Given® Diagnostic Imaging System

User's Manual

DRAFT

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TRADEMARKS

The RAPID™ Application and the M2A™ Capsule are trademarks of Given® Imaging Limited. Given® is a registered trademark of Given® Imaging Limited.
MS Windows is a registered trademark of Microsoft Corporation.

WARRANTY

Given® Imaging Limited warrants that the components of the Given® Diagnostic Imaging System have been designed, manufactured, packaged and tested with reasonable care and is free from any type of defects. Given® Imaging Limited is not liable for any incidental or consequential loss, damage, or expense arising , directly or indirectly , from the use of the Given® Diagnostic Imaging System. Given® Imaging Limited obligation as implied in this warranty, is to repair or replace any component of the system. Customers are liable for all matters beyond Given® Imaging Limited control such as handling, storage, cleaning, misuse, treatment and diagnosis. This warranty is in lieu of and excludes all other warranties whether expressed or implied warranties of merchantabilty or fitness.

FCC ID#=O8PGIVENIMAGING

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 Given® Imaging Diagnostic System.

US Federal Law restricts this device to sale by or on the order of a physician

Table of Contents

Given® Diagnostic Imaging System

System Overview

The Given® Diagnostic Imaging System is an easy-to-use non-invasive and ambulatory device that permits visualization of the patient's gastrointestinal tract, especially the small intestine.

The system is comprised of three main components:

- M2A™ Capsule

- Data Recorder Set

- RAPID™ Application Software and Workstation

RAPID™ Workstation

Waist Belt

Data Recorder

Sensor Array
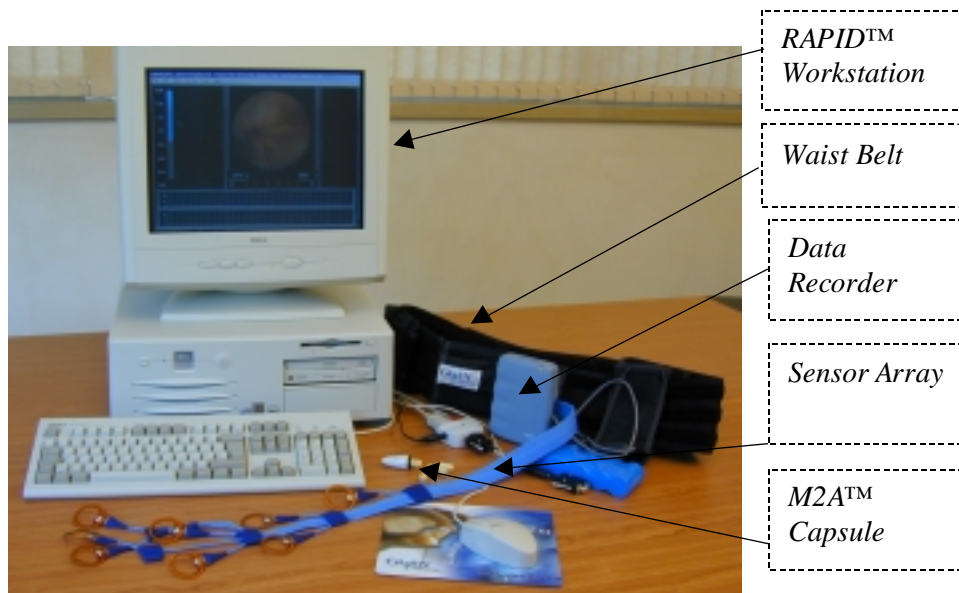
M2A™ Capsule

The M2A™ Capsule acquires pictures of the gastrointestinal tract and transmits them to the Data Recorder. The Data Recorder stores the pictures and downloads the data to the RAPID™ Workstation. On the workstation, the data is processed into a colorful, easy-to-control Patient RAPID™ Report (PRR) video movie. You can view the PRR movie to analyze and make diagnoses about any abnormalities in the gastrointestinal tract.

Even though the Given® Diagnostic Imaging System performs the complicated tasks of filming the digestive activity and image and other data processing, it is very easy to use, eliminating the need for sedation. Moreover, it does not require the patient to undergo an invasive and uncomfortable procedure, and assists in the early detection of pathologies of the small bowel.

M2A™ Capsule

The ingestible imaging M2A™ Capsule acquires video images while traveling along the patient's gastrointestinal tract. The M2A™ Capsule is propelled by peristalsis through the gastrointestinal tract and does not require a pushing force to propel it through the bowel.

The M2A™ Capsule contains a miniscule color video camera with a flash (CMOS Imager), a watch battery, a transmitter, and an antenna, all of which are embedded within a regular size ingestible capsule. The Capsule is a two-dome, cylinder shaped unit having an outer diameter of 11mm and length of 26mm, and it is made out of biocompatible plastic.

M2A™ Capsule with blister

M2A™ Capsule

M2A™ Capsule with holder
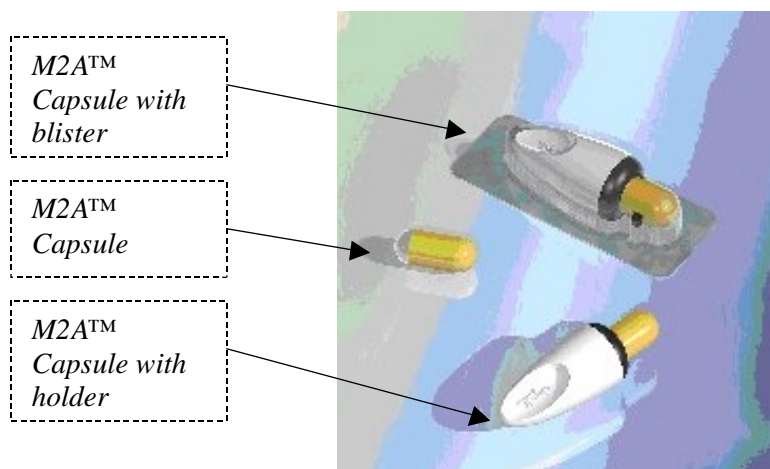
The M2A™ Capsule is provided ready for ingestion, stored in a blister, a hermetically sealed magnetic packaging. The proximity of a magnet in the blister inactivates the M2A™ Capsule.

Each M2A™ Capsule comes with a holder that covers the Capsule's imager and enables you to handle the M2A™ Capsule until ingestion.

The M2A™ Capsule starts immediately after its removal from the proximity of the magnet in the blister and the consequent closing of the magnetic switch in the capsule. After a brief (less than one minute) test by the physician to verify that the capsule is active, the capsule is ingested by the patient. While active, the capsule transmits images at a rate of 2 images per second. For each image, an illuminating light flash of 100ms is applied with the illuminating LEDs. When the battery power is depleted, the transmitter disables the imager and switches the M2A™ Capsule off.

For specification and technical parameters of the M2A™ Capsule, refer to *System Specifications* on page *15*. For Indications and Contraindications, refer to *Indications and Contraindications* on page *9*.

Data Recorder Set

The Data Recorder Set includes the following items:

- Data Recorder

- Sensor Array

- Battery Pack

- Waist Belt

- Battery Charger

Data Recorder

The Data Recorder is an external receiving/recording unit that receives the data transmitted by the M2A™ Capsule.

The Data Recorder is a portable Walkman™-size battery-operated unit attached to a waist belt worn by the patient during the examination.

