



PillCam® Platform

Setup & Maintenance

RAPID® 7

DOC-1530-01

August 2010

Book 1

Book 1: Setup & Maintenance

Book 2: Performing Capsule Endoscopy

Book 3: Using the RAPID® Software

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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.



Note

Changes or modifications not expressly approved by Given Imaging Limited could void authority to operate the PillCam Platform.

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Introduction

Conventions

Screen elements, such as text on the screen in messages, or in menus, as well as button names are in bold and italics: e.g. ***Capture*** button.

Screen names, are in a bold type face: e.g. **DataRecorders** screen.

The footer shows the page number company name or the chapter number.

The header shows the equipment name and chapter name.

A note is information or remark that receives emphasis and looks as follows:



A caution warns you about possible damage to equipment, and looks as follows:



A warning warns you about possible harm to people and looks as follows:



Welcome to the PillCam Platform

The PillCam Platform enables minimally invasive visualization of the gastrointestinal tract.

The system consists of:

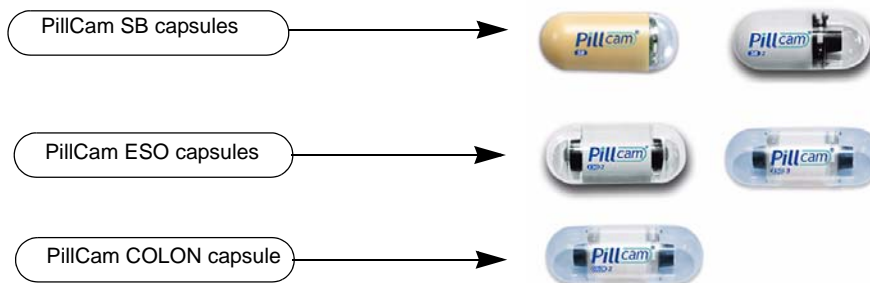
- PillCam video capsules—PillCam SB, PillCam ESO, and PillCam COLON, that acquire pictures of the gastrointestinal tract and transmits them to the DataRecorder
- DataRecorder, which stores the images collected during the examination for subsequent video creation with the full RAPID software
- RAPID software, which processes and transforms the raw image data into a conveniently viewable RAPID video

PillCam Video Capsule

PillCam video capsules are video cameras for imaging the intestinal tract. The capsules, about the size of a large vitamin pill, are equipped with tiny battery, transmitters with antenna, and Light Emitting Diodes (LEDs) for each video camera head, all encapsulated in a biocompatible plastic casing.

There are three PillCam video capsule types:

- PillCam SB capsules are used for examination of the small bowel.
- PillCam ESO capsules are used for examination of the esophagus.
- PillCam COLON capsules are used for examination of the colon.



PillCam SB capsules contain one video camera while the PillCam ESO and PillCam COLON capsules each contain two video cameras.

After activation and ingestion, the PillCam video capsule is propelled by peristalsis through the gastrointestinal tract. The video cameras positioned behind a clear plastic dome acquire images while the PillCam video capsule travels along the patient's gastrointestinal tract. The transmitter sends images to the DataRecorder for storage.

For specification and technical parameters of the PillCam video capsules, see *System Specifications* on page 32. For Indications and Contraindications, see chapter two of Book 2: Performing Capsule Endoscopy.

Handling the PillCam Video Capsule

Each PillCam video capsule comes in its own box that enables the handling of the capsule until ingestion. A magnet close to the capsule in the box keeps it inactive until removal from the box. The capsule is active immediately after removal from the box.

To ensure the capsule remains inactive, it must be in the box. PillCam video capsules are packed at Given Imaging Ltd. in a controlled process, ensuring the capsule is only activated after removal from its box.



Caution

- Removal of a PillCam video capsule from its box activates it.
- Keep in the box until use.
- Store the capsules **only** in packaging supplied with the product.
- Do not use a PillCam video capsule if packaging is damaged.

DataRecorders

The DataRecorder is a compact battery-operated unit worn by the patient during the examination. It receives and stores the image data transmitted by the PillCam capsule. There are two models currently available: DataRecorder 2 and DataRecorder 3.

DataRecorder 2

The DataRecorder 2 consists of a receiver, a processor module, and a memory device for storing the data transmitted by the PillCam video capsule.

The standard DataRecorder 2 Kit includes the following items:

- DataRecorder 2
- Standard RecorderBelt
- Two RecorderBelt extensions
- Pouch + suspenders
- Li-Ion battery pack
- DataRecorder 2 Cradle and adaptor
- 8-lead and 3-lead SensorArray
- DataRecorder 2 Carrying case

The battery of the DataRecorder 2 is charged in the cradle either with its adaptor or while inside the DataRecorder 2.



The DataRecorder 2 is ready for operation when its battery is charged and the SensorArray is connected. When the DataRecorder 2 is on, it starts recording as soon as a signal is received from any PillCam video capsule. When the capsule LED blinks, the DataRecorder 2 is receiving data. When the signal from the PillCam video capsule is too weak, the LED does not blink.

















DataRecorder 2 Automatic Shutdown

After the DataRecorder 2 has been initialized with patient data, it goes into a standby mode when removed from its cradle and starts recording as soon as a signal is received from any PillCam video capsule. If no signal is received, the DataRecorder automatically shuts down after 90 minutes. This feature ensures that the DataRecorder 2 preserves sufficient battery power to record a complete study.

DataRecorder 2 LED Indications

The following table describes the LED indicators and their status/color for each of the most common DataRecorder 2 events/status.

LEDs 	DataRecorder 2 Status	
	DataRecorder is ON but not initialized. DataRecorder does not capture capsule signals.	
	DataRecorder is initialized with patient data and ready to capture capsule signals. DataRecorder shuts down if no capsule signals are received for more than 30, 60, or 90 minutes, depending on the DataRecorder software version.	
	DataRecorder is exchanging status or data with RAPID or RAPID RT. LED blinking rate varies according to the communication flow.	
	DataRecorder is capturing capsule signals. Blinking rate = capsule frame rate.	
	DataRecorder has stopped capturing capsule signals for more than 5 seconds.	
	DataRecorder is detecting a capsule in sleep mode. Blinking rate = every five seconds (in any color).	
	DataRecorder is malfunctioning.	
 <20 seconds	DataRecorder is synchronizing with a capsule. This is normal functioning.	
 >20 seconds	DataRecorder detects capsule signal, but is not recording it. This is a malfunction.  Note Check the SensorArray connection or have patient move to a different location.	
	Maximum Level	Battery Charge level When charging, the Battery LEDs do not blink. When DataRecorder is out of the Cradle, the Battery LEDs blink once every 5 seconds.
	25%	
	Below 10%	

DataRecorder 2 Cradle

The DataRecorder 2 Cradle is used to charge the DataRecorder 2 or to charge a spare battery externally. It is also used to discharge the battery before starting the recharge, when the Cradle detects that the battery needs refreshing (i.e., the battery gauge needs calibration). Thus occasionally, when inserted into the cradle, before charging starts, the Cradle may discharge first the battery and then start recharging.

The cradle also connects the DataRecorder 2 to the computer for performing patient check-in and creating a video. The green LED on the cradle indicates that the DataRecorder 2 is charged and ready for use.

- The red LED, when lit continuously, indicates a defective battery.
- The red LED, when blinking, indicates that there is a problem with the cradle.



Warning

Never connect the DataRecorder 2 to the SensorArray while the DataRecorder 2 is in its cradle.

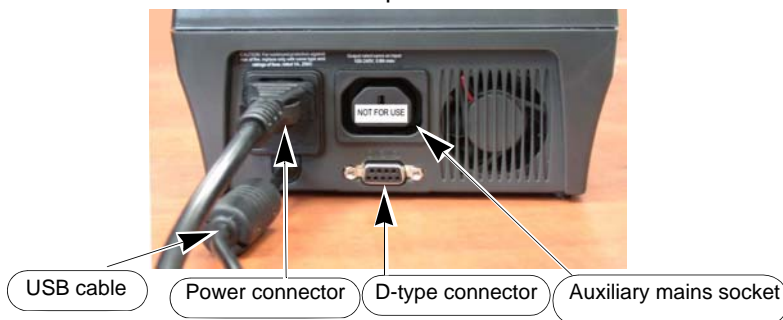
Cradle Connections

There are four connections on the back panel of the cradle. Only two of them are used with standard operation of the cradle: the power connector and the USB cable connection.



Note

When connecting more than one DataRecorder 2 to the computer, it is recommended to use a USB-powered hub.



The D-type connector and Auxiliary mains socket-outlet are for service use only.



Warning

- The cradle is for indoor use only.
- Never charge non-rechargeable batteries.
- All cells containing mercury, cadmium, or lead as electrochemical substances are subject to special waste disposal requirements.
- This charger is a class A product. In a domestic environment, this charger may cause radio interference.

DataRecorder 3

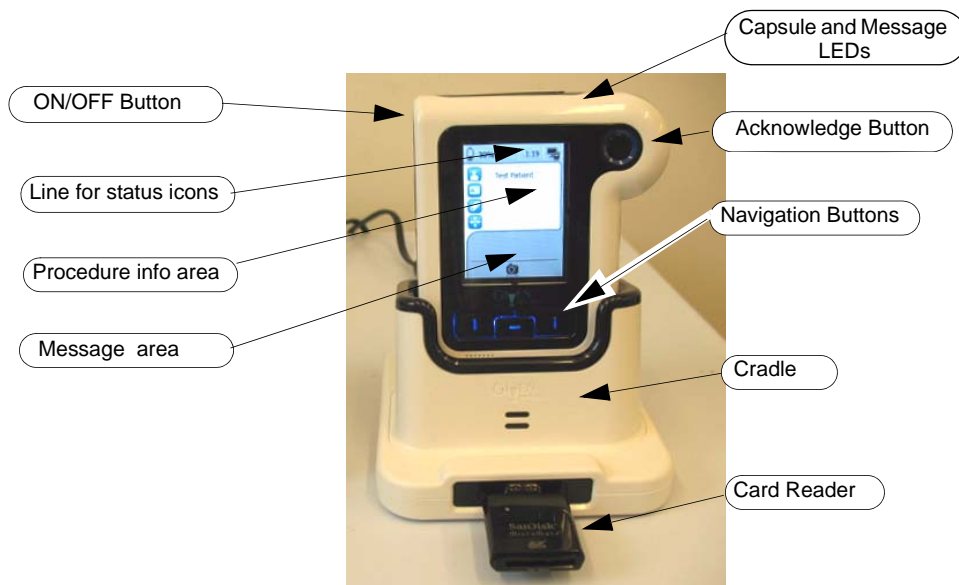
The DataRecorder 3 consists of a receiver, a transmitter, and a memory device for storing the data transmitted by the PillCam capsule.

