quality

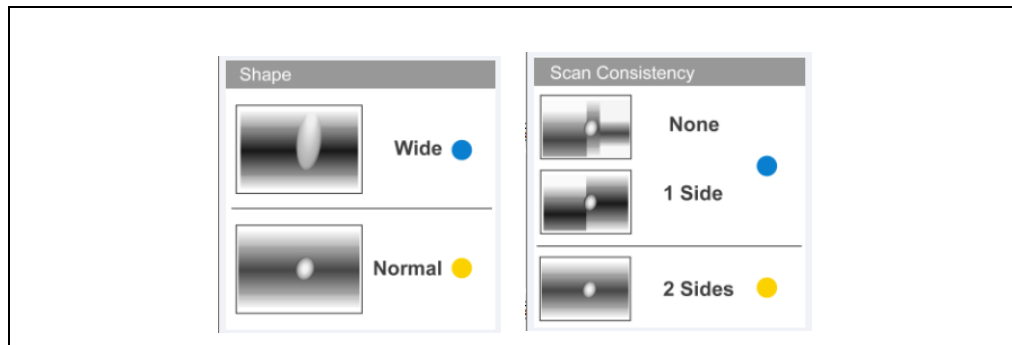


Assess suspect intensity, scan consistency, shape/width, and background (refer to the Help text and diagrams for illustrations, by hovering over the question mark icon).

Figure 66: Help Text for Suspect Quality



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Options marked orange are considered positive, and options marked blue are considered negative. The suspect quality assessment concludes the quality characteristics answers to a final answer – Low/Medium/High. This final answer can be changed manually.

The more positive indicators, the higher the suspect quality, meaning a more reliable suspect.

See examples in Table 2.

Table 2: Suspect Quality Examples

<p>Background</p>	<p>Partial:</p>	<p>Full:</p>
<p>Shape/width</p>	<p>Wide (over a third of the angular range):</p>	<p>Normal:</p>

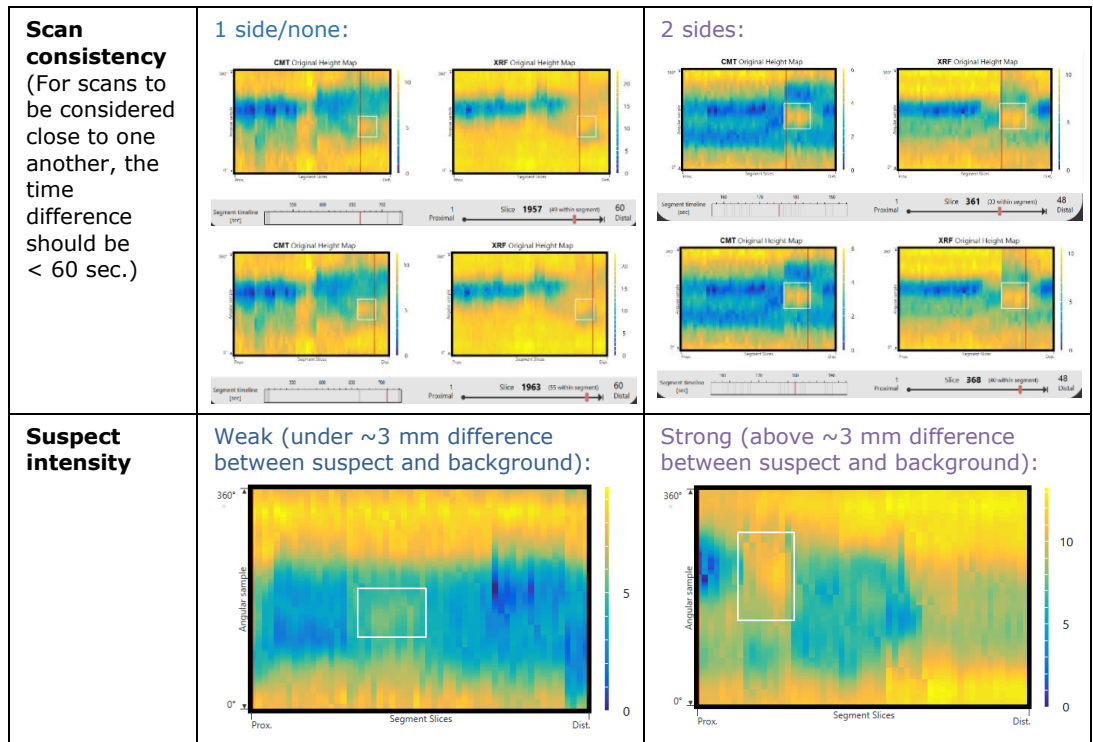
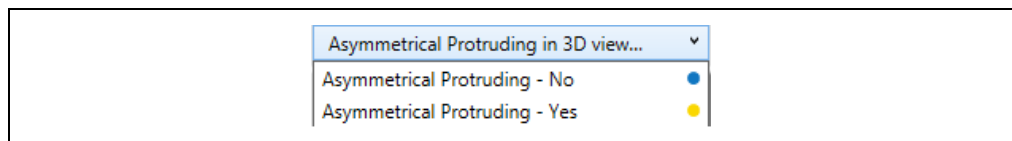
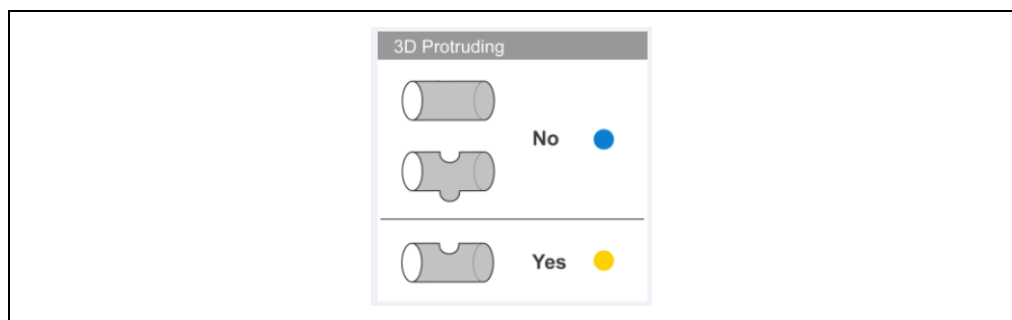


Figure 67: Asymmetrical Protruding in 3D View



Mark the suspect with an ROI. Then, switch to 3D Views and examine suspect visibility in 3D models (Refer to the Help text and diagrams for illustrations, by hovering over the question mark icon ^②). A suspect that is prominent in 3D as well as 2D is more reliable.

Figure 68: Help Text for Asymmetrical Protruding



See examples of 3D protruding in Table 3.

Table 3: 3D Examples

Asymmetrical 3D protruding:	No 3D protruding:
-----------------------------	-------------------

