C-Scan System
User Reference Manual

CHANGE HISTORY		
Rev. number	**Change Owner**	**Change description**
01	Michal Nachmanovich	Initial release
02	Michal Nachmanovich	ECO 228. Cautions, Warning chapter revising.Labels updating
03	Michal Nachmanovich	Revising the chapter of C-Scan view
04	Michal Nachmanovich	ECO-19-000034 Relaxation of lower BMI to ≥19
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06	Linur Yeter & Hadas Shahar	Update following DOC003233 rev07 and FDA input G200327 Dec18 2020:Instruct to store the C-Scan Cap in biohazard package after excretion (instead of flash in toilet) {URM.16} Instruction for the subject to contact clinic after 100 hours (instead of 150) {URM.54} Added: contraindications for diameter of stools, GI bleeding, GI surgery {URM.85-87}. Adding instructions for the clinic on how to disable the malfunction indication. Update the C-Scan System Procedure- General overview.
07	Linur Yeter	Update following FDA input G200327/A001 (25 Feb 2021): Detailed instructions for the clinic in case the C-Scan Cap is not excreted after more than 100 hours from ingestion.
08	Linur Yeter	Addition of caution following FCC comment (complies with part 15 of the FCC Rules)
09	Linur Yeter	Addition of IP symbol labeling (section 9)
10	Linur Yeter	Update following DEKRA audit (CAPA94) to include an up-to-date C-Scan View Packaging Labels (section 9.5)
11	Yaara Tirosh	- Update C-Scan View related chapters (7,8,10) according to C-Scan modified View version for the IDE supplement submission. - Update X-ray source change back to W-181 (Tungsten) in section 9, Technical Description (Table 9 & section 9.3 C-Scan Cap Label)
12	Daniella Bleistein	ECR-21-000071 • Typo corrections and general updating of wording for clarification of text throughout the document. • Updated the type of food supplement fiber pills to be used during the procedure • Section 6.1 & 7.3 adding requirement to start contrast agent and dietary fiber pills intake approximately 48 hours pre C-Scan® Cap ingestion. • Section 6.1.3 ○ Added preparation step – to clean the skin with alcohol before attaching the C-Scan Track stickers

CHANGE HISTORY

Rev. number	Change Owner	Change description
		○ Added instruction to keep the Kit package (containing the Cap) in close proximity to the Track when preparing for capsule ingestion ○ Added instruction to follow the contour of the C-Scan Track units when tightening the liners • Section 6.2 ○ Added instruction – contrast agent may be ingested without dissolving it in a glass of water, per the patient's preference. Same instruction added also to 7.3 ○ Added instruction to give the patient dietary fiber pills equivalent to 1500 mg (e.g., Psyllium Husk Caps 500 mg) to intake after capsule ingestion • Section 4.5 "Cautions" – removed ''can be flushed in the toilet'' • Added new section 6.7 & 7.8 C-Scan® user interface notifications C-Scan® user interface notifications to list the notifications generated by the C-Scan® Track • Added new section 6.4 Radioactive source not properly concealed – malfunction notification instruction, to provide clear instructions if the rare malfunction of radioactive source within the C-Scan® Cap is not properly concealed occurs • Adding "Being near powerful electromagnetic fields such as those created by MRI or CT devices" to the list of prohibited activities during the procedure in section 7.2, to align with device cautions • Adding relevant notes to emphasize device cautions that appear in section 4.5 also in section 7Instruction for use to the subject
13	Daniella Bleistein	Updated section 4.2 Contraindications to align fully with CIP exclusion criteria: know motility disorders of chronic constipation and ongoing diarrhea, as well as any condition believed to have an increased risk for capsule retention including diverticulosis.
14	Sivan Peleg-Cohen	Update C-Scan View related chapters (8,9,10) according to C-Scan modified View version for the IDE May 2022 5-days notice submission.

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C-Scan® System

User Reference Manual

Revision 14

Rx Only
"CAUTION Investigational device. Limited by Federal (or United States) law to investigational use."

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1 Using this guide

1.1 Purpose

This guide includes instructions for: the clinic team, the subject and the analysis team.

- The sections that apply to the clinic team in this UM will be given to the clinic team as a separate instructions document - DOC001591 C-Scan System Clinic Team IFU.
- The sections that apply to the subject in this UM will be given to the subject as a separate instructions document - DOC001592 C-Scan System-Patient Instruction for Use.
- Instructions for the C-Scan® View system is described in section 8-11 on this manual.
  Detailed instructions for the C-Scan® View analysis process is described in a separate instructions document - DOC001212 C-Scan view user guide and training.

1.2 List of Acronyms

Acronym	Description
CRC	Colorectal Cancer
IBD	Inflammatory Bowel Disease
BIT	Built-In Test
BMI	Body Mass Index
CMT	Compton Scattering
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
WGTT	Whole Gut Transit Time
SF	Suspicious Finding
Colon model	Estimated capsule path in colon

1.3 Conventions

- Note - A note provides clarification, extra information, or refers to related material.
- Caution- A Caution warns about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment or other property.

- Warning- A Warning warns about a situation which, if not avoided, could result in death or serious injury.
- Contraindications- Specific situations in which the device and procedure should not be used because it may be harmful to the person.

2 Applicable Documents

1. C-Scan System- Clinical team IFU DOC001591
2. C-Scan System- Patient IFU DOC001592
3. C-Scan view user guide and training DOC001212

3 About C-Scan®

The C-Scan® System enables a subject-friendly, preparation free and painless evaluation of colorectal abnormalities. Using the C-Scan® System, suspicious findings such as colorectal polyps can be identified. Polyps in the colon may become cancerous and may develop to colorectal cancer thus, it is important to identify it at an early stage before they are becoming cancerous. Identification of polyps by the C-Scan® help define subject as elevate risk for Colorectal Cancer (CRC) and refer the subject to colonoscopy procedure for removing the polyps. The C-Scan® system is designed to evaluate the presence of polyps without the need for fasting and prior bowel cleansing.

The Procedure: The subject swallows the C-Scan® Cap and can continue with his daily routine. He is required to swallow contrast agent (15ml 3 times a day) and to intake dietary fiber pills (1500 mg, 3 times a day) starting 48 hours prior to C-Scan® Cap ingestion, and while the C-Scan® Cap travels painlessly through the gastrointestinal tract. After the C-Scan® Cap is excreted the data collected by the C-Scan® system is analyzed and the GI physician reviews the analysis in the C-Scan® view and generates the final report as to whether the subject is assessed to be at average or at elevated-risk.

4 Indications, Contraindications, Adverse Events, Warnings, Cautions

4.1 Indication for Use

C-Scan® is intended to identify adult subjects 50 years or older, within the average risk population, who are at elevated risk for polyps. It is intended for subjects who are poor candidates for colonoscopy or decline colonoscopy, or who had an incomplete colonoscopy. Polyps have been shown to be associated with the development of colorectal cancer. C-Scan® is not intended to replace colonoscopy. A positive C-Scan® result should be followed by colonoscopy.

4.2 Contraindications

- Any condition believed to have an increased risk for capsule retention, known strictures, known bowel adhesion or 'obstacles' to free passage of the capsule

(such as diverticulosis, intestinal tumors, radiation enteritis) or incomplete colonoscopies as determined by a physician
- Cardiac pacemakers or other implanted electromedical devices
- Dysphagia or other swallowing disorders
- Known allergy to Iodine
- Abdominal circumference larger than 125cm
- Paediatric population under the age of 22
- Known IBD (Crohn's, ulcerative Colitis)
- Acute kidney failure
- Pregnant or nursing women
- Subjects who undergo nuclear imaging or therapy during the last 4 weeks from using the C-Scan® System
- Subjects at high risk for CRC: adenomatous polyps; a personal history of CRC; a family history of CRC or adenomatous polyps diagnosed in a relative before age 60 years; high risk due to a history of inflammatory bowel disease of significant duration or the presence of one of two (2) hereditary syndromes
- A subject with known motility disorders:
  - Chronic Constipation: less than three (3) bowel movements/week, without the use of laxatives within the last 3 months.
  - Ongoing diarrhea defined as passage of loose or watery stools at least three times within 24-hour.
  - Gastroparesis (delayed gastric emptying)
- Prior history of gastrointestinal tract surgery
- Significant changes in the frequency or diameter of stools within the last 3 months
- GI bleeding within the last 3 months i.e. rectal outlet bleeding, hematochezia or melena

4.3 Adverse Events

The following adverse events may occur when undergoing the C-Scan® procedure:
- Change in bowel habits during the C-Scan® Cap passage- constipation, soft stool or diarrhea
- Abdominal pain, cramps or discomfort during the passage of the C-Scan® Cap
- Discomfort in the oesophagus following the swallowing of the C-Scan® Cap
- Loss of appetite
- Irritation from the C-Scan® Track attached to the back of the subject
- Back pain due to the C-Scan® Track
- Aspiration of the C-Scan® Cap that may cause chocking
- Long retention of the C-Scan® Cap that may require intervention
- Obstruction, perforation, and mucosal injury or bleeding
- Allergic reaction to contrast medium
- Blood in the stool (small amount)

- Nausea

4.4 Warnings

Alerts about a situation which, if not avoided, could result in death or serious injury.

- If the subject has had prior abdominal or pelvic surgery, the physician should consider the compatibility of the subject for the C-Scan® procedure.
- When swallowing the C-Scan® Cap there is a rare possibility of choking. If the subject exhibits any symptoms and/or clinical signs of choking (laboured breathing, wheezing, involuntary coughing, etc.), the recommended first-aid procedure should be followed.
- In subjects with unsuspected strictures of the GI tract, C-Scan® Cap can potentially cause intestinal obstruction resulting in the need for hospitalization and surgery.
- Instruct the subject to seek immediate medical attention if, after ingesting C-Scan® Cap, there is any abdominal pain, nausea, or vomiting.

4.5 Cautions

Caution is used for a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment or other property.

<u>Procedure related:</u>

- Read the manual before using the system for the first time.
- Make sure the subject received the IFU and thoroughly understands the procedure.
- Make sure that trained personnel, familiar with all the C-Scan® System operating procedures, use the system.
- Only one C-Scan® Cap should be ingested at a time.
- Subject shall contact the clinic in case of swallowing more than one C-Scan® Cap.
- If excretion of the C-Scan® Cap from the subject has not been positively verified, and the subject develops unexplained post-procedure abdominal pain, vomiting, or other symptoms of obstruction, contact the physician for evaluation and possible abdominal X-ray examination.
- Final diagnosis of the C-Scan® data should be made only by physicians who are trained in the interpretation of C-Scan® images.
- A “No” result of C-Scan® examination does not exclude the possibility of colon pathology, polyps or colon cancer.
- Women at child-bearing age shall use contraceptives during the procedure.
- Subject with any known condition that precludes compliance with device instructions shall not go through the C-Scan® procedure.

<u>Environment compatibility related:</u>

- During the procedure the subject should not be near any source of powerful electromagnetic fields such as one created near an MRI or CT device.

- During and after the procedure the subject should not immerse the C-Scan® Track in any liquid (no- bath, pool, Jacuzzi and swimming).
- During the procedure the subject should not travel by airplane.
- During the procedure the subject should not perform any active or contact sport (such as running, Jogging, physical training in the gym, ball games, Skiing, contact sports).
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
  Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Product related:

- C-Scan® Cap are MR unsafe thus C-Scan® Cap excretion shall be verified before subject undergo MRI procedure.
- CT image may be impaired by the presence of the capsule thus if abdominal CT is required it shall be performed after C-Scan® Cap excretion.
- The C-Scan® Cap includes radiation source thus it should be kept in the dedicated package until the procedure.
- The C-Scan® Cap should be stored in a safe place, out of the reach of children and infants.
- If a child has accidentally swallowed the C-Scan® Cap seek immediate medical help.
- Do not use the C-Scan® kit after its expiry date indicated on the Kit.
- If there is a doubt concerning the integrity of the C-Scan® Cap for example due to dropping or biting, the C-Scan® Cap should be returned to its original package and it should not be used.
- Instruct the subject to avoid biting the C-Scan® Cap prior to swallowing.
- C-Scan® Cap should be ingested only in the presence of authorized medical personnel.
- Activation of the C-Scan® Track shall be done when the C-Scan® Cap and C-Scan® Track are placed in their dedicated location inside package.
- The C-Scan® Cap shall be ingested only after successful initialization indication from the C-Scan® Track.
- Subject shall contact the clinic team in case an alarm in on (Malfunction indication include a vibration with repeated beeps and a red LED will light up on the C-Scan® Track).
- The C-Scan® Track shall not be exposed to intense sunlight or high temperature.
- The C-Scan® Cap cannot be thrown into the trash or be flushed in the toilet.
- Do not connect the cable between the C-Scan® Track and the C-Scan® View while the system is still attached to the subject's back.
- Do not disassemble batteries or C-Scan® track with batteries inside.

- Use the C-Scan® system only with components\ accessories purchased from or approved by Check-Cap.
- Changes or modifications not expressly approved by Check-Cap could void the user's authority to operate the C-Scan® equipment.

4.6 Benefit and Risks of the C-Scan® procedure

Benefits:

- C-Scan® system is subject-friendly tool for structural analysis of the colon.
- C-Scan® system provides an alternative for those subjects who refuse or cannot undergo colonoscopy procedure.
- No cleansing of the intestine is required prior the use of the C-Scan® system.
- The procedure does not require sedation, intubation or bowel insufflation.
- Subjects may continue with their normal daily routine during the procedure.
- C-Scan® system offers a simple, safe and non-invasive alternative to traditional imaging procedures.

Risks:

- Exposure to radiation. The C-Scan® Cap includes radiation source and in rare cases a local radiation exposure may occur.
- Abdominal X-ray may be required in order to verify the C-Scan® Cap excretion in cases that the C-Scan® Cap in the GI system for more than 2 weeks.
- C-Scan® Cap retention of more than 2 weeks may require intervention in order to extract the C-Scan® Cap.
- Rare risk of choking during the C-Scan® Cap ingestion.
- Obstruction, perforation, and mucosal injury or bleeding.
- Allergic reaction to Iodine contrast medium.

5 C-Scan® system

5.1 C-Scan® System Components

The C-Scan® system includes three main parts:
C-Scan® Cap, C-Scan® Track and C-Scan® View (illustrated in Figure 1)

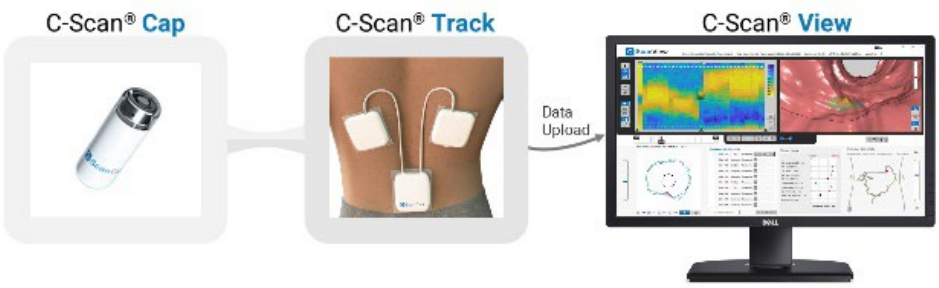


Figure 1: C-Scan® system parts

C-Scan® Cap

An ingestible capsule enabling intra-colon visualization, based on an X-Ray source and an array of detectors. During C-Scan® procedure the subject can continue with his daily routine. The C-Scan® Cap is ingested by the subject and propelled by peristalsis natural motility, it passes through the gastrointestinal tract and excreted naturally.
The C-Scan® Cap is designed to start scanning when the capsule enters the colon. While stationary (which is most of the time) the C-Scan® Cap is set at an idle mode and the radiation X-ray source is blocked. During normal procedure, Large Intestine receives dose up to 1 mGy (the same as single Abdomen x-ray), other organs doses are much lower. The C-Scan® Cap is powered by onboard batteries and is designed to operate up to 150 hours.

C-Scan® Track

The C-Scan® Track is an external device that wirelessly communicates with the C-Scan® Cap: tracks the Cap position, sends commands to the C-Scan® Cap, receives and stores imaging data sent by the C-Scan® Cap. The C-Scan® Track also records the transit time from capsule ingestion to excretion and enables data download for analysis in the C-Scan® View software.
The C-Scan® Track contains several LEDs, which blink at a fixed rate, as well as a vibration and a buzzer. These features provide an indication of proper functioning of the system and alert in case of a system malfunction, see section 6.7 for a detailed overview of the system's notifications.
The C-Scan® Track is attached to the subject's back via adhesive skin pouches. The subject can continue his routine behavior with the C-Scan® Track attached to his back.

C-Scan® Kit

The C-Scan® Kit contains the C-Scan® Cap and the C-Scan® Track.

C-Scan® View

The C-Scan® View software is a client/server-based application that enables test's data analysis, and report generation.

The C-Scan® View main functions are:

- Load and display test information and data
- Images review - enables to view structural information of the colon wall
- Generate test report
- Store test information, data and results on server

5.2 The C-Scan® System Procedure- General overview

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

At the clinic-

- Preparing the subject for the ingestion of the C-Scan® Cap and testing the system.
- Attaching the C-Scan® Track to the subject's back, performing the Cap ingestion and discharging the subject.

At the subject's home-

- The subject continues with his daily routine while ingesting the contrast agent and fiber supplement. Once the procedure has been completed (after Cap excretion), the subject informs the clinic and coordinate the C-Scan® Track collection.

Analysis process-

- Data download from the C-Scan® Track to the C-Scan® View software.
- Pre-Analysis of the data by a dedicated analysis team, including below steps:
  - Procedure data review- data sanity assessment.
  - Procedure data analysis- identify suspects and determine procedure data quality level.
  - Pre-analysis summary- log comments for the analyzing GI physician.
    Pre-analysis process output: detailed summary including procedure data evaluation and a list of potential suspects.
- A certified GI physician performs final analysis, including the below steps:
  - Pre-analysis summary review including
    - Procedure's quality level
    - Potential suspects (pending GI physician's discretion, reanalysis and/or adding/replacing suspects is applicable).
  - Final interpretation and decision – determine patient's risk level, average or high risk.
  - Decision summary - comments and recommendations.
  - Final report and signoff.

6 Instruction for use for the clinic team

This section is for the clinic team use. It describes the steps for completing a C-Scan® procedure. It includes the following information:

- Preparations before procedure
  - Subject compliance verification
  - Subject preparation
  - Equipment preparation
- C-Scan® Cap Ingestion procedure
- During the procedure days (from C-Scan® Cap ingestion to excretion)
- Post procedure (after C-Scan® Cap excretion)
- Analysis & Report reception

6.1 Preparations before procedure

Before ingesting a C-Scan® Cap the following tasks must be performed:

6.1.1 Subject compliance Verification

- Verify that the subject does not have any of the contraindications described in section 4.2.
- Provide the subject with contrast agent and dietary fiber pills, and instruct the subject to start intake following the below schedule:
  - Contrast agent: 15 ml every 8 hours starting approximately 48 hours prior to C-Scan® Cap ingestion
  - Dietary fiber pills: 1500 mg, every 8 hours starting approximately 48 hours prior to C-Scan® Cap ingestion
- Before the procedure contact the subject, verify the ingestion hour and location and ask him/her to skip the meal before the procedure. Water and coffee are allowed. Instruct the subject to wear comfort clothes.

6.1.2 Subject preparation before procedure

Review the IFU with the subject and repeat the highlights:

Note: Introduce the C-Scan® system to single subject per room.

- Instruct the subject what to expect before, during, and after the procedure.
  Inform the subject about the required materials that needs to be used during the procedure and the pattern of usage: contrast agent, fibers, possible laxatives.
  Note: Intake of **contrast agent** 3 times a day (morning, noon and evening) is extremely critical for the success of the procedure. Without it the imaging of the colon will not be performed properly, and no data will be obtained!
  Note: Dietary fiber pills should be taken 3 times a day (morning, noon and evening).
- Subject shall continue routine medication intake.
- Instruct subject regarding permitted and prohibited activities during the procedure.
- Explain the possible risks involved with using the C-Scan® system.