The standard DataRecorder 3 Kit includes the following items:

- DataRecorder 3
- Pouch + shoulder strap
- DataRecorder 3 cradle
- External power supply

SensorArrays are not part of the standard kit, and are supplied separately.

The battery of the DataRecorder 3 is charged while the DataRecorder is in its cradle.



The DataRecorder is ready for operation when its battery is charged, removed from the cradle, and the SensorArray is connected. When ON, the DataRecorder initiates pairing procedure (see *DataRecorder-Capsule Pairing* in chapter 4 of the Procedure Manual) as soon as a signal is received from a capsule. When the capsule LED on the DataRecorder blinks in blue, the DataRecorder is receiving data from a paired capsule.



Acknowledge Button

The Acknowledge button is used by the patient in response to DataRecorder messages, including regimen instruction messages during post ingestion regimen (see *Post Capsule Ingestion Instructions* in Book 2: Performing Capsule Endoscopy) to acknowledge receiving the message.

Navigation Buttons

The Navigation buttons are used:

- For manual capsule pairing process (see *DataRecorder-Capsule Pairing* in Book 2: Performing Capsule Endoscopy, Chapter 4)
- To interact with the DataRecorder (see *Navigation Buttons Legends on page 12*)

Battery Status

The battery icon  on the screen indicates the status of the battery in 10% increments.

When the battery charge is below 10% the battery icon turns red. When the battery charge is below 5% the DataRecorder shuts down.

When the DataRecorder 3 is charging in its cradle, the bottom LED in the cradle is orange. When the DataRecorder is ready for use, the bottom LED in the cradle is green.

DataRecorder Automatic Shutdown












After the DataRecorder has been initialized with patient data, it goes into a standby mode when removed from its cradle and starts recording as soon as a signal is received from a paired capsule. If after 90 minutes no paired signal is received, the DataRecorder automatically shuts down.

The DataRecorder 3 also turns off five minutes after End of Procedure .
















DataRecorder 3 LED Indications





The following table describes the LED indicators and their status/color for each of the most common DataRecorder 3 events/status.

LEDs	DataRecorder 3 Status
	DataRecorder is initialized with patient data and ready to capture capsule signals. DataRecorder shuts down if no capsule signals are received for more than 90 minutes.
 Blinking	DataRecorder is receiving capsule signals before capsule pairing is achieved. Blinking rate = capsule frame rate
 Blinking	DataRecorder is receiving paired capsule signals. Blinking rate = capsule frame rate.
 Blink every 5 seconds	DataRecorder has stopped receiving capsule signals for more than 5 seconds.
	DataRecorder has started downloading.
	DataRecorder has stopped recording because the memory card is full.
 Blinking	There is an instruction on the DataRecorder screen.
 	DataRecorder is malfunctioning.
 Blinking	DataRecorder detects capsule signal, but is not recording it. This is a malfunction. Check the SensorArray connection or have patient move to a different location.
	The LEDs on the navigation buttons blink in blue once every 5 seconds when the DataRecorder is on, out of the cradle and the LCD screen is off. Pressing any of the navigation buttons when the LCD screen is OFF will turn the LCD screen ON.

DataRecorder 3 Error Message Guide













Popup	Message	Popup	Message
	No valid approved memory card is detected. Verify approved card is in the DataRecorder.		Do not move DataRecorder from cradle
	Memory card is write-protected		SensorArray hardware failure. Consult a technician.
	Memory card error. Remove + reinsert card.		Wrong SensorArray type
	Insufficient memory on card		No USB connection to cradle. Check connection. If connection is OK and error persists, consult a technician
	SensorArray not connected. Connect the SensorArray		Wrong software on memory card
	Cradle error		Fatal error. Consult a technician.
	End of procedure		

DataRecorder 3 Check-in Screen Icons

Icon	Name
	Patient Name
	Patient ID
	Procedure
	Regimen








DataRecorder 3 Screen Icons

The following icons appear in the top status line of the DataRecorder screen.









Icon	Explanation	Icon	Explanation
	Start pairing procedure		SensorArray not connected
	Pairing succeeded		DataRecorder is initialized
	Data not downloaded		DataRecorder is waiting for initialization
	Data downloaded		SensorArray failure
	Wrong SensorArray type		Small bowel detection
	End procedure, Memory full		Regimen Reminder numbers appear in status line when in Real Time Viewing mode

Battery and Capsule Icons

The following icons appear in the top status line of the DataRecorder screen.

Icon	Battery Status	Icon	Capsule Reception Status
	Battery fully charged		Signal weak, recording with noise
	Battery charge level at 10% intervals		Signal strong, recording with noise
	Battery empty, DataRecorder shuts down		Signal weak, but recording OK
			Signal strong, and recording OK

Navigation Buttons Legends

Icon	Action when pressed	Icon	Action when pressed
	Confirm		Confirm SB detection and activate instruction #1
	Scroll up		Activate Real-Time viewing (followed by pressing the left and right buttons)
	Scroll down		Mark frame
	Exit Real-Time viewing		Switch video head (in Real-Time viewing mode)

DataRecorder Cradle

The DataRecorder Cradle is used to charge the DataRecorder.

The cradle also connects the DataRecorder to the computer for performing patient check-in and creating a video.



- The top LED is orange when the DataRecorder is in the cradle.
- The bottom LED is orange when charging the battery.
- The bottom LED is green when the DataRecorder is fully charged.

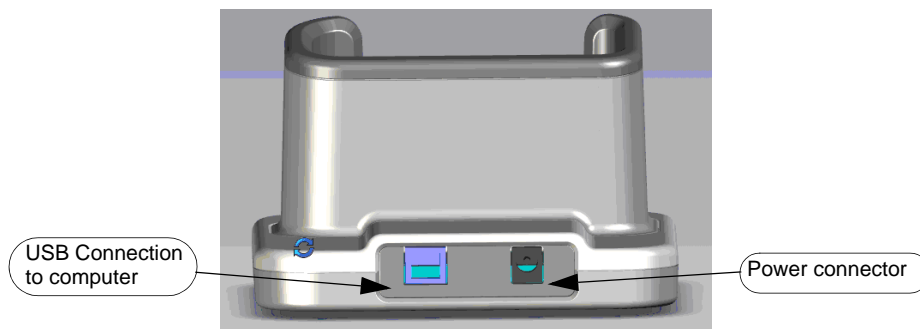


Warning

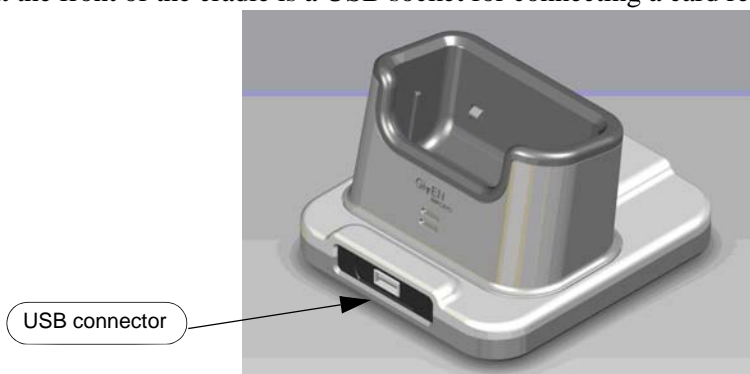
Never connect the DataRecorder to the SensorArray while the DataRecorder is in its cradle.

Cradle Connections

There are two connections on the back panel of the cradle: the power connector and the USB connection to computer.



At the front of the cradle is a USB socket for connecting a card reader or USB storage device.



Note

Connect only USB storage devices, DataRecorder 3 memory cards (in its reader), or self-powered external hard drives to the DataRecorder 3 cradle. Other USB devices may not function as indicated.



Warning

- The cradle is for indoor use only.
- Never charge non-rechargeable batteries.
- All cells containing mercury, cadmium, or lead as electrochemical substances are subject to special waste disposal requirements.
- This charger is a class A product. In a domestic environment, this charger may cause radio interference.

External Power Supply

The Cradle is connected to the mains power through an external power supply.



Caution

Use **only** this power supply.

RecorderPouch

The DataRecorder 3 RecorderPouch is a pouch with an adjustable strap to hold the DataRecorder. The patient must wear the DataRecorder at all times while the PillCam video capsule is active inside the patient. Use the waist strap to anchor the DataRecorder and the SensorArray connector to the patient's body.

SB SensorBelt

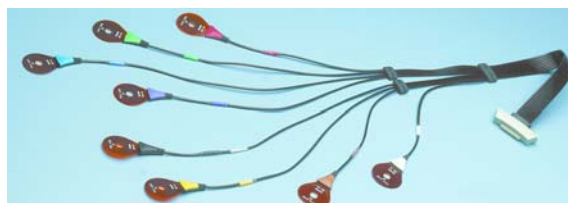
The SB SensorBelt receives data from the PillCam video capsule and transfers it to the DataRecorder. The sensor is connected to the DataRecorder module by a flexible cable and is worn at the waist of the patient over a thin shirt. The SB SensorBelt is used for PillCam capsule endoscopy of the small bowel.

SensorArray

The SensorArray receives data from the PillCam capsule through the sensors and transfers it to the DataRecorder. Each sensor is connected to the DataRecorder module by a flexible cable. The sensor is built of a flexible printed circuit board (PCB) and is attached to the skin by means of a disposable, medical adhesive sleeve.

The SensorArray used in a capsule endoscopy depends on the capsule type and the DataRecorder type:

- **8-lead SensorArray:** used with DataRecorder 2 and PillCam SB and PillCam COLON capsules



- **8-lead SensorArray DR3:** used with DataRecorder 3 and PillCam SB 2 and PillCam COLON 2 capsules. This SensorArray also transmits control signals to the COLON 2 capsule through the transmitter loop antenna.



- **3-lead SensorArray:** used with DataRecorder 2 and PillCam ESO 2 capsules



- **3-lead SensorArray DR3:** used with DataRecorder 3 and PillCam ESO 3 capsules

**Note**

All components of the PillCam Platform are Latex free.

Given Workstation

The Given Workstation is a dedicated computer designed for processing, displaying, storing the acquired images, and generating the RAPID videos.

To control access to the Given Workstation and to make sure that only authorized personnel may use the relevant files on the Given Workstation, a multi-user configuration is provided, see *Multi-User Setup on page 27*.

**Note**

When RAPID is installed on a personal computer, it functions nearly identically to the Given Workstation. Throughout this manual, references to the workstation apply also to the RAPID computer except where otherwise noted.