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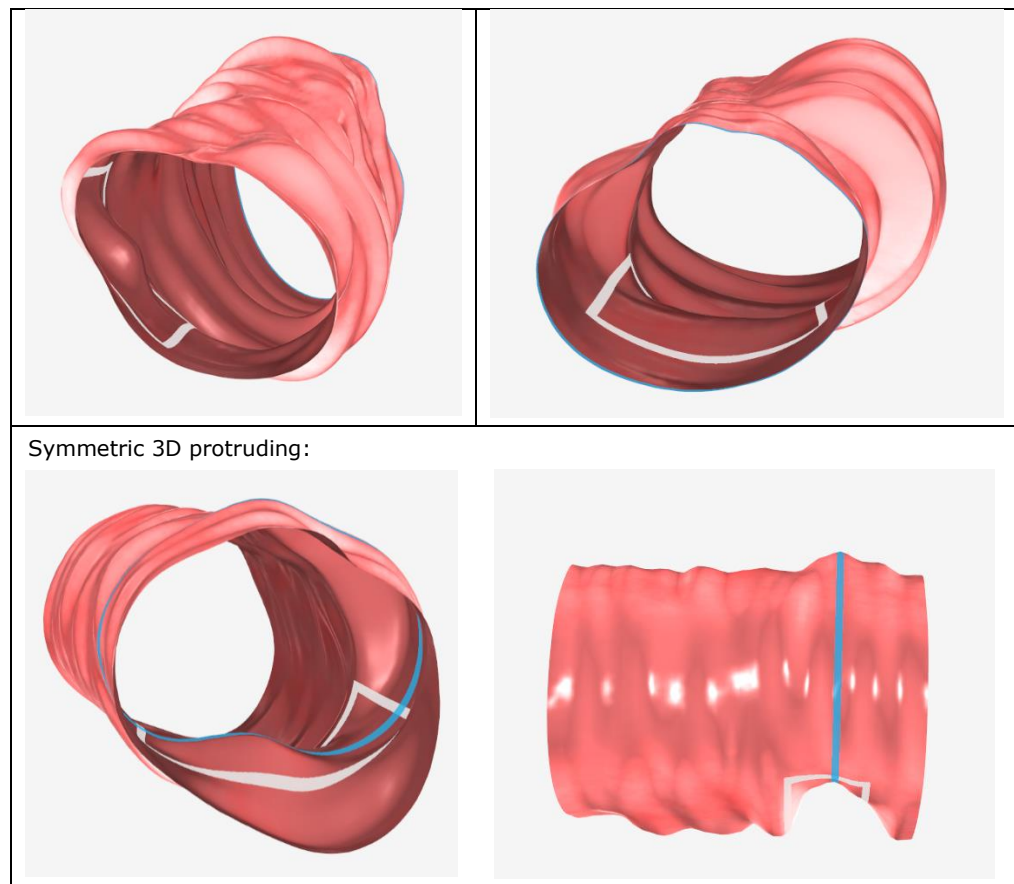
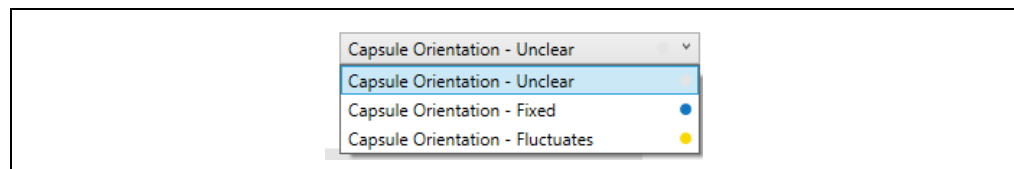


Figure 69: Local Orientation



The capsule local orientation in the marked ROI is evaluated and the averaged orientation status is chosen automatically in the analysis wizard. This status can be changed manually.

Capsule local orientation in the vicinity of slices composing the suspect can be examined in the motility tab.

The Capsule Orientation graph shows the change of the capsule orientation throughout the segment: pitch, yaw, and Δ (a measurement representing the maximal angular changes of the capsule).

Slice status is considered static if $\Delta < 35^\circ$. See examples in Table 4.

In some cases, the track sensors cause invalid orientation changes, and then the automatic indicators cannot be determined. "Local orientation" indicator options are both colored in grey in this case.

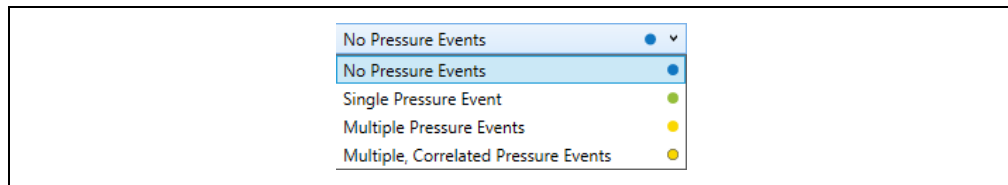
Fluctuates status is more likely to appear around a suspect, since the capsule has to move around a suspicious finding. "Local orientation" indicator is colored accordingly, "Fluctuates" option in yellow and "Fixed" option in blue.

Table 4: Capsule Orientation Examples

<p>Fixed local orientation</p>	<p>Local orientation - Fluctuates Fixed</p> <p>Capsule Orientation [°]</p> <ul style="list-style-type: none"> ● Pitch ● Yaw ● Δ
<p>Fluctuates local orientation</p>	<p>Local orientation - Fluctuates Fixed</p> <p>Capsule Orientation [°]</p> <ul style="list-style-type: none"> ● Pitch ● Yaw ● Δ
<p>Status cannot be determined (due to track sensor issue)</p>	<p>Track Sensors [mm]</p> <p>Local orientation - Fluctuates Fixed</p> <p>Capsule Orientation [°]</p> <ul style="list-style-type: none"> ● Pitch ● Yaw ● Δ

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Figure 70: Pressure Events



Pressure events are identified and counted in each segment.

The pressure status in the analysis wizard is chosen automatically from the pressure indicator. This status can be changed manually.

False detection or miss-detections of pressure events can occur. If the user recognizes an event with more than 3 samples and amplitude higher than ~0.25 mm Hg, it can be referred to as a pressure event.

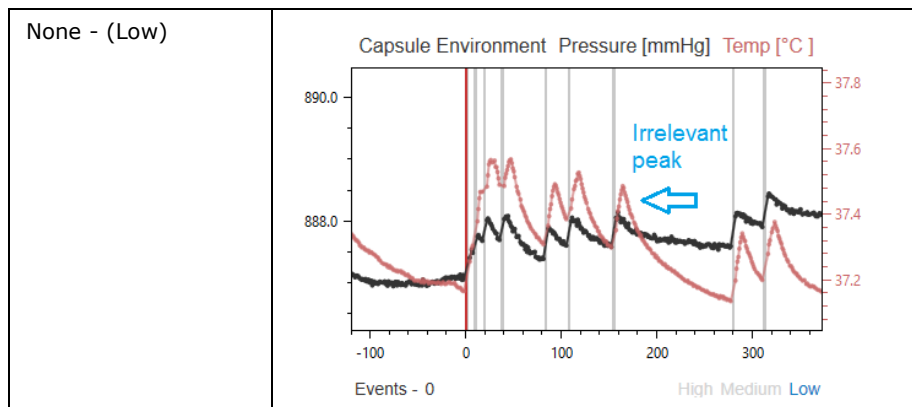
Immediately after a scan is captured, a peak in pressure and temperature graph occurs. Those peaks are not relevant for suspect analysis. True pressure events are reflected only in the black pressure graphs, while the temperature graph remains smooth at the same time points.

- Multiple events correlated with events in orientation are not detected by the pressure indicator and can be detected by the user.

A pressure event near the polyp is considered a positive indicator for a suspicious finding. Pressure events indicator is colored accordingly, "High" option in yellow, "Medium" option in green and "Low" option in blue.

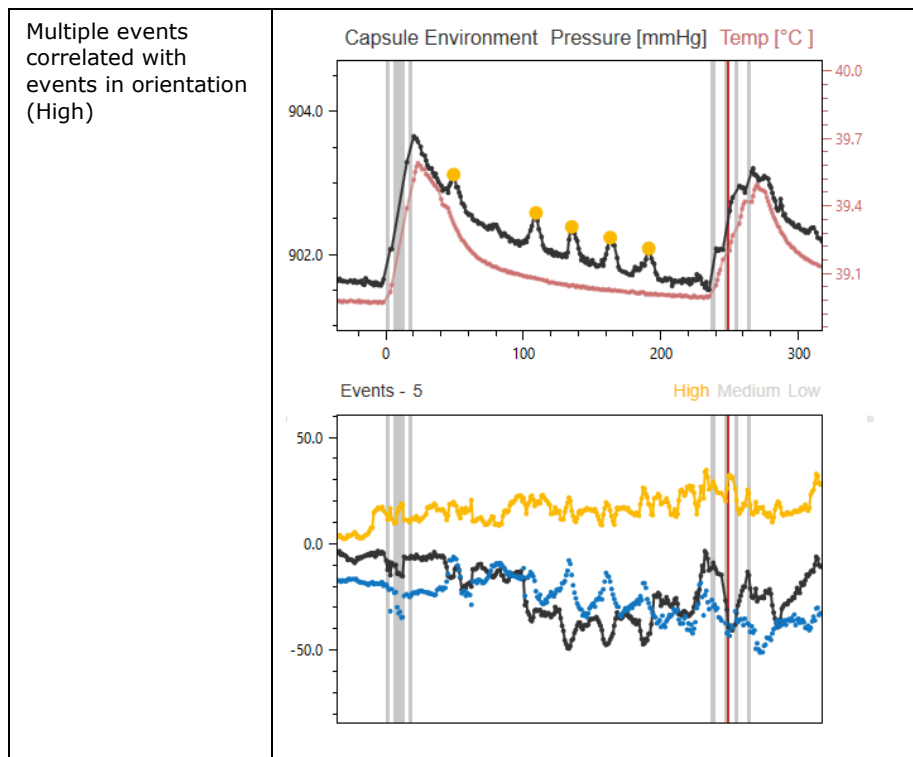
See examples in Table 5.