- Inform the subject to contact the clinic if the following occurs: Pain or discomfort, detachment of the stickers on the back, beeping of the Track, Capsule excretion.
- Explain how to remove and send the C-Scan® Track.
- Write the subject identification details and C-Scan® details on the designated C-Scan® package. Give it to the subject and make sure he understands how to send the C-Scan® Track and C-Scan® Cap at the end of the procedure.
- Specify alarms and indications which require subject's attention:
  In case of malfunction, the C-Scan® Track vibrates, beeps and a red LED lights up. In this case the subject should contact the clinic. See section 6.7 for a detailed overview of the system's notifications.

6.1.3 Equipment preparation before procedure

The following steps should be performed:

1. Verify that the C-Scan® Kit package is intact with no damages
   Note: Do not use a C-Scan® Cap if the package is damaged.
2. Verify that the seal is intact. Remove the MEDICAL DEVICE label which seals the package. If the box has been opened, discontinue the procedure and contact Check-Cap for further directions.
3. Activation of the C-Scan® Track (illustrated in Figure 2)
   Open the C-Scan® Kit package and activate the C-Scan® Track by pressing the "On" button continuously (about 3 seconds) until you feel a vibration. A green LED will light up and start to blink right next to the activation button.
   This step turns the device on.
   Note: Do not remove C-Scan® Track and C-Scan® Cap from their package before activation is completed.
   After turning the C-Scan® Track ON you will see several colorful blinks of the LED and hear auditory indications. Activation will take up to 30 seconds, at the end, a green LED will start blinking every 2 sec. (see figure 2A).

   In case of failed activation, a red LED will appear for about a minute, (see figure 2B) discontinue the procedure and contact Check-Cap for further instructions.

Figure 2: Activation of the C-Scan® Track

4. Attach the Track to the subject's back:
   Note: This step shall be performed only after activation of the C-Scan® Track.
   Equipment needed: C-Scan® Track, C-Scan® Track position stencil, stickers, body marker, razor and medical grade alcohol.
   Note: The C-Scan® Track stickers must be applied directly to smooth skin for proper adhesion. Make sure there are no obstacles, such as hair. If needed, shave the designated attachment area. Clean the area with alcohol and let the skin airdry before attaching the stickers.

   The C-Scan® Track attachment process:
   Prepare the subject for attaching the C-Scan® Track by marking its exact location on the lower back using the provided stencil and body marker. as illustrated in Figure 3.

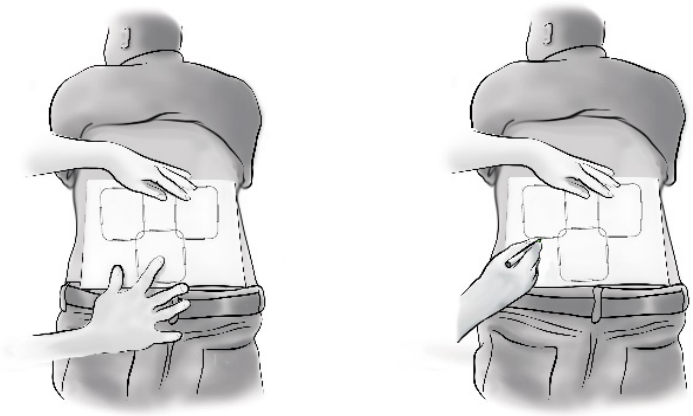


Figure 3: Illustration of the use of the stencil (location template)

Detailed steps:

- Place the C-Scan® Track position stencil on the subject's back and use the body marker to mark the outline where the C-Scan® Track should be attached.

The lower frame of the stencil shall be placed around 2 cm above the groove of the buttock along the spine. Once the stencil is located, the places for the three stickers shall be marked.

- Remove the stencil.

1. Take the C-Scan® Track and stickers from the C-Scan® Kit package. Be sure to keep the Kit package (containing the Cap) in close proximity to the Track at all times during this step.

- Remove the liner from the biggest sticker and attach it to the subject's skin just above the buttocks according to the mark previously made. Do the same for the remaining two upper stickers, as illustrated in Figure 4.

  Note: Be aware of the marking right (R) and left (L) on the stickers intended for the upper unit of the C-Scan® Track and place them accordingly to the right and left of the spine.

  Note: When placing the stickers, ask the subject to lean forward (at a 45-degree angle) and put his hands against a wall or on a table for stability. This helps ensure a strong and correct adhesion of the stickers.

Figure 4: Attachment of the stickers

- Insert the C-Scan® Track into the pockets on the stickers- the main unit in the lower pocket and the two smaller upper units, left and right (labeled **L** and **R**) in the upper pockets, as illustrated in Figure 5.
- Before closing the pockets, please make sure:

  A- You followed the right **R** and left **L** markings on the stickers and on the C-Scan® Track units.

  B- Labels on all 3 C-Scan® Track units are facing towards you.

  C- The cables connecting the upper units to the lower central unit do not intersect.

  D- A flashing green LED can be seen on the bottom right corner of the main unit.

  Note: When the C-Scan® system is active, the indication of a flashing green LED is visible every 2 sec (during the whole procedure).

2. Use the liners attached to the top of the stickers to lock and tighten the C-Scan® Track in each of the three pockets. Be sure to follow the contour of the units when tightening the liners.

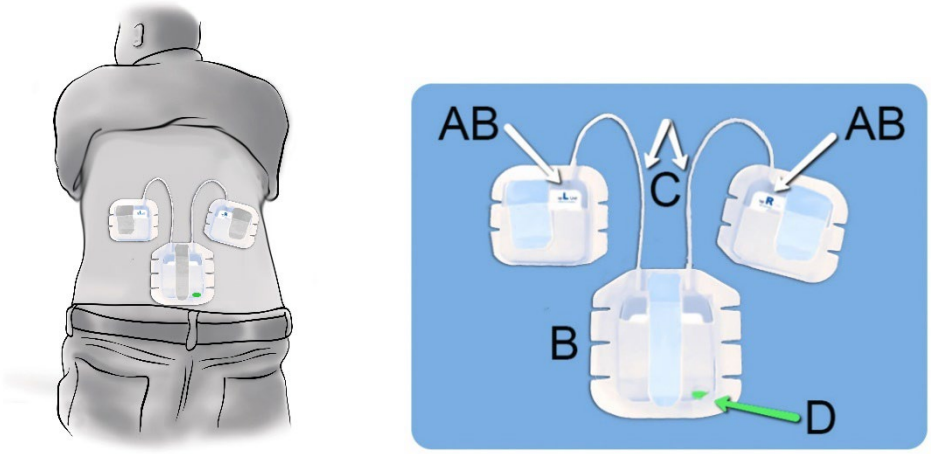


Figure 5: Attaching the C-Scan® Track to the back

6.2 C-Scan® Cap ingestion procedure

Once the C-Scan® Track is attached to the subject back follow the steps below:

1. Take the C-Scan® Cap box out of the C-Scan® Kit and verify that it is intact and close.
   Note: If the box has been opened, discontinue the procedure and contact Check-Cap for further directions.
2. Hand the C-Scan® Cap sealed box to the subject. The subject opens the C-Scan® Cap box by removing the "Remove before ingestion" label on the side of the box and releasing the blue clasp downward (preferably above a table).
   Note: Be sure to keep the box above a table or similar work top to prevent accidentally dropping the Cap on the floor. If it falls – it must not be ingested.
3. Ask the subject to stand.
   Note: Ingestion should be performed while subject is standing.
4. Instruct the subject to take the C-Scan® Cap from the box just before swallowing and put it in his mouth.
   Note: Instruct the subject to avoid biting the Cap or hold it between the teeth.
5. Give the subject glass of water and instruct him to ingest the C-Scan® Cap with water.
6. Following the capsule ingestion give the subject a glass of water with 15ml of contrast agent (Omnipaque 350mg Iodine /ml) and instruct him to drink the whole glass. The patient may also intake the contrast agent without dissolving it in a glass of water, per the patient's preference.
7. Thereafter, give the patient dietary fiber pills equivalent to 1500 mg (e.g., Psyllium Husk Caps 500 mg).
8. Document the date and time of the C-Scan® Cap ingestion.

9. Give the subject the required materials (contrast material and fiber pills) for the procedure.
10. Verify that the subject has the Subject IFU and understands the requirements.
11. Release the subject home.

6.3 During the procedure days (from C-Scan® Cap ingestion to excretion)

- Subject continues normal life routine during the procedure days.
  Note: In case the subject feels unwell consider inviting him for a medical check.
- After capsule excretion subject shall contact the clinic team to inform that the capsule was excreted and send the C-Scan® Track and Cap for analysis using the dedicated package received at the ingestion procedure.
- In case the C-Scan® Cap is not excreted after more than 100 hours from ingestion, the clinical team shall:
  1. Instruct the subject to stop taking fiber supplements and contrast agent.
     Note: Instruct the subject to not remove the C-Scan® Track from the back at this point.
  2. Prescribe abdominal X-Ray to verify the location of the C-Scan® Cap within the GI system.
  3. Evaluate the subject for obstruction symptoms.
  4. In case Capsule is still in the colon and the subject feels well and shows no obstruction symptoms, continue to monitor for symptoms of obstruction and for excretion of the capsule for additional 50 hours.
     During the same time, instruct the subject to start colonoscopy preparation followed by a colonoscopy procedure for Capsule retrieving. If symptoms of obstruction occur, instruct the subject to stop the bowel preparation immediately and contact the clinical team.
  5. In case Capsule is still in the colon and there are signs of bowel obstruction, surgical retrieval of the capsule may be required. Instruct the subject not to take any laxatives or fiber supplements. Proceed with the safest and best clinical practice, which may include radiologic imaging such as CT abdomen and pelvis or hypaque enema, or endoscopic retrieval e.g. if capsule is located in the recto-sigmoid colon when an enema may be administered.
  6. In case there are no obstruction symptoms, and the Capsule is located in the upper GI tract, an endoscopic procedure for retrieving the Capsule will be performed.
  7. In case there are obstruction symptoms, or the Capsule is in an unreachable position for both endoscopy and colonoscopy, or if the subject cannot tolerate the bowel preparation due to worsening symptoms, a surgical procedure for Capsule retrieval may be performed. In such a case, prior to the surgical procedure, the physician may consider an abdomen CT scan to evaluate the Capsule's location and exclude other causes for symptoms.

- At 150 hours (7 days) from ingestion, instruct the subject to remove the C-Scan® Track and coordinate its collection.

6.4 Radioactive source not properly concealed – malfunction notification instruction

- Instruct the patient to contact the clinic if he/she experiences the following notification from the C-Scan® Track: Red LED + Buzzer + Vibration
- This indication implies the radioactive source within the C-Scan® Cap is not properly concealed. This is a very rare malfunction. However, if it occurs the clinic team shall act according to the instructions below:

1. Instruct the patient to:
   a. Start colonoscopy preparation
   b. NOT remove the C-Scan® Track from the back at this point
   c. Stop taking fiber supplements and contrast agent
   d. Continue to check the stool collector before disposal, as detailed in the Subject IFU, but **NOT** to collect the capsule when it is excreted. The capsule should be flushed down the toilet to reduce the radiation exposure to the patient and the surroundings.
      Note: This is **the only scenario** where capsule can be disposed in the toilet. Otherwise, it is prohibited to flush the C-Scan® Cap down the toilet.
   e. Inform the clinic if the excreted capsule has been identified or if the excretion notification has been heard and seen (Green LED + Buzzer).
2. If the capsule is still in the colon after 48 hours from colonoscopy preparation start, perform colonoscopy to extract the capsule.
3. If there is uncertainty about the capsule excretion after 48 hours, perform an abdominal X-ray.

- **Note:** Following the acknowledgment of the event, the clinic can instruct the subject how to disable the indication, in order to avoid a state of ongoing discomfort to the subject and to ensure he stays with the C-Scan® Track attached to his back. This is done by pressing the C-Scan® Track “ON button” for ~2[sec]. This action will be considered as an acknowledgment by the user and disable the buzzer and vibration indication (the red LED indication will remain flashing as long as the problem occurs).

6.5 Post procedure- after C-Scan® Cap excretion

The procedure concludes upon excretion of the C-Scan® Cap.
When the C-Scan® Cap is excreted, the C-Scan® Track indicates the end of the procedure with an audible indication- a series of short beeps, repeated within 1 minute.
The excreted capsule should be located in the stool and collected by the subject using the collection kit provided.

The subject should store the excreted capsule in the dedicated biohazard package, coordinate the package collection and notify the clinic about the excretion.
After the indication of excretion, the subject shall take the C-Scan® Track out of the sticker's pockets, place it in the C-Scan® package that includes the subject identification details and C-Scan® details and coordinate its collection.
The stickers shall be removed from the back and discarded.
After the subject informs that the C-Scan® Cap is excreted verify the subject has sent both the C-Scan® Cap and Track to analysis.

6.6 Analysis & report reception

The data from the C-Scan® Track is downloaded to the client, uploaded to the server and processed to create a structural colon wall reconstructed model displayed in the C-Scan® View, as well as the Whole Gut Transit Time (WGTT) data. Pre-analysis is done by an experts' analysis team, who review the structural information to identify suspicious findings which are protruding and/or bulging on the colon wall. All the analysis data is uploaded to the server. A GI expert physician downloads the data, examines pre-analysis results and performs final data analysis using the C-Scan® View. The physician determines the final decision as to whether the subject is assessed to be at average or elevated-risk and generates the test report.

6.7 C-Scan® user interface notifications

The C-Scan® Track may generate the below listed notifications

Table 1. C-Scan® user interface notifications

Notification		Implication
Initial activation		
Green LED + Vibration		Device power up (pressing ON button) - BIT process initiated
Blue LED→ red LED→ Vibration → Buzzer		C-Scan Track initialization
Blue LED blinking		Initial self-test (BIT) in process
	→ Red LED	BIT fail
	→ Green LED	BIT pass (single blink – track alive / double blinking – track and capsule communicated)
Error during procedure		
Red LED + Buzzer + Vibration		Radioactive source not properly concealed **CAUTION see section 5.4 for instructions**
Rapid blue LED blinking		Track battery exhausted
Capsule excretion – end of procedure		
Slow blue LED blinking (1 sec on, 1 sec off) + Buzzer intermittent during 1 min		Capsule excretion
Slow blue LED blinking (1 sec on, 1 sec off)		Capsule is no longer in the subject's body

7 Instruction for use to the subject

This section is for the subject use. It describes the steps for completing a C-Scan® procedure and includes the following information:

- Permitted activities during the procedure
- Prohibited activities during the procedure
- C-Scan® procedure
- Daily routine during the procedure
- Post procedure- After C-Scan® Cap excretion
- When to contact the Clinic

7.1 Permitted activities during the procedure:

- Eating and drinking as usual
- Driving/ travelling (except for air travelling)
- Showering with the C-Scan® Track on your back
- Taking routine medications
- Daily routine, except for the activities listed in section 7.2

7.2 Prohibited activities during the procedure:

- MRI procedures, unless in case of emergency
  Note: This device is MR unsafe. Be sure to notify the medical team about the C-Scan® Cap and C-Scan® Track if the procedure is necessary
- Active sports such as: running, jogging, physical training in the gym, ball games, skiing, contact sports, etc.
- Prolonged immersion in water: bathing, swimming, Jacuzzi and sauna
- Travel by airplane
- Being near powerful electromagnetic fields such as those created by MRI or CT devices

7.3 C-Scan® procedure

Please read carefully the contraindications, warnings, cautions and possible adverse events before going through the procedure.
Contrast agent and dietary fiber pills intake shall begin approximately 48 hours prior to the scheduled C-Scan® Cap ingestion following the below schedule:

- Contrast agent: 15 ml every 8 hours
- Dietary fiber pills: 1500 mg, every 8 hours

The C-Scan® procedure performed at the clinic, includes attachment of the C-Scan® Track to your back and ingestion of the C-Scan® Cap.
The C-Scan® Track that records the data from the C-Scan® Cap will be attached to your back.

Note: If you are a woman of child-bearing age, you must use contraceptives during the C-Scan® procedure
Note: Do not bite the C-Scan® Cap prior to swallowing it
Note: Do not connect any devices to the C-Scan® Track USB port.
Note: Do not attempt to open, puncture or damage the Track.
Note: Do not expose the C-Scan® Track to intense sunlight or high temperature.
You will be asked to ingest the C-Scan® Cap, in the presence of a physician.
After swallowing, you will be sent home with a subject instructions packet which will include instructions on following daily routine, the required materials and the package for sending the C-Scan® Track for analysis following the C-Scan® Cap excretion.

7.4 Daily routine during the procedure

- Keep the C-Scan® Track attached to the back during the procedure until C-Scan® Cap excretion.
  Note: If the C-Scan® system is active and working properly, an indication of a flashing green LED is visible every 2 sec on the C-Scan® Track.
  Note: If the excretion indication not heard 100 hours (4 days) from ingestion contact the clinic.
  Note: If the excretion indication not heard 150 hours (7 days) from ingestion remove the C-Scan® Track and contact the clinic.

- <u>Ingestion of contrast agent:</u>
  Contrast agent should be taken 3 time a day until C-Scan® Cap excretion, up to full 4 days (100 hours).
  The contrast agent used in this procedure is water soluble Iodine (Omnipaque).

  Detailed instructions:
  - Take the measuring cup and pour **15 ml** of contrast agent into the cup (see measuring strip).
  - Pour the contrast agent into a glass of water/juice, mix well and drink it fully. You may also intake the contrast agent without dissolving it in any liquid, per your preference.
  - Repeat these steps **3 times a day**: morning, noon and evening (with or without food).

  Important notice: The contrast agent is extremely critical for the success of the procedure. Without it the imaging of your colon will not be performed properly, and no data will be obtained!

- <u>Ingestion of dietary fibers:</u>
  Fibers should be taken 3 times a day until C-Scan® Cap excretion, up to full 4 days (100 hours).

  Detailed instructions:

- Dietary fiber pills equivalent to 1500 mg (e.g., Psyllium Husk Caps 500 mg, as directed by the clinic team) should be taken with a glass of water, 3 times a day - morning, noon, and evening.

7.5 Post procedure- after C-Scan® Cap excretion:

Note: Do not throw the C-Scan® Cap into the trash or flush it in the toilet.
The procedure concludes upon excretion of the C-Scan® Cap.
Once the C-Scan® Track detects that the C-Scan® Cap is excreted from the body it indicates the end of the procedure with audible indication- a series of short beeps, repeated within 1 minute.
The excreted capsule should be located and collected using the collection kit provided to you on the ingestion day, according to the instructions detailed below.
After the indication of C-Scan® Cap excretion, take the C-Scan® Track units out of the pouches attached to your back. Place the units in the C-Scan® Track package you received from the clinic, ship according to instructions given to you by the clinic.
Remove the stickers from your back and discard.

<u>C-Scan® Cap Collection instructions:</u>

1. Place the disposable stool collector on the toilet seat following the instructions for use provided with it. Be sure to use it with every excretion.
2. Make sure the following accessories needed for collection are within reach: disposable gloves, tongs/ tweezers/ wooden spatulas, waste bag, bio-hazard plastic bag, capsule box).
3. During your bowel movement, pay attention to the system beep sound indicating capsule excretion.
4. Use gloves, tweezers and spatulas to locate and collect the capsule.
5. Wash the capsule with soap and water and place it in the small box provided to you in the collection kit.
6. Insert the box into the bio-hazard plastic bag, seal it and lay the bag in the C-Scan® Cap return package.
7. Coordinate the package collection and notify the clinic.

Important notes:

- Carry all the required equipment with you when you leave the house.
- Make sure you use the stool collector with every bowel movement.
- Pay attention, while sitting on the toilet for the audible indication.
- It is possible that the environment of the collection container will cause a delay in identifying the excretion of the capsule from the body, which will lead to a delay in the audible indication of the C-Scan® Cap excretion. Please check the stool collector before disposal, even if you have not heard the audible indication.

- If the capsule return box is not with you, be sure to warp the capsule bag with any soft material (product protection) and place the bag in an alternative container with a similar size to the capsule return box.
- Do not put the capsule in your pockets, keep it away from the body.