The Data Recorder is comprised of a receiver, processor module and a hard disk drive for storing the data. All of these components are encased in a plastic (ABS) box.

The Data Recorder is ready for operation once you connect the Battery Pack and the Sensor Array to the Data Recorder. However, the actual recording requires that the input signal cross a threshold. A green blinking LED indicates whether and when the Data Recorder records data.

Sensor Array

The Sensor Array receives data from the M2A™ Capsule and transfers it to the Data Recorder. It is comprised of 8 identical sensors. Each sensor is connected to the Data Recorder module by a flexible coaxial cable. The sensor is built of flexible printed circuit board (PCB) and is attached to the skin by means of disposable, medical adhesive pads.

Battery Pack

The Battery Pack is the power supply of the Data Recorder. It includes 8 Nickel-metal 6V rechargeable batteries. The Battery Pack is disconnected from the Data Recorder at the end of each examination and is connected to the Charger supplied with the Given® Diagnostic Imaging System to be ready for the next procedure.

Waist Belt

The Waist Belt is an adjustable waist-belt that includes two pouches to hold the Data Recorder and the Battery Pack. The belt also includes a flap to hold the excess Battery Pack-Data Recorder cable. The Waist Belt also contains shielding that facilitates FCC compliance. The Waist Belt must therefore be worn at all times while the M2A™ Capsule is active inside the patient.

Battery Charger

The Battery Charger charges the Battery Pack and should be used after each examination.

Sensor Array

Sensor Array cable

Data Recorder

M2A™ Capsule

Battery Pack

M2A™ Capsule with holder
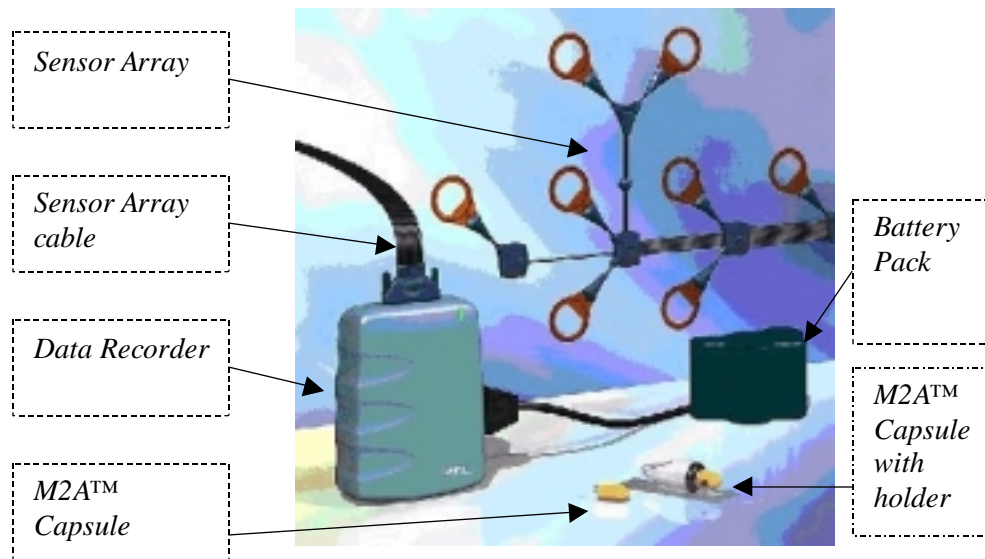
For specification and technical parameters of the Data Recorder, refer to *System Specifications* on page *15*.

RAPID™ Application Software and Workstaion

The RAPID™ Workstation is a modified standard personal computer designed for storage, presentation and processing of the acquired images and for generating reports.
The RAPID™ (Reporting and Processing of Images and Data) Application Software is a program installed on the Workstation, which performs various tasks as the following table lists:

Task	Explanation
Recorder communication	Enables Recorder initialization and data download from the Recorder to the workstation.
Data conversion	Handles various data formats.
Image processing	Performs the image processing algorithm and condenses up to 10 hours of filming into a 30 minute movie.
Video display	Displays the Patient RAPID Report (PRR).
Thumbnail display	Enables copying individual images from the movie, to display, annotate, print and save them.
AVI movie	Creates a short movie of the selected image and its adjacent images.
Timebar display	Shows the exact time of the current image displayed in the Video section.
Patient Check-In	Enables etntry and storage of all patient information.

Note:

	To use the RAPID™ Application, you should be familiar with Microsoft Windows® interface and capable of using a mouse.

Indications and Contraindications

Indications

The Given® Diagnostic Imaging System is intended for the detection of pathologies as an adjunctive tool in the diagnosis of small bowel gastrointestinal disorders and diseases.

The Given® Diagnostic Imaging System may be used in hospitals, outpatient clinics and physician offices. After the M2A™ Capsule is ingested the patient is not restricted to a medical environment.

Contraindications

The M2A™ Capsule is contraindicated for use under the following conditions:

- In patients suspected to suffer from intestinal obstruction based on the clinical picture or pre-procedure testing and profile.

- In patients with cardiac pacemakers or other implanted electromedical devices.

- During pregnancy.

- With patients who have known or suspected gastrointestinal obstruction or strictures. Prior abdominal surgery is a relative contraindication to the use of the M2A™ Capsule.

Warnings

A Warning indicates a condition that may endanger the patient or the operator.

Warnings

- The M2A™ Capsule should be used only after consulting a physician.

- A thorough understanding of the technical principles, clinical applications and risks associated with the Given® Diagnostic Imaging System is necessary before using this product. Read the entire manual before using the system for the first time.

- To prevent the patient from being exposed to unforeseen risks during passage of the M2A™ Capsule, make sure the patient thoroughly understands the procedure, and provide the patient with a copy of the *Patient Instructions for Undergoing Capsule Endoscopy*. (You can print it from the RAPID™ Application.)

- If there is reasonable doubt concerning the integrity of the M2A™ Capsule due to dropping, biting or any other eventuality, it should not be used until consulting with an authorized Given® representative and should be deactivated by returning it in its holder into its blister.

- Do not use an M2A™ Capsule after its expiration date.

- Instruct the patient to avoid biting the M2A™ Capsule prior to swallowing.

- After ingesting the M2A™ Capsule and until it is excreted, the patient should not be near any source of powerful electromagnetic fields such as one created near an MRI device.

- The patient should be instructed to contact the physician immediately if after ingesting the M2A™ Capsule he/she has any abdominal pain, nausea or vomiting.

- The patient should be instructed to keep the Data Recorder Waist Belt on throughout the procedure, for a minimum of 8 hours.

- This M2A™ Capsule must be stored in a safe place out of the reach of children and/or infants.

- If contrary to instructions a patient ingested two capsules, he/she should be instructed to contact the physician immediately.

- If a child has accidentally swallowed an unused or spent M2A™ Capsule, the child should be brought immediately to a hospital.

- The M2A™ Capsule should be ingested only in the presence of authorized personnel. The patient should be instructed not to let his/her relatives, neighbors or acquaintances use the M2A™ Capsule.

- This device has not been tested in pediatric population (children 18 and below) and safety in young children is unknown.

Precautions

A precaution indicates a condition that may damage the equipment.

Precautions

- USA Federal law restricts this device to sale by or on the order of a physician.

- Make sure that only trained personnel familiar with all of the Given® Diagnostic Imaging System operating procedures use the system.

- Use the system only with components purchased from Given® Imaging Ltd. Use of other components can void the system's warranty and may damage it.