Table 5: Pressure Event Examples



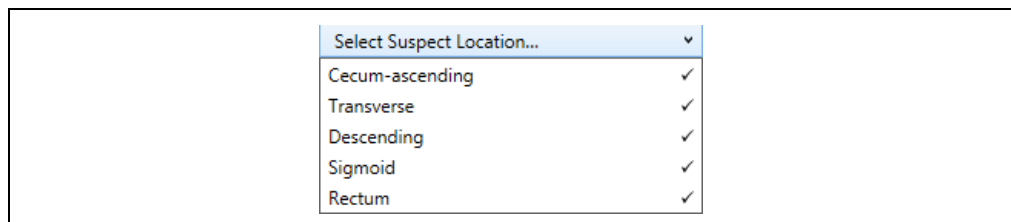
<p>Single unmarked event (Medium)</p>	
<p>Single marked event (Medium)</p>	
<p>Unmarked multiple events (Medium)</p>	
<p>Marked multiple events (High)</p>	

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The following questions are do not affect the wizard statistical analysis and are saved for research and statistical analysis only.

Figure 71: Colon Model Location



Check the segment location in the Segment Locator on the 2D Maps tab and the capsule position on the Motility tab. Then, select the approximate location of the suspect in the colon (Refer to the Help text and diagrams for illustrations, by hovering over the question mark icon).

Figure 72: Help Text for Suspect Location

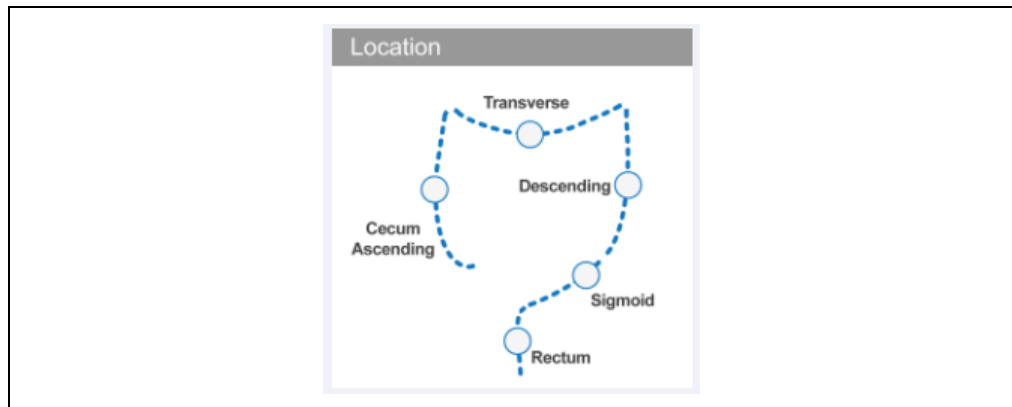


Figure 73: Clinical Opinion

The image shows a software interface element: a dropdown menu. The menu is currently open, showing the selected option "Suspect Evaluation..." at the top with a downward arrow. Below it are two other options: "Weak Suspect" next to a blue circular icon, and "Strong Suspect" next to a yellow circular icon.

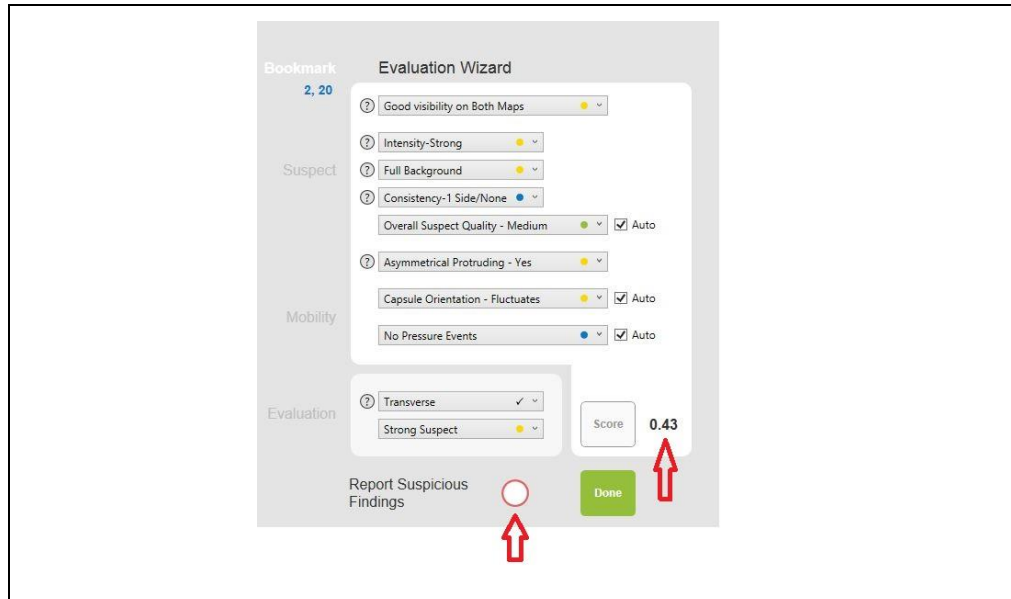
Select the answer that matches your overall opinion about the suspect, relying on your own clinical experience.

When the "Score" button is clicked, a score (between 0 and 1) is generated (see Figure 74). The higher the score, the greater the statistical likelihood of the suspect being a suspicious finding. The wizard's algorithm compares the suspect profile, built using the physician answers, to a clinical database, and determines how statistically similar it is to a suspicious finding profile. A score above 0.4 is considered as a high score.

Suspicious findings can be marked and sent to the report (see Figure 74).

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Figure 74: Suspect Analysis Result



The answers used by the algorithm are saved in the Results tab (Figure 75).

Use the suggested score combined with personal evaluation of the suspect to decide whether the finding is suspicious or not. Personal evaluation is based on the suspect reliability and clinical experience. Log suspicious findings in the report tab.

Please refer to DOC001212 C-Scan View Physician training document for more information about analyzing suspects

7.11 Results Screen – General

All suspects' evaluation are saved in the results screen (Figure 75). Analysis results can be deleted using the delete button. Suspects can be sent to the report from the results screen.

Figure 75: Results Tab

C-ScanView	Review		Results				Report				
	Check-Cap	2017 Dec 14	8:56 AM	X							
Suspect		Morbidity		Evaluation		Report					
Visibility	Asymmetrical Perceiving	Intensity	Background	Consistency	Quality	Orientation	Pressure	Score	Strong Suspect	Delete	Report Suspicious Findings
Cecum - Ascending											
Transverse	2.20	2	✓	✓	✓	Med	Fluctuates	0.43	✓		🎯
Descending											
Sigmoid	12.317	1	✓	✓	✓	Med	Fixed	0.05	-		🚫
Rectum											