RAPID 7 Software

RAPID 7 supports PillCam capsule endoscopy of the GI tract with all PillCam video capsules. RAPID 7 supports patient check-in/DataRecorder initialization, video creation, viewing of the RAPID video, and generation of a Capsule Endoscopy Report.

Setting Up the System

Setup Requirements

Set up your office to accommodate the new PillCam Platform. Review the following Workstation specifications:

Four electrical outlets are required to connect the following components: Workstation computer, monitor, printer, and one cradle. Each additional cradle requires an additional outlet.



Note

You may use a Given approved power strip.



Caution

Do not connect any component of the PillCam Platform to the same outlet as any appliance or device that has a high power requirement (refrigerators, generators, devices with motors, etc.). When setting up the system, make sure that the total power requirements for all of the devices connected to a single outlet or circuit do not exceed the rated limit for that circuit. If you are not sure of the rated limit, please consult your maintenance department or an electrician.

Do not use a KVM Switch with the PillCam Platform.

The dimensions of the Workstation components are listed below:



Note

Extra space is needed for air circulation and cable connectors behind the Workstation.

Given Workstation

The footprint of the Given Workstation is about 18 cm (W) x 47 cm (D) x 45 cm (H).

DataRecorder and Cradle

The cradle of any DataRecorder with its cable connections have a footprint of about 8-12 inches (20-30 cm).

The DataRecorder is kept in its cradle when not in use.

Storage Space for the PillCam Capsule Box

Provide a storage space that is protected from any powerful electromagnetic source, for storing the PillCam video capsule 1box.

Main Platform Components

Following is a list of items which you need to connect in order to set up the PillCam Platform:

- Given Workstation
- Monitor
- Keyboard
- Mouse
- Printer
- DataRecorder with Cradle

Connecting the Components



Warning

The Given Workstation has either an automatic or a manual Voltage Select Switch. In case the workstation has a manual switch:

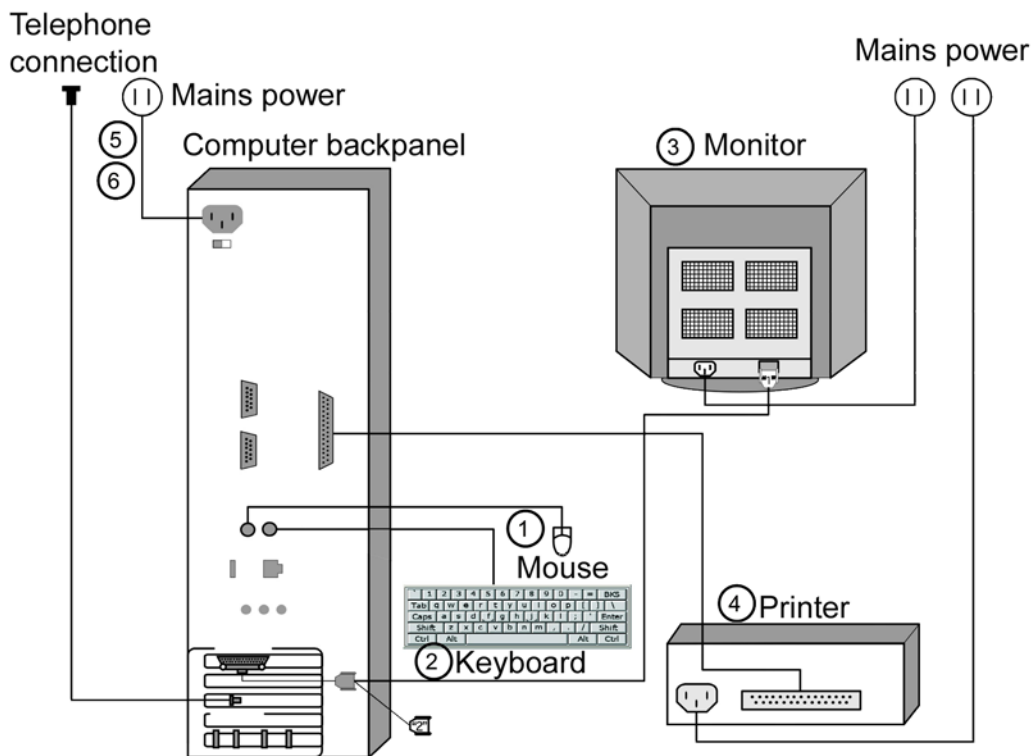
- verify that the workstation's voltage is set according to the local voltage prior to connecting the Given Workstation to the wall outlet.
- If the voltage is not set according to the local voltage, do not connect the system. Call the Given Customer Support.



Caution

Voltage mismatch will damage the Given Workstation.

Use the following sketch as an aid in setting up the PillCam Platform:



Dell Given Workstation

The following table lists the items that connect to the Given Workstation back panel:

Connection	Explanation
Power cord	Connects the Given Workstation to the electric socket.
Keyboard	Connects the Given Workstation to the keyboard.
Mouse	Connects the Given Workstation to the Mouse
Monitor	Connects the Given Workstation to the monitor.
Parallel Port	Connects to the parallel printer cable that connects the Given Workstation to the printer.
USB Port	Connects to the USB cable that connects the Given Workstation to the printer, as an alternative to using Parallel Port.
USB 2 Port	The USB 2.0 ports connect to the USB cables that connect the Given Workstation to the DataRecorder Cradle and to the Card reader.
Modem	Connects to the telephone cable that connects the Given Workstation to a phone line. Don't connect at setup. Connect the modem only if instructed to do so by Given Customer Support.

**Note**

You will need the telephone connection only for some maintenance operation on your WorkStation. Connect the modem of the Given Workstation only when instructed to do so by Given Customer Support. To connect, insert the Modem cable into the Modem connector and the other jack phone connector of the Modem cable into the phone outlet.

Connecting the Given Workstation

1. Connect the Mouse cable to the Mouse connector.
2. Connect the Keyboard cable to the Keyboard connector.
3. Connect the monitor to the Workstation.
 - a. Unpack the monitor.
 - b. Using the provided stencil, apply to the front of the monitor the adhesive black label of the Given logo included in the System Accessory box.
 - c. Connect the DVI-VGA adaptor to the monitor connector at the Workstation's back panel.
 - d. Connect the monitor cable to the DVI-VGA adaptor at the Workstation's back panel.
4. Connect the printer to the LPT connector or to the USB connector, depending on the printer's connection cable.
5. If the Workstation's voltage setting is manual, verify that the Workstation's voltage matches the local voltage. If it does not, call Given Customer Support.

**Warning**

Do not connect the components to the wall electric outlet until you verify the Workstation voltage matches the local voltage.

6. After voltage verification, connect the power cable of the Given Workstation to the electric outlet.
7. Connect the power cable of the monitor to the wall electric outlet.

Connecting the DataRecorder Cradle

You can connect the cradle only to the USB2 ports that are side by side in a separate slot on the back panel of the Workstation.



If you are not using a Given Workstation, use a USB hub for connecting more than one cradle to your computer.



Note

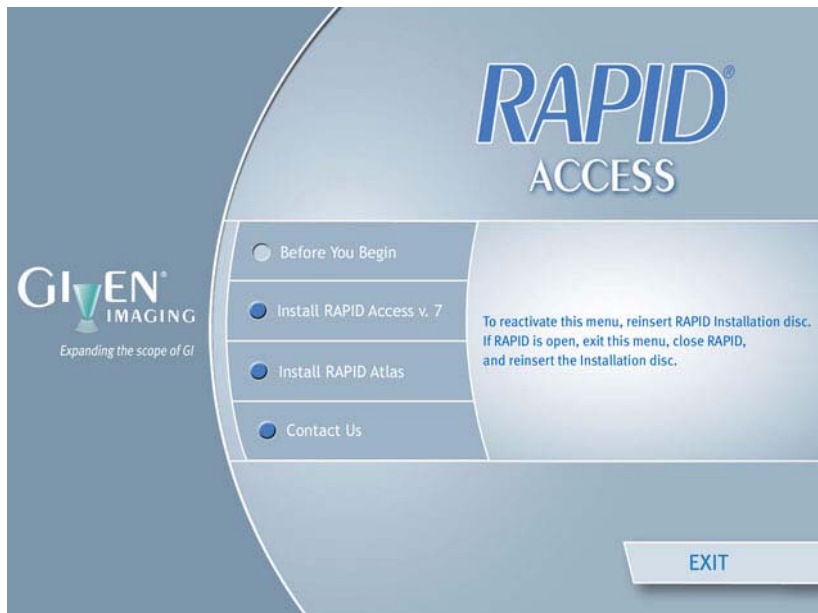
If you use more than one cradle, make sure each one is connected to a different power outlet.

Software Installation

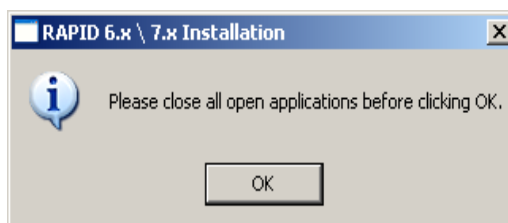
Before installing any new application, close all other applications currently running on the computer.

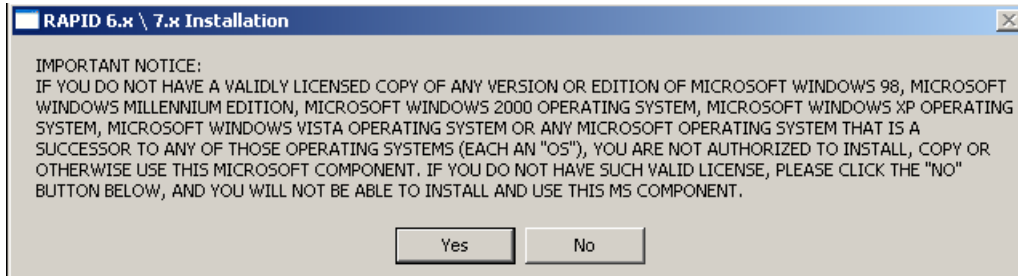
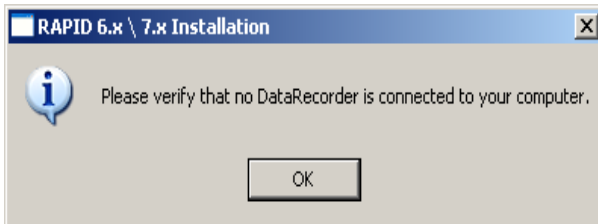
RAPID Installation