7.6 When to contact the Clinic

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

- Any sensation of pain or discomfort.
- Detachment of the C-Scan® Track stickers from the back.
- Changes in bowel habits. Consult the clinic in case of major changes (constipation or diarrhea).
- C-Scan® Cap excretion.
- In case the C-Scan® Cap has still not been excreted 4 days post ingestion.
- In case of malfunction indication from the C-Scan® Track - vibration, repeated beeps, and red LED light.

Note: If you feel something is not right, at any time during the procedure or immediately after, and if there are any questions or doubts contact the clinic.

7.7 Analysis & report reception

The data from the C-Scan® track is downloaded and processed to create a structural colon wall reconstructed model displayed in the C-Scan® View and analyzed by an expert team.

A certified physician performs final analysis, reviews the data and the analysis summary and generates the final report as to whether you are at average or at elevated risk for colon polyps.

7.8 C-Scan® user interface notifications

The C-Scan® Track may generate the below listed notifications.

Table 2. C-Scan® user interface notifications

Notification	Implication
Error during procedure	
Red LED + Buzzer + Vibration	Please contact the clinic team immediately
Rapid blue LED blinking	Track battery exhausted
Capsule excretion – end of procedure	
Slow blue LED blinking (1 sec on, 1 sec off) + Buzzer intermittent during 1 min	Capsule excretion
Slow blue LED blinking (1 sec on, 1 sec off)	Capsule is no longer in the subject's body

8 C-Scan® View Installation Guide

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. It is installed by Check-Cap on a PC supplied by Check-Cap.
Note: 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 colon reconstruction, and generates a procedure report.

- The C-Scan® View is comprised of the following components: PC with USB port, Monitor, Keyboard, Mouse.
- 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.

Note: Be sure to locate the C-Scan® View outside the Subject 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 6 and Figure 7, PC Package – with Accessory Package.

Figure 6: PC Package – with Accessory Package

Figure 7: 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 8

Figure 8: Accessory Package

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

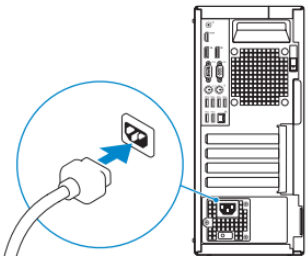
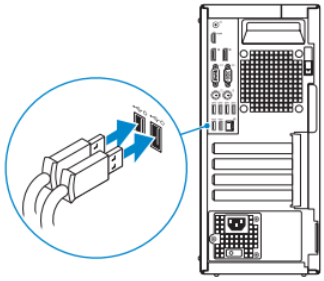


Figure 9: PC Connection to Power

Remove the mouse from the Accessory Package.

Figure 10: Mouse

Connect the mouse to any of the USB ports on the rear of the PC, as shown in Figure 11.



TT

Figure 11: 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 11
Connect the network cable, as shown in Figure 12.

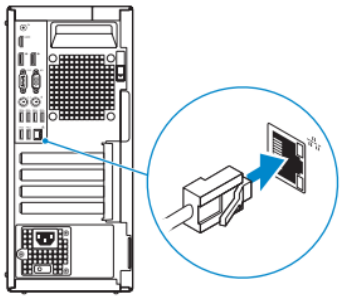


Figure 12: Network Connection

Prepare the monitor for operation, according to the monitor user manual provided in the monitor package.
Open the monitor package to attach the monitor stand, as shown in Figure 13
Setting up the monitor:

1. Follow the instructions on the flaps of carton to remove the stand from the top cushion that secures it.
2. Insert the stand base blocks fully into the stand slot.
3. Lift the screw handle and turn the screw clockwise.
4. After fully tightening the screw, fold the screw handle flat within the recess.

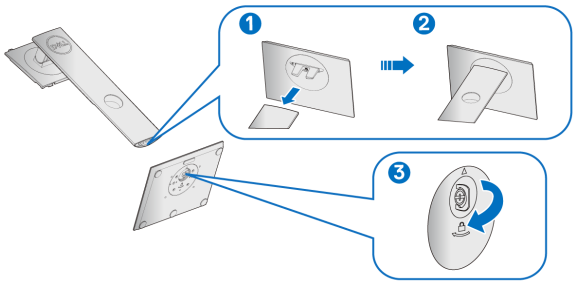


Figure 13: Monitor stand

5. Lift the cover, to expose the VESA area for stand assembly as shown in Figure 14

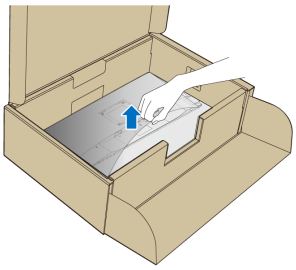


Figure 14: Monitor cover

6. Attach the stand assembly to the monitor, as shown in Figure 15.
   a. Fit the 2 tabs on the upper part of the stand to the groove on the back of the monitor.
   b. Press the stand down till it snaps into place.

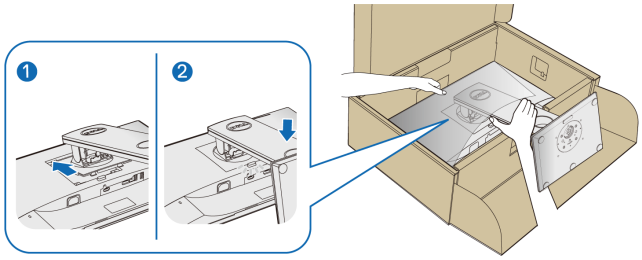


Figure 15: Attaching the stand

7. Place the monitor upright.
   Note: Lift the monitor carefully to prevent it from slipping or falling

- Connecting your monitor:
  Note: Before you begin any of the procedures in this section, follow the Safety instructions, provided with the monitor.
  Route the cables through the cable-management slot before connecting them.
  Do not connect all cables to the computer at the same time.
  To connect your monitor to the computer:
  1. Turn Off your computer and disconnect the power cable.
  2. Connect the DisplayPort cable (Figure 16) and the power cable (Figure 16) from your monitor to the computer, as shown in Figure 17.

Figure 16: DisplayPort cable

Figure 17: Monitor Power Cable

Figure 18: DisplayPort cable connection

Turn on the PC by pressing the power button (see Figure 19). Make sure screen is on.
Note: Check the completeness of the power cord before booting the C-Scan® View.

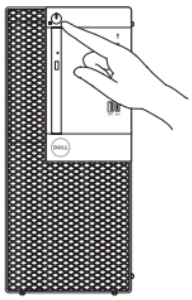


Figure 19: Power-on Button

The workstation is intended to be operated in an office setting like standard PC operation, see Figure 20.

- Office desk - height 70-75 cm
- PC display - at eye level
- Keyboard & Mouse – on tabletop

Figure 20: Fully Installed System

Upon system boot, the Login screen is displayed (see Figure 21).

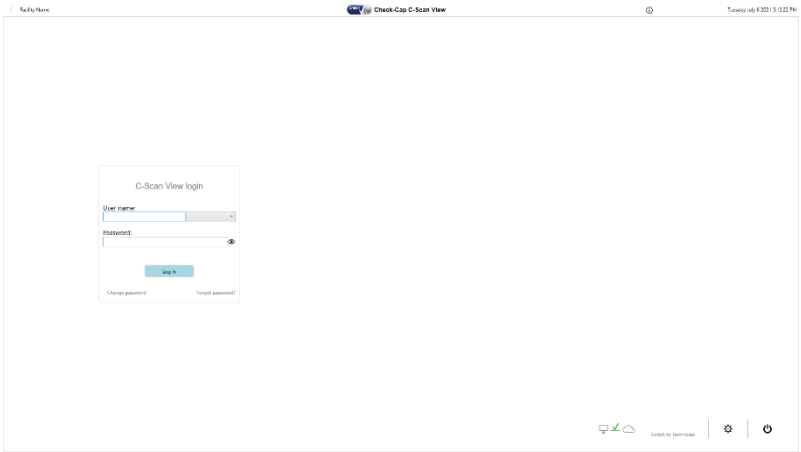


Figure 21: Login Screen

Click User Settings on the Welcome screen to open the User Settings window. The User Settings dialog opens, as seen in Figure 22.

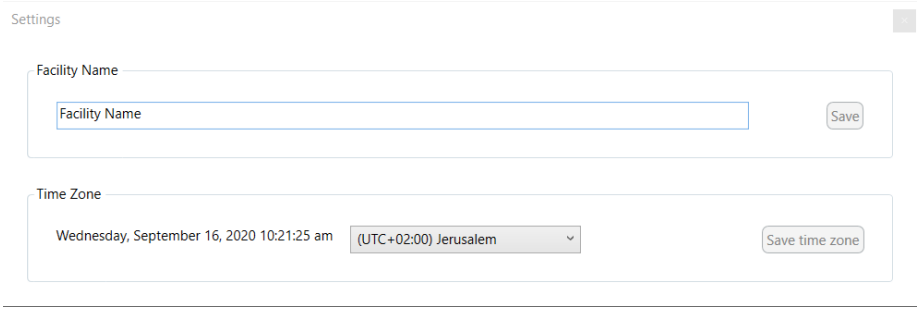


Figure 22: User Settings

Edit the Facility Name and click Save.
Change the time zone to your local time zone and click Save time zone. Click “X” to discard the changes and to return to the Login screen.

9 Using C-Scan® View Application

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 application users. It is installed by Check-Cap on a PC supplied by Check-Cap.
Note: 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.
Note: Check the completeness of the power cord before booting the C-Scan® View.
The C-Scan® View software is a client/server-based application that enables procedure data download from the C-Scan® Track, data analysis, and report generation.

The C-Scan® View is comprised of the following components:
- PC with USB ports
- Monitor, Keyboard, Mouse
- USB-C cable

The C-Scan® View main functions are:
- Load and display procedure information and data
- Images Review - enables the user to view structural information of the colon wall
- Produce procedure report
- Store procedure results on server

The C-Scan® View software requires user Login.
Application users' types and roles:
1. **Loader**- perform C-Scan® Track data download to workstation and upload to application database cloud server.
2. **Analyst**- perform pre-analysis on procedure data and upload to application database cloud server.
3. **Supervisor**- review and approve analyst's pre-analysis. Can also perform pre-analysis and upload to application database in cloud server.
4. **Physician**- review and approve supervisor's pre-analysis. Perform final analysis, create report and upload all to application database in cloud server.
5. **Users admin**- can create and manage application users and permissions.

C-Scan View Case Life Cycle

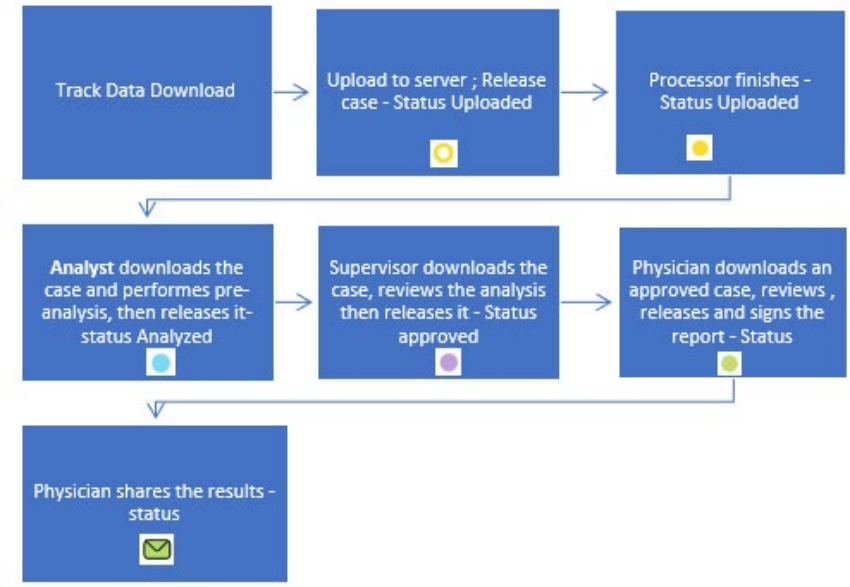


Figure 23- C-Scan View Case Life Cycle

9.1 C-Scan® View Application Login Screen

The C-Scan® View application requires user's login.
Upon system boot, the Login screen is displayed, as shown in Figure 24.

Figure 24: C-Scan® View Login Screen

Actions available in login screen are specified in Figure 25.

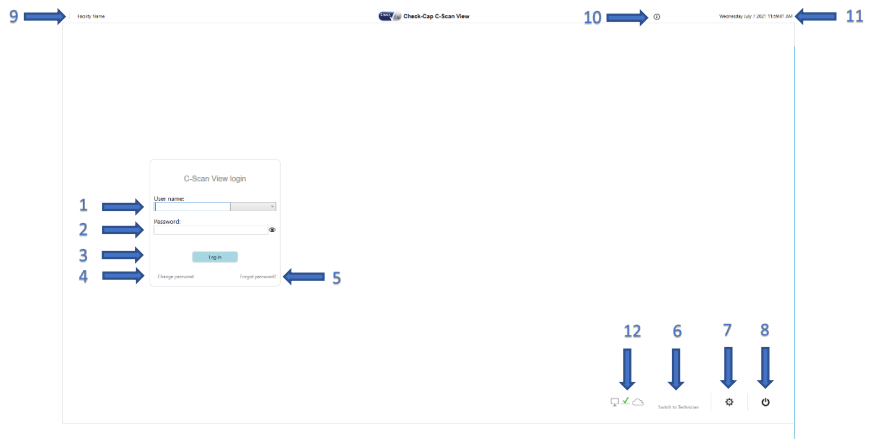


Figure 25: Login Screen

1. Username field
2. Password field
3. Login button
4. Change password button
5. Forgot password? button
6. Switch to Technician user button
7. User settings button
8. Shutdown PC button
9. Facility name display
10. Application info button
11. Date and time display
12. Network connection

9.1.1 User Login

To login to application, first acquire login information from a User's Admin. To login enter username or choose it from the list, enter your password (you can verify your password by pressing the eye icon next to it) and click **Log in**.

9.1.2 Password Change

To change your password, click **Change password.**

The "Change Password" dialog opens, see Figure 26.

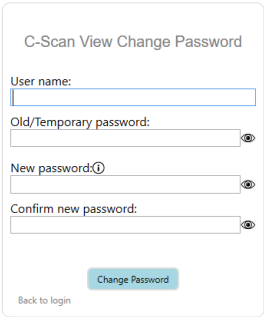


Figure 26: Change Password

A valid password must contain at least one uppercase letter, one lowercase letter, one number and one symbol, with a total of 8-15 characters.

9.1.3 Forgotten Password

If you forgot your password, click **Forgot password** and follow instructions to reset your password, see Figure 27.

1. Enter Username
2. Click “Reset Password”

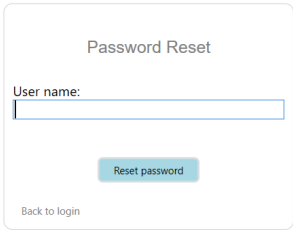


Figure 27: Password Reset

3. A temporary password will be sent to your email account (entered upon user creation), see application message in Figure 28

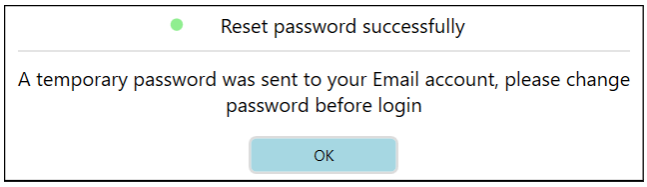


Figure 28: Password Successfully Reset Message

4. Click **OK**.
5. The “Change Password” dialog opens, see Figure 26.
6. Check your email account for a notification message, see Figure **29**

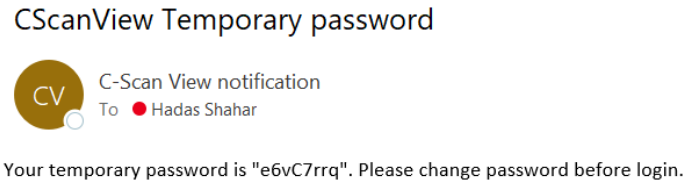


Figure 29: Password Reset Notification Email

7. Enter temporary password and a new password of your choice according to the instructions in “Change Password” dialog (Figure 26).
   A valid password must contain at least one uppercase letter, one lowercase letter, one number and one symbol, with a total of 8-15 characters.

9.1.4 Switch to Technician

An authorized service technician can sign out from the application and sign in as a Technician. The technician can view the system log and access the system BIOS and Windows utilities.

To login as technician, go to Login window:

1. Click **Switch to Technician**.
2. Choose Technician user.
3. Enter the Technician password to log in.

9.1.5 User Settings

In the login screen, Clicking **User Settings** button ⚙ opens the User Settings window (see Figure 30).

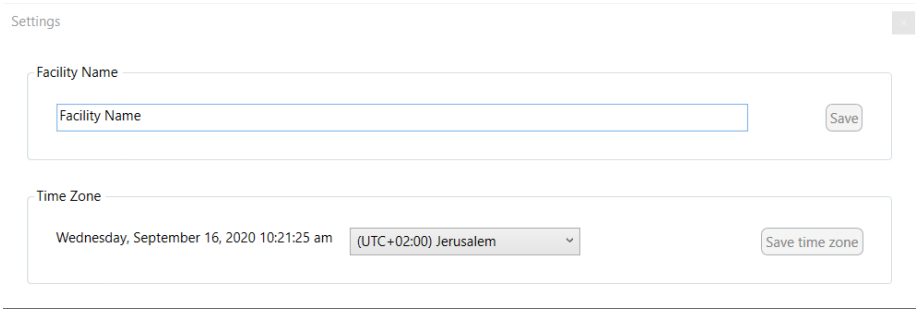


Figure 30: User Settings

To change the Facility Name, edit and click **Save**.
To change the time zone, choose the desired time zone from the list and click **Save time zone**. Click **X** to discard the changes and to return to the Login screen.

9.1.6 Application info

By clicking the 'i' icon (#10,Figure 25) a menu opens (see Figure 31), that includes the application's versions, **Licenses**, **Case State Legend** which illustrates the possible cases status, **C-Scan User Reference Manual** and **C-Scan View User Guide and Training**; each document is displayed in a pop-up window after clicking the document's name. Last, for any problem or inquiry the user can contact the customer support via contact info provided in **Support** or even "send log to support" when facing errors or issues.

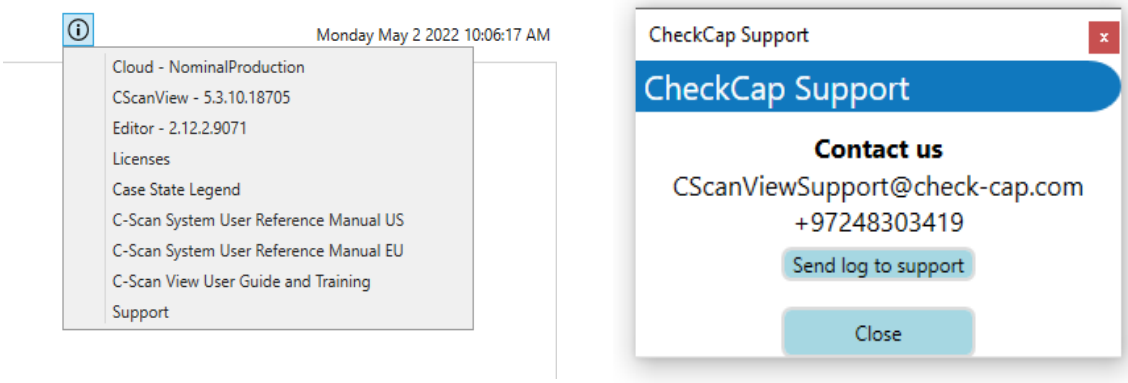


Figure 31: Application info menu

9.2 C-Scan View Updates

Whenever a new application update is ready, the application will suggest updating (see Figure 32).

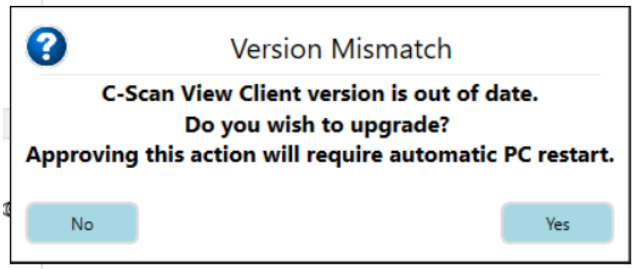


Figure 32: Application Update

Whenever a new system update is ready a **System update available** button appears at the top of the screen (See Figure 33), click it to initiate the update.