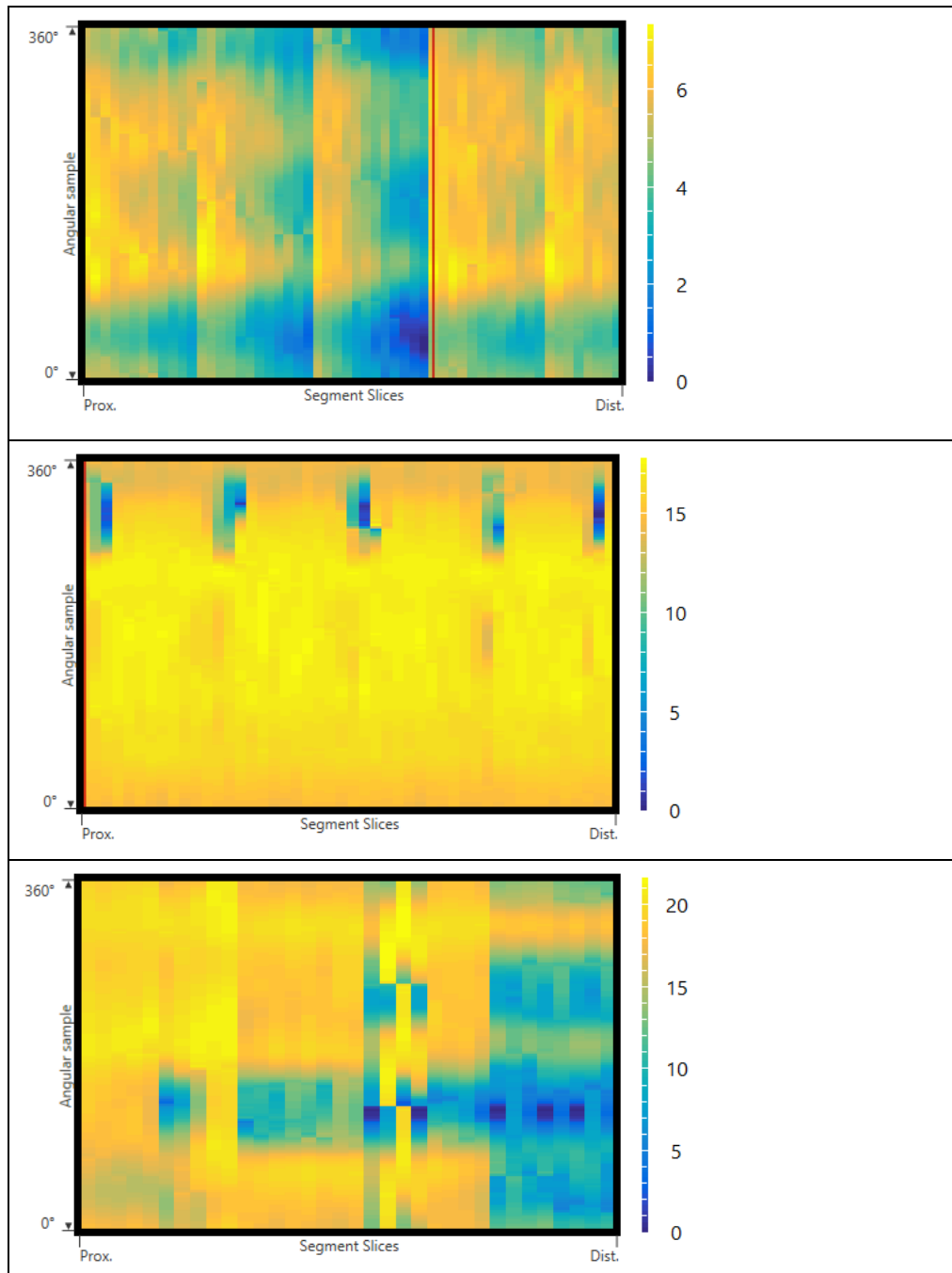
7.12 Imaging Data Validity

The reconstruction algorithm performs a validity check on all scanned data acquired by the capsule.

The reconstruction algorithm is designed to filter faulty scans only, while not affecting proper clinical data. Minor issues may still be visible, resulting in a few artifacts (See examples in Table 6).

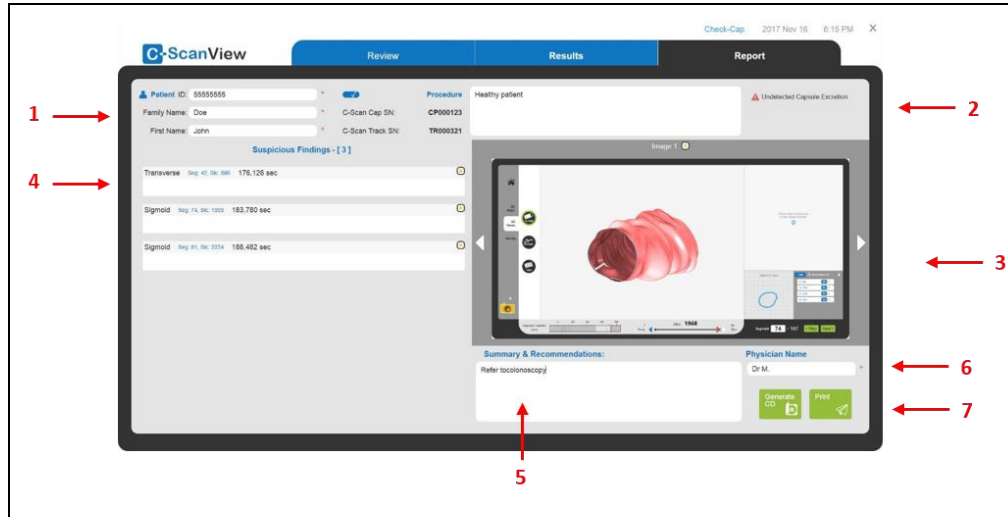
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Table 6: Images with Artifacts



8 Creating a C-Scan® System Report

Figure 76: C-Scan® View Report Screen

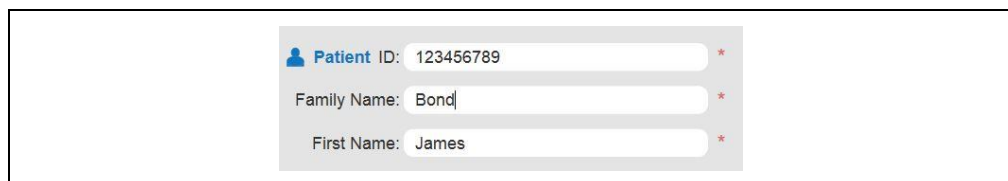


- 1. Patient field
- 2. Procedure field
- 3. Screen capture field
- 4. Suspicious findings field
- 5. Physician comment fields
- 6. Physician name
- 7. Generate CD and Print icons

The Report screen displays all the patient data that was entered at the beginning of the procedure and the snapshots taken during the review.

8.1.1 Patient Field

Figure 77: Patient Field



The Patient Field shows the patient name and ID that were entered at the beginning of the session. The fields are editable and can be changed or updated.

8.1.2 Procedure Field

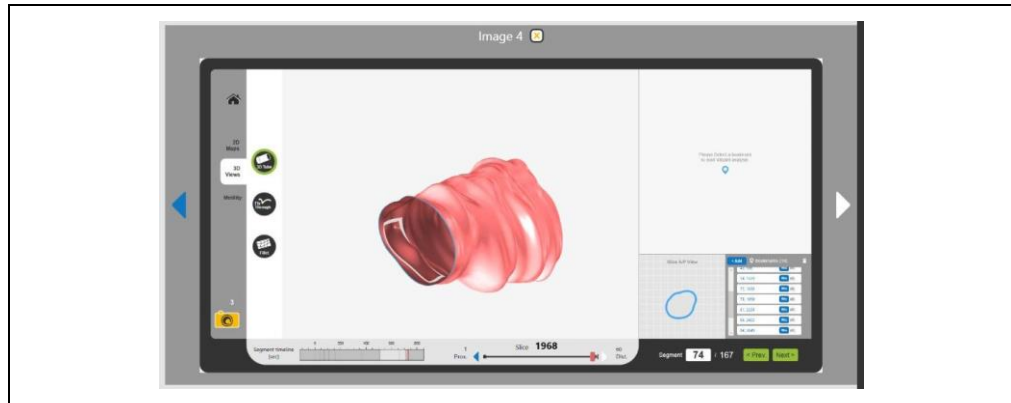
Figure 78: Procedure Field



Creating a C-Scan® System Report

The Procedure Field displays the *C-Scan*® *Cap* Serial Number and the *C-Scan*® *Track* Serial Number. Remarks that were entered in the Patient Details window at the beginning of the procedure are displayed in the remarks field. This field is editable, allowing additional remarks, up to the 1000 character limit.

Figure 79: Screen Capture Field

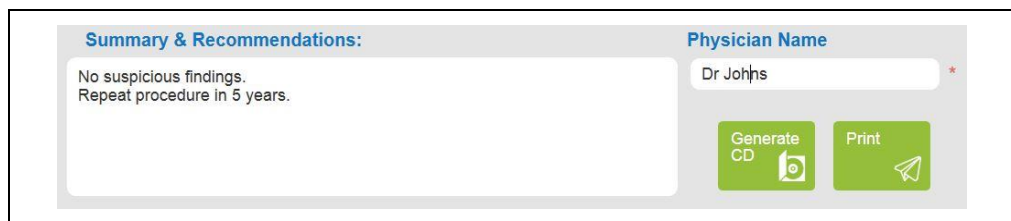


The Screen Capture Field displays all the screen captures taken during the review session. Click on the arrows to scroll through the screen captures. Each screen capture is numbered consecutively.

Each screen capture in the report window has an exit button (X) next to it. Delete any unwanted snapshots by clicking on the X to the left of the snapshot.

8.1.3 Physician Comment Fields

Figure 80: Physician Comment Fields



The Physician Comment Fields contains editable fields for the physician to record findings, remarks and recommendations. The fields are:

- Summary & Recommendations – Maximum length is 1000 characters.
- Physician Name – Maximum length is 20 characters.