1. Insert the RAPID 7 Installation disc into the DVD drive. The RAPID 7 installation menu screen appears.

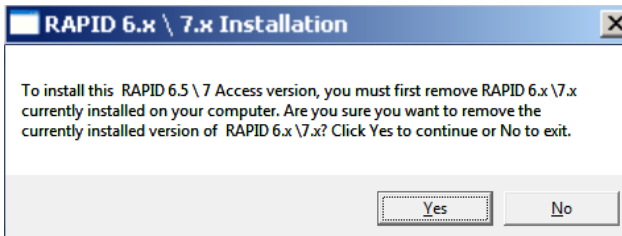


2. Click **Install RAPID Access v. 7**. The following screens appear.





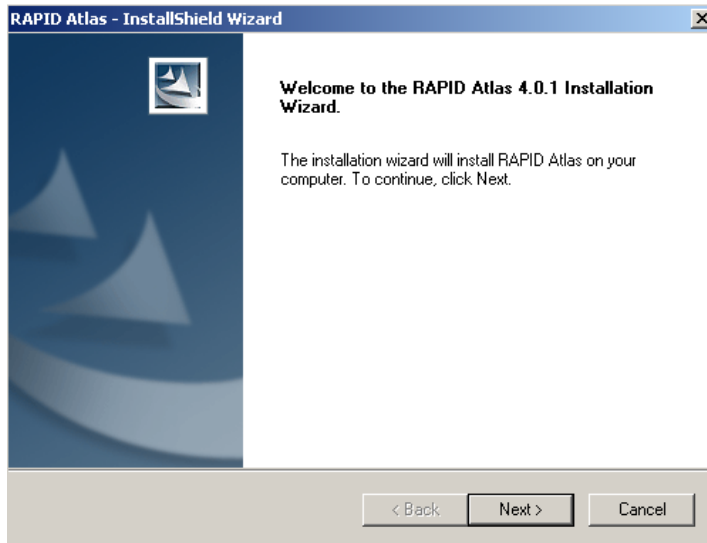
3. If you have a valid licensed copy of the Operating System, click **Yes**. The following screen appears.



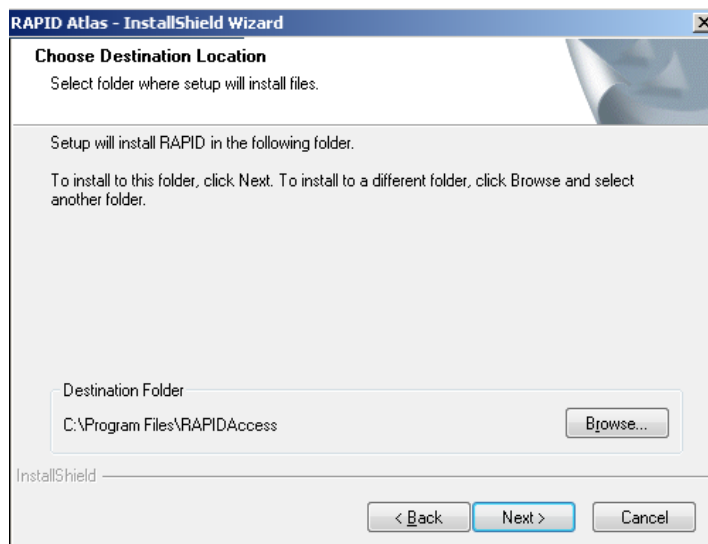
4. Click **Yes**. The following screen appears.



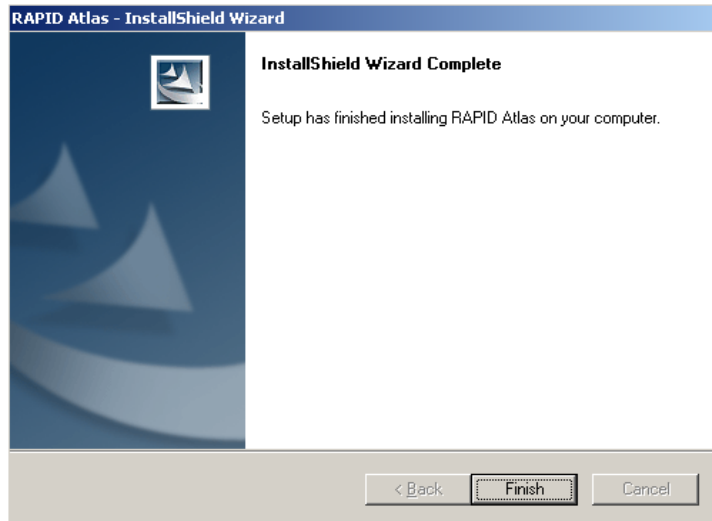
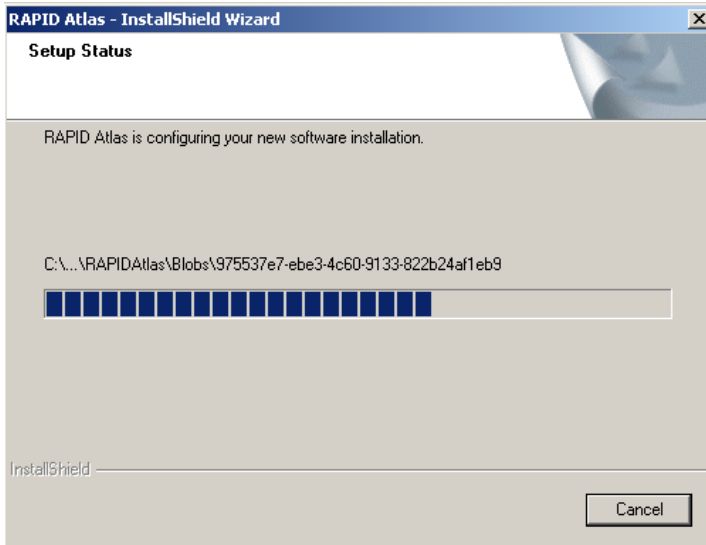
5. Click **Yes**. The InstallShield Wizard for the RAPID Atlas appears.



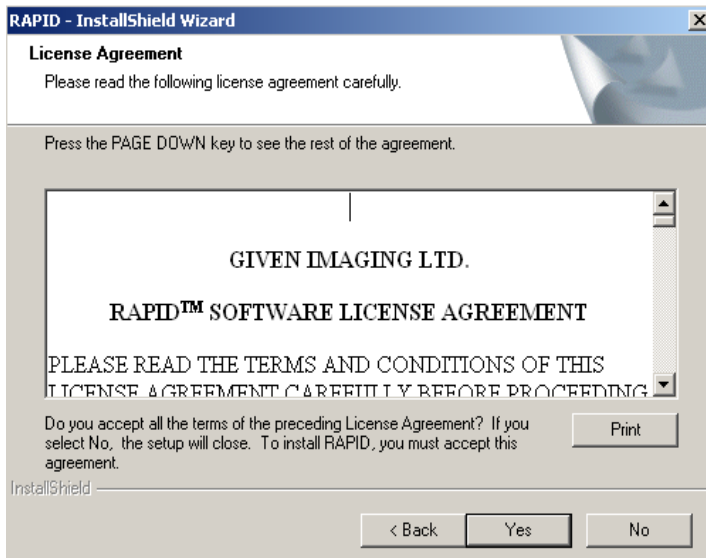
6. Click **Next**. The following screen appears.



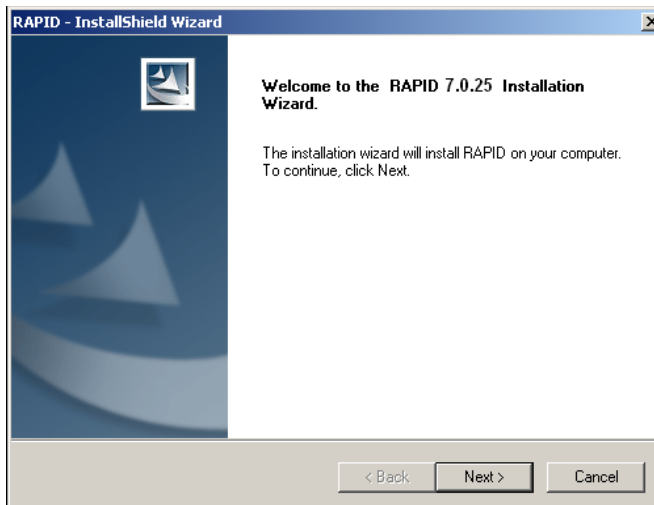
7. Click **Browse** if you wish to install in a different location. To continue with the installation, click **Next**. The following screen appears.



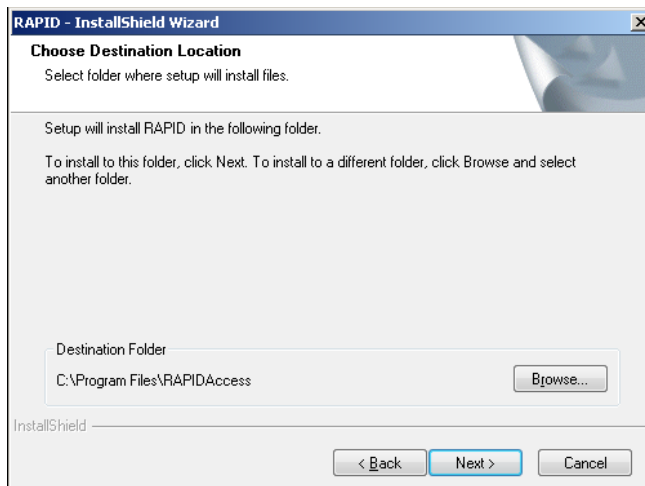
8. Click **Finish**. As soon as the progress bar is full, the License Agreement screen appears.



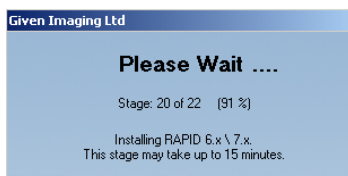
9. To continue the installation and accept the license agreement, click **Yes**. If you wish to print the license agreement before reading it, click **Print**. The following screen appears.



10. Click **Next**. The following screen appears.



11. Click **Browse** if you wish to install in a different location. To continue with the installation, click **Next**. The **Please Wait** screen appears and the installation starts.



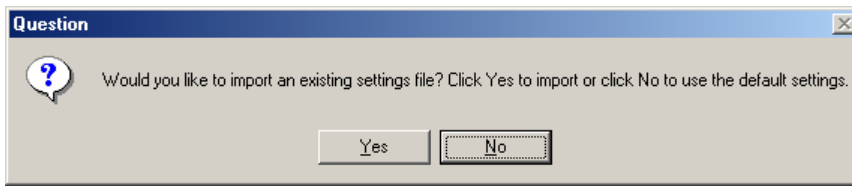
Depending on the computer configuration, this stage takes at least several minutes.

If the installation fails, the following message appears: **RAPID installation has failed**. In that case, restore the previous version of the RAPID Software.