Figure 33: System Update

9.3 C-Scan® Track Data Download and Upload to Server

To download the procedure data into the C-Scan® View, login as a loader user and connect a C-Scan® Track (only one) to the C-Scan® View using the included USB cable (Figure 34).

Figure 34: Connecting the C-Scan® Track to the C-Scan® View

Click the **Connect C-Scan® Track** button (see Figure 35).

Figure 35: Connect C-Scan® Track Button

If C-Scan® Track connection fails, the C-Scan® View displays the following notification: “Connect to C-Scan® Track failed. Please connect C-Scan® Track cable” (see Figure 36). Go to troubleshooting section 11 for more instructions.

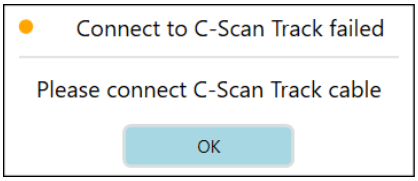


Figure 36: C-Scan® Track Failure to Connect Error Message

After successfully connecting a C-Scan® Track the Procedure Details window opens (see Figure 37).

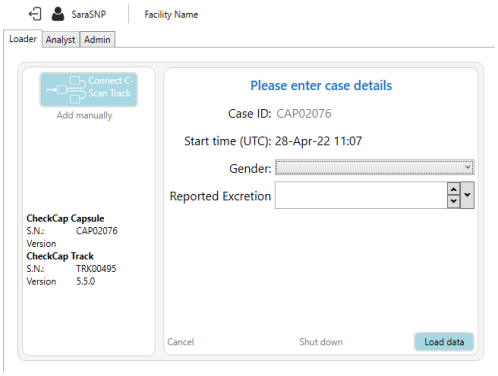


Figure 37: Procedure Details Window

- Verify that the C-Scan® Cap Serial Number and the C-Scan® Track Serial Number match those used in procedure. (If the information on the screen is incorrect, click **Cancel** to close the window. Connect the C-Scan® Track with the correct serial number to the C-Scan® View and continue the download).
- Choose Subject's gender, Male/Female.
- Click **Load data**.

While C-Scan® Track data is downloaded, a progress bar is displayed (see Figure 38):

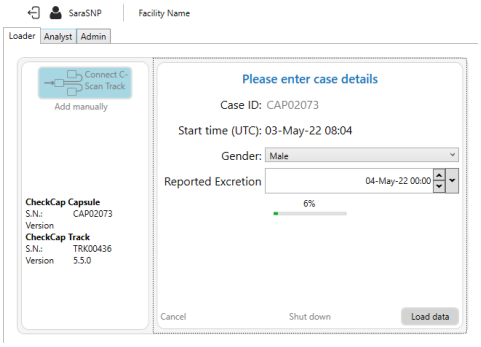


Figure 38: Procedure Downloading Progress Bar

Once procedure data download is finished, the following message appears (Figure 39):

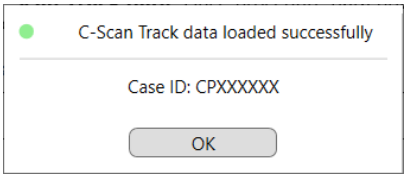


Figure 39: Procedure Downloaded Successfully Message

Click **OK**.

9.3.1 C-Scan® Track shutdown

The C-Scan Track can be shut down from View station, by pressing the Shut-down button located in the lower middle part of the window (see Figure 37).

Once loaded successfully, the procedure can be seen in **My Local Files** (see Figure 40):

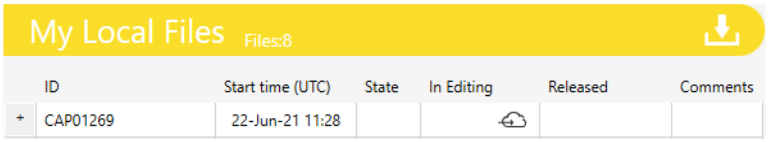


Figure 40: Procedure In My Local Files

To add a comment on a specific case, click the plus button in the left side , a menu pops up, click on **Comments**, a window pops up (see Figure 41) :

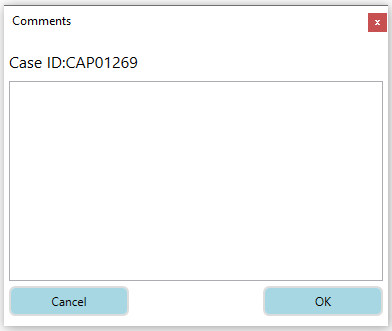


Figure 41: Add your comment

Add your comment, press ok to save and close the window. The comment icon appears in the Comment column in My Local Files indicating that a comment was added and can be reviewed and edited by clicking the comment icon (See Figure 42).

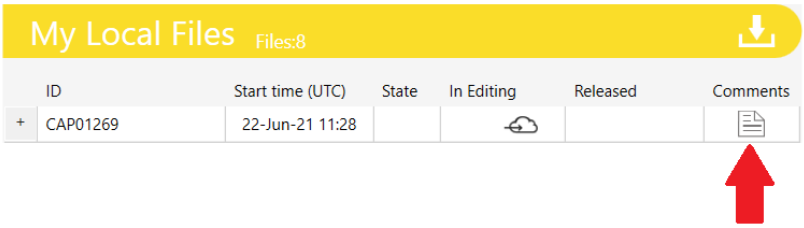


Figure 42:Comment indication

Click the server upload button to upload procedure data to the server database. The following message appears (See Figure 43):

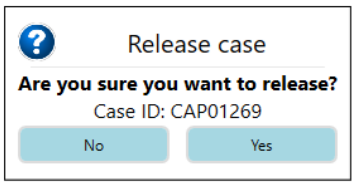


Figure 43: Approve Release Massage

To cancel, click **No**. To approve procedure upload to server, click **Yes**.

Once procedure release is initiated, the procedure data is uploaded to the server database and a progress bar appears next to the procedure in My local files (see Figure 44):

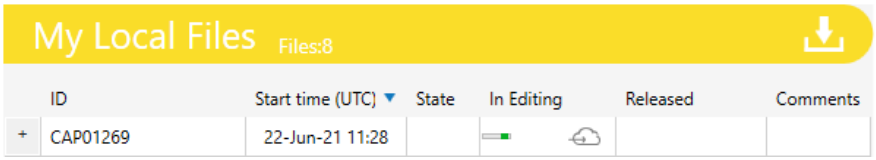
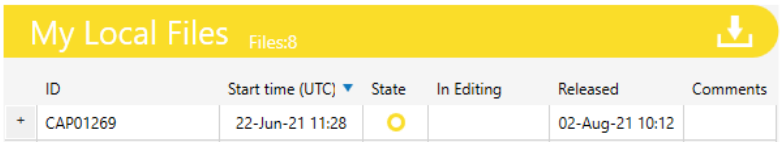


Figure 44: Procedure Upload Progress Bar

Once procedure upload to server database is complete, the following indication appears (see Figure 45):

Locally:



On server:

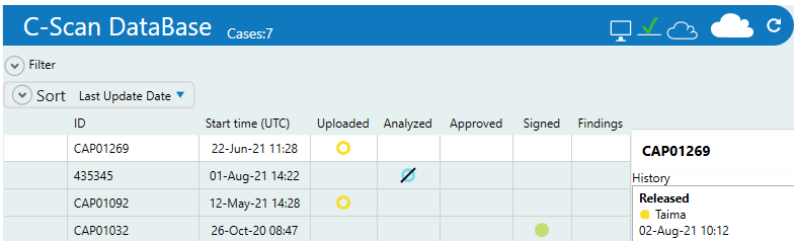


Figure 45: Procedure Upload to Server Database Completion Indication

Once procedure is uploaded to the server database, procedure processing on server automatically begins. An indication appears on the procedure history details next to C-Scan® data base table (see arrow on Figure 46):

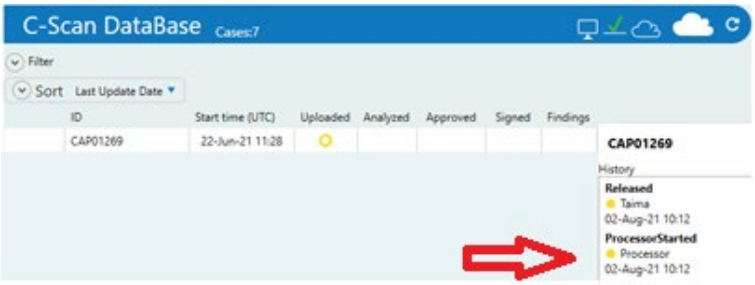
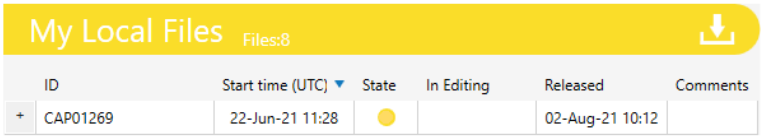


Figure 46: Procedure Processing Start Indication

Upon successful completion, the following indication appears (See Figure 47):

Locally:



On server:

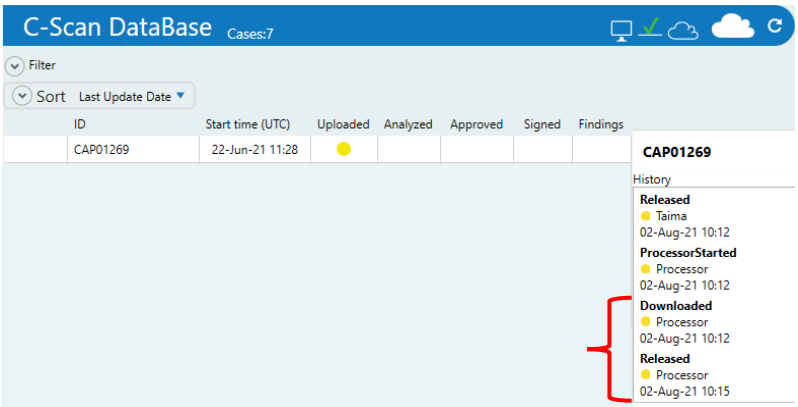
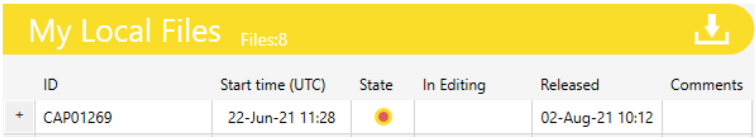


Figure 47: Procedure Processing Completion Indication

If procedure processing on server fails, a failure indication appears, a red filling of status circle (see Figure 48)

Locally:



On server:

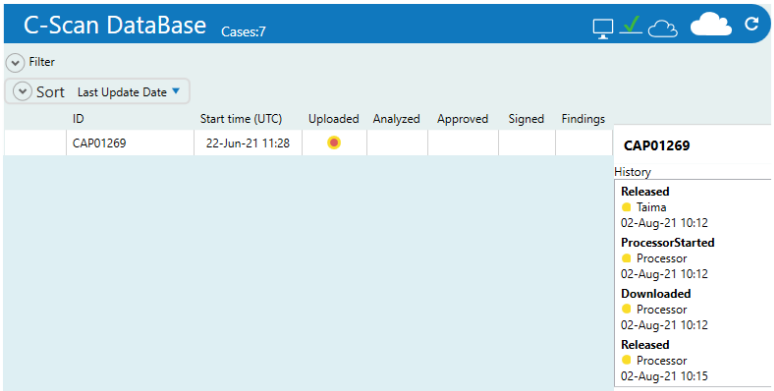


Figure 48: Procedure Processing Failure Indication

9.4 Add a Failed Procedure to Database

If C-Scan Track connection is not possible, or any reason that procedure data cannot be loaded to C-Scan® View, click the **Add manually** button (see Figure 49).

Figure 49: Report Failed Case Button

Failed case Procedure Details window opens (see Figure 50).

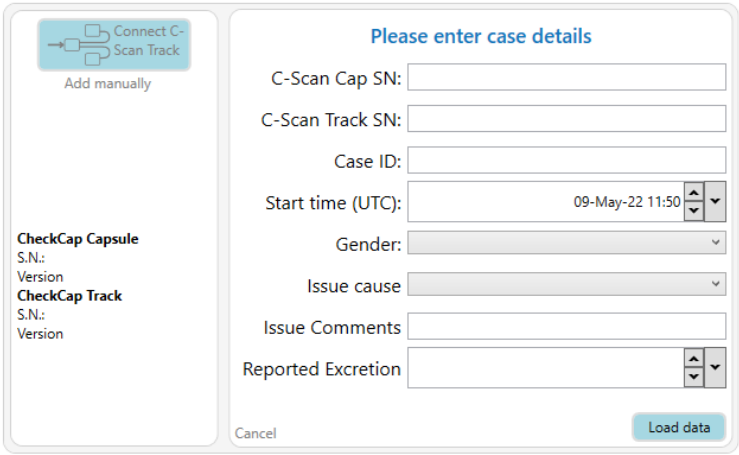


Figure 50: Procedure Details Window

- Enter C-Scan® Cap Serial Number and C-Scan® Track Serial Number (Case ID automatically updated according to Cap SN).
- Choose Start time (UTC).
- Choose Subject gender Male/Female.
- Choose issue cause from list.
- Add comments, such as additional information about failure cause.
- Choose Excretion time.
- Click **Load data**.

9.5 Managing your local files

9.5.1 Data Base

The Data Base section includes:

- Filter (see #1 in Figure 51)
- Sort (see #2 in Figure 51)toggles and the
- Cases Table - with all the cases that have been uploaded to server (see #3 in Figure 51)
- Case history (see #4 in Figure 51) which shows history details of the highlighted case; notice that clicking on a procedure line in my local files highlights it's relevant line in the Data Base, if it was already released, and the opposite is also true.

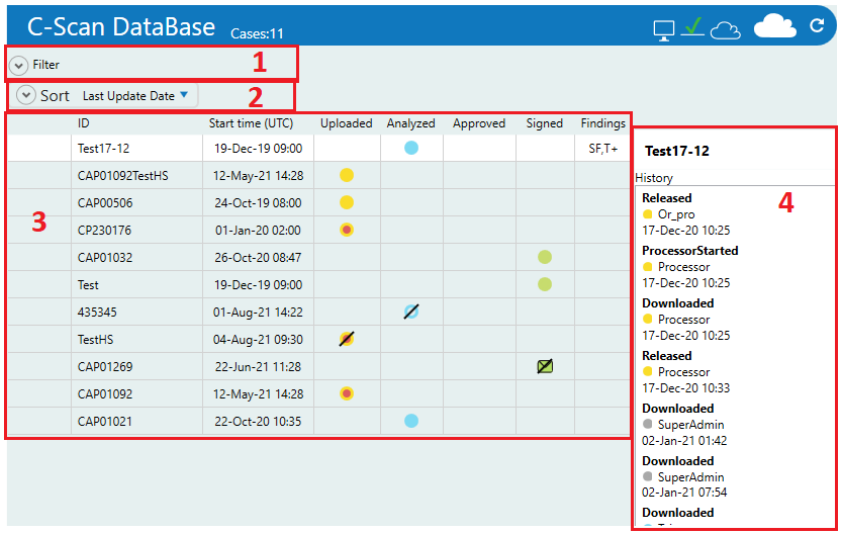


Figure 51: Data Base

Filter

The filter (see #1 Figure 51) can be used to see a subset of the cases in the data base. The filter can be applied by State, Issue, Case ID, C-Scan Cap SN, C-Scan Track SN, Findings, Risk Level, User Name, Procedure Start Date, Last Update Date and Patient Gender (See Figure 52)

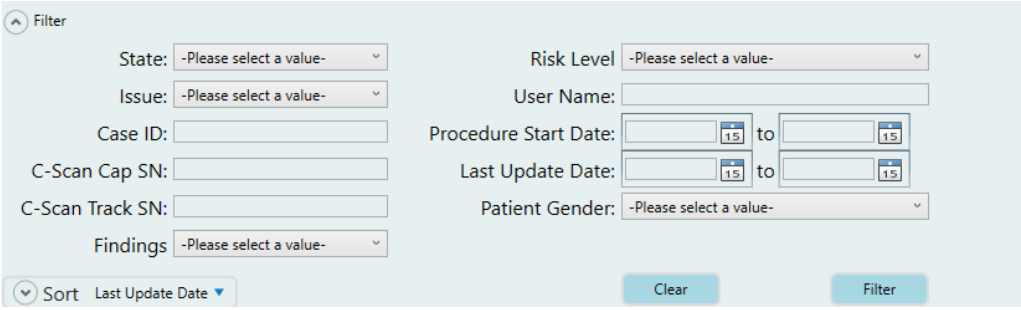
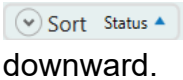
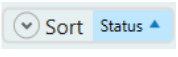


Figure 52: Filter details

Sort

Cases can be sorted by Last Update Date, Status or Issue in ascending or descending order. For example, if we choose to sort by status in ascending order it will show 

, the order can be flipped by clicking it 

then the arrow will be downward.

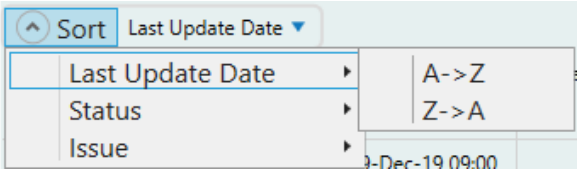


Figure 53: Data

Cases table

The Cases table includes the procedures ID, Day of ingestion (Start time), a colored circle is shown in the relevant field according to case status (see case state legend for further explanation 9.1.6). Hovering over the circle also displays verbal explanation of case status. In the findings column T+ is shown if WGGT exceeds threshold or/and SF if suspicious findings were found, otherwise this field stays empty.

9.5.2 Procedure Download from Data Base

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

The C-Scan® View application requires users' login.

To login to application enter a username and password.

(See Chapter 9.1.1)

Procedures are available for download from the **C-Scan® data base**, by clicking the **Download** button on the desired procedure line.

Use the **Update** button to see most updated cases available for download.

In case of Analyst user, download procedures with "Uploaded" procedure status (See Figure 54 for example of procedure status).

In case of Supervisor user, download procedures with "Analyzed" procedure status.

In case of Physician user, download procedures with "Approved" procedure status.

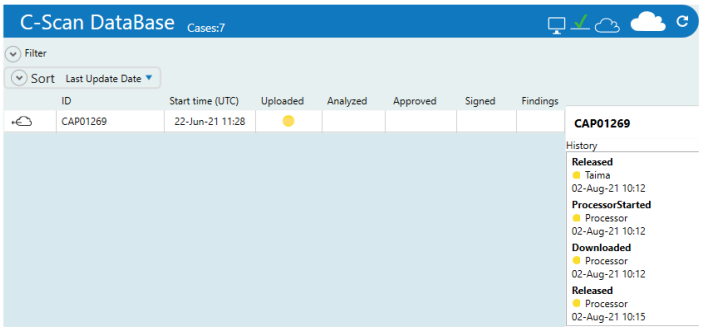


Figure 54: Procedure for Download

Procedure history can be seen on right side of C-Scan® data base.

While downloading case, a progress indication can be seen on C-Scan® data base (See Figure 55).

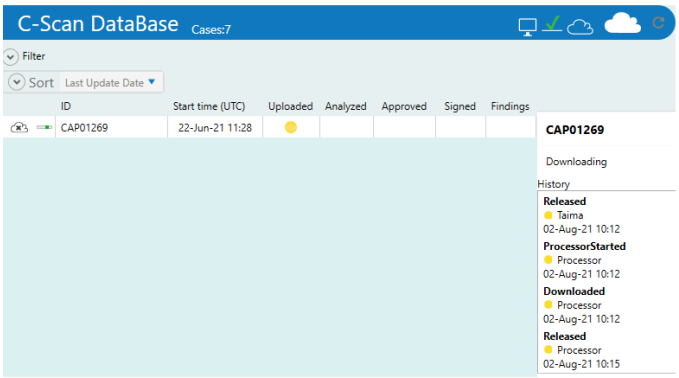


Figure 55: Procedure Download Progress Indication

To cancel download press . A **Download canceled** massage appears confirming your action.
Once case is downloaded, it is visible in My local files (see Figure 56).