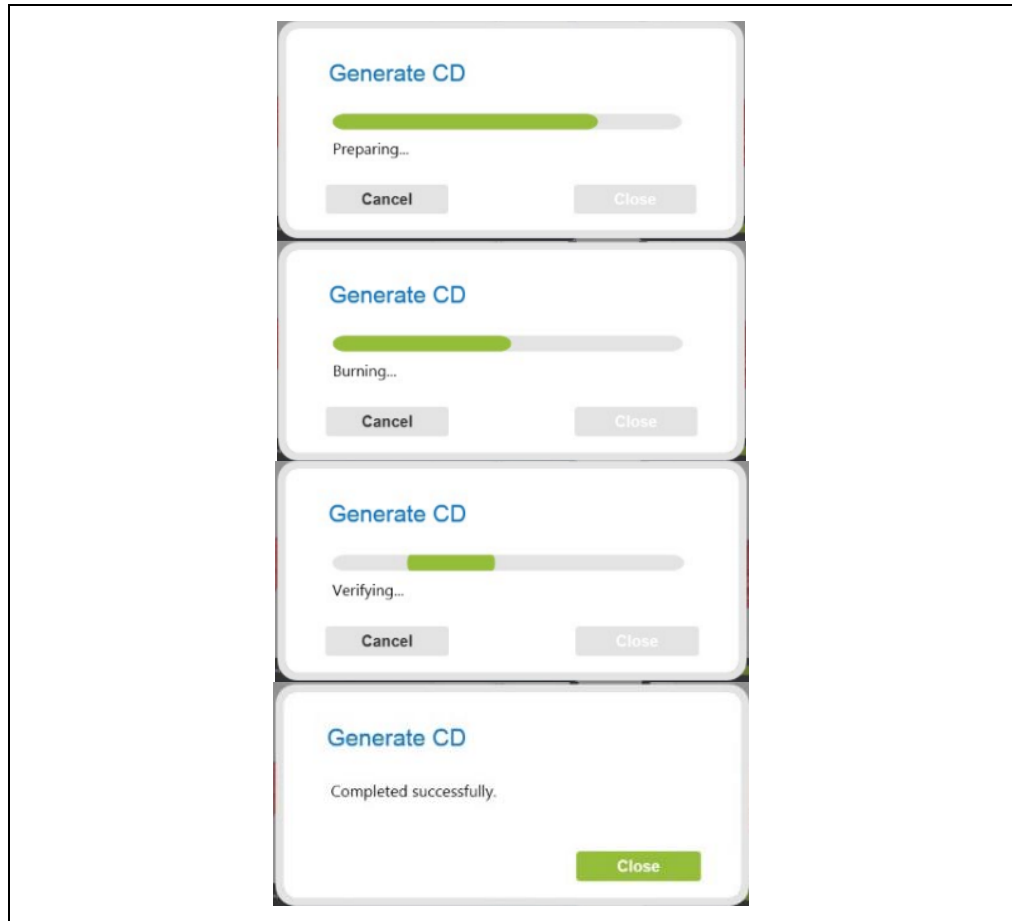
The Report Window also contains two icons:

- **Generate CD** – Make sure there is a blank writable CD in the CD drive, wait a while after inserting the CD before the burn process can start and then click Generate CD to create a procedure results CD. The procedure 3D reconstructed results and the PDF report are copied to the CD.

Note: The C-Scan® View does not save the raw data.

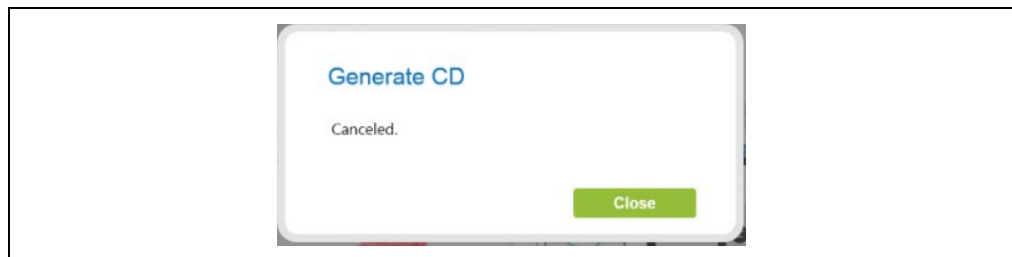
The CD generation process is displayed in a series of pop-up windows. Once the process is done, a message indicates the CD was successfully created.

Figure 81: Generate CD Progress



CD generation can be cancelled at any point in generation process. Click **Cancel** to stop the process. A window pops up – click **Close** to return to the Report screen.

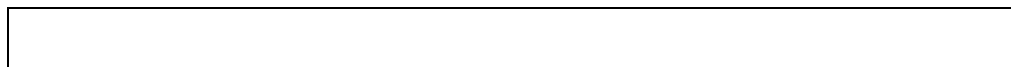
Figure 82: Generate CD Cancel




If the CD creation failed, a notification message appears with the following text: "Failed to create a CD. Please insert a blank CD."

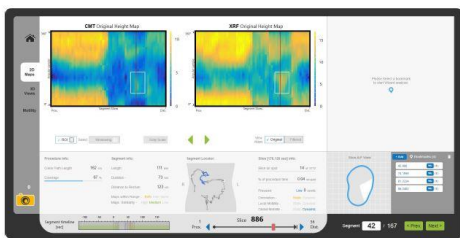
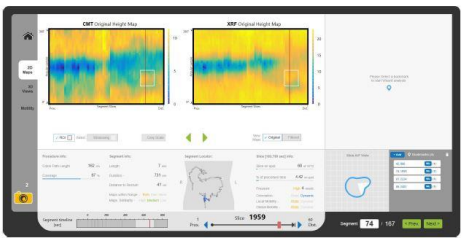
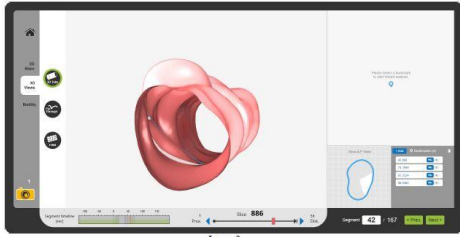
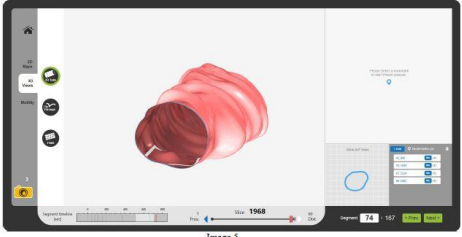
- **Print** – Press the **Print** icon to print the report on the attached printer.

Figure 83: C-Scan® Report – 4 Structured Pages



Creating a C-Scan® System Report

<p style="text-align: center;">C-Scan Report 2018 Jan 10 13:34:17</p> <p>General</p> <p>Patient: Family Name: Doe First Name: John ID: 55555555</p> <p>Procedure: C-Scan Cap SN: CP000123 C-Scan Track SN: TR000321</p> <p>System Notifications: Undetected Capsule Excretion</p> <p>Remarks: Smoker</p> <p style="text-align: right; font-size: small;">Doc Id: 55555555, 2018 Jan 10 13:34:17 C-Scan Report 1 / 6</p>	<p>Suspicious Findings (3)</p> <p>Colon Map (A/P view):</p>  <p>Colon Coverage: 67 %</p> <p>Suspicious Finding 1 Location: Transverse Segment 42, Slice 886 Time: 176,126 sec.</p> <p>Suspicious Finding 2 Location: Sigmoid Segment 74, Slice 1959 Time: 185,780 sec.</p> <p>Suspicious Finding 3 Location: Sigmoid Segment 81, Slice 2224 Time: 185,482 sec.</p> <p style="text-align: right; font-size: small;">Doc Id: 55555555, 2018 Jan 10 13:34:17 C-Scan Report 2 / 6</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

 <p style="text-align: center;">Image 1</p>	 <p style="text-align: center;">Image 3</p>
 <p style="text-align: center;">Image 2</p> <p style="text-align: right; font-size: small;">Doc Id: 55555555, 2018 Jan 10 13:34:17 C-Scan Report 3 / 6</p>	 <p style="text-align: center;">Image 5</p> <p style="text-align: right; font-size: small;">Doc Id: 55555555, 2018 Jan 10 13:34:17 C-Scan Report 4 / 6</p>

9 Ordering the C-Scan® Kit and Disposing of the Used Components

Before ordering the C-Scan® System:

- Check the local code for handling radioactive devices. See Chapter 10: Technical Description for the C-Scan® Cap technical specifications.
- Check the clinic procedures for receiving, handling, and storing radioactive devices.
- Verify who is certified to receive the shipment. This person should be the only one to receive the C-Scan® System and must be trained in handling, receiving, and storing radioactive devices.