To restore:

- a. Insert RAPID 7 Installation CD.
- b. Click **Install RAPID** and follow the instructions on the screen.

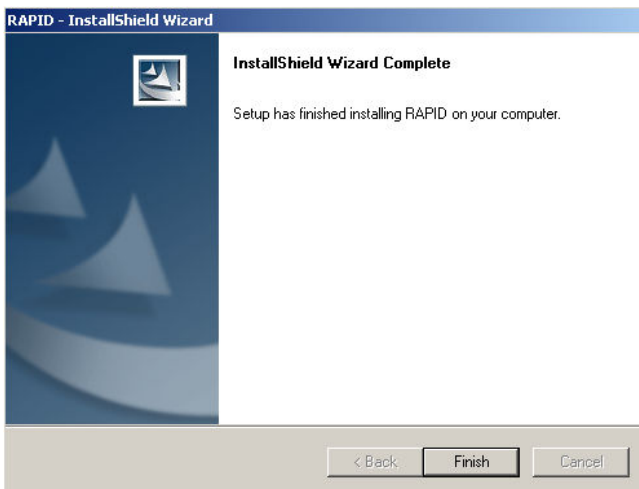
12. Just before the end of the installation, the following screen appears.



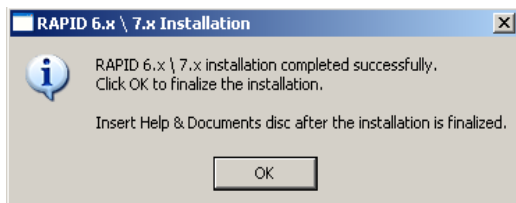
This refers to an exported **System Wide Settings** xml file.

If you wish to import such a file, click **Yes** and browse for the file location. A message warns you that the imported file will overwrite an existing settings file and asks whether you wish to continue.

13. Click **Yes**. If RAPID installation continues uninterrupted, the following screen appears as soon as all the stages are completed.



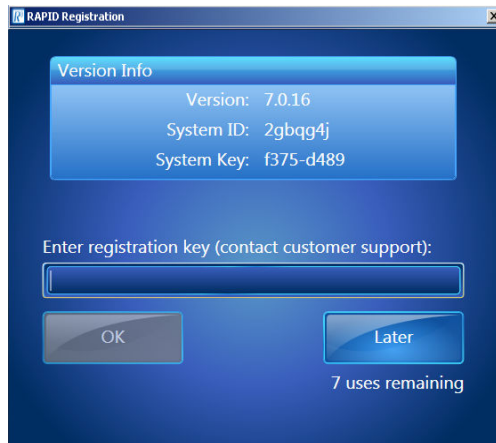
14. To complete the installation, click **Finish**. The following screen appears.



Registration

Unrestricted use of RAPID requires registration via the Given registration center. You must supply requested information to obtain the Registration Key.

The registration screen appears at the end of the installation process:



Note

Keep the registration window open until you finish the registration. Each time you open the registration window, a new System Key appears and any Registration Key based on a previous System Key will not be accepted.

If you click **Exit**, you can open and use the RAPID software, but after seven uses without registering, you must first perform registration in order to use RAPID.

15. Obtain a Registration Key via the Given registration center online or by phone:
 - online: <https://portal.givenimaging.com/RapidRegistration>
 - by phone: call your local Given customer support center
16. Be ready to provide the Given registration center with the following information:
 - System ID (from the registration screen)
 - System Key (from the registration screen)
 - RAPID DVD serial number (supplied with the DVD)
 - Your customer ID
17. Enter the Registration Key received from the Given registration center.



Note

The registration process uses ONLY lower case letters and numbers.

18. Click **OK**.



Note

If you do not register during installation, the next six times you open RAPID, it will ask you to register. After seven uses without registering, you cannot use RAPID without first performing registration.

Wide Screen Compatibility

In order to get optimal image and reduce risk of getting blurred or distorted images and fonts, the user should set his display resolution according to his screen manufactures' recommendations with these restriction in mind:

- RAPID's minimal supported horizontal resolution is 1024.
- RAPID's minimal supported vertical resolution is 768.

For example here some recommended resolutions for different screens:

Aspect Ratio	Minimum Resolution
4:3	1024 x 768
16:9	1360 x 768
16:10	1280 x 800

Multi-User Setup

System Administration

Different users in the RAPID may be defined. The settings values set by each user are saved so that each time that user logs in to the system, the relevant settings are in effect. Thus, different users may set different use profiles for themselves. Each user needs to log in with his or her username and password.

The default password of the user **rapid** is blank (no need for password), the default password of the user **rapidadmin** is **rapidadmin** (case sensitive). The password for rapidadmin can be changed by the rapidadmin user.

The user **rapidadmin** is meant to be used by a site-assigned system administrator to define additional users as required.

To Define a User

1. When Windows (re)starts (on a computer installed with RAPID) after completing RAPID installation, the Windows **Log On to Windows** screen appears.
2. In the *User* field type **rapidadmin** (not case sensitive). In the password field type in your password (if you haven't changed it since installation, it is still **rapidadmin**). Click **OK**.

3. Wait for the **Given Workstation Manager** screen to appear.



4. Click **Add New User**. The **Add New User** screen appears.
5. Type in a new **User name** and **Password** for the new user.



Note

The password you type in at this stage is a temporary password. The user is requested to change it when he logs on for the first time.

6. Click **Add User**. The message **User xxx was added successfully** appears.
7. Repeat steps 4–6 for each new user.

To Delete User Account

1. Click **Delete User Account**. The **Delete User Account** screen appears.
2. From the list, select which user you want to delete and click **Delete User**. The message **You chose to delete xxx User. Are you sure?** appears.
3. Click **Yes**. The message **xxx Account was deleted successfully** appears.

To Set a New Password for a User

If a user has forgotten his password, you can create a new one.

1. Click **Set New Password For User**.
2. From the list, select the relevant user.
3. Type the new password in the **New Password** field, and in the **Confirm New Password** field.

**Note**

This new password will again be a temporary one, to be changed when the user logs on for the first time with this password.

4. Click **Set Password**.

The message *xxx's Password was changed successfully* appears.

To Change the Password of the Administrator

1. Click **Change Admin Password**.

The **Change Rapidadmin Password** screen appears.

2. Type in your current password in the **Old (Current) Password** field.
3. Type in your new password in the fields **New Password** and **Confirm new Password**.
4. Click **Change my Password**.

The message *RAPID Administrator Password was changed successfully* appears.

**Note**

For security reasons, all users should change their default passwords to a chosen password.

Change the Given Workstation's Time and Date

Access to the standard **Date/Time properties** screen of Windows is disabled on a Workstation with RAPID 7 installed. Only the administrator can change the time and date of the system.

1. Click **Change System Date/Time**. The **Date/Time properties** screen appears.
2. Make the desired changes and click **OK**.
3. Log off as Rapidadmin user.

System Logs

System Logs are all the actions performed on the Workstation. The following items are recorded into the system log files:

- the physician (username) who performed the action
- the time and date of the action
- what action was performed (log on, log off, all actions such as adding, deleting and printing data)

The **Given Workstation Manager** screen allows you to view the logs and to create a backup of the logs.

To View the Logs

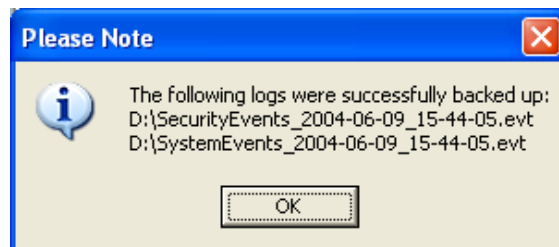
To view the logs, click **View Logs**. The **Log Viewer** screen appears.

To view more details about one of the events, select and double click the relevant line and the **Event Properties** screen of that specific action appears.

To Create a Backup of the Logs

Creating a backup of the logs involves saving the data to a removable storage device (such as CD, Disk-On-Key, or USB Mass Storage Device) and deleting this data from the Workstation.

1. Connect your storage device or media to the Workstation.
2. Click **Backup Logs**. The **Logs Backup** screen appears.
3. Select the relevant removable disk from the list and click **Backup**. Both the Security Events and the System Events are backed up through this command. The following message appears:


























4. Click **OK**.
The system will delete these files once they are backed up successfully onto a removable device. To check this, click **View Logs** again on the **Given Workstation Manager** screen. The system log will be empty and the security log shows that the logs were backed up.
5. Click **Log Off** in the **Given Workstation Manager** window.
6. Click **Yes** to confirm exit.

Technical Description

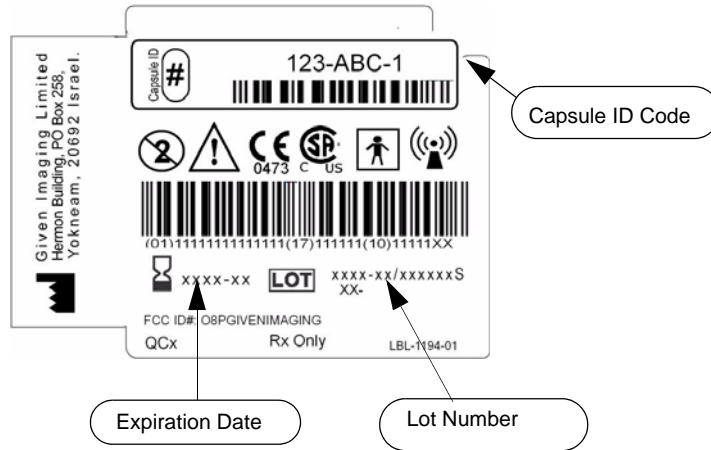
System Labeling

The following table lists the labels attached to various components of the PillCam Platform:

Labeling	Explanation	
	The PillCam video capsule should not be stored and used near any powerful magnetic fields such as the one created by an MRI.	
	The PillCam video capsule is intended for single use only.	
	Attention! Consult the documentation provided with the PillCam Platform.	
	Temperature limits	 Non-ionizing radiation
	Type BF equipment	 RoHs
	FCC compliance	 Capsule ID
	CE mark	 IPX8 Ingress protection
	C-Tick mark	 Do not Iron
	CSA mark	 Latex free
	Expiration date	 Machine wash - warm
	Recycle	 Do not tumble dry
	Lot number	 Do not dry clean
	Indoor use only	 Do not use bleach

Capsule Labeling

Each box has a label at the bottom as shown below. Each capsule is marked with the expiration date, lot number, and a unique Capsule ID code.



Essential Performance

PillCam Video Capsules

ON-Mode

Data transmitting to DataRecorder is considered to be essential performance of the PillCam capsules. The PillCam capsules shall transmit data continuously monitored by on-line image display as received by DataRecorder.

OFF-Mode

No unintentional transmissions are allowed.