- When dispensing the M2A™ Capsule use the Capsule's holder.

- To ensure proper imaging acquisition, verify the following:

  - The patient has fasted for a period of 8 hours prior to the M2A™ Capsule ingestion.

  - The Battery Pack is fully charged.

  - The Sensor Array is properly attached to the patient's body.

Adverse Events

In patients with strictures of the gastrointestinal tract, the M2A™ Capsule can potentially cause intestinal obstruction resulting in the need for hospitalization and surgery. The use of the M2A™ Capsule in patients with strictures of the gastrointestinal tract is contraindicated.

Based on the experience gained so far, there is no adverse event related to the proper use of the Given® Diagnostic Imaging System.

System Labeling

The following table lists the labels attached to various components of the Given® Diagnostic Imaging System.

Labeling	Explanation
	The M2A™ Capsule should be stored and used at a distance from any powerful magnetic fields such as the one created by an MRI.
	The M2A™ Capsule is intended for single use only.
	Attention! Consult the documentation provided with the Given® Diagnostic Imaging System.
	Class II equipment
	Type BF equipment
	FCC compliance

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System Specifications

Note:

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

M2A™ Capsule

Properties		
Physical	Dimensions	Length: 26mm Diameter: 11mm
	Weight	3.7 gr
	Material	Biocompatible plastic
Optical	Illumination	4 white light emitting diodes
	Field of View	140^0
	Effective Visibility	Distance: 3 cm
	Magnification	1:8
	Min. Detectable Object	Less than 0.1mm
Operational	Sampling Rate	2 fps
	Operating Time	7 ± 1hours
	Mechanical Safety	Passed 50 kg bite test
	Chemical Safety	Resistant to dissolution in pH=2 to pH=8
	Battery Type	Silver Oxide batteries
	Operating Temperature	$20 - 45C^0$
	Storage Temperature	$0 - 50C^0$

Data Recorder

Software	Proprietary firmware
Recording time	Up to 10 hours
Weight	305 gr
Battery type	External, nickel-metal, 6V, 6500mAH
Battery Pack weight	912gr
Sensor Array	8 flat 40 mm diameter flexible PCB
Operating Temperature	$5 - 50C^0$
Storage Temperature	$-40 - 70C^0$
Shielding	Shiledex® Supra, from Less EMF Inc.

RAPID™ Application Software

Software	RAPID™ proprietary
Languages	English/French/German/Italian/Spanish
Data export	JPEG Images, AVI Movies, HTML Reports
Displayed data	Images, Timebar and other diagnostic data.
Event marker	Annotated thumbnails
Viewing rate	1-25 fps

	REMOVE!!!

About this Manual

This manual guides you through the use of the Given®
Diagnostic Imaging System. It instructs you on how to
connect, and use the system.

The manual is comprised of the following chapters:

Chapter 1: **Given® Diagnostic Imaging System** –
describes the Given® Diagnostic Imaging System,
indications and contraindications, System specifications and
this Manual.

Chapter 2: **System Setup** – instructs you on how to set up
the Given® Diagnostic Imaging System.

Chapter 3: **Getting to Know the RAPID™ Application** –
describes and instructs you on how to use the RAPID™
Application.

Chapter 4: **Performing Capsule Endoscopy** – instructs you
on how to prepare and check in the patient, deploy the
Receiving set and dispense the M2A™ Capsule. The chapter
also includes a troubleshooting section to guide you on how
to cope with various potential difficulties.

Conventions

Menu, dialog box, tab and button names and options are bolded and begin with uppercase letters. For example: Click **Save** or select the **Save All** option.

Convention	Explanation
<**Space bar**>	Keyboard keys
File > **Open**	Open the **File** menu and select the **Open** option.
	An important note
Bulleted List	A one step procedure or a list of items. • Click **Open**.
Numbered List	A multistep procedure. You need to perform the procedure step by step according to the order of the steps.
	A warning
	A precaution

Contacting Given® Imaging

Information and Technical support for the RAPID™
Application and other system components is available from:

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System Setup

Before Your System Arrives

Before the Given® Diagnostic Imaging System arrives in your clinic prepare the following:

- Five outlets: an outlet for the computer, monitor, power supply, printer and an outlet for the charger.

Note:

✳	You may use a multiple outlet.

- Space for placing the system components: a computer, monitor and a printer.

- Space next to the Workstation for the Connection Box and its wiring (about 8-12 inches, 20-30 cm) and for the Data Recorder.

- A storage space protected from any powerful electromagnetic source for storing the M2A™ Capsule 10-Pak box.

Connecting the System

This section describes the various connectors and cables of the Given® Diagnostic Imaging System and instructs you on how to connect the system.

Items to Connect

Following is a list of items you need to connect in order to setup the Given® Diagnostic Imaging System:

- RAPID™ Workstation

- Monitor

- Keyboard

- Intel Mouse with Thumbwheel

- Printer

- Connection Box

- Connection Box Power Supply

- Data Recorder

- Battery Pack

- Telephone Connection

- 9-pin Male-Female Cable

- 9-pin Female-Female Cable

- LAN Network Cable

Connecting the Workstation

Use the back panel of the workstation for connecting the monitor, keyboard, mouse, printer, LAN cable, modem, and the Connection Box according to the scheme below:

Printer Backpanel

Monitor Backpanel

Telephone Line

Workstation Backpanel

Parallel/Printer Port

LAN Network Socket

Monitor

Modem

Serial (com) Port 2   **Serial (com) Port 1**

USB
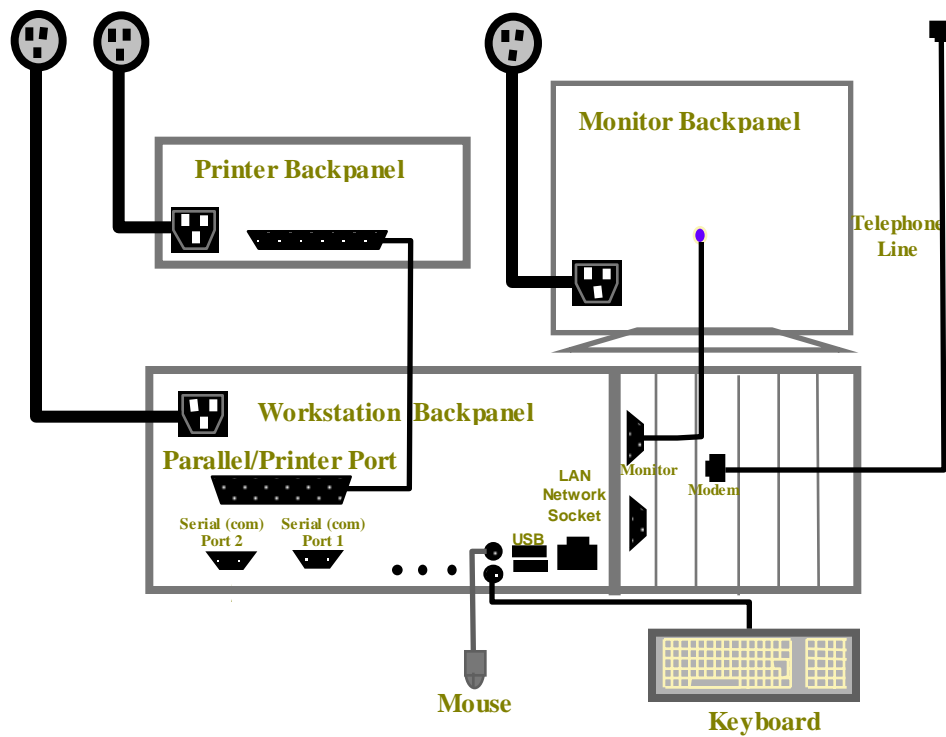
Mouse

Keyboard

The following table lists the connectors of the Workstation back panel:

Connector	Explanation
Power cord	Connects the Workstation to the electric socket.
Keyboard	Connects the keyboard to the Workstation.
Mouse	Connects the mouse to the Workstation.
Monitor	Connects the monitor to the Workstation.
Parallel Port	Connects the Workstation to the printer.
USB Port	Connects the Workstation to the printer, alternative to Parallel Port.
LAN	Connects the Workstation to the Connection Box to transfer data from the Recorder to the Workstation and vice versa.
COM	Connects the Workstation to the Connection Box.
Modem	Connects the Workstation to a phone line.