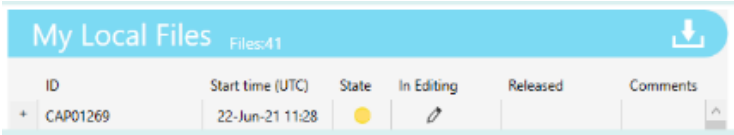


Figure 56: Procedure Downloaded

To analyze procedure, click the **Analyze** button . C-Scan® View editor opens.
Editor startup takes time. While editor starts, application header is still active. Editor application can always be maximized to full screen by clicking **Bring editor to front button** in application header (See Figure 57).

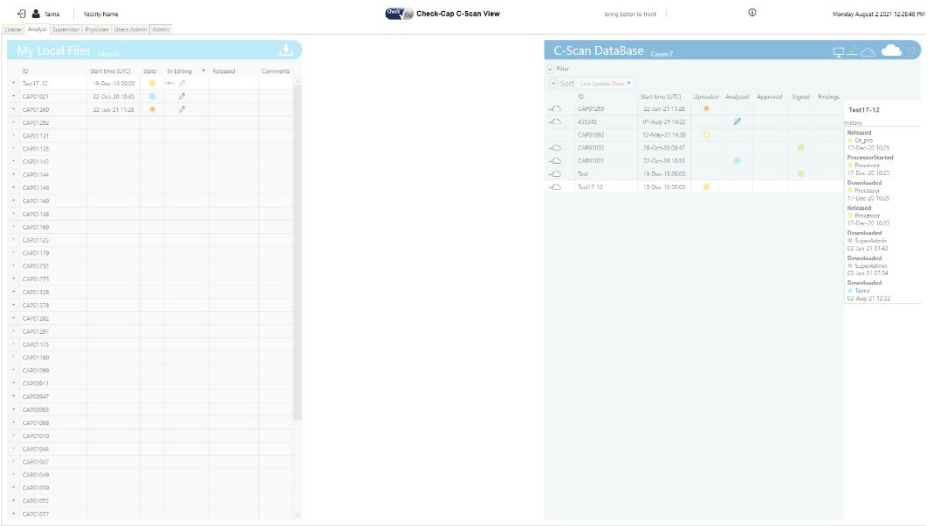


Figure 57: Editor Startup

Once Editor starts loading, a progress bar is displayed while loading the procedure data (see Figure 58). See **Chapter 9.6** for instructions for use of C-Scan® View editor.

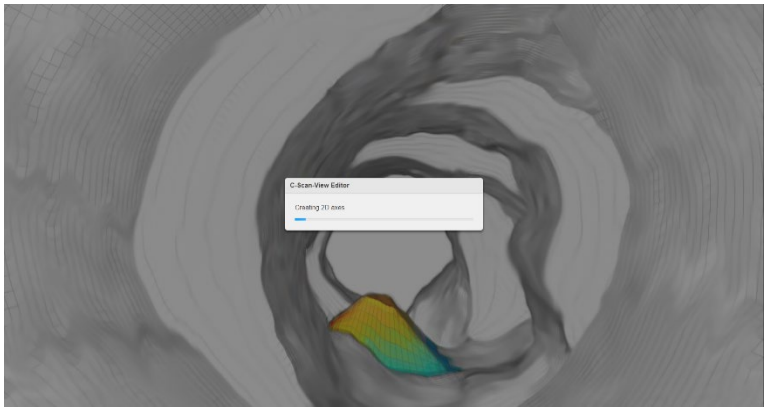


Figure 58: Procedure Data Loading Progress Bar

9.5.3 Deleting Records from Your Local Files

Your local files display all procedures uploaded/downloaded.

You can delete a procedure from your local files, by clicking the '**+**' button on the procedure line then on **X** out of the menu that opens, on the left side (see Figure 59)

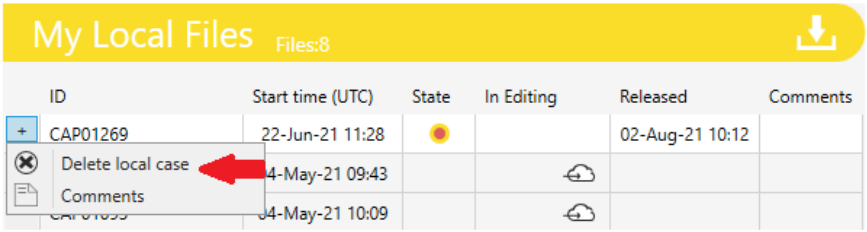


Figure 59: Deleting a procedure from local files

After clicking the **X** button, a message appears to make sure the deletion is intentional (see Figure 60).

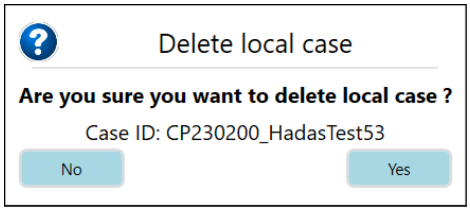


Figure 60: Deleting A Procedure from Local Files Confirmation Message

Click **Yes** to delete, **No** to cancel.

In case you are trying to delete a local case as a **loader**, before releasing it, this means the data is deleted before backed up in server. A message appears to make sure the deletion is intentional (see Figure 61).

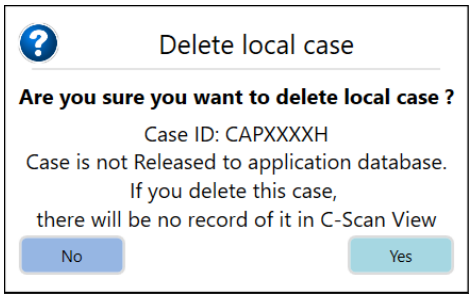


Figure 61: Deleting Local Procedure Only Confirmation Message

The C-Scan® View application does not delete local files automatically. In case local disk is full, C-Scan® Track upload or Procedure download from database is no longer possible. The application will notify and ask to delete local files (see Figure 62).

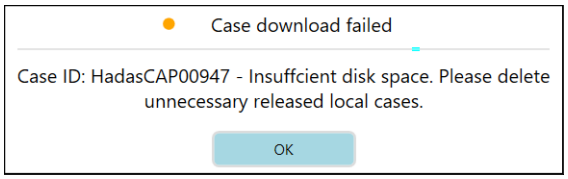


Figure 62: Local Disk Is Full Message

9.5.4 Analyzing/Viewing Procedures on Your Local Files

Analyst user - to analyze a procedure, click the **Analyze/Review Pre-analysis** button on the specific procedure in your local files and wait for the editor to open procedure data.
Supervisor/ Physician users - to analyze a procedure, click the **Review Pre-analysis** button on the specific procedure in your local files and wait for the editor to open procedure data.
After completing pre-analysis/analysis, Click **X** button on top right corner of editor to close the editor and return to C-Scan® View main screen. Make sure you save your work before confirming editor closing.
If a procedure was already analyzed and released to server database, it can still be viewed in the Editor, by clicking the '+' then **View** button on the specific procedure in your local files (see Figure 63).

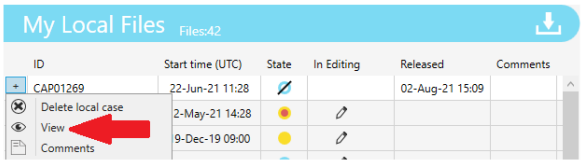


Figure 63: View analyzed case

See chapters **9.5.4 & 9.6** for instructions for use of editor for procedure analysis.

9.5.5 Uploading/Releasing Your Local Files to The Database

Loader user- to upload C-Scan® Track data to the server database, click the **Release** button on the specific procedure in your local files.

Analyst/supervisor user- to upload procedure pre-analysis to the server database, click the **Release** button on the specific procedure in your local files.

9.5.6 Physician Report - Analysis Upload and Report Signing

Physician user- to upload procedure final analysis to the server database click the **Release** button on the specific procedure in your local files. A pop-up message appears, see Figure 64.

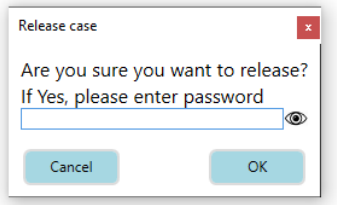


Figure 64: Physician Release

To release the procedure to the server database, enter your password and click **OK**.
The editor opens in a special mode for physician report preview and electronical signing, see Figure 65.

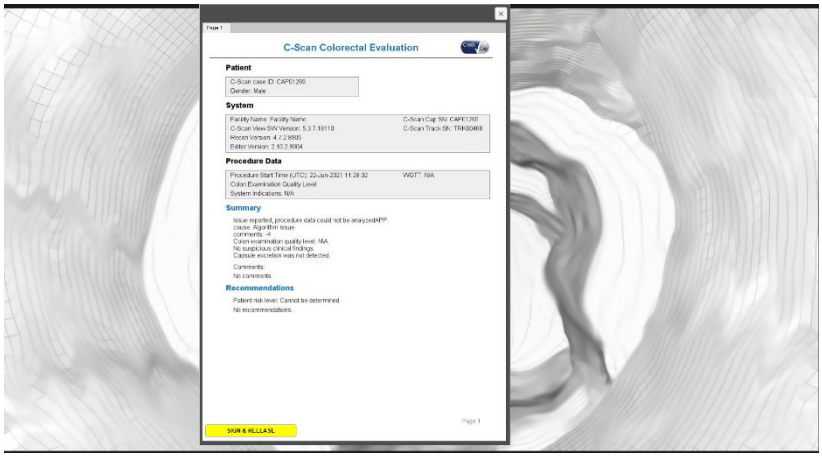


Figure 65: Physician Sign & Release

Click the pages tabs to see every page.
To sign and release the report to the server database, click **Sign & Release.**
A progress bar is displayed, see Figure 66.

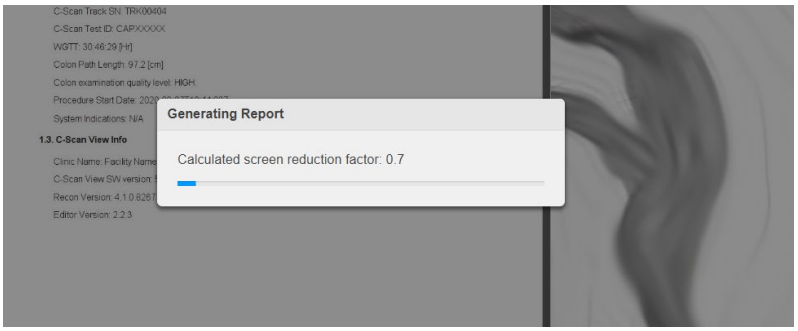


Figure 66: Physician Sign & Release Progress Bar

Once action completed, the signed report is displayed.

9.5.7 Physician Share Report

To share the report via Email, click the **Share** button on the specific procedure in your local files. The share report dialog opens, see Figure 67.

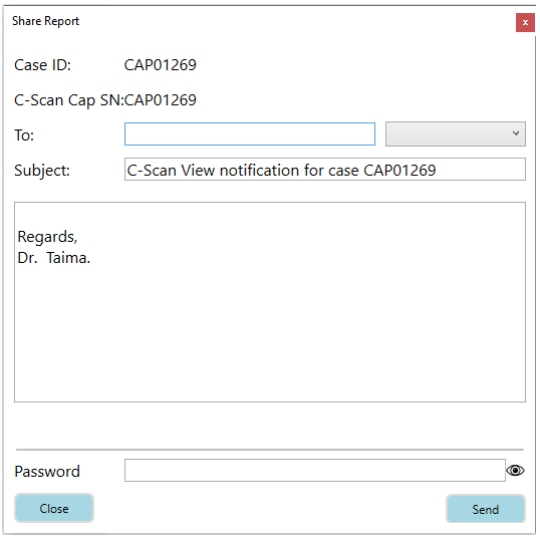


Figure 67: Physician Share Report

Fill in the desired E-mail address or choose one from the list of previously used addresses. Add text to the E-mail body and click **Send**. A confirmation message appears once report is sent, see Figure 68.

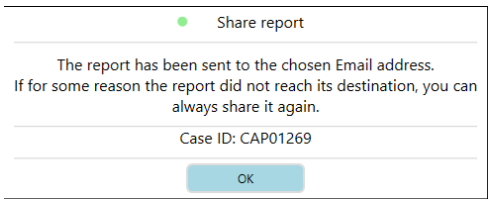


Figure 68: Report Shared Message

9.6 C-Scan® View Editor

9.6.1 Editor introduction

C-Scan® View Editor is used to analyze procedure data. Users able to perform analysis are Analyst, Supervisor and Physician.

- **Analysts** - use the Editor to perform pre-analysis, review entire data, identify suspects, analyze suspects, and mark suspicious findings.
- **Supervisors** - use the Editor to review pre-analysis performed by the analysts, prior to physician final analysis. Supervisors can also add suspects, perform suspect analysis and add findings**.**
- **Physicians** - use the Editor to perform final analysis. Review pre-analysis and release a procedure report. Physicians can also add suspects, perform suspect analysis and add findings.

To analyze a case, first login to the C-Scan® View application (see 9.1.1 for instructions).
Choose a procedure for analysis on the C-Scan® Database and download it to your local files (see 9.5.1 for instructions).
Open the procedure data using the editor (see 9.5.2 for instructions).
The editor Pre-Analysis screen can be seen in Figure 69.

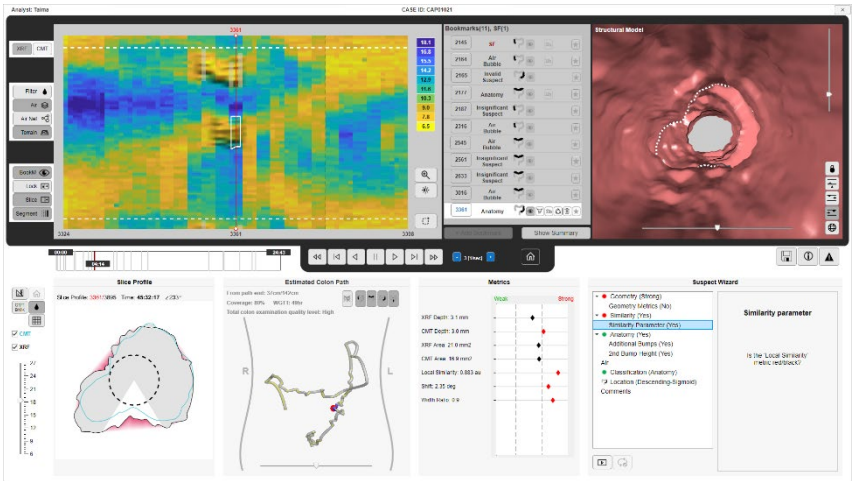


Figure 69: C-Scan® View Editor Pre-Analysis Screen

A released case can be downloaded for local analysis only, and the cases ID in the Editors header includes: CASE ID: XXXX (Released case! local analysis only).
The Editor allows the user to review the reconstructed colon built using procedure data, displayed in form of 2D slices, 2D maps, structural model and estimated capsule path.
Editor pre-analysis screen main functionalities include:

- Slice profile (#1 in Figure 70)
- XRF/CMT maps (#2 in Figure 70)
- Structural model (#3 in Figure 70)
- Estimated capsule path (#4 in Figure 70)

- Bookmarks table (#5 in Figure 70)
- Suspect wizard (#6 in Figure 70)
- Buttons control (#7 in Figure 70)

See following chapters for detailed information on editor functionalities.

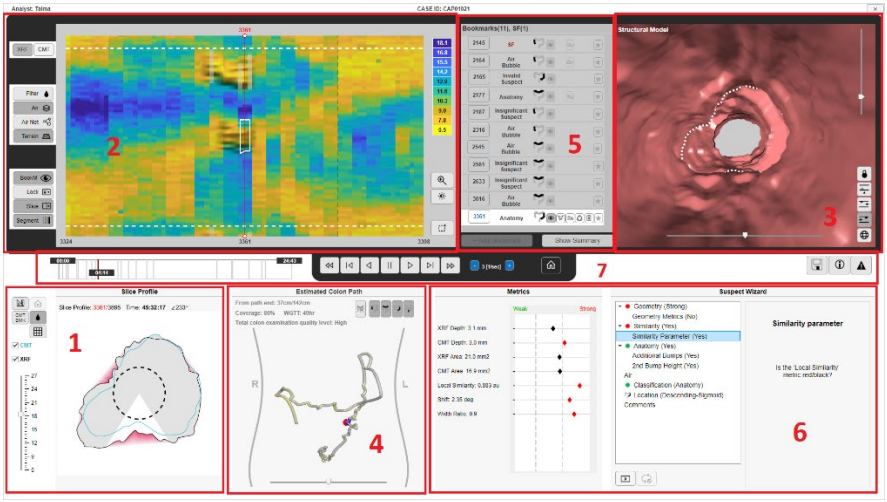


Figure 70: C-Scan® View Editor Main Functionalities

9.6.2 Slice Profile

The 2D slice (#1 in Figure 70) is the basic reconstructed unit, representing the distances from capsule center to colon wall. For additional information and background on reconstruction process see DOC001212 C-Scan® View User Guide and Training.

The slice profile view (see Figure 71) displays a 2D cross section of the reconstructed colon, the current slice marked in the XRF/CMT map.

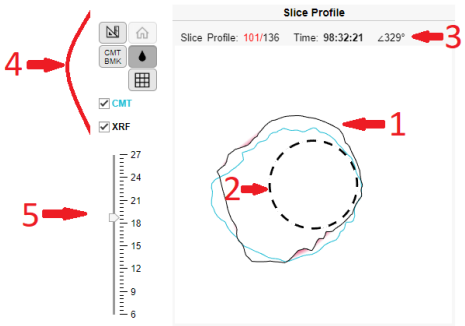


Figure 71: Slice Profile

Default display shows smoothed XRF and CMT slices (#1 in Figure 71), surrounding capsule illustration (#2 in Figure 71).

Inward bump in XRF is highlighted in red (see Figure 72).

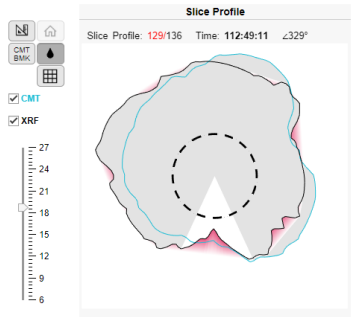


Figure 72: Slice Profile Bump Highlighted and ROI Marking

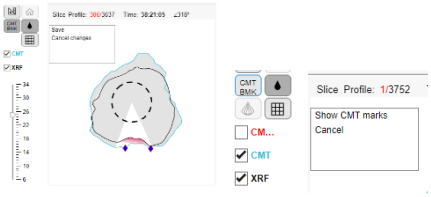
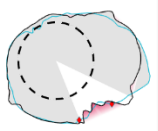
In case a bookmark is marked, the ROI is highlighted in white, and the rest of the slice is gray (see Figure 72). For details on bookmarks, see 9.6.10.

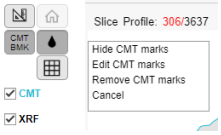
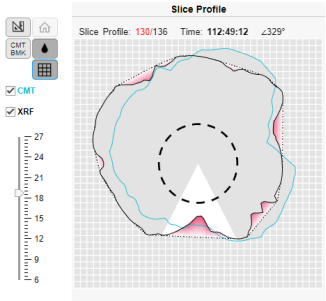
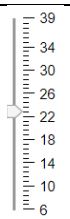
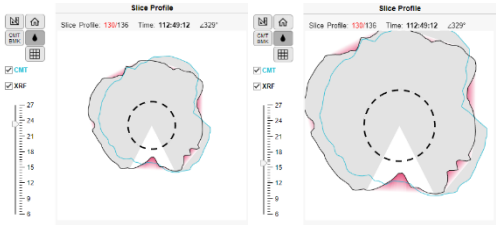
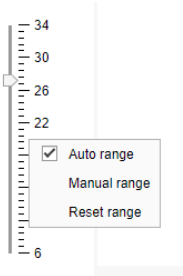
Slice profile information (#3 in Figure 71) includes:

- Number of current slice out of total number of slices in procedure
- Current slice time from procedure start
- Slice rotation angle (slice can be rotated using mouse scroll, angle will update accordingly)

Slice profile control (#4,5 in Figure 71) is detailed in Table 3.