DataRecorder 2 and DataRecorder 3

Data receiving by DataRecorder is considered to be essential performance of the DataRecorder 2 and DataRecorder 3.

Warnings

- PillCam Platform and its components need special precautions regarding EMC and need to be installed and put into service according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communications equipment can affect the PillCam video capsule and the DataRecorder.

- PillCam video capsules and DataRecorder should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- PillCam video capsules and DataRecorder may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- Do not disassemble or modify the battery pack. The battery pack is equipped with built-in safety/protection features. Should these features be disabled, the battery pack can leak acid, overheat, emit smoke, burst and/or ignite.
- Do not use or leave the battery pack of the DataRecorder near a heat source such as a fire or a heater (+80°C or higher). If the resin separator should be damaged owing to overheating, internal short-circuiting may occur to the battery pack, possibly leading to acid leakage, smoke emission, bursting and/or ignition of the battery pack.
- Do not immerse the battery pack in water or seawater and do not allow it to get wet. Otherwise, the protective features in it can be damaged, it can be charged with extremely high current and voltage, abnormal chemical reactions may occur in it, possibly leading to acid leakage, smoke emission, bursting and/or ignition.
- Do not recharge the battery pack near fire or in extremely hot weather. Otherwise, hot temperatures can trigger its built-in protective features, inhibiting recharging, or can damage the built-in protective features, causing it to be charged with an extremely high current and voltage and, as a result, abnormal chemical reactions can occur in it, possibly leading to acid leakage, overheating, smoke emission, bursting and/or ignition.
- To recharge the battery pack, use the DataRecorder cradle and observe the recharging conditions. A recharging operation under non-conforming recharging conditions (higher temperature and larger voltage/current than specified, modified battery charger, etc.) can cause the battery pack to be overcharged, or charged with extremely high current, abnormal chemical reaction can occur in it, possibly leading to acid leakage, overheating, smoke emission, bursting and/or ignition.
- Do not pierce the battery pack with a nail or other sharp objects, strike it with a hammer, or step on it. Otherwise, the battery pack will become damaged and deformed, internal short-circuiting can occur, possibly leading to acid leakage, overheating, smoke emission, bursting and/or ignition.
- Do not strike or throw the battery pack. The impact might cause leakage, overheating, smoke emission, bursting and/or ignition. Also, if the protective feature in it becomes damaged, it could become charged with an extremely high current and voltage, abnormal chemical reactions can occur, which can lead to acid leakage, overheating smoke emission, bursting and/or ignition.
- Do not use an apparently damaged or deformed battery pack. Otherwise, acid leakage, overheating, smoke emission, bursting and/or ignition of the battery pack may occur.
- If the battery pack leaks and the electrolyte gets into the eyes, do not rub them. Instead, rinse the eyes with clean running water and immediately seek medical attention. Otherwise, eye injury may result.
- If recharging operation fails to complete even when a specified recharging time has elapsed, immediately stop further recharging. Otherwise, acid leakage, overheating, smoke emission, bursting and/or ignition can occur.
- Do not put the battery pack into a microwave oven or pressurized container. Rapid heating or disrupted sealing can lead to acid leakage, overheating, smoke emission, bursting and/or ignition.

- If the battery pack leaks or gives off a bad odor, remove it from any exposed flame. Otherwise, the leaking electrolyte may catch fire and the battery pack may emit smoke, burst or ignite.
- If the battery pack gives off an odor, generates heat, becomes discolored or deformed, or in any way appears abnormal during use, recharging or storage, immediately remove it from the equipment or cradle and stop using it. Otherwise, the problematic battery pack can develop acid leakage, overheating, smoke emission, bursting and/or ignition.
- The use of accessories, transducers and cables other than those supplied or approved by Given Imaging as replacement parts for internal DataRecorder components, may result in increased emissions or decreased immunity of the PillCam Platform.

Cautions

- Do not use or subject the battery pack to intense sunlight or hot temperatures such as in a car in hot weather. Otherwise, acid leakage, overheating and/or smoke emission can occur. Also, its guaranteed performance will be lost and/or its service life will be shortened.
- The battery pack incorporates built-in safety devices. Do not use it in a location where static electricity (greater than the manufacturer's guarantee) may be present. Otherwise, the safety devices can be damaged, possibly leading to acid leakage, overheating, smoke emission, bursting and/or ignition.
- The guaranteed recharging temperature range is 0°C to +45°C. A recharging operation outside this temperature range can lead to acid leakage and/or overheating of the battery pack and may cause damage to it.
- If acid leaking from the battery pack comes into contact with your skin or clothing, immediately wash it away with running water. Otherwise, skin inflammation can occur.
- For recharging procedures, refer to *DataRecorder 3 on page 66*.
- If you find rust, a bad odor, overheating and/or other irregularities when using the battery pack for the first time, return it to your supplier or vendor.

System Specifications



Note

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

PillCam SB Capsule

Properties		
Physical	Dimensions	Length: 26 mm Diameter: 11 mm
	Weight	3.30 gr
	Material	Biocompatible plastic
Optical	Illumination	6 white light emitting diodes
	# of imaging heads	1
	Field of view	140° ISO-8600-3
	Effective visibility	Distance: 3 cm
	Magnification	1:8
	Min. detectable object	Less than 0.1 mm
	Operational	Frame rate
Operating time		7 ± 1 hours
Chemical safety		Resistant to dissolution in pH=2 to pH=8
Battery type		Silver Oxide batteries
Operating temperature		20–45°C
Storage temperature		0–50°C

PillCam SB 2 Capsule

Properties		
Physical	Dimensions	Length: 26 mm Diameter: 11 mm
	Weight	2.89gr.
	Material	Biocompatible plastic
Optical	Illumination	4 white light emitting diodes
	# of imaging heads	1
	Field of view	156° ISO-8600-3
	Effective visibility	Distance: 3 cm
	Min. detectable object	Less than 0.1 mm
	Operational	Frame rate
Operating time		≥ 8 hours
Chemical safety		Resistant to dissolution in pH=2 to pH=8
Battery type		Silver Oxide batteries (3V)
Operating temperature		20–45°C
Storage temperature		0–40°C

PillCam ESO 2 Capsule

Properties		
Physical	Dimensions	Length: 26 mm Diameter: 11 mm
	Weight	2.89 gr
	Material	Biocompatible plastic
Optical	Illumination	4 white light emitting diodes for each head
	# of imaging heads	2
	Field of view	169° ISO-8600-3 for each head
	Effective visibility	Distance: 3 cm
	Min. detectable object	Less than 0.06 mm
Operational	Frame rate	up to 9 fps per head
	Operating time	30 minutes
	Chemical safety	Resistant to dissolution in pH=2 to pH=8
	Battery type	Silver Oxide batteries
	Operating temperature	20–45°C
	Storage temperature	0–50°C

PillCam ESO 3 Capsule

Properties		
Physical	Dimensions	Length: 31.5 mm Diameter: 11.6 mm
	Weight	2.9 gr
	Material	Biocompatible plastic
Optical	Illumination	4 white light emitting diodes for each head
	# of optical heads	2
	Field of view	172° ISO-8600-3 for each head
	Effective visibility	Distance: 0–30 mm
	Min. detectable object	0.09 mm
Operational	Frame rate	35 fps per head
	Operating time	30 minutes
	Chemical safety	Resistant to dissolution in pH=2 to pH=8
	Battery type	Silver Oxide batteries
	Operating temperature	20–45°C
Storage temperature	0–40°C	

PillCam COLON 2 Capsule

Properties		
Physical	Dimensions	Length: 31.5 mm Diameter: 11.6 mm
	Weight	2.9 g
	Material	Biocompatible plastic
Optical	# of optical heads	2
	Illumination	4 white light emitting diodes on each side
	Field of view	172° ISO-8600-3
	Effective visibility	Distance: 0–30 mm
	Min. detectable object	0.09 mm
Operational	Operating time	Total: 10 hours:
	Chemical safety	Resistant to dissolution in pH=2 to pH=8
	Battery type	Silver Oxide batteries
	Operating temperature	20–45°C
	Storage temperature	0–30°C
Uplink communication	Operating frequency	434.1 MHz
	Frame rate	4–35 fps
	Data rate	2.7 Mbps and 8.1 Mbps
	Modulation type	MSK/Digital data
	Frequency band standards	FCC CFR 47 part 15 section 15.209 ERC 70-03 Annex 1 band F1
Downlink communication	Effective radiated power	-48.8 dBm (measured in 120 kHz bandwidth)
	Operating frequency	13.56 MHz
	Receiver Bandwidth	± 150 KHz
	Frequency band standards	FCC CFR 47 part 15 section 15.225 ERC 70-03 Annex 9 band F

SensorArray DataRecorder 2

Versions: SB, COLON, ESO

Sensor size	Diameter 40 mm
Color	black
Material	plastic
SB = COLON SensorArray	8 sensor elements
ESO SensorArray	3 sensor elements

SensorArray DataRecorder 3

Properties

Reception antenna	# of sensor elements	3 or 8 sensors
	Sensor size	Diameter: 40 mm
	Color	Black
	Material	Polyurethane, Teflon
	Antennas wire material	Coax wire
Transmission antenna	Antenna structure	Loop antenna
	Size	1.90 m
	Color	Black
	Material	Polyurethane, Teflon

SB SensorBelt for DataRecorder 2 and DataRecorder 3

SensorBelt Insert

Dimensions	365 mm x 90 mm
Insert material	Polypropylene
Number of sensors	4
Sensor dimensions	Diameter 40 mm
Cable length	550 mm
Cleaning method	Wipe with medical alcohol wipes
Expected life	500 procedures

SensorBelt Cover and Straps

Cover dimensions	385 mm x 125 mm
Cover and strap material	100% polyester
Fits abdomen size	60 - 130 cm
Washing instructions	Machine wash, warm, Use mild detergent Hang dry Do not dry clean, Do not use bleach
Expected life	40 wash cycles

DataRecorder 2 /2C

Software	Proprietary firmware
Recording capacity	DataRecorder 2: @2fps for 10 hours DataRecorder 2C: @4fps for 10 hours
Weight	500 gr., including battery pack.
Operational Power	6–8 VDC, 0.1–0.3 A
Battery type	Internal, Li-Ion, 7.2 V, 4400 mAH
Battery Pack weight	200 gr.
Operating temp.	0–40°C
Storage temp.	0–55°C
Shielding	Shieldex Supra, from Less EMF Inc.
Classification	<ul style="list-style-type: none"> internally powered (complies with requirements for Class I equipment while connected to supply mains through charger) Type BF applied part Ordinary equipment