➤ **To connect the workstation**

1. Connect the IntelliMouse (Intel Mouse w/Thumbwheel)) cable to the Mouse connector.

2. Connect the Keyboard cable to the Keyboard connector.

3. Insert the LAN cable to the LAN connector.

Note:

> The LAN cable is a special cable and cannot be replaced by a standard LAN cable

4. Connect the Monitor cable to the Monitor connector.

5. Insert the Modem cable to the Modem connector and the other jack phone connector of the Modem cable to the phone outlet.

6. Connect the printer to the LPT connector or to the USB connector, according to your printer connection cable.

7. Connect the Connection Box cable to COM 1.

8. Connect the Power cable of the monitor to the electric socket.

9. Connect the Power cable of the Workstation to the electric socket.

Connecting the Connection Box

The Connection Box connects between the Workstation and the Data Recorder.
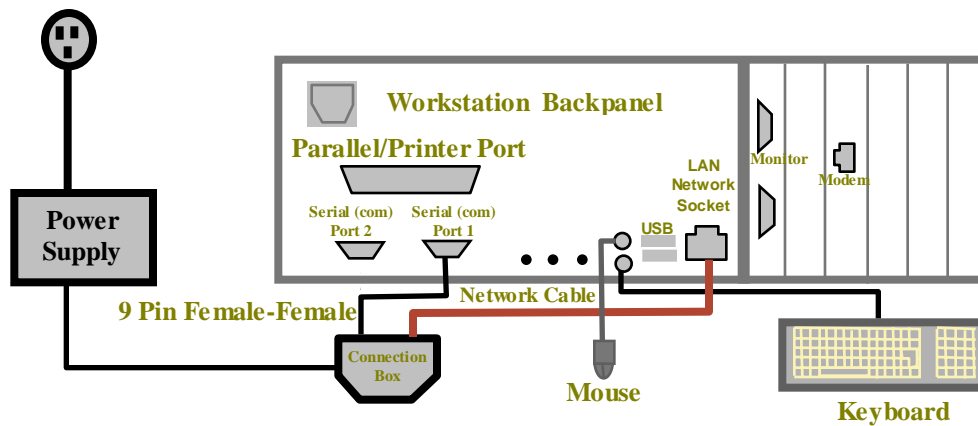
The following table lists the connectors and indicators of the Connection Box.

Connector/Indicator	Explanation
9-pin Male connector	Connects the Connection Box to the Workstation with a 9-pin Female-Female cable
LAN connector	Connects the Connection Box to the Workstation with the LAN cable.
Power Supply	Connects the Connection Box to the electric socket
9-pin Female connector	Connects the Connection Box to the recorder with a 9-pin Male-Female cable.
Control LED	Indicates that the Connection Box is connected to the electric socket and is operating.

➢ **To connect the Connection Box**
1. Connect the 9-pin Male connector of the Connection Box to the serial Com 1 of the Workstation with the 9-pin Female-Female connection cable.

2. Connect the LAN cable to the LAN connector of the Connection Box.

3. Connect the Connection Box to the Power supply.

4. Connect the Power supply to the electric socket.

5. Verify that the Control LED is on.

6. To connect the Recorder cable to the Connection Box, connect the Male connector of the Recorder cable to the Female connector of the Connection Box.

Note:

	Connect the Recorder to the Connection Box only when instructed to do so.

System Setup Scheme

Once you have finished connecting the Given® Diagnostic Imaging System, use the following figure to verify the various connections.
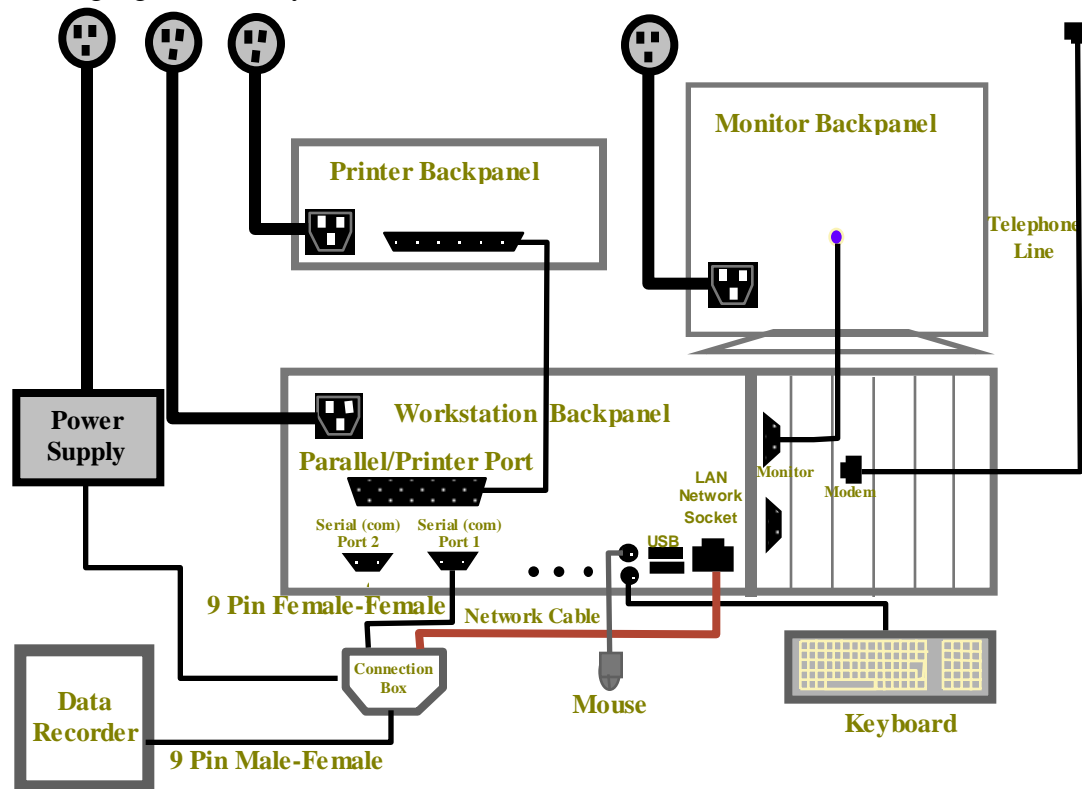
Getting to Know RAPID™

Running the RAPID™ Application

The RAPID™ Application software complies with the conventions of Windows® operating system applications conventions. However, various functions of the Windows operating system are disables or modified to enable the proper function of the RAPID™ Application..