Table 3: Slice profile control

Button /Action	Description	Default
	Measure ruler, allowing the user to measure distance and angle between two points	Off
	Filter on/off, default display on (slices are smoothed)	On
CMT BMK	Toggle CMT bookmark view, allowing the display and editing of CMT bump limits. On first click, a menu appears with options to show CMT marks or cancel menu window.  CMT BMK - when on (after pressing on `show CMT marks'), CMT bump limits are marked on CMT slice with red dots: 	Off

	-The second click on the toggle, when already on, will open a menu with editing options-  allowing to edit or remove the CMT limits and save or cancel the changes per slice. When pressing the editing option, the red dots of the CMT bump limits become blue and it is possible to move them.	
	Grid view, added along with slice convex marking: 	Off
	CMT/XRF line visibility toggle. Add/remove lines in case they overlap, and visibility is compromised	Both signals marked
	Slice profile scale (#5 in Figure 71) allows zoom in (right picture) and zoom out (left picture):  Possible to control the range type by left click on the ruler –automatic range will reset the zoom once performing any change in the 2D map. Manual range allows the user to decide on the range. 	According to slice size, no fix default
	Returns to original slice's scale, in case it was in zoom in or out	Disabled

9.6.3 2D XRF/CMT Map

The 2D XRF/CMT map (#2 in Figure 70) displays a constant number of slices, connected to create a 2D map of the reconstructed colon. The XRF/CMT headline enables toggle between the two signals. For additional information and background on reconstruction process and XRF/CMT signals see DOC001212 C-Scan® View User Guide and Training.

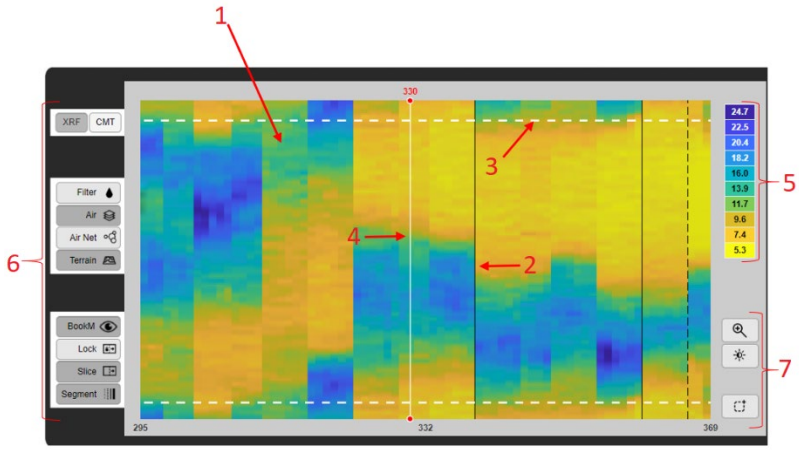


Figure 73: XRF/CMT Map

The lines (#2 in Figure 73) represent time differences between slices.
A gray dashed line marks a 0-60 sec jump (#1 in Figure 74).
A black dashed line marks a 60-600 sec jump (#2 in Figure 74).
A thin solid black line marks a 600-3600 sec jump (#3 in Figure 74).
A thick solid black line marks a >3600 sec jump (#4 in Figure 74).

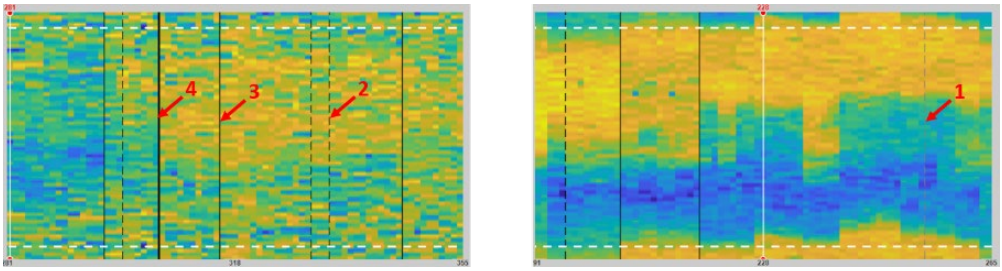


Figure 74: Time Reference Lines In XRF/CMT Map

The **map edges** are duplicated cyclic upwards and downwards to avoid missing features in edges (#3 in Figure 73).
The map can be cyclically rotated using mouse scroll.
The **current slice** displayed in profile view is marked in the XRF/CMT map (#4 in Figure 73) and the slice number is written in red. The current slice mark can be moved in several ways:

- Clicking and dragging the current slice mark
- Clicking anywhere to the right/ left of the current slice mark will move the current slice mark by one slice to that direction.

- Double clicking anywhere on the map, the current slice mark will jump to that location
- Right click on slice number enables jumping to selected slice. First a Go to option opens (Figure 75). Clicking it open a small window to enter a specific slice number or time (HH:MM:SS format) (Figure 76)

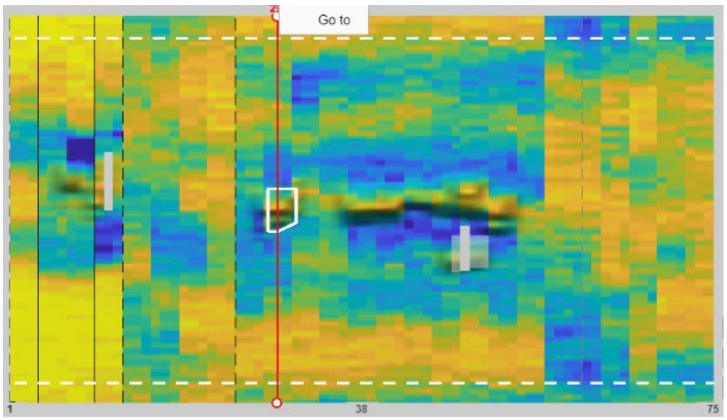


Figure 75: Go to Specific Slice

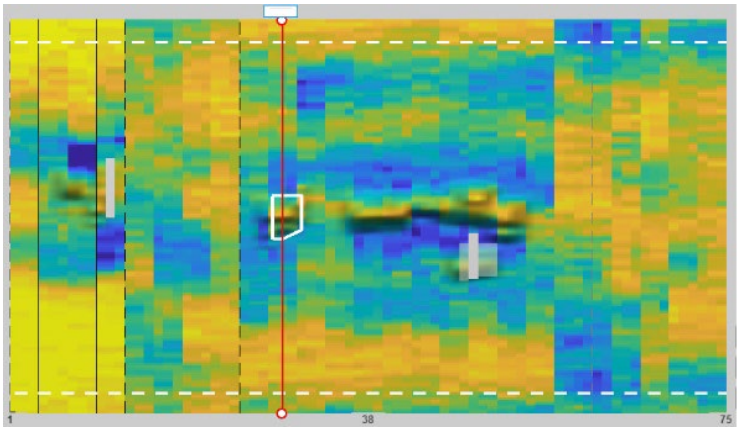


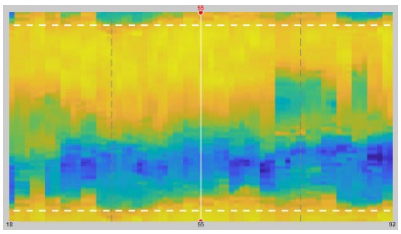
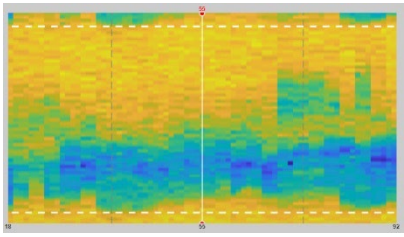
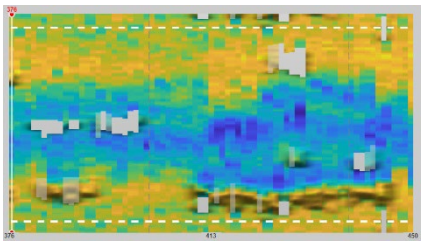
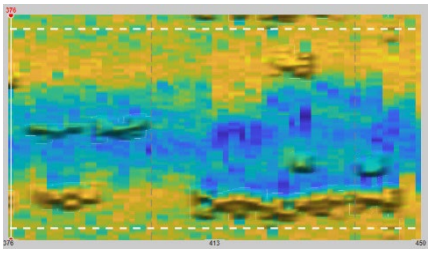
Figure 76: Enter Specific Slice Number or Time

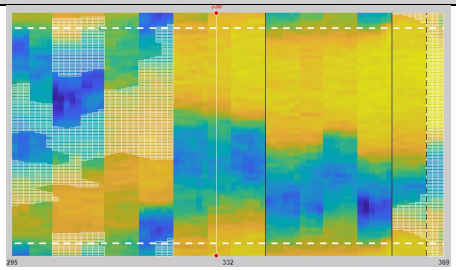
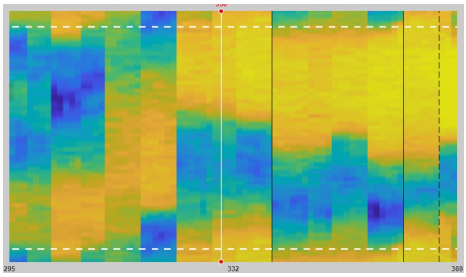
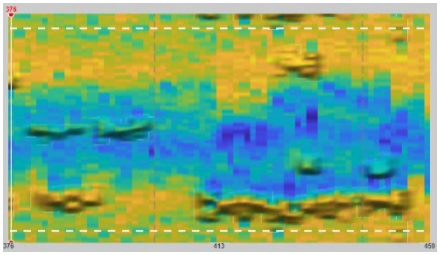
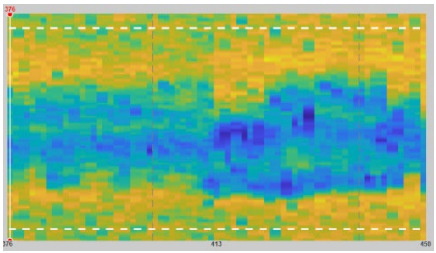
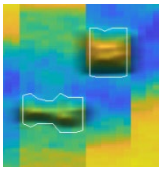
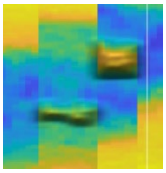
The **color scale** of XRF/CMT maps (#5 in Figure 73) indicated the distances seen in the slices composing the maps, the map dynamic range while yellow indicates smaller distance and blue larger ones.

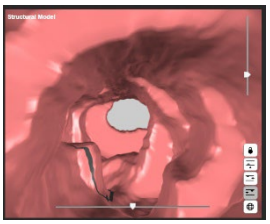
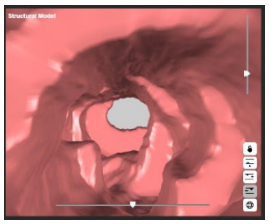
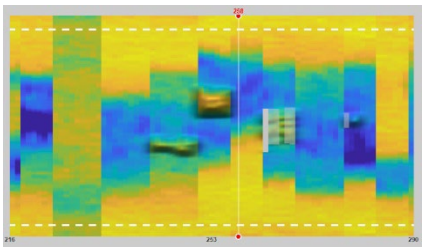
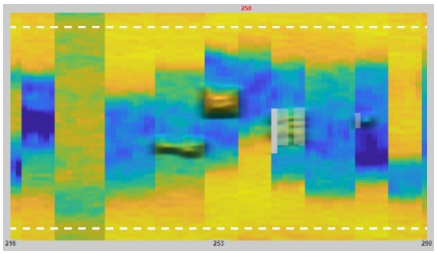
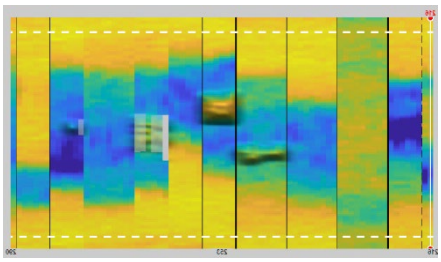
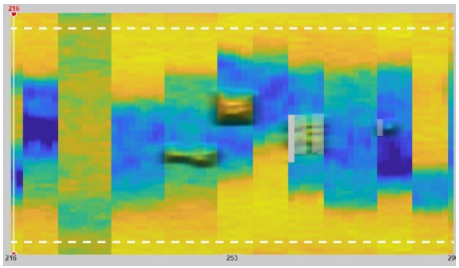
XRF/CMT map control (#6, #7 in Figure 73) is detailed in Table 4

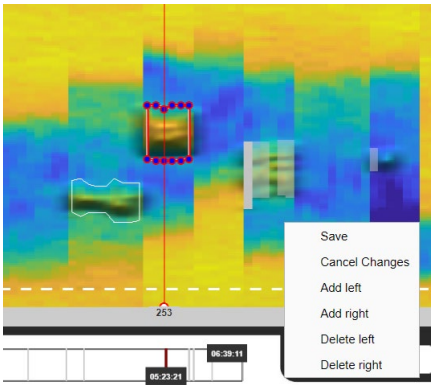
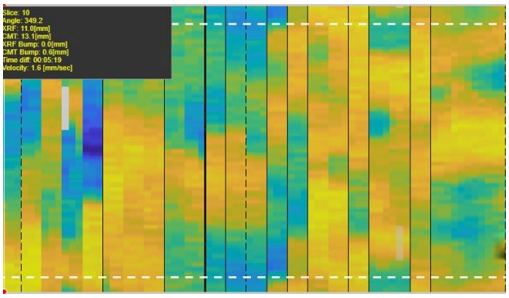
Table 4: XRF/CMT Map Control

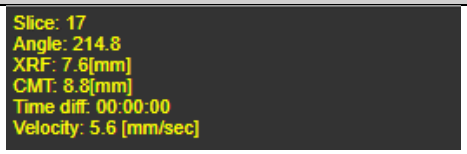
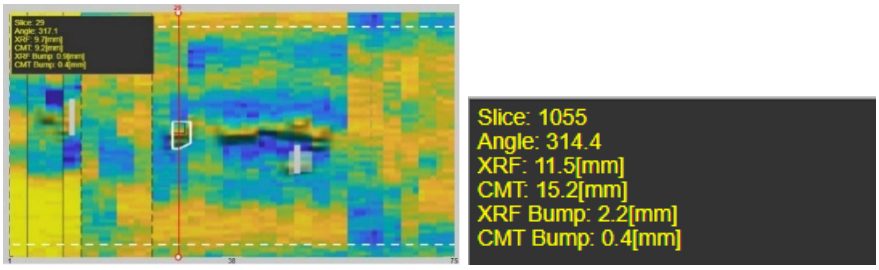
Button/Action	Description	Default
XRF CMT	XRF/CMT headline enables toggle between the two signals. Click a signal or the button to switch the map displayed.	XRF
Filter	Filter on/off – map smoothing.	Off

Button/Action	Description	Default
	Filter on:  Filter off: 	
Air	Air overlay – air presence marking on top of terrain markings (for air indication outside terrain, use Air Net) The less transparent the marking the greater the air presence detected. Air overlay on:  Air overlay off: 	On
Air Net	General air overlay “Air Net” –air indication on all slices (unlike the above Air overlay, that applies only on terrain). It’s turned on automatically once entering the Air questions section in analysis wizard and turned off afterwards (for more information see DOC001212 C-Scan® View User Guide and Training). Air Net on:	Off

Button/Action	Description	Default
	 Air Net off: 	
Terrain	Terrain on/off – inwards bumps in slices are highlighted in 2D map. Terrain on:  Terrain off: 	On
BookM	Bookmark visibility – bookmarks are marked in all displays. On:  Off:  On: Off:	On

Button/Action	Description	Default
	On:  Off: 	
Lock	Lock current slice positioning when scrolling.	Off
Slice	Current slice visibility. On:  Off: 	On
Segment	Segment lines visibility. On:  Off: 	On

Button/Action	Description	Default
	Zoom in – allows to zoom in inside XRF/CMT map by marking a rectangle area.	Off
	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.	Off
	Automatic ROI - Use the ROI button to mark a region of interest around a suspect in the 2D map. An automatic algorthms fitts the marking around the suspect. The fitted ROI can be edited by right clicking the ROI and choosing **edit** or clicking the edit bookmarks button in bookmarks table. Dots marking ROI appear and a menu opens:  The dots can be moved up and down, slices can be added or removed (add/delete right/left). Changes can be saved or canceled.	Off
Right click inside map	Shows information on clicked pixel in image.  Slice number, Angle, XRF and CMT distances, Time difference between clicked pixel and current slice, Cap velocity at the clicked pixel.	

Button/Action	Description	Default
	 If the pixel is highlighted with terrain, additional info is displayed- XRF Bump and CMT Bump metrics (Depths). 	

9.6.4 Structural Model

The Structural model (#3 in Figure 70) shows the slices connected to form a structural view of the reconstructed model. There are arranges in the order of acquisition, not considering time differences and positioning in space.

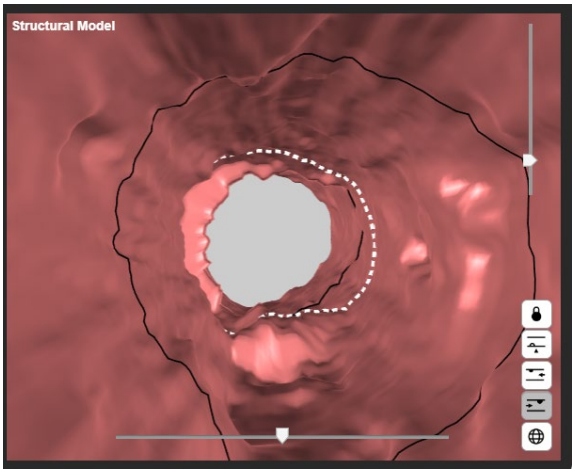
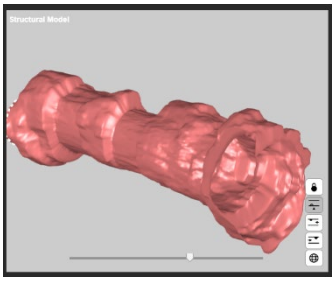
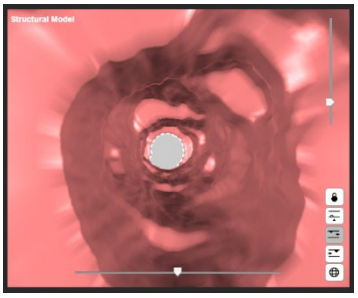
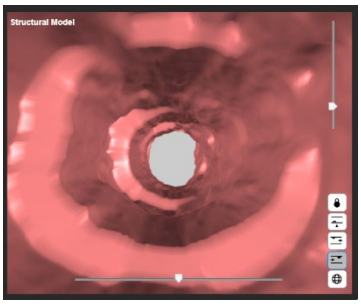


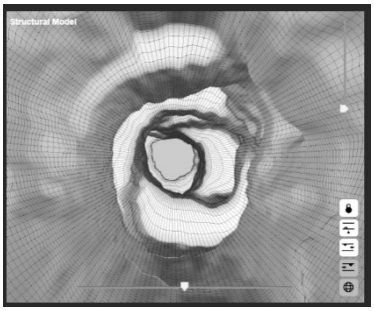
Figure 77: Structural Model

Structural Model control is detailed in Table 5

Table 5: Structural Model Control

Button/ Action	Description	Default
	Lock structural model on a bookmark – allows to move back and forth over a bookmark for better visualization.	Off

	Structural model: outside view  The controller enables rotation the tube around a fixed axis. The tube can also be rotated freely using the mouse.	Off
	Structural model: inside from back view  The upper right controller enables forward and backwards movement inside the tube. The middle lower controller enables 360 sideways movement inside the tube around a fixed point.	Off
	Structural model: inside from front view  The upper right controller enables forward and backwards movement inside the tube. The middle lower controller enables 360 sideways movement inside the tube around a fixed point.	On

	Tissue like / wire wallpaper toggle 	Off

9.6.5 2D Map Timeline

The 2D map timeline in the control panel (#7 in Figure 70) displays the position of the currently selected slice (in red) relative to other slices in 2D map, see Figure 78.