Cradle DataRecorder 2

Properties

Weight	890 g
Size (without battery inserter)	14[D] x 165[W] x 97[H]mm
Color	black
Mains power connections	1x male power cable plug
power mains range	100 to 240V

DataRecorder 3

Properties

Physical	Software	Proprietary firmware
	Recording capacity	Up to 15 hours @ LCD OFF
	Weight	500 g., including battery pack.
	Operational Power	3.5–4.2 VDC, 0.15–0.5 A
	Battery type	Internal, Li-Ion, 3.8 V typical, 8800 mAH
	Operating temp.	0–40°C
	Storage temp.	0–55°C
	Shielding	No belt shielding
	Classification	<ul style="list-style-type: none"> internally powered (complies with requirements for Class I equipment while connected to supply mains through charger) Type BF applied part Ordinary equipment
Receiver (Rx)	Operating frequency	434.1 MHz
	Bandwidth of the receiving section in this band	10 MHz
Transmitter	Operating frequency	13.56 MHz
	Frequency band	ISM
	Modulation type	Linear Chirp
	Type of modulated signal	Digital data
	Frequency of modulating signal	20.25 dBm
	Effective radiated power	-27.4 dBm

Cradle DataRecorder 3

Properties

Weight	250 g
Operating temp	0–45°C
Color	White & Black
Mains power connections	1x male power cable plug
power mains range	Input Voltage: Maximum 5.25V, Min 4.75V Input Current: Maximum 4A, Min 100 mA

DC Power Supply

Properties

Weight	300 g
Input connector	3 pole AC inlet IEC320-C14C
Input Voltage	90 - 246 VAC
Output voltage	5V DC, 5 Amp
Protections	Short circuit/ Over load/ Over voltage/ Over temp.

DataRecorder 3 Memory Card

Properties

Dimensions	24mm x 32mm x 2.1mm
Weight	2.5 g
Capacity	≥16GB
Rating	Class 6: 40X or higher, 6 MB/sec minimum data transfer rate
Storage temperature	-40°C–85°C
Security	Built-in write-protect switch prevents accidental data loss
Compatibility	SDHC host devices; not compatible with standard SD-enabled devices/readers
File format	FAT 32

RAPID Software


Software	RAPID proprietary, version 7
Languages	English/French/German/Italian/Spanish/Portuguese/Dutch/Swedish/Finnish/Danish/Chinese-Mandarin/Korean/Russian/Greek
Data export	JPEG Images, (AVI) Video clips, grml (Given proprietary) files, HTML Reports, generic XML-format Capsule Endoscopy report data.
Displayed data	Single and multi images, Timebar, Colorbar with region specific color and other diagnostic data.
Event marker	Annotated thumbnails
Viewing rate	5–80 fps
Viewing Modes	SingleView, DualView, QuadView, Mosaic View, Double-Head View (ESO and COLON)
Run Modes	Normal, QuickView, SBI

Guidance and Manufacturer's Declarations

PillCam Capsules (No PillCam COLON 2)

Guidance and manufacturer's declaration - electronic emissions		
The PillCam capsules are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam capsules capsule should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PillCam capsules use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electronic emissions			
The PillCam capsules are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam capsules should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable
Surge, IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			


Guidance and manufacturer's declaration - electronic emissions			
The PillCam capsules are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam capsules should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of a PillCam capsule, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF	3 VRMS		
IEC 61000-4-6	150 kHz to 80 MHz	Not applicable	Not applicable
Radiated RF	3 V/m		$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz	3 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
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: 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).			
NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b .			
NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol: 			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PillCam capsules are used exceeds the applicable RF compliance level above, the PillCam capsules should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PillCam capsules.			
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the PillCam capsules			
The PillCam capsules are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PillCam capsules can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PillCam capsules 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 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.			

PillCam COLON 2 Capsules

Guidance and manufacturer’s declaration - electromagnetic emissions		
The PillCam COLON 2 capsules are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam COLON 2 capsules capsule should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PillCam COLON 2 capsules use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The PillCam capsules are suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
The PillCam COLON 2 capsules are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam COLON 2 capsules should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The PillCam COLON 2 capsules are intended for use in the electromagnetic environment specified below. The customer or the user of the PillCam capsules should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of a PillCam capsule, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz MHz range $d = 2.3\sqrt{P}$ 800 MHz to 2500 MHz
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>NOTE 3: 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).</p> <p>NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol: </p>			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PillCam capsules are used exceeds the applicable RF compliance level above, the PillCam capsules should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PillCam capsules.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the PillCam COLON 2 capsules			
The PillCam COLON 2 capsules are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PillCam COLON 2 capsules can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PillCam COLON 2 capsules 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 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.			


DataRecorder 2(C)

Guidance and manufacturer's declaration - electronic emissions		
The DataRecorder 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the DataRecorder 2 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DataRecorder 2 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 The DataRecorder 2 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electronic emissions			
The DataRecorder 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the DataRecorder 2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electronic emissions			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U _T (>95 % dip in U _T) for 0.5 cycle 40 % U _T (60 % dip in U _T) for 5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles <5 % U _T (>95 % dip in U _T) for 5 sec	<5 % U _T (>95 % dip in U _T) for 0.5 cycle 40 % U _T (60 % dip in U _T) for 5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles <5 % U _T (>95 % dip in U _T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DataRecorder 2 requires continued operation during power mains interruptions, it is recommended that the DataRecorder 2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U _T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electronic emissions			
The DataRecorder 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the DataRecorder 2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of DataRecorder 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 VRMS 150 kHz to 80 MHz	3V _{ms}	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz range $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz range

Guidance and manufacturer's declaration - electronic emissions	
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: 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).	
NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b .	
NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol: 	
a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DataRecorder 2 is used exceeds the applicable RF compliance level above, the DataRecorder 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DataRecorder 2.
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.


Recommended separation distances between portable and mobile RF communications equipment and the PillCam ESO capsule			
The DataRecorder 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DataRecorder 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DataRecorder 2 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 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.			

DataRecorder 3

Guidance and manufacturer's declaration - electromagnetic emissions		
The DataRecorder 3 is intended for use in the electromagnetic environment specified below. The customer or the user of the DataRecorder 3 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Data Recorder 3 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	The Data Recorder 3 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
The DataRecorder 3 is intended for use in the electromagnetic environment specified below. The customer or the user of the DataRecorder 3 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ (>95 % dip in U_T) for 0.5 cycle $40\% U_T$ (60 % dip in U_T) for 5 cycles $70\% U_T$ (30 % dip in U_T) for 25 cycles $<5\% U_T$ (>95 % dip in U_T) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DataRecorder 3 requires continued operation during power mains interruptions, it is recommended that the DataRecorder 3 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The DataRecorder 3 is intended for use in the electromagnetic environment specified below. The customer or the user of the DataRecorder 3 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile RF communications equipment should be used no closer to any part of DataRecorder 3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF, IEC 61000-4-6	3V _{rms} 150 kHz to 80 MHz	3V _{rms} 150 kHz to 80 MHz	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E ₁] = 3 V/m	Recommended separation distance: $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz range $d = 2.3\sqrt{P}$ 800 MHz to 2500 MHz range
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>NOTE 3: 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).</p> <p>NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol: </p>			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DataRecorder 3 is used exceeds the applicable RF compliance level above, the DataRecorder 3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DataRecorder 3.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the DataRecorder 3			
The DataRecorder 3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DataRecorder 3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DataRecorder 3 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 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.			

Maintenance

Charging DataRecorder

Disclaimer

The DataRecorder cradle is a non-medical device, used for charging the DataRecorder from Given Imaging Ltd.

Important Safety Instructions



Note

Before using the DataRecorder Cradle, read all instructions on cautionary markings on the Cradle, on the Battery and on the DataRecorder.



Caution

Use only the provided power cable for the DataRecorder Cradle.
Charge the DataRecorder in its dedicated Cradle only.



Warning

Changes or modifications to this equipment not expressly approved by the party responsible for compliance (Given Imaging Ltd.) could void the user's authority to operate the equipment.

Use only a fully charged DataRecorder. In general, including first time use, charging the DataRecorder is an overnight process and should not be performed in the vicinity of the patient. When you receive the DataRecorder after an examination, charge it immediately until the green LED is lit, and leave it in its cradle.



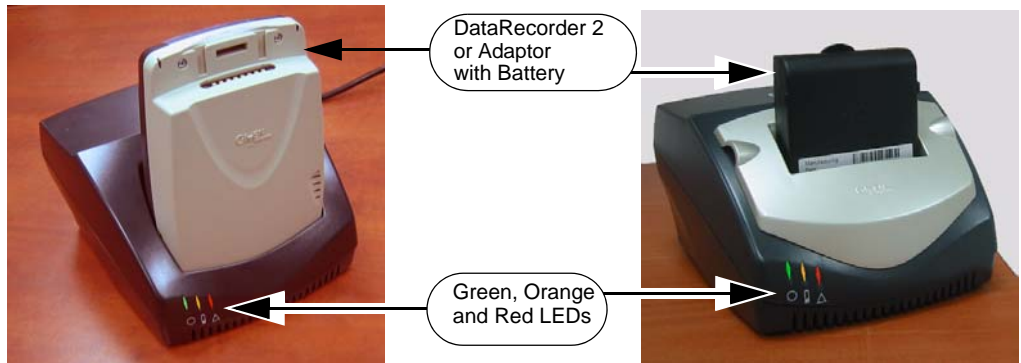
Note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular

installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

DataRecorder 2



The following table lists and explains the LEDs (from left to right) of the DataRecorder 2 Cradle and their meaning:

LED	Status	Explanation
Green	On	Battery Pack is ready for use
Orange	On	Battery Pack is charging
	Blinking	Battery Pack is discharging
Red	On	Battery Pack is faulty

To Charge the DataRecorder 2

1. First plug the power cable into the cradle and plug the power cable into the wall outlet.
All three LEDs turn on for a self-test that takes 5 seconds. After 5 seconds all LEDs turn off, and the cradle is idle and ready for use.

If after the self-test the red LED blinks, the battery pack is faulty. Contact Given Imaging Customer Support.
2. Insert the DataRecorder 2 or the DataRecorder 2 Li-Ion battery with its adaptor into the cradle.
All three LEDs of the cradle blink for 4 seconds, before the charging process starts (orange LED is on).



Note

If the Cradle detects that the battery needs refreshing (i.e., the battery gauge needs recalibration), it will automatically discharge the battery before recharging it. The orange LED on the cradle blinks during discharging.

We recommend manually discharging the DataRecorder 2 battery once every three months, even if the DataRecorder 2 is not used. This will prevent the DataRecorder 2 from discharging automatically at an inconvenient time, since the discharge is an overnight process that may take up to 12 hours.