During its operation, the RAPID™ Application writes files and reads files from pre-defined locations on the RAPID™ Workstation hard disks. Handle files only through the RAPID™ Application and not by using the Windows Explorer application. Do not change directory and file names.

Note:

✦	The directory and file names should not be modified unless under instructions from Given® Imaging technical support.

There are two hard disks in the RAPID™ Workstation. It allows a total separation of RAPID™ Application software from RAPID™ Application data. The RAPID™ Application data is always written to disk E. Raw data downloaded from the Data Recorder is written to the Recorder data directory

while PRR data is written to Patient Rapid Report directory .
Data in these subdirectories should never be meddled with.

Before using the RAPID™ Application, you should create a
"User" subdirectory on drive E:\. Whenever he saves images
as files, use the "User" subdirectory. To copy files from the
RAPID™ Workstation use only the "User" subdirectory.

Running the RAPID™ Application is very easy and simple.
All you need to do is to double-click the RAPID™
Application icon that appears on the Workstation desktop.

➢ **To run the program**

1. Turn on the computer. The Windows desktop appears

2. Double click the RAPID™ Application icon.

    The RAPID™ Application is running and the main
    screen appears.

Selecting a Language

You can change the language of the RAPID™ Application.
By default, the RAPID™ Application language is English.
You can change it to either one of the following languages:

- French
- Spanish
- German

For the language change to take effect, you have to restart the
RAPID™ Application.

➢ **To change the language**

1. Select Tools > Options.

The **Options** window appears:

Click here to select a language
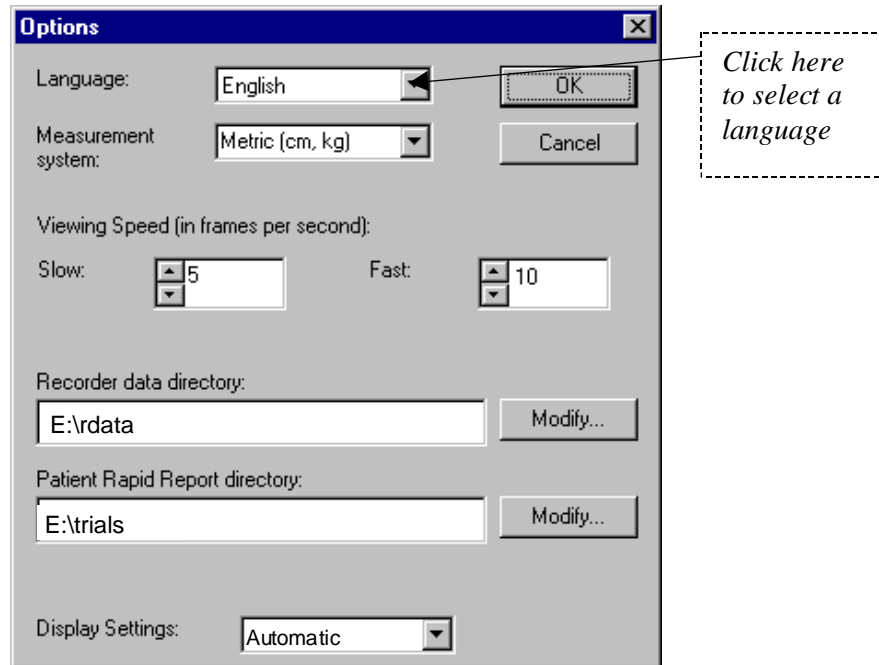
2. Open the **Language** drop-down list and select the desired language.

3. Click **OK**.

4. Select **File** > **Exit** option to close the application.

5. Double click the RAPID™ Application icon to re-run the program.

   The RAPID™ Application is running with the language of your choice.

Changing Display Settings

The RAPID™ Application is supplied with a default **Automatic** display setting. With this setting, the RAPID™

Application Main Screen has a resolution of 480x640 pixels. This setting enables a clear view of the PRR movie.

You can change the display settings of the RAPID™ Application to reduce the size of the RAPID™ **Main Screen**. For the display setting change to take effect, you have to restart the RAPID™ Application.

➢ **To apply specific display settings**

1. Select **Tools** > **Option**.

   The **Options** window appears.
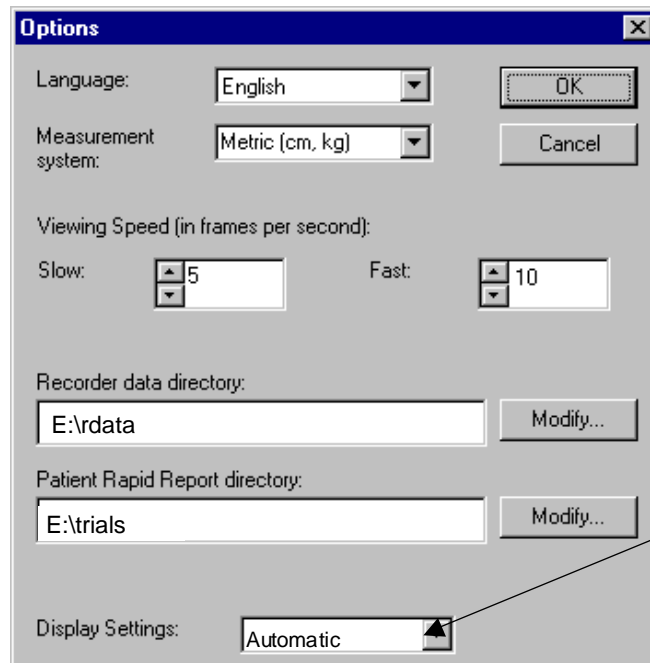
Click here to select display settings

2. Open the **Display Settings** drop down list and select **None**.

3. Click **OK**.

4. Select **File** > **Exit** option to close the RAPID™ Application.

5. Double click the RAPID™ Application icon.

Changing the Units

You can set the unit of measure for the measurements that you type in dialog boxes. By default, the RAPID™ Application is using centimeters and kilograms. You can set the unit of measure to inches and pound.

➢ **To change the unit of measure**

1. Select Tools > Options.

The **Options** window appears:

Click here to select the unit of measure
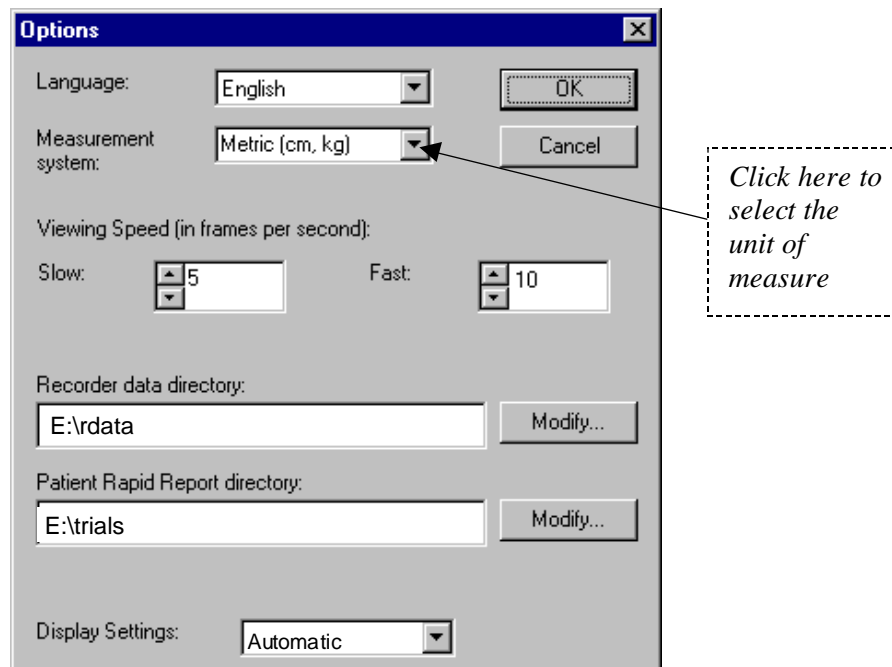
2. Open the **Measurement System** drop-down list and select the desired measurement system.