9.1 Ordering the C-Scan® Cap

9.1.1 Before Ordering

- Discuss the examination with the patient, obtain the patient approval, and have the patient sign the consent form.
- Provide instructions to the patient regarding preparing for the procedure.
- Set the date and time for ingestion. Due to the manufacturing restrictions of the C-Scan® Cap, designating a set day of the week for ingestion will help ensure receipt of the C-Scan® System in a timely manner.

9.1.2 Ordering

Contact Check-Cap to order the C-Scan® System:

Address	Check-Cap Ltd. 29 Abba Hushi Ave. P.O.Box 1271 Isfiya, 3009000 Israel
Telephone	+972-4-821-1258
Fax	+972-4-821-1267
Email	info@check-cap.com

Note: Order the C-Scan® System at least two weeks prior to the procedure date, as the radioactive material is inserted into the C-Scan® Cap on a “just-in-time” basis to maintain the longest possible capsule life. The radioactive core is inserted into the C-Scan® Cap just prior to shipping.

Upon receipt of the order, Check-Cap:

- Plans production and hot assembly time line
- Assembles, tests, pairs, and packages the C-Scan® System



Ordering the C-Scan® Kit and Disposing of the Used Components

- Ships the *C-Scan® System* to the clinic by courier certified to carry radioactive devices

Note: The shipment is sent door to door and not to the clinic storeroom. The clinic must have its dedicated person with a permit for handling RA materials, on site to receive the shipment. Do not break the seal on the *C-Scan® Kit* box. This should be done only by the physician, nurse, or technician at the time of the procedure.

9.2 Returning the C-Scan® Cap

Once the *C-Scan® Cap* is expelled, the patient should follow the directions in the Instructions for Use for returning the *C-Scan® Cap* and *C-Scan® Track* to the clinic.

The clinic's designated person should then do the following:

1. Pack the *C-Scan® Cap* in the original box and place it back in the original package. This action complies with the requirements for keeping the proper distance from the radioactive device.

The contrast agent and other accessories and consumables should stay with the clinic. They can be used by other patients as long as they do not expire and are still in their original intact condition.

Discard the patient's kit according to local codes and guidelines.
















10 Technical Description

10.1 System Labeling








System:

Labeling	Explanation
<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">EC</div> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">REP</div> <div style="margin-left: 10px;"> <p>CEpartner4U BV</p> <p>Esdoornlaan 13</p> <p>3951 DB Maarn</p> <p>The Netherlands</p> </div> </div>	<p>EC Rep</p>

Technical Description

Labeling	Explanation
	CE Mark
	Single use only - Do not re-use.
	Consult accompanying documents (required to consult for Safety)
	Serial number
	Manufacturer
	Date of Manufacture [YYYY,MMM,DD]
	Use-by date [YYYY, MMM, DD]
	"Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)."
	Caution, consult accompanying documents
	Do not use if the package is damaged
	Non-ionizing radiation
	Radioactivity
	Type BF equipment
	Catalogue number
	Keep dry

Technical Description

Labeling	Explanation
	Fragile, handle with care
	Humidity limitation
	Product contains natural rubber latex
	Temperature limit
	LOT number
	Not for general waste
	"I-White" label - Safe transport of radiation material label

10.2 C-Scan® Kit Labels

Each *C-Scan® Kit* box has a label on the cover as shown in Figure 85. Each box is marked with the expiration date, lot number, and a unique *C-Scan® Kit* serial number.

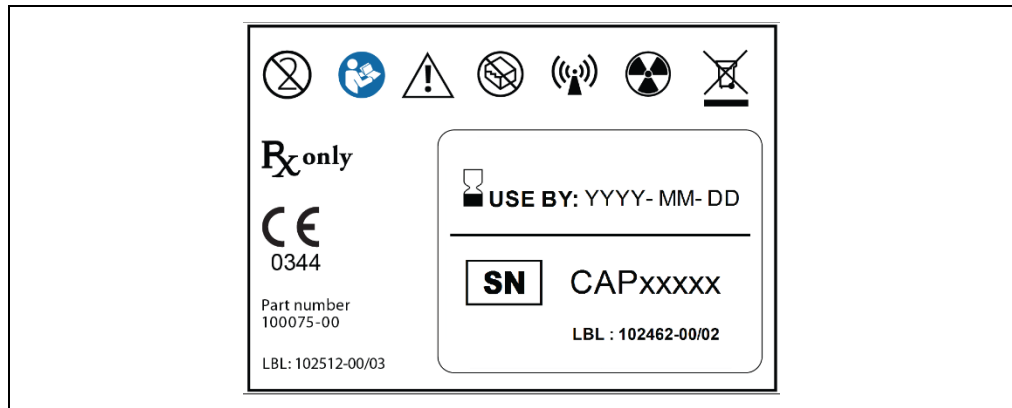
Figure 84: C-Scan® Kit Labels



10.3 C-Scan® Cap Label

Each capsule box has a label at the bottom as shown in Figure 85. Each capsule is marked with the expiration date, lot number, and a unique capsule serial number.

Figure 85: C-Scan® Cap Label

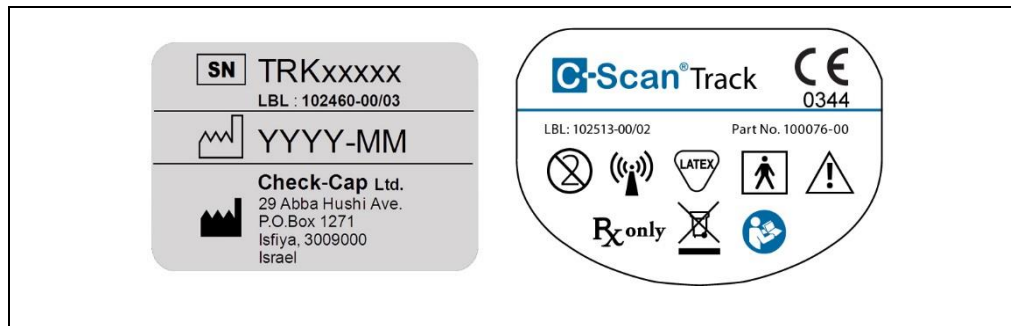


10.4 C-Scan® Track Label

The C-Scan® Track has two labels on the sensor units as shown in Figure 86. Each C-Scan® Track is marked with a unique serial number.

Technical Description

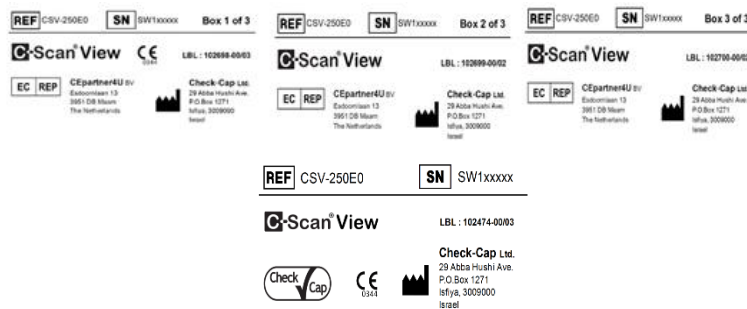
Figure 86: C-Scan® Track Labels



10.5 C-Scan® View Labels

The C-Scan® View has four labels. 3 Packing labels on the PC package, Monitor package and Printer package and a label on top of the PC as shown in Figure 86. Each C-Scan® View is marked with a unique serial number.

Figure 87: C-Scan® View Labels



10.6 Essential Performance

10.6.1 C-Scan® Cap

The C-Scan® Cap has 3 modes of operation: Standby, BIT and Active. Upon power connection the C-Scan® Cap switches to Standby mode. The C-Scan® Cap stays in Standby mode as long as it does not receive a valid wakeup request to switch to BIT mode, from the C-Scan® Track via the communication channel.

Once, a valid wakeup request is received by the C-Scan® Cap it switches to BIT mode and only if all BIT tests are successfully passed the C-Scan® Cap switches to Active mode. In Active mode the C-Scan® Cap continually communicates with the C-Scan® Track and performs scans until it is expelled from the body.

10.6.1.1 Standby Mode

Standby mode is C-Scan® Cap lowest power consumption mode. In this mode C-Scan® Cap main microcontroller doesn't execute any operations and the only active unit is the communication unit, which is completely autonomic.