3. As soon as the DataRecorder 2 or its Battery Pack are fully charged, the green LED turns on, and the Orange LED turns off. Leave the DataRecorder 2 in its Cradle until the next examination.



Note

You can check the status of the DataRecorder 2 by pushing the button on the back of the DataRecorder 2 momentarily. All 4 LEDs must be lit before an examination.



Manual Discharge of DataRecorder 2


If the Cradle detects that the battery needs refreshing (i.e., the battery gauge needs recalibration), it will automatically discharge the battery before recharging it. The orange LED on the cradle blinks during discharging.

We recommend manually discharging the DataRecorder 2 battery once every three months, even if the DataRecorder 2 is not used. This will prevent the DataRecorder 2 from discharging automatically at an inconvenient time, since the discharge is an overnight process that may take up to 12 hours.

To discharge the DataRecorder 2 Battery

1. Make sure the appropriate battery is inside the DataRecorder 2.
2. Insert the DataRecorder 2 into its cradle.
3. From the **Procedures** screen, select the relevant DataRecorder 2 by clicking the DataRecorder 2 bar.

The buttons on the right side of the screen become available.

4. Click  to open the **DataRecorder Info** screen.
5. At the bottom of the screen, click **Start Discharge**.

A message appears: **Discharge may take up to 12 hours. Are you sure you want to start discharge?**

6. Click **OK**.

While the battery is being discharged, its battery status indicates **Discharging**:

- in the bottom left corner of the **DataRecorder Info** screen
 - in the DataRecorder 2 bar in the **DataRecorders** screen
 - the orange LED on the cradle blinks
7. To return to other RAPID functions, click **Close**.
 8. If you need to stop the discharge (also for automatic discharge) while it is in progress, return to the **DataRecorder Info** screen and click **Stop Discharge**.

If you stop the automatic discharge process in the middle, the battery LEDs may not indicate the correct battery status.



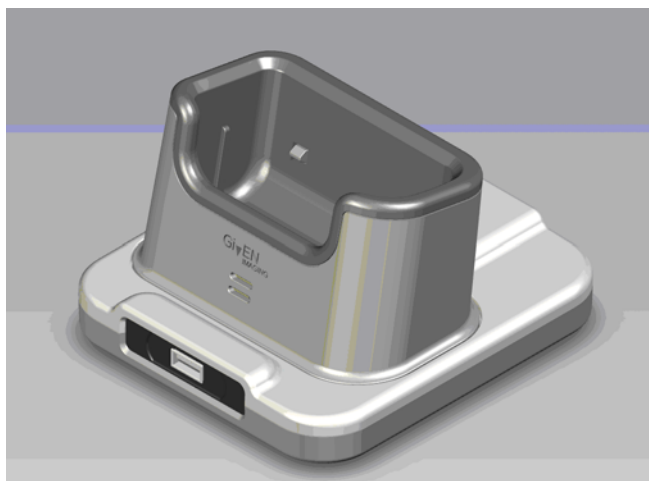
Note

Do not charge the battery in the vicinity of the patient.

For more information on charging the DataRecorder 2, see *Charging DataRecorder on page 63*.

Make sure the DataRecorder is fully charged for SB and Colon Capsule Endoscopy, and that at least two of the four battery LEDs light up for an ESO Capsule Endoscopy.

DataRecorder 3



The following table lists and explains the LEDs of the DataRecorder 3 Cradle and their meaning:

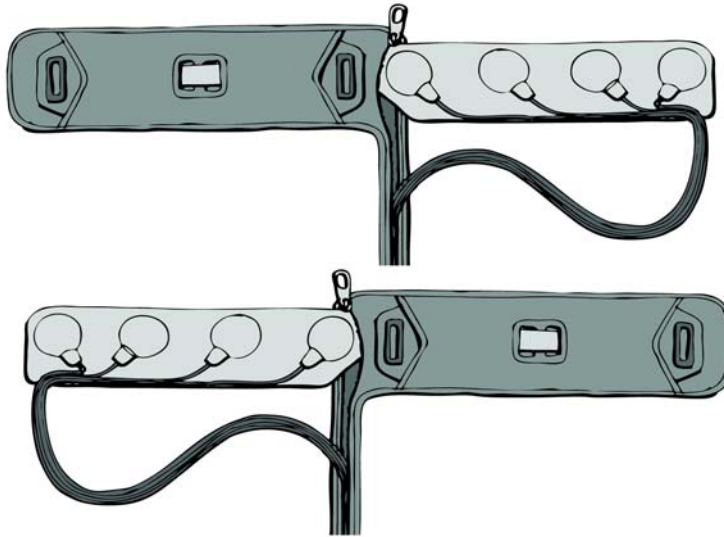
LED	Status	Explanation
Green	On	Battery Pack is ready for use
Yellow	On	Battery Pack is charging
	Blinking	Battery Pack is charging

To Charge the DataRecorder

1. First plug the power cable into the cradle and plug the power cable into the wall outlet.
2. Insert the DataRecorder into the cradle. The bottom LED is orange when charging the battery.
3. As soon as the DataRecorder is fully charged, the bottom LED turns green. Leave the DataRecorder in its cradle until the next examination.

SensorBelt Cleaning

The SensorBelt may be machine washed **after removal of the SensorBelt Insert**.



Follow instructions on the care label and use a mild detergent.

The surface of the SensorBelt may be wiped with any commonly used disinfectant.

The SensorBelt Insert may be wiped gently with alcohol (up to 70%).

SensorArray Cleaning

For mild cleaning (dirt, sweat), wipe the sensors gently with alcohol (up to 70%). The alcohol will not remove the adhesive. Since alcohol is a polar solvent, do not use lavishly, and allow to dry for 20 minutes.

To remove adhesive from the SensorArray (not from the human body), use White Benzene.



Note

White Benzene **MUST** be used in a ventilated area with all precautions defined in the manufacturer's instructions.

Alternatively, use one of the following medical adhesive removers to remove adhesive:

- B-508 Secure Solvent
- B-202 Hollister Solvent
- B-206 Detachol Adhesive Remover

Use all precautions as defined by the manufacturer.

Troubleshooting

RAPID Video

Problem	Cause	Action
Short Video	<ul style="list-style-type: none"> • Capsule • DataRecorder Battery • DataRecorder Mishandling 	<ul style="list-style-type: none"> • Contact Customer Support • Send video on CD/DVD
Gaps	<ul style="list-style-type: none"> • Capsule • Interference • Mishandling • Physiological 	<ul style="list-style-type: none"> • Inform Capsule Lot # • Do not use the same DataRecorder
Bad image quality	<ul style="list-style-type: none"> • Stripes in video • Pixilation/confetti • Dark/red/orange image 	
Video shorter than capsule operating time without either ingestion phase images or body exit images	<ul style="list-style-type: none"> • Capsule • DataRecorder Battery • Interference 	<ul style="list-style-type: none"> • Send video on CD/DVD • Contact Customer Support
No Localization	Malfunction of the SensorArray	Contact Customer Support

Saving and Opening Video

Problem	Cause	Action
Cannot locate video	<ul style="list-style-type: none"> • Video was not saved in E:\Videos • Incorrect patient's name 	Contact Customer Support
Cannot locate findings	<ul style="list-style-type: none"> • Findings were not saved under patient's folder • Findings were saved with the wrong name 	<ul style="list-style-type: none"> • See <i>Saving Your Findings</i> in chapter four of Book 3: Using the RAPID Software • Contact Customer Support

SensorArray

Problem	Cause	Action
Connector is damaged	<ul style="list-style-type: none"> • Mishandling • End of Life 	Contact Customer Support
Sensor is torn from its wire		
Insulation of the sensor wire is damaged		

Printer

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

CD/DVD

Problem	Cause	Action
Cannot burn CD/DVD	CD/DVD is not blank or compatible with CD/DVD ROM	Contact Customer Support
	Wrong Burning procedure	Contact Customer Support
Cannot eject CD/DVD	A video on the disc is open	Close the video and retry

RAPID Software

Problem	Cause	Action
Cannot open RAPID	Software or Hardware corruption	Contact Customer Support
Cannot open RAPID Atlas	Atlas installation is incomplete or incorrect	<ul style="list-style-type: none"> • Reinstall Atlas • Contact Customer Support
	XML corruption	Contact Customer Support

Capsule

Problem	Cause	Action
DOA (Dead On Arrival): LEDs do not light up when capsule is removed from its box	Capsule failure	<ol style="list-style-type: none"> 1 Send capsule to Given Imaging Ltd. 2 Open another capsule 3 If second capsule from 10-pak is DOA, contact Customer Support

Given Workstation

Problem	Cause	Action
Blue screen	Hardware malfunction	<ol style="list-style-type: none"> 1 Send RAPID and Given Workstation log files 2 Contact Customer Support.
Given Workstation does not boot up	Hardware malfunction	Contact Customer Support
Given Workstation DOA	Transportation mishandling	Contact Customer Support

Problem	Cause	Action
Given Workstation does not recognize USB storage device	USB storage device is not compatible	Contact Customer Support
	Malfunction of the USB connection on Given Workstation	1 Change USB port 2 Contact Customer Support
	USB storage device malfunction	Contact Customer Support
Given Workstation does not recognize printer	Malfunction of the USB connection on Given Workstation	1 Change USB port 2 Contact Customer Support
	Printer malfunction	Contact Customer Support
	Printer driver is missing	Contact Customer Support

Cradle

Problem	Cause	Action
All LEDs are flashing red	All LEDs are flashing red	1 Disconnect cradle for mains power 2 Reconnect cradle to mains power 3 If problem persists, contact Customer Support
DataRecorder cannot be placed in cradle	Hardware malfunction	Contact Customer Support

DataRecorder

Problem	Cause	Action
Cannot initialize DataRecorder	Computer does not recognize DataRecorder	1 Check USB and power connection 2 Contact Customer Support
Cannot create video	Error message is displayed	Send error message to Customer Support
	Not enough space... message is displayed	Delete PRRs from hard drive
	Workstation freezes during video creation	Contact Customer Support
Capsule LED does not blink in blue when capsule is activated	<ul style="list-style-type: none"> No pairing performed, or pairing was not successful 	1 perform Capsule pairing 2 If problem persists, contact Customer Support 3 Send malfunctioned capsules to Given Imaging Ltd.



Note

For LED behavior see *DataRecorder 3 LED Indications on page 9*, and Error messages displayed on the DataRecorder screen, see *DataRecorder 3 Error Message Guide on page 10*.

Low Signal

If a low signal is detected during the examination, the following message appears.



A low signal detected during the examination may be due to:

- Improper use of the SensorArray
- A defective SensorArray
- A DataRecorder malfunction

If this message is displayed, Contact Customer Support.

Click **OK** to close the message.

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