Figure 78: Editor Map Timeline

9.6.6 Play Bar

The play bar in the control panel (#7 in Figure 70) enables XRF/CMT maps control, see Figure **79**.

Figure 79: Play Bar

Play bar functions are detailed in Table 6

Table 6: Play Bar Control

Button/ Action	Description	Default
	Go to beginning – moves to first slice	Off
	Previous window – moves a window backward	Off
	Continuous scrolling backwards	Off
	Pause scrolling	Off
	Continuous scrolling forwards	Off

	Next window – moves a window forward	Off
	Go to the end – moves to last slice	Off
x1.00	+ increase continuous scrolling speed - decrease continuous scrolling speed	X1.00
	Home- moves all display to default configuration	On

9.6.7 General Buttons

The general buttons in the control panel (#7 in Figure 70) can be seen in Figure 80.

Figure 80: General Buttons

In case C-Scan® Cap excretion from body was not detected, an indication is displayed next to general buttons, see Figure 81

Figure 81: C-Scan® Cap Excretion Not Detected Indication

General buttons functions are detailed in Table 7

Table 7: General Buttons Functions

Button/ Action	Description
	Save analysis – saved current work in local archive
	App Information – opens an info window, about procedure and application: Technical Details, Clinical Details, Processing Details, Data Details, Software Details and Algo Details.
	Report on case issue, see additional details in 9.6.8.

9.6.8 Report on Case Failure

Reporting a failed case due to C-Scan® Track loading issues or C-Scan® Track loss is done according to instructions in 9.4.

Reporting failure detected during pre-analysis/analysis by an analyst/supervisor/physician, is done from the editor, using the **Report issue** button , opening a pop up (see Figure 82: Report Case Failure).

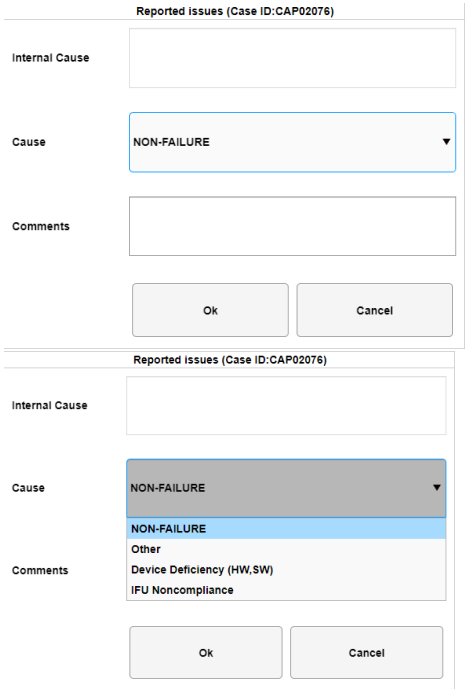


Figure 82: Report Case Failure

Choose the cause and any additional comments and click **Ok**. The **Report issue** button turns red , indicating an issue to next users in workflow**.**
If you are a supervisor or a physician, and a previous user has logged a failure, the editor will open with the failure pop up (see Figure 82: Report Case Failure), which allows you to add information to failure cause and comments.
You can also delete the cause and comments, thus canceling the raised issue decision, which will update upon your analysis release to data base.

9.6.9 Estimated Colon Path

The editor displays the estimated capsule path, AKA colon model (#4 in Figure 70), based on the capsule movement in the colon (see Figure 83).

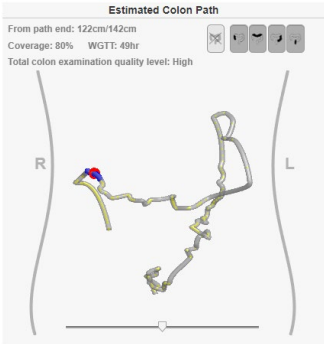


Figure 83: Estimated Colon Path

The colon model is divided into four anatomical sections: Cecum-Ascending, Transverse (containing both flexures), Descending-Sigmoid and Rectum (see Figure 84).

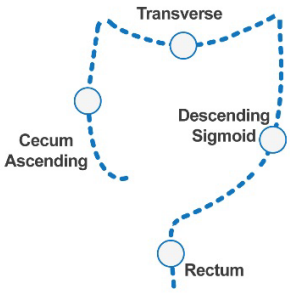


Figure 84: Estimated Colon Path

Additional information in this display includes:

- Current slice distance from rectum
- Coverage%, meaning Percentage of colon model covered by scans. This number related to colon model only, not necessarily entire colon of subject.
- WGTT (whole gut transit time) – time from C-Scan® Cap ingestion to excretion. If excretion was not detected or if capsule battery ended before capsule excretion, this duration is shorter than actual WGTT.
  If the WGTT exceeds a predefined threshold, it is colored red, and this should be taken into consideration in procedure analysis.

Examination quality level

To calculate examination quality level for pre-analysis summary, the analyst must mark which physiological segments exist in the colon model, by clicking the segments pictures, see Figure 83. This does not relate to scans, only to existence in colon model.
A segment clicked is highlighted and considered part of colon model. The segments chosen must be continuous since the colon model is always displayed in one piece.
See example in Figure 85, where Cecum-Ascending and Transverse are chosen.

Figure 85: Segments Marking for Examination Quality Level

9.6.10 Bookmarks

Analyst/Supervisor/Physician can add a suspect bookmark to the bookmarks table (see Figure 86, #5 in Figure 70).

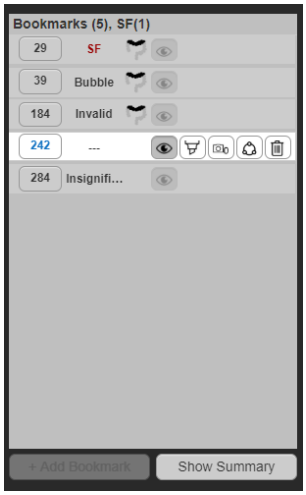


Figure 86: Bookmarks Table

To add a bookmark, mark an ROI around region of interest of a suspect using the **Automatic ROI** button . To add it as a bookmark, click the **+Add Bookmark** button

(enabled only after marking an ROI).

In the bookmarks table, the slice number can be clicked providing quick access to the marked ROI (in all windows).

Current bookmark viewed is highlighted in blue in bookmarks table.

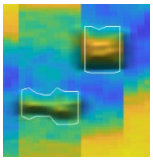
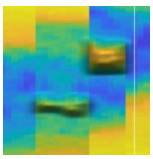
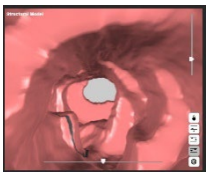
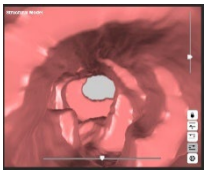
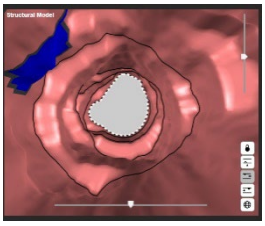
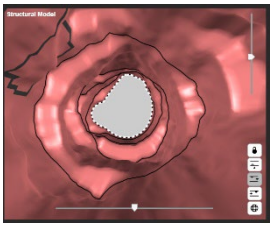
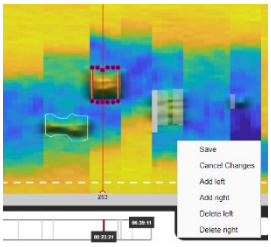
Bookmarks table headline indicated number of bookmarks and number of Sf (suspicious findings).

After bookmark suspect analysis, if a classification was chosen, it appears next to the slice number.

Actions on bookmarks are detailed in Table 8.

Table 8: Bookmarks Table Display and Buttons

Button/ Action	Description	Default
45	Bookmark quick access – clicking slice number moves all windows to marked ROI.	

	Bookmark visibility – bookmarks are marked in all displays. On:  Off:  On: Off: On:  Off: 	On
	Bookmark filled in structural model. On in left picture, off in right picture  	Off
	Take snapshot for report. Once clicking, a list opens with the following options for snapshots: • Standard set (includes 2D map, 3D model and Profile) • 2D map (XRF/CMT map) • 3D model (structural view) • Profile (slice profile) • Colon model (estimated colon path) • Gallery (Displays all taken snapshots)	Off
	Edit bookmark – enables bookmark ROI editing. Once clicked, dots marking ROI appear and a menu opens:  The dots can be moved, slices can be added or removed (add/delete right/left). Changes can be saved or canceled.	Off
	Delete selected bookmark. Once clicked a message appears to make sure the deletion is intentional-	Off

	"Are you sure you wish to delete the bookmark? Yes/No". Click Yes to delete bookmark or No to cancel.	
	Mark a specific bookmark.	

9.6.11 Suspect Metrics

The metric section displays seven metrics (Figure 87, #6 in Figure 70), evaluating the suspect based on a database of known SFs. Suspect metrics are used during the analysis process. For more details see DOC001212 C-Scan® View User Guide and Training.

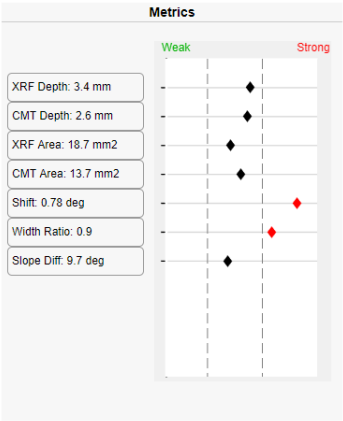


Figure 87: Suspect Metrics

When pressing on each of the metrics buttons, a window opens that displays the metric's value per slice in the ROI. The value is stated in the right end of the window. A red dot marks the current slice location. If the metric is not calculated for a specific slice, 'Nan' value will appear. See Figure **88**.

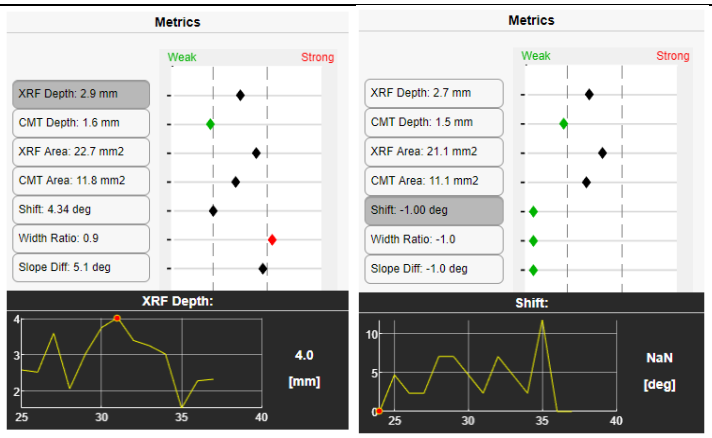


Figure 88: Metric's Value per Slice

9.6.12 Suspect Wizard

As part of analysis process, the suspect wizard (see Figure 89, #6 in Figure 70) is used.

To start the analysis process, click the **Start/restart the wizard** button

A classification of a suspect can be changed manually by clicking on the **Classification** (see Figure 89) which will enable button, click it and override your answer.

For more information on suspect analysis process, see DOC001212 C-Scan® View User Guide and Training.

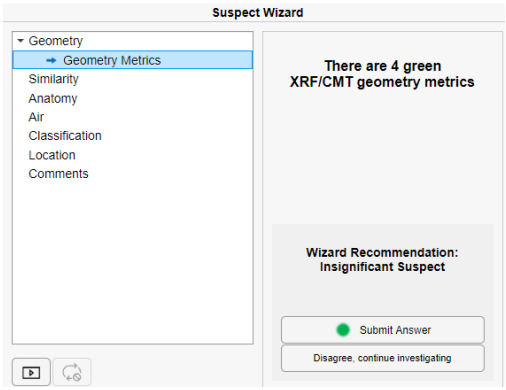


Figure 89: Suspect Wizard

9.6.13 Pre-analysis Summary

A physician performing final analysis, should review the pre-analysis performed by the analyst and supervisor. The editor opens in the pre-analysis summary window seen in Figure 90. Other users can review this page by clicking on Show summary button, (see #5 Figure 70).

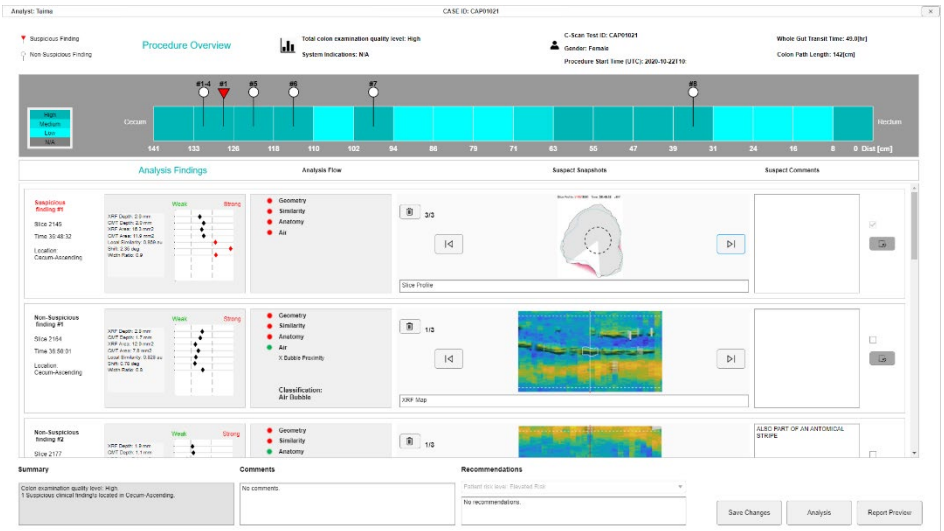


Figure 90: Pre-analysis Summary

If a suspicious finding was found during pre-analysis, the subject risk level is updated to elevated risk due to SF, Pre-analysis summary shows the procedure highlights and list of suspects found:

- Procedure general information (#1 in Figure 91)
- Procedure quality information (#2 in Figure 91)
- Suspicious and Non-suspicious findings table (#3 in Figure 91)
- Procedure summary, comments and recommendations (#4 in Figure 91)
- Action buttons (#5 in Figure 91)

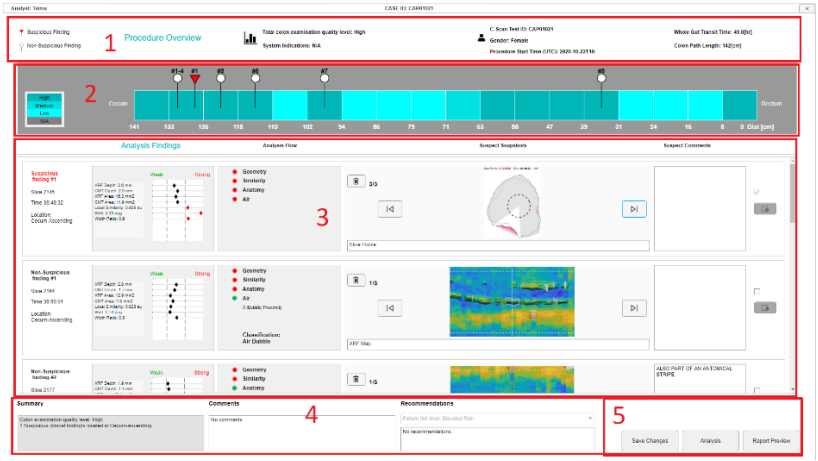


Figure 91: Pre-Analysis Summary Highlights

Procedure Overview (#1 in Figure 91) includes:

- Total colon examination quality level (for additional information, see chapter 9.6.9)
- System indications
- C-Scan® Test ID (procedure ID)
- Gender
- Procedure Start Time (UTC): (YYYY-MM-DD-HH:MM:timezone)
- Whole Gut Transit Time (for additional information, see chapter 9.6.9)
- Colon path length

Procedure quality information (#2 in Figure 91)

Procedure quality diagram shows the estimated quality throughout the capsule estimated path (see Figure 92). Optional levels are Low/Medium/High according to the color bar shown in the left side (NA option is relevant for non-selected sections).

Findings are marked according to their location on estimated capsule path. SF (Suspicious Findings) is marked with red triangle, non-SF with white circle.

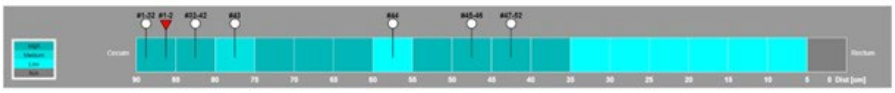


Figure 92: Procedure Quality

Findings table (#3 in Figure 91)

If suspicious findings were reported during pre-analysis, their information and pictures appear at the top of the Findings table (see #1 Figure 93).

Figure 93:Findings Table

A suspicious finding is automatically marked to appear in procedure report. A series of non-suspicious findings appear bellow the SF's (see #2 Figure 93) if there was any.

Suspect's information (slice number, time in procedure and location) is displayed in the left side bellow the suspect's classification (Suspicious/Non-suspicious finding). Suspect's parameters are displayed In the Analysis Findings column, next to the analysis flow.

Browsing snapshots gallery can be done using the right and left arrows, next to the snapshot. Snapshot number out of total number of snapshots is displayed on the top left corner of the snapshot gallery.

Snapshots can be deleted using the delete button .

Comments column shows comments entered during suspect analysis process and can be edited or added.

Non-suspicious findings are not marked to appear in the report but can be manually added to the report by checking the box near the suspect comments.

All findings can be viewed with additional data directly in analysis window by clicking the **Analysis** button (see #5 in Figure 91) or the **jump to suspect analysis** button to jump to a specific suspect in the analysis window. Return to pre-analysis summary by clicking the **Show summary** button. Going back to analysis window, changes can be made to pre-analysis; suspects can be added/removed.

Procedure summary, comments and recommendations (see #4 in Figure 91)

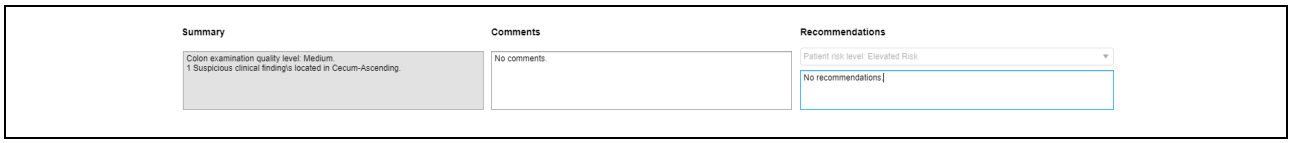


Figure 94: Procedure Summary, Comments and Recommendations

Summary field includes suspicious findings if there are any, total quality level and an indication when WGTT exceeds threshold.
Comments field is free text.
Recommendations field shows subject risk level: Average/elevated risk (chosen automatically according to findings in analysis and WGTT). Automated section can be changed manually, unless SF was found the risk level is determined as elevated risk and cannot be changed.
Recommendations field also includes a free text field.
After reviewing all findings and the total estimated quality level of the procedure, the summary, comments, and recommendations fields for any other information the analysts reported, the physician can decide whether the subject risk level is average/elevated and add recommendations.

Action buttons (#5 in Figure 91)
See description of Action buttons functions in Table 9.

Table 9: Pre-Analysis Summary Action Buttons

Button/ Action	Description
Save Changes	Click to save changes made in pre-analysis summary
Analysis	Click to go to analysis window, showing complete procedure data
Report Preview	Click to see a report preview

Click **X** button on top right corner of editor to close the editor and return to C-Scan® View main screen.
To sign, release and share report instructions see 9.5.6, 9.5.7.

9.6.14 Report Preview

Once physician completes the pre-analysis review, and decides on subject risk level and recommendations, clicking **Report Preview** shows a preview look of the report (see Figure 95). The report is not generated at this point, report signing is done via C-Scan® View main application, see 8.5.6. After report is signed it can be shared, see 9.5.7.