10.6.1.2 BIT Mode

System BIT process is a test sequence between a *C-Scan® Cap* and *C-Scan® Track* with matching IDs. During this process each subsystem verifies its proper functionality. Some of the tests are autonomic and some require the participation of both subsystems. The final approval of the system BIT is granted only by the *C-Scan® Track*. If the *C-Scan® Cap* does not receive system BIT approval\disapproval after completing BIT execution, the *C-Scan® Cap* switches back to Standby mode.

10.6.1.3 Active Mode

Active mode is *C-Scan® Cap* main mode of operation. Only in Active mode the *C-Scan® Cap* can perform scans and transmit acquired data.

X-ray transmission occurs only while the *C-Scan® Cap* is in motion inside the colon, limiting radiation exposure. To detect *C-Scan® Cap* motion, the *C-Scan® Cap* generates a positioning signal, which is interpreted by the *C-Scan® Track* Scan Control Algorithm which then informs the *C-Scan® Cap* to open the concealment cover and begin the scan. When the *C-Scan® Track* determines that the motion has ended, the *C-Scan® Cap*'s X-ray source is concealed. In this mode, radiation leakage measured on the capsule surface does not exceed 0.05% of source activity.

The *C-Scan® Cap* verifies that the X-ray source is concealed. If the X-ray source is not concealed, the *C-Scan® Cap* sends a message to the *C-Scan® Track* informing it that the X-ray source is exposed. It continues to send the message until the *C-Scan® Track* acknowledges. If the problem is not resolved by the *C-Scan® Track*, it sends a malfunction indication to the patient, who should contact the clinic immediately.

10.6.2 *C-Scan® Track*

The *C-Scan® Track* is an external device attached to the patient back. The *C-Scan® Track* tracks the *C-Scan® Cap* position, sends commands to the *C-Scan® Cap*, receives and stores imaging data sent by the *C-Scan® Cap*, and interfaces at the end of the procedure with the *C-Scan® View*.

The *C-Scan® Track* has several main modes of operation:

- Idle mode – includes sleep mode
- Calculation cycle mode – a single process of *C-Scan® Cap* position estimation and full SCA calculation
- *C-Scan® Cap* temperature/pressure data transfer mode - *C-Scan® Cap* sensor data is received through RF

The *C-Scan® Track* consists of the following units:

- Positioning System - a localization device that tracks and records the position and orientation of the *C-Scan® Cap*, enabling intra-colon mapping for the purpose of colon surface imaging.
- Data Recorder - a recording device that captures the *C-Scan® Cap* data (imaging, etc.) to a non-volatile memory. Data transmission is through RF communication during the *C-Scan® Cap* transition in the GI tract. The recorder also enables data retrieval through the USB Interface Unit following procedure completion.

Technical Description

- Processing Unit – an embedded device that controls localization and recording functions, running an embedded Scan Control Algorithm through which the *C-Scan® Cap's* scan mechanism is operated.
- User Interface Unit – Sends status indicators to the patient.
- USB Interface Unit – USB interface that enables data transfer from the *C-Scan® Track* to the *C-Scan® View*, as well as production and service needs.

10.6.3 C-Scan® View

The *C-Scan® View* is an offline, standalone application that processes and displays the data acquired by the *C-Scan® System*. The *C-Scan® View* imports procedure data from the *C-Scan® Track*, manages patient information, displays the 3D colon reconstruction, and generates a procedure report and a results CD.

10.7 System Specifications

Note: Specifications are subject to change without prior notice and without any obligation to users on the part of the manufacturer.

Note: Specifications are rounded to the appropriate decimal place.

Table 7: Technical Specifications

<i>C-Scan® Cap</i>	
Mechanical Dimensions (Length x Diameter)	35mm x 12mm (1.4" x 0.5") +/- 5%
Weight	13 gram (0.5 oz.)
Material	Biocompatible
X-ray source	W-181 (Tungsten)
<p>The <i>C-Scan® Cap</i> radiation source is assembled within a 3mm-thick Tungsten concealment. It also incorporates a permanent shielding of 0.5mm-thick Aluminum foil, as part of the radiation canister structure.</p> <p>RADIATION QUALITY is constant, guaranteed, and verified, thanks to isotope-based source. Hence no ADDED FILTER required.</p> <p>In normal use, dose levels might increase mainly due to abnormal motility, i.e. the capsule remaining static. Procedure duration then limits the dose level to two orders-of-magnitude lower than the acceptable threshold for deterministic effects.</p> <p>The RADIATION DETECTORS integrated into the <i>C-Scan® Cap</i> are based on CdTe/CZT crystals, demonstrating nearly-perfect Quantum Efficiency within the imaging energies range.</p> <p>The maximum total attenuation of all items interposed between the patient and the radiation detectors is equivalent to less than 0.2mm thick Aluminum layer.</p> <p>The <i>C-Scan® Cap</i> radiation source housing ensures negligible exposure to any OPERATOR or STAFF.</p>	
Hot phase shelf life	Up to 2 weeks
Operating Temperature	+5°C (41°F) to 45°C (113°F)
Operating Humidity	100% Relative Humidity
Operating Pressure	520 mmHg to 940 mmHg

Storage and Transportation Temperature	-10°C (-4°F) to 45°C (113°F)
Storage and Transportation Humidity	10 to 80% Relative Humidity
Storage and Transportation Pressure	520 mmHg to 1200 mmHg
Operating Frequency RF Band	433.5 MHz ±127 KHz
RF Modulation Type	2 FSK , 38.4 Kbit/sec
Effective Radiated Power	10 dbm
Battery Type	Silver Oxide - 399ZGB (0% mercury)
Battery Life	maximum 100 hours
<i>C-Scan® Track</i>	
Mechanical Dimensions Sensor Unit (Length x Width x Depth)	<100 mm x 100 mm x 20 mm (1.4" x .5")
Weight Sensor Unit	< 60 grams
Mechanical Dimensions Power Unit (Length x Width x Depth)	50 mm x 50 mm x 20 mm
Weight Power Unit	<30 gram
<i>C-Scan® Track</i> Weight	250 gram (.5 oz)
Material	Withstands common detergents and perfumes, isopropyl alcohol (IPA), Methylated spirit and water swiping
Operating Temperature	+5°C to +45°C
Operating Humidity	10 to 80% Relative Humidity
Mechanical Shock	300 m/s ² (30g) duration 6 ms
Water Drops	IP24
Storage and Transportation Temperature	-10°C (-4°F) to 45°C (113°F)
Storage and Transportation Humidity	10 to 80% Relative Humidity
Storage and Transportation Pressure	520 mmHg to 1200 mmHg
Operating Frequency RF Band	433.5 MHz ±127 KHz
RF Modulation Type	GFSK
Effective Radiated Power	10 dbm
Battery Type	AA Lithium 03-2033
Battery Life	Max. 100 hours

10.8 Guidance and Manufacturer’s Declaration

Table 8: Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The *C-Scan® System* is intended for use in the electromagnetic environment specified below. The customer or the user of the *C-Scan® System* should assure that it is used in such an environment.

Technical Description

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The <i>C-Scan® System</i> uses 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	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 9: Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The <i>C-Scan® System</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>C-Scan® System</i> 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines; ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	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	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <i>C-Scan® System</i> requires continued operation during power mains interruptions, it is recommended that the <i>C-Scan® System</i> be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m, 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Table 10: Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The <i>C-Scan® System</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>C-Scan® System</i> should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <i>C-Scan® System</i>, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	$d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>

Technical Description

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *C-Scan® System* is used exceeds the applicable RF compliance level above, the *C-Scan® System* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *C-Scan® System*. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

10.9 Compliance with FCC regulations:

Statement: 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. See 47 CFR Sec. 15.105(b). 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 the receiver.
- Connect the equipment to 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.

11 Troubleshooting

11.1 C-Scan® View

Problem	Cause	Action
C-Scan® View error: Load CD Failure Screen	CD DAMAGED	Contact Customer Support
C-Scan® View error: Processing Data Failed	DATA FAILURE	Contact Customer Support

11.2 Downloading Data from C-Scan® Track

Problem	Cause	Action
C-Scan® View error: Failed to connect to C-Scan® Track.	C-Scan® Track connection	Please check C-Scan® Track connection". Check the C-Scan® Track connection to the PC and click OK to close the message and return to the Welcome screen.