3. Click **OK**.

The RAPID™ Application is running with the unit of measure of your choice.

Main Screen

The RAPID™ **Main Screen** enables you to watch the PRR movies and to diagnose irregularities in the gastrointestinal tract. The following sections introduce you to the various sections of the RAPID™ **Main Screen** and guide you through the various available menu options.

Timebar section *Main screen menus* *Displays patient details* *Video section* *Thumbnail section*

Indicates the time of the current image *Control buttons*
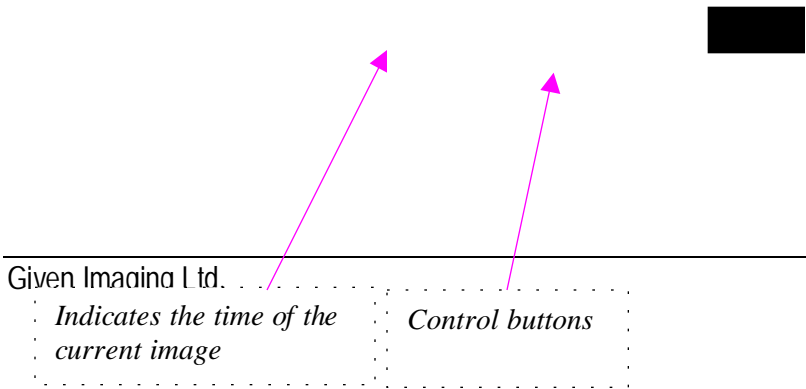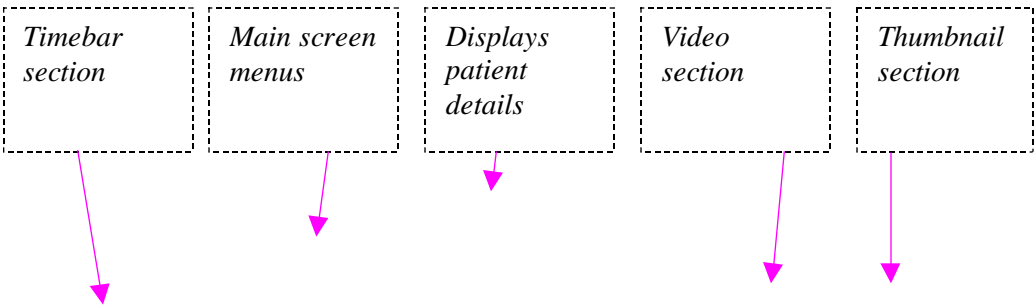
The RAPID™ **Main** screen is comprised of the following sections:

- Title bar

- **Menu** section.

- **Video** section

- **Thumbnail** section

- **Timebar** section

Title Bar

The title bar displays the patient ID, initials and test date. You entered these details during the Check-In process and they were derived from the recorder during download.

Main Screen Menus

The drop-down menus of the RAPID™ **Main Screen** enable you to use the various options available through the menus. The following tables list the various menus and their options.

File Menu

The **File** menu enables you to open or to save the PRR movies and groups of thumbnails and to quit the RAPID™ Application.

Option	Explanation
Open	Enables you to select a PRR movie of previous examinations.
Save Video As	Saves the video under a different file name. However, while watching the movie, the name of the movie as derived from the recorder appears in the **Title bar**.
Open Thumbnail	Opens a selected file of thumbnails.
Save Thumbnails As	Saves a selection of thumbnails as a GRML file. The file name is comprised of the movie name from which you created the reproductions with the extension TN.GRML.
Print Screen	Creates a printout of the RAPID **Main Screen** with the current display.
Print Setup	Opens the standard **Print** window.
File list	Displays a list of the last 7 files you opened.
Exit	Quits the RAPID™ Application.

Video Menu

The **Video** menu enables you to control the PRR movie.

Option	Explanation
Step Forwards	Moves forward to the proceeding frame.
Step Backwards	Moves backward to the previous frame.
Play Forwards	Starts the movie.
Play Backwards	Plays the movie backward.
Pause	Temporarily stops the movie presentation.
Restart	Restarts the movie.
End	Moves the PRR movie to the last frame.
Go To Frame	Moves the movie to a frame that matches a specific time indication.
Capture Thumbnail	Duplicates a frame along with 100 adjacent images, 50 before and 50 after the thumbnail.

Online Menu

The **Online** menu enables you to check in a patient and to download and construct a PRR movie.

Option	Explanation
Patient Check-In	Opens the **Recorder Initialization** screen.
Recorder Download	Opens the **Recorder Download** screen.
Service	This option is enabled only for an authorized Given® technician.

Tools

The **Tools** menu allows you to change the RAPID™ Application interface and to set the source and target path prior to the download.

Option	Explanation
Options	Defines the RAPID™ Application interface language, movie speed, Data Recorder directory and the Patient RAPID Report directory prior to the download.
Help	Provides information on the RAPID™ Application version. It also enables you to print the *Patient Instructions for Undergoing Capsule Endoscopy* and the RAPID™ Application User's Manual.

Video Section

The **Video** section includes the presentation area and the Control Buttons. The Control Buttons are located at the bottom of the **Vide**o section and they allow you to do the following:

- Set the projection rate

- Play/stop the movie

- Move backwards or forwards frame by frame

- Move to the last frame

- Rewind the movie

- Create thumbnails.

The **Video** section also displays the exact time of each frame that is currently projected, as derived from the Recorder.

Thumbnail Section

The **Thumbnail** section presents images from the movie, and enables you to annotate the snap shots. For further information, refer to *Thumbnail Section* on page *60*.

Timebar Section

The **Timebar** section is synchronized with the PRR movie and it displays the time in relation to the frame currently

presented in the **Video** section. In addition it presents the time of any thumbnail. For further information, refer to *Timebar* on page *68*.

Patient Check-In

The RAPID™ Application enables you to check in the patient who is intending to undergo the Capsule Endoscopy.

The checking in process includes the following:

- Patient Registration – filling in the Registration computerized form.

- Recorder Initialization – downloading patient details to the Recorder.

- Disconnecting the Recorder.