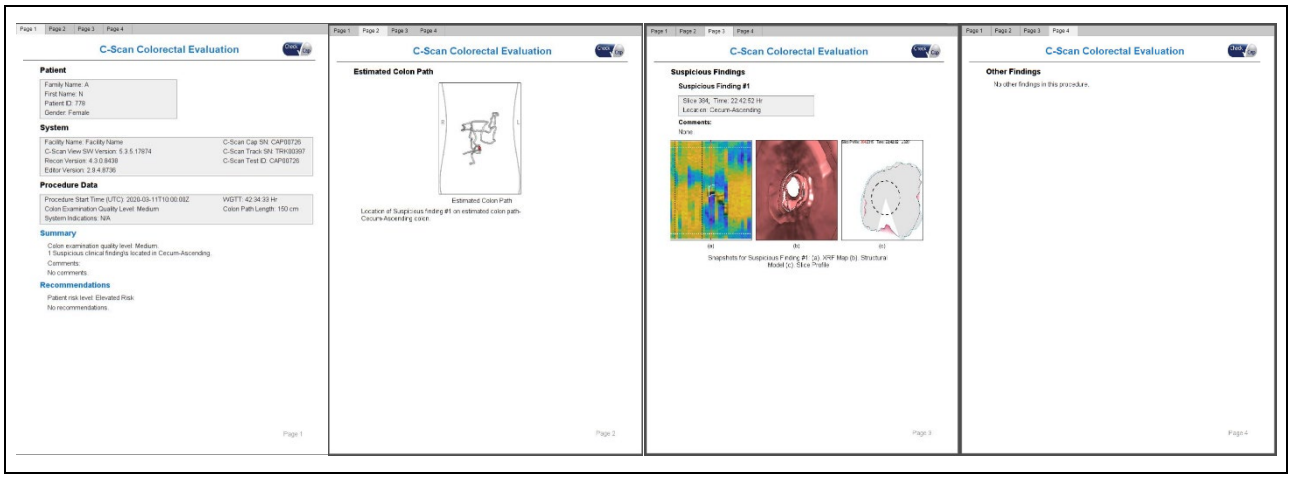


Figure 95: Report Preview

10 Technical Description

10.1 System Labeling

Table 10: Labeling Explanations

Labeling	Explanation
	Single use only - Do not re-use.
	Consult accompanying documents (required to consult for Safety)
SN	Serial number
	Manufacturer
	Date of Manufacture [YYYY-MM-DD]
	Use-by date [YYYY-MM-DD]
Rx only	“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
REF	Catalogue number
	Protected from touch by fingers and objects greater than 12 millimeters, and high-pressure water jets from any direction.

Labeling	Explanation
	Keep dry
	Fragile, handle with care
	Humidity limitation
LATEX	Product contains natural rubber latex
	Temperature limit
LOT	LOT number
	Not for general waste
CAUTION RADIOACTIVE MATERIAL	Caution Radioactive Material
NON STERILE	Non-Sterile
MR	MR Unsafe

10.2 C-Scan® Kit Labels

Each C-Scan® Kit box has a label on the cover as shown in Figure 96. Each box is marked with the expiration date, lot number, and a unique C-Scan® Kit serial number.

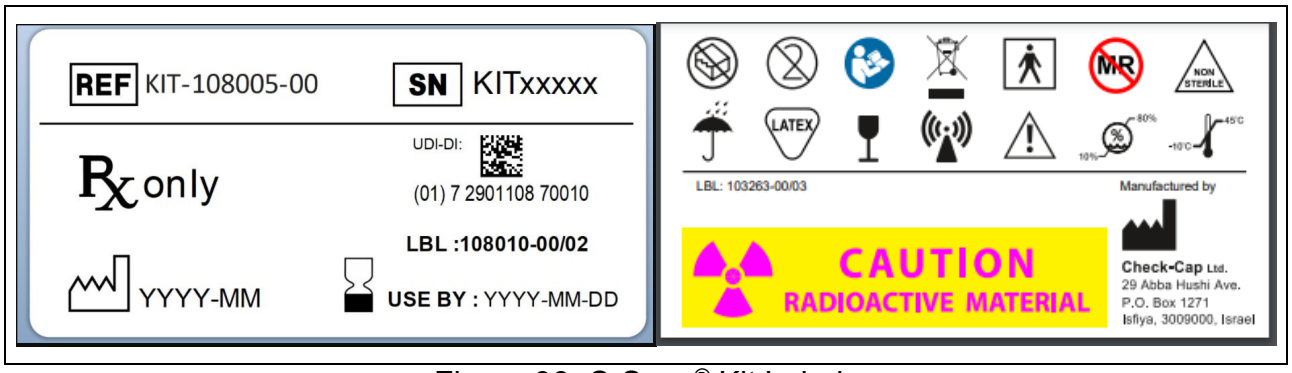


Figure 96: C-Scan® Kit Labels

10.3 C-Scan® Cap Label

Each capsule box has a label at the bottom as shown in Figure 97. Each capsule is marked with the expiration date, lot number, and a unique capsule serial number.

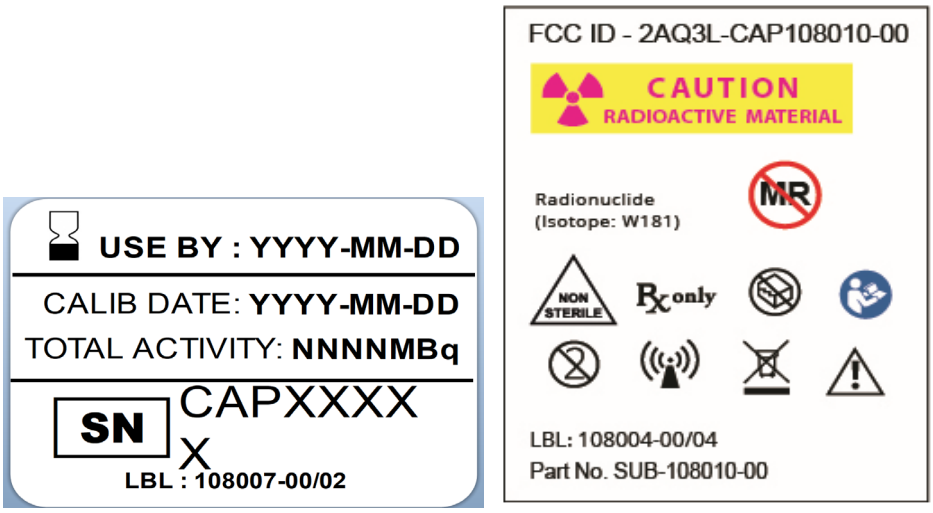


Figure 97: C-Scan® Cap Label

10.4 C-Scan® Track Label

The C-Scan® Track has two labels on the sensor units as shown in Figure 98.
Each C-Scan® Track is marked with a unique serial number.

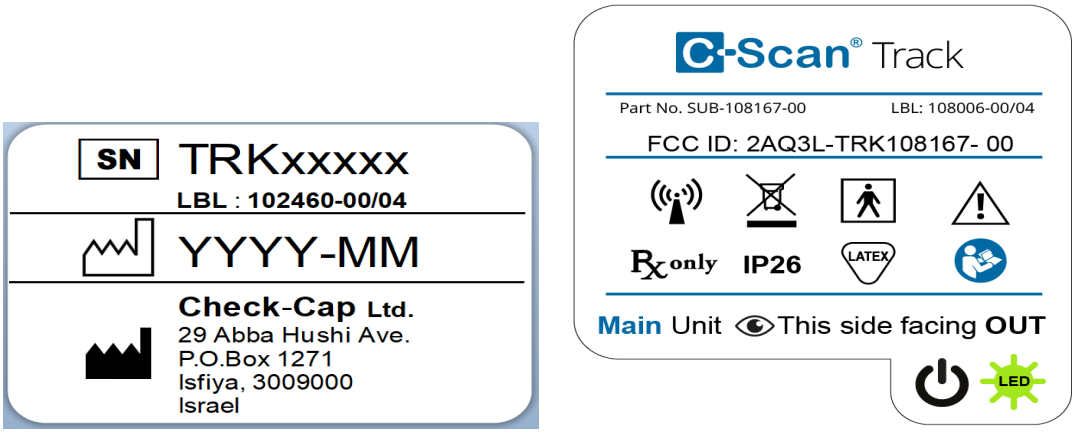


Figure 98: C-Scan® Track Labels

10.5 C-Scan® View Labels

The C-Scan® View has four labels. 3 Packing labels on the PC package, Monitor package and a label on top of the PC as shown in Figure 99, Figure 100.
Each C-Scan® View is marked with a unique serial number.

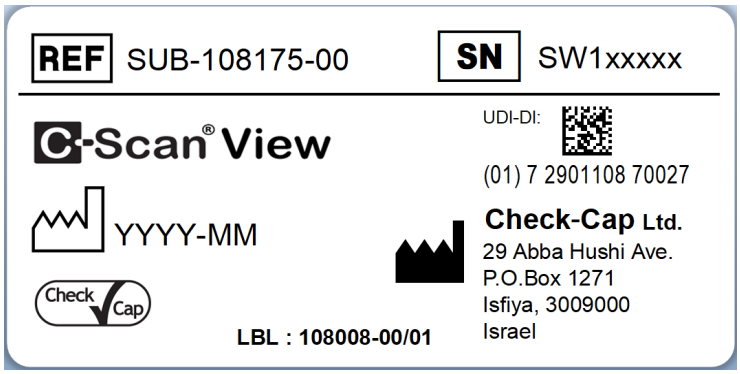


Figure 99: C-Scan® View Production Label

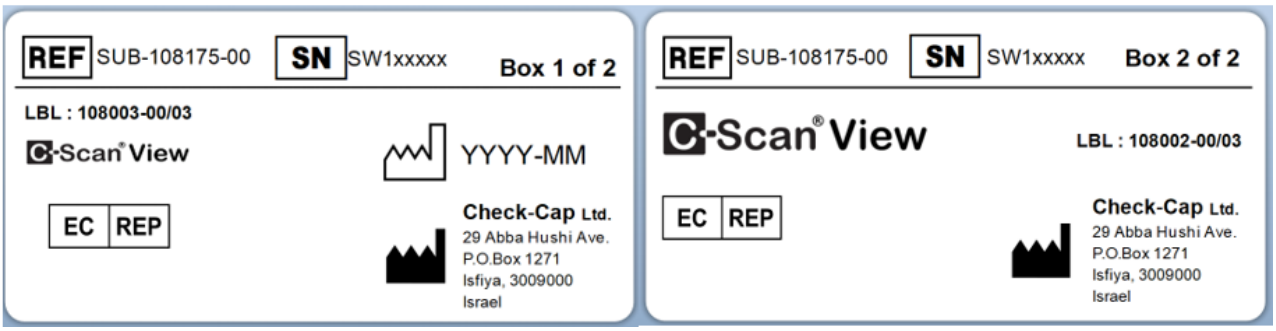


Figure 100: C-Scan® View Packaging Labels

10.6 C-Scan® Modes of Operation

10.6.1 C-Scan® Cap

The C-Scan® Cap has 3 modes of operation: Standby, BIT and Active. 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.

- Standby Mode:

Standby mode is C-Scan® Cap lowest power consumption mode. In this mode C-Scan® Cap only active unit is the communication unit, which is completely autonomic.

- 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 self-test and some require the participation of both subsystems. The final result of the system BIT is granted only by the C-Scan® Track.

- 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.
The C-Scan® Cap verifies that the X-ray source is concealed. If there's a suspect for the X-ray source not being concealed, the C-Scan® Cap sends a message to the C-Scan® Track informing it that the X-ray source is exposed. If the issue is not resolved by the system, the C-Scan® Track indicates a malfunction to the subject, who should contact the clinic immediately.

10.6.2 C-Scan® Track

The C-Scan® Track is an external device attached to the subject 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, which 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.
- 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 –Provides status indicators to the subject and operator.

- 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 a client/server-based 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 subject information, displays the 3D colon reconstruction, and generates a procedure report.

10.7 System Specifications

Specifications are subject to change without prior notice and without any obligation to users on the part of the manufacturer.
Specifications are rounded to the appropriate decimal place.

Table 11: Technical Specifications

C-Scan® Cap	
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)
The C-Scan® Cap radiation source is assembled within a 3mm-thick Tungsten concealment. RADIATION QUALITY is constant, guaranteed, and verified, thanks to isotope-based source. Hence no ADDED FILTER required. 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. The RADIATION DETECTORS integrated into the C-Scan® Cap are based on CdTe/CZT crystals, demonstrating nearly perfect Quantum Efficiency within the imaging energies range. The C-Scan® Cap radiation source housing ensures negligible exposure to any OPERATOR or STAFF.	
Shelf life	Up to 2 weeks
Operating Temperature	+5ºC (41ºF) to 45ºC (113ºF)
Operating Humidity	100% Relative Humidity
Operating Pressure	520 mmHg to 940 mmHg
Storage and Transportation Temperature	-10ºC (-4ºF) to 45ºC (113ºF)
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 , 100 Kbit/sec
Effective Radiated Power (Avg @ 3[m] in Air)	-52 [dBm]
Battery Type	Lithium Ion – 3.8[V]
Battery Life	maximum 150 hours
C-Scan® Track	
Mechanical Dimensions Sensor Unit (Length x Width x Depth)	< 70mm X 75mm X 15mm
Mechanical Dimensions Main Unit (Length x Width x Depth)	< 86 mm x 76 mm x 22 mm
C-Scan® Track Weight	210 grams
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	IP26
Storage and Transportation Temperature	-10ºC (-4ºF) to 45ºC (113ºF)
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 (Avg @ 3[m] in Air)	-20 [dBm]
Battery Type	Lithium-Ion 3.8[V]
Battery Life	Max. 150 hours

10.7.1 Guidance and Manufacturer's Declaration

Table 12: Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The C-Scan® Cap and C-Scan® Track 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 13: Guidance and Manufacturer's Declaration- C-Scan® Cap and C-Scan® Track Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	For use in a typical domestic, commercial, or hospital environment.
RATED Power frequency (50 Hz) magnetic field IEC 61000-4-8	30 A/m, 50 Hz	30 A/m, 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF EM fields 61000-4-3	10 V/m 80 MHz - 2,7 GHz	10 V/m 80 MHz - 2,7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the C-Scan® Cap and C-Scan® Track, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz 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 meters (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710 MHz, 745 MHz, 780 MHz 28 V/m 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz 9 V/m 5240 MHz, 5500 MHz, 5785 MHz	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710 MHz, 745 MHz, 780 MHz 28 V/m 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz 9 V/m 5240 MHz, 5500 MHz, 5785 MHz	

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.
NOTE 3: The table is per IEC (EN) 60601-1-2 4th Edition

Table 14: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the C-Scan® Track and C-Scan® Cap

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

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.37	0.74
1	N/A	1.2	2.3
10	N/A	3.7	7.4
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

10.7.2 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- C-Scan® View

Problem	Action
The PC fails to start.	1. Make sure that your computer is switched ON and all the components receive power. 2. Make sure that all the cables are firmly connected to their respective ports. 3. Make sure that the cables are not damaged or frayed. 4. Try to start the PC. If the above fails to resolve the problem, contact customer support.
A specific key does not work or sticks.	1. Turn OFF the PC. 2. Using a can of compressed air, clean around the problem key. 3. Retest the keyboard.
The keyboard does not respond.	1. Disconnect the keyboard USB cable and then reconnect in the USB port. Test the keyboard. 2. If the keyboard still does not respond, try the keyboard USB cable in another USB port on the computer. 3. If the keyboard still does not respond, in the C-Scan® View software application shut the PC down using the mouse. 4. Restart the PC and check whether the problem persists. If the above steps fail to resolve the problem, contact customer support.
The mouse does not respond.	1. Make sure that the surface you are using has enough of a pattern in it so that the mouse can see it. A mouse pad is best. (The mouse senses movement by reflections. It is harder for the mouse to sense movement on a uniform surface.) 2. Make sure that the opening on the bottom of the mouse is clean. 3. Disconnect the mouse USB cable and reconnect it in the USB port. Test the mouse. 4. If the mouse still does not respond, try the mouse USB in another USB port on the computer. 5. If the mouse still does not respond, perform hard shutdown of the PC and check whether the problem persists. If the above steps fail to resolve the problem, contact customer support.
C-Scan® View does not respond or crashes.	Perform hard shutdown of the PC. If this fails to resolve the problem, contact customer support.
Bluescreen error.	Perform hard shutdown of the PC. If this fails to resolve the problem, contact customer support.
C-Scan® View software does not load correctly.	Perform hard shutdown of the PC. If this fails to resolve the problem, contact customer support.

C-Scan® Track connection failed.	1. Make sure that the USB cable connecting the C-Scan® Track is firmly connected to the USB port and to the C-Scan® Track. 2. Make sure that the cables are not damaged or frayed. 3. Make sure only one C-Scan® Track is connected. 4. Check whether the problem persists. 5. If the above steps fail to resolve the problem, connect the cable to a different port. 6. Check whether the problem persists. 7. If this fails to resolve the problem, restart the PC. 8. Check whether the problem persists. If the above fails to resolve the problem, contact customer support.
C-Scan® Track loading failed.	Disconnect the C-Scan® Track and try again. If this fails to resolve the problem, contact customer support.
Monitor problem.	Perform troubleshooting as indicated in *Troubleshooting* section in the Dell P2414H User's Guide.
Network connection problem	1. Check the network cable is connected properly. 2. Make sure that the cables are not damaged or frayed. 3. Restart the PC. 4. Check whether the problem persists. If this fails to resolve the problem, contact customer support.
C-Scan® View Processing Data Failed	Contact Customer Support
C-Scan® View report share failure	1. Make sure a network connection exists. 2. Make sure the E-mail address is valid and accurate. If this fails to resolve the problem, contact customer support.
C-Scan® View data upload/download failure	1. Make sure a network connection exists. 2. Try again. If this fails to resolve the problem, contact customer support.
C-Scan® View login failure	1. Make sure a network connection exists. 2. Make sure the username and password are correct. If this fails to resolve the problem, contact customer support.
C-Scan Track connection cable is damaged	1. Replace with spare cable included with C-Scan® View. 2. If you need an additional cable, contact customer support.

For any problem or inquiry, the user can contact the customer support. Contact info is provided in the info button, located in the application header. Click **Support** to see Contact info or even "send log to support" when facing errors or issues.

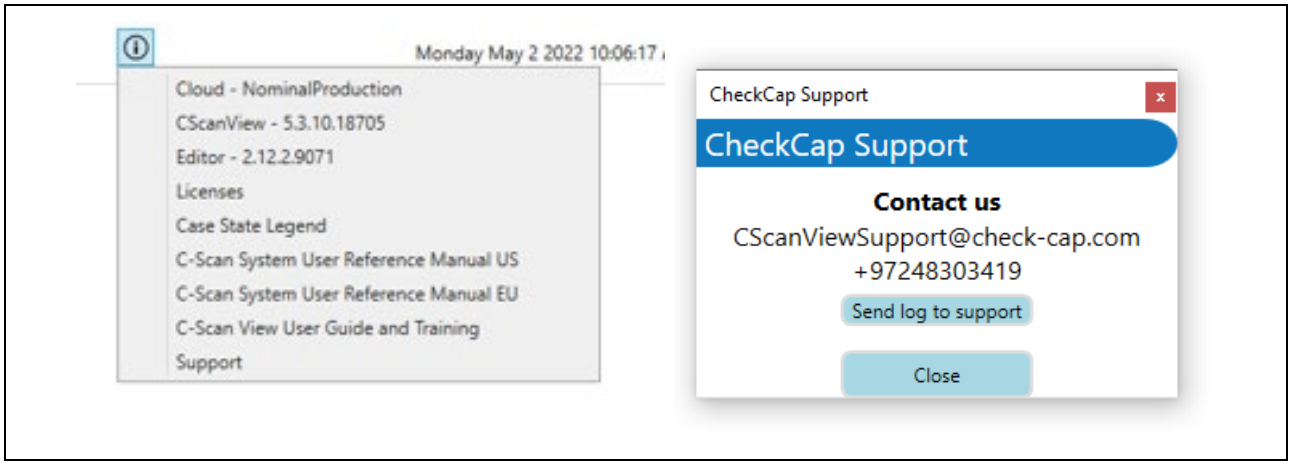


Figure 101: Application info menu