11.3 Printer

Problem	Cause	Action
Cannot print report	Printer is turned off	Turn printer on
	Printer is not set as default printer	Set printer to Default Printer
	Printer has a malfunction	Contact Customer Support

11.4 CD/DVD

Problem	Cause	Action
Cannot burn CD/DVD	CD/DVD is not blank or compatible with CD/DVD ROM	Contact Customer Support
	Wrong burning procedure	Insert a new CD/DVD and burn again

11.5 C-Scan® Kit

Problem	Cause	Action
Pairing fails, it is indicated by a longer series of Beeps (5 sec.).	C-Scan® Cap failure	Please contact Check-Cap for possible actions.

Troubleshooting

<p>Capsule malfunction indicated by repeated Audible beeps</p>	<p><i>Open Concealment mechanism causing high radiation exposure</i></p>	<p>The physician should invite the patient to clinic and consider various options to remove capsule out of the GI tract.</p>
----------------------------------------------------------------	--------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------

12 Information for User

This section contains all the information in the Patient Diary plus additional instructions for the clinic.

12.1 Patient and Clinic Information

The following information should be entered on the front page of the Patient Diary:

- Patient Name (and a copy of the patient clinic sticker, if one exists)
- C-Scan® Track Serial Number
- Clinic Contact Information (usually a sticker)

12.2 Activities Allowed During the Procedure

The following activities are allowed during the procedure:

- Eat normally. There are no restrictions as to the type of food.
- Daily routine, except for those activities listed in Section 12.3.
- Work
- Sleep
- Driving/riding in car or public transportation
- Sitting, standing, walking
- Taking a shower (leaving the Recorder attached to the back)

12.3 Activities Not Allowed During the Procedure

- Full-body immersion in water, such as:
 - Taking a bath
 - Swimming
 - Hot tub (Jacuzzi)
- Active sport such as
 - Jogging
 - Physical exercise in the gym
 - Sauna
 - Ball-games
 - Skiing
 - Contact sports
- Travel. For example:
 - Flights
 - Boat trips
 - Long train trips
 - Long car trips
- Close proximity to areas with high electromagnetic fields such as: high voltage electric poles, transformer stations, radio and TV transmitter stations, etc.
- CT or MRI procedures (unless it is an emergency, then be sure to notify the medical team about the capsule and Track).

12.4 Must Do

The following activities are required during the procedure:

- Take all medications as normal
- Take the Contrast Agent and Fiber at the designated times – morning, noon, and evening. Each vial contains one portion.
- Keep the Patient Diary with you and keep a record of your activities

12.5 Patient Bag Checklist

Check the Patient Bag against this inventory list. If anything is missing, contact the clinic.

Patient Bag Inventory List

- 15 portions Fiber Supplement/Contrast Agent
- 5 Stool Collection Devices
- 1 FIT Kit (For clinical study only, not required for normal use of the device)
- 3 Pairs Disposable Gloves
- 1 Tong
- Sealable Plastic Bags
- 5 Alcohol
- 3 Extra Stickers

12.6 Keeping Your Patient Diary

The Patient Diary is an important part of the procedure. Make sure you read it and understand the procedure. Enter the time that the activity is performed – no other input is necessary.



Information for User

Activity	Day 1	Day 2	Day 3	Day 4	Day 5
Morning-Take Contrast Agent/Fiber	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Noon - Take Contrast Agent/Fiber	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Evening - Take Contrast Agent/Fiber	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Breakfast	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Lunch	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Dinner	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Shower 1	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Shower 2	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Sleep	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Driving	Enter Time	Enter Time	Enter Time	Enter Time	Enter Time
Bowel Movement 1	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit
Bowel Movement 2	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit
Bowel Movement 3	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit	Enter Time <input type="checkbox"/> Used Collection Kit
Other	Briefly Describe	Briefly Describe	Briefly Describe	Briefly Describe	Briefly Describe

12.7 Using the Stool Collection Device

Note: Make sure you use a collection device for every bowel movement.

Information for User

12.7.1 Attaching the Stool Collection Device Container

Figure 88: Using the Stool Collection Device – Lay on Top of the Toilet Seat



1. Place the single use container onto the toilet bowl, on top of the seat. Be sure to orient it to fit into the seat.

Figure 89: Using the Stool Collection Device and Accessories



2. Prepare the required accessories needed for retrieving the capsule:
 - Gloves
 - Plastic bag
 - Tongs
 - Alcohol wipes
3. Have the bowel movement (do not use toilet paper yet).



4. Pay attention to audible indication of capsule excretion. The C-Scan® Track signals when the capsule is excreted.
5. Stand up and look into the container and search for the capsule (use the gloves and tong
6. Use the tongs to retrieve the capsule from the collection container.
7. Rinse the capsule under running water and place it in the plastic bag.
8. Place the plastic bag with the capsule in the Procedure Bag to return to the clinic.

Caution: Do not urinate into the collection container.

12.8 Retrieving the Capsule at the End of the Procedure

1. The C-Scan® Track signals when the capsule is excreted.
2. Use the tongs to retrieve the capsule from the collection container.
3. Rinse the capsule under running water and place it in the plastic bag.
4. Place the plastic bag with the capsule into the cardboard box and then in the Procedure Bag to return to the clinic.

12.9 In Case of Malfunction

If you get a malfunction indication, consisting of repeatable audible beep and vibration, contact the clinic.

12.10 When to Call the Clinic

Note: If you feel something is not right, at any time during the procedure or immediately after, contact the clinic.

If any of the following occur, contact the clinic for further directions:

- Any sensation of pain or discomfort
- The C-Scan® Track sends a malfunction indication
- One or more C-Scan® Track sensors detaches from the sticker
- One or more C-Scan® Track stickers detach from the body
- Capsule is expelled
- After 4 days the capsule is not expelled

12.11 Guidelines for the Clinic

The following are possible calls you may receive from the patient, and suggested actions you should take (see figure 90 **flow chart** in last page).

- Capsule is Not Found After C-Scan® Track Indicates it Was Expelled
 - Advise the patient to look in the toilet. If it is found, the patient should bring it to the clinic.
 - If the capsule is not found, the patient should speak with a physician at the clinic as there is a chance it wasn't expelled despite the positive indication. The physician might recommend using a laxative at home to try to expel the capsule. Make sure that the patient knows to use the collection kit during any bowel movements. Or, the physician might recommend coming to the

Information for User

clinic to examine the patient personally. In all cases, the clinic protocols and the physician determine the course of action.

- **Capsule Not Expelled After 4 Days**
 - If 4 days have passed and the capsule was not expelled, the patient should speak with a physician at the clinic (if needed, be sure to initiate a contact with the patient). The physician might recommend using a laxative at home to try to expel the capsule. Make sure that the patient knows to use the collection kit during any bowel movements. Or, the physician might recommend coming to the clinic to examine the patient personally. In all cases, the clinic protocols and the physician determine the course of action.
- **Technical Malfunction – C-Scan® Track Sent a Fault Indication**
 - Verify that the indication was from the C-Scan® Track and not a background noise. A C-Scan® Track safety fault indication is identified by a series of repeated beeps
 - Ask the patient if a single indication was received, or was it repeated at regular intervals.
 - Ask if the patient feels something.
 - If it is a Safety malfunction (risk of higher than usual body radiation exposure), have the patient come to the clinic ASAP.
 - The clinic team (technician and/or physician) should perform, in case the capsule has not been excreted and collected already, abdominal X-Ray to assure the capsule location within the GI tract.
 - In the case of Safety Malfunction, intervention is required to remove the capsule without delay (recommended within 24 hours). Intervention, based on the physician's decision and imaging of the capsule's location, may include: use of laxatives, fibers, removal by colonoscopy, or by surgery.
 - Efforts should be made to minimize the patient's exposure by removing the capsule out of the body.

Note: Once the faulty capsule is out (by natural excretion or removed by colonoscopy) place it in the Kit box and notify the sponsor ASAP

- **Sensor or Recorder Detaches from Body**
 - Ask the patient:
 - Did the C-Scan® Track fall from the sticker?
If one or more sensors detach from the sticker, have the patient reattach the sensor to the Velcro. Mark in the diary that the sensor fell.
 - Did the sticker detach from the body?
If one or more stickers detach from the body, have the patient try to attach a new sticker in approximately the same place on the back. Mark in the diary that the sensor fell. If the patient is in the proximity of the clinic, have the patient come to the clinic.
 - Is the sticker intact and the sticker detached from the sensor?
If the sticker detached from the sensor have the patient try to reattach it. In any case, the patient should come to the clinic to have it checked.

Figure 90: End of Procedure Flow Chart