➢ **To check in a patient**

1. Select Online > Patient Check-In.

   The following screen appears guiding you through connecting the Recorder.
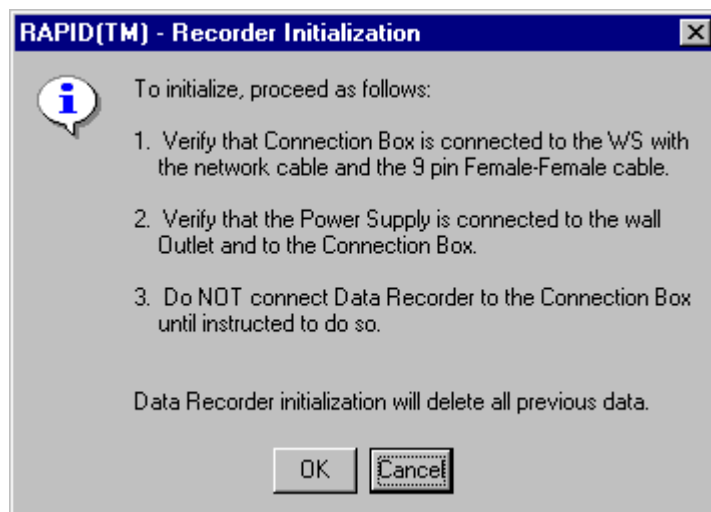
2. Follow the instructions on the **Recorder Initialization** screen:

    Verify that the Connection Box is connected to the computer.

    Verify that the power supply is connected to the electric socket.

    Verify that the Connection Box is connected to the power supply.

    Verify that the Recorder is NOT connected to the Connection Box.

Note:

	Connect the Recorder to the Connection Box only when instructed to do so.

3. Click **Yes.**

    The **Add New Patient** window appears.

Enter patient's details

Enter protocol number and date of test

Messages area

Click to initialize the Recorder

Click to cancel

4. Under **Patient Initials** enter the information as follows:

In **F**, enter the first letter of the patient's first name.

In **L1**, enter the first letter of the patient's last name.

In **L2**, enter the second letter of the patient's last name.

5. Under **ID**, enter the number of patient in the clinical protocol.

6. Open the **Gender** drop-down list and select the required gender.

7. Under **Birth Date**, click the arrow and select the required date of birth.

8. Open the **Physique** drop-down list and select either skinny, normal, stocky or potbelly. Use the following figure:

| skinny | normal | stocky | potbellied |
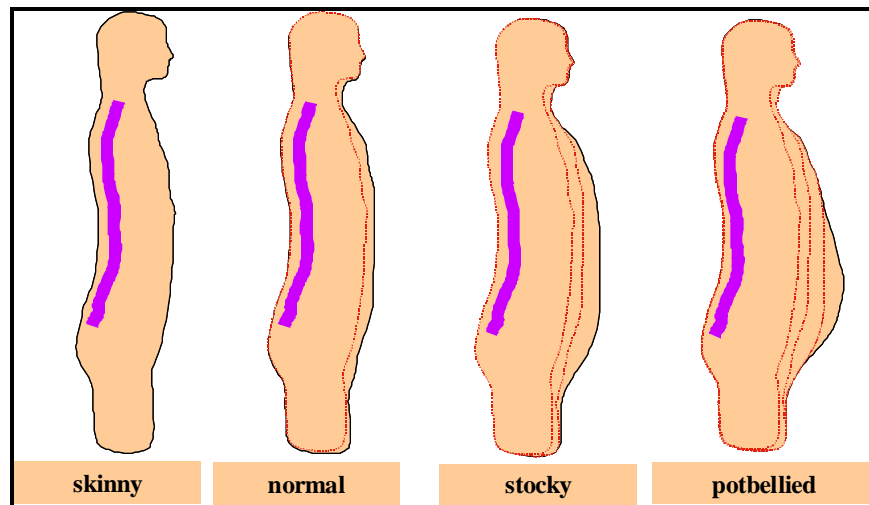
9. Under **Protocol Number**, enter the code of the clinical trial protocol, you have been assigned by Given® Imaging Limited, Division of Medical Affairs.

10. Under **Test Date**, enter the date of the test.

11. Click **Check-In Patient**.

    In the **Message** area, a message appears asking you to connect the Data Recorder to the Data Recorder cable.

12. Connect the Data Recorder to the Data Recorder cable. Connect the 9-pin Female connector of the Data

Recorder cable to the 9-pin Male connector of the Data Recorder.

In the **Message** area, a message appears notifying you that the Recorder initialization starts. The details you entered during the patient registration are saved in the Data Recorder directory and are downloaded to the Data Recorder.
Upon completion, a message appears notifying you that the Data Recorder initialization is complete.

Once the initialization process is complete a message appears asking you to disconnect the Data Recorder.

13. Disconnect the Recorder from the Data Recorder cable.

Creating a Movie

Once you open the RAPID™ Application **Main Screen** and you wish to watch a PRR movie, perform either one of the following:

- Create a movie.

- Select and watch an existing movie.

Creating a PRR Movie

To create a movie, you need to download raw data from the Recorder to the workstation. This process is comprised of two stages:

- Defining Data Recorder and Patient RAPID Report directories.

- Connecting the Recorder to the workstation.

Defining Directories

Recorder data directory - Define a directory for saving the downloaded raw data. The default path is:
E:\rdata.

Patient Rapid Report directory - Define a path for saving the processed data, i.e., the PRR movie. The default path is:
E:\trials.

> **To define the directories**

1. Select Tools > Options.

   The **Options** window appears:

Define here a directory

Click to modify the default Input or Output path

Define here a directory
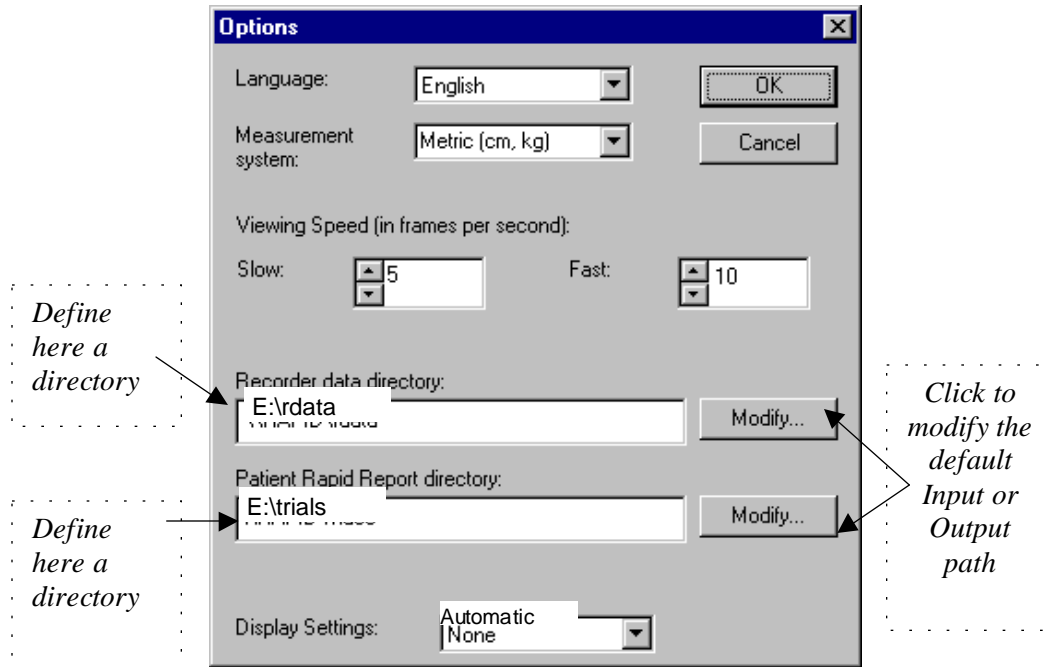
2. The default Recorder Data directory is:
   E:\ rdata. You should not change this setting unless
   instructed so by Given® Imaging technical support.
   To change the setting, click **Modify** and define the path
   of your choice.

3. The default Patient RAPID Report is:
   E:\trials. You should not change this setting unless
   instructed so by Given® Imaging technical support.
   To change the setting, click **Modify** and define the path
   of your choice.

4. Click **OK** to apply the changes and to close the **Options**
   window.

Note:

	The Data Recorder requires a shared \rdata directory in order to be able to download data to the workstation. This directory should not be modified unless under instructions from Given® Imaging technical support.

Connecting the Recorder and Downloading

Once you have defined directories for saving the downloaded and the processed data, you can connect the Recorder and download the raw data. The RAPID™ Application guides you on how to connect the Recorder to the workstation. All you need to do is to follow the instructions on the screen.

➢ **To connect the recorder and start downloading**

1. Select Online > Recorder Download option.

    The **Recorder Download** window appears.
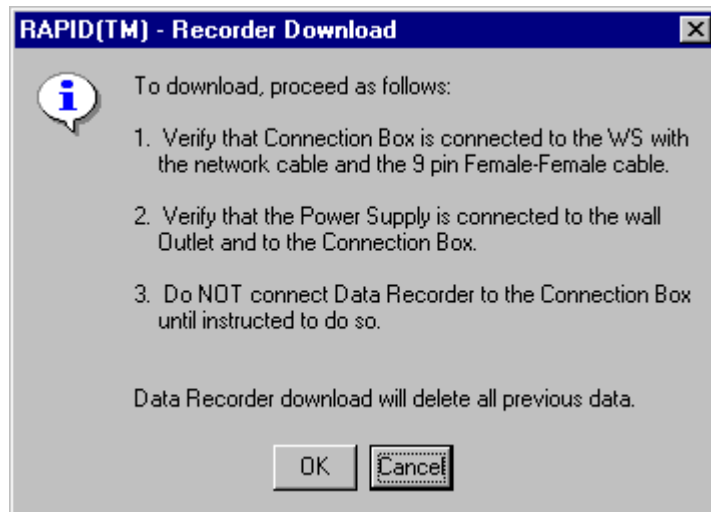
2. Follow the instructions that appear on the **Recorder Download** screen:

- Verify that the Connection Box is connected to the computer.

- Verify that the power supply is connected to the electric socket and to the Connection Box.

- Verify that the Recorder in NOT connected to the Connection Box.

3. Verify that all files in the Recorder data directory path can be deleted. If they cannot be deleted, click **Cancel** and re-define a shared \rdata Recorder data directory path.

Note:

| | If, in the **Recorder Download** window, you click **Cancel**, the download does not start and we advise you to define a new Data Recorder directory. |

4. To proceed, click **OK**.

A message appears asking you to connect the Data Recorder to the Connection Box.

5. Connect the Data Recorder to the Recorder cable.

All raw data is being downloaded and simultaneously the movie is being constructed and saved in the Patient RAPID Report directory. During the construction, the movie is projected in the **Vide**o section. Once the download and the construction are complete, messages appear respectively. The first frame of the movie appears in the **Video** section.

PRR Movie Name

Once the download process is complete, a new PRR movie appears in the Output path you have defined. The movie file name is comprised of the following components separated by an underscore. The components are derived from the Recorder during the download process:

- A prefix (GI)

- Patient's initials

- Examination date in the following format: (YYYY/MM/DD)

- Patient number

- File extension (GTD)

For example, the file name GI_JBS_2000/12/06_12349.GTD is a PRR movie of a patient number 12349 whose initails are JBS and who went through the examination on 12/06/2000.

Precaution

Do not modify the files in the Patient RAPID report directory in any way. Modification may result in loss of files.

Selecting an Existing Movie

The PRR movies are stored on the workstation in the Video folder unless you choose to save them in another location or under a different name.

If you saved a movie under a different name, once you open the file and watch the movie, the **Title bar** of the RAPID™ **Main Screen** displays the original movie name.

➢ **To select a movie**

1. In the RAPID™ **Main Screen**, select **File** > **Open**.

    The **Open** window appears indicating the default directory of the PRR movies.

2. The default directory of the PRR movie appears. If you stored the video in another location, navigate to the desired location.

3. Select the desired movie (*.gtd file) and click **Open**. Once the movie is loaded the first frame appears in the **Video** section and you can start watching the movie.

Guidelines for Watching the Movie

*   Verify that the display setting is **Automatic**. If not, increase the RAPID™ Application resolution by setting display setting to **Automatic**.

*   Dim the lights in the room.

Watching the PRR Movie
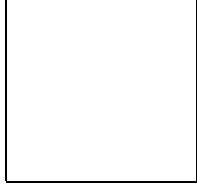
The **Video** section enables you to watch the video captured by the M2A™ Capsule during the examination. The PRR movie is comprised of a series of single images and it can present from 1 to 25 frames per second according to the selected movie speed.
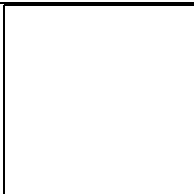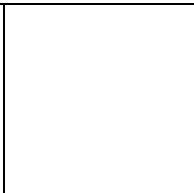
Primary Screening of the Movie

A primary screening of the movie is available while watching the movie in Automatic speed mode. The Automatic speed mode changes from a fast display rate to a slow rate according to differences between consecutive images. When the RAPID™ Application detects large differences between adjacent images, it slows down the show rate to enable a better look at the images.

The video presentation is synchronized with the **Timebar** section. The **Timebar** progresses as the movie progresses.

To control the movie presentation, use the Control Buttons located at the bottom of the **Video** section. The following table lists the Control Buttons and the action each button provides:

Button	Action
A **F** **S** Video speed	Selects the projection rate. The available rates are Automatic, Slow and Fast. The **Video Speed** button changes according to the selected speed.
◀❙ Restart	Restarts the movie.
◀❙ Back Step	Moves back to the previous frame.
◀ Play backward	Plays the movie backward. If you click the **Play backward** button, the **Play forward** button changes to the **Pause** button while the movie is playing.
Play forward	Plays the movie forward. If you click the **Play forward** button, the **Play backward** button changes to the **Pause** button while the movie is playing.
Pause	Stops the movie and a still picture appears. The **Pause** button changes to a **Play** button.
Forward	Moves forward to the next image.

Step	
End	Moves to the last frame of the movie.
Capture Thumbnail	Duplicates a frame. The duplication immediately appears in the **Thumbnail** section.

Selecting the PRR Movie Speed

There are three available modes of the PRR movie speed: Automatic, Fast and Slow.

Automatic – automatically sets the display rate of the images (between maximum 25 frames per second and a minimum 5 frames per second) according to the rate of change in successive images. When the RAPID™ Application detects a large difference between successive images, it slows down the show rate to enable a careful examination of the pictures.

Fast – displays the movie in fast speed of 10 frames per second (default). You can change the Fast rate by selecting **Tools** | **Options**.

Slow – displays the movie in slow speed of 5 frames per second (default). You can change the Slow rate by selecting **Tools** | **Options**.

Setting the Fast and Slow Speed Rate

By default the fast speed is 10 frames per second and the slow speed is 5 frames per second. The **Options** window allows you to change the default settings of the **Fast** and **Slow** modes.

➢ **To change the default settings of Fast and Slow modes**

1. Select Tools > Options.

2. The **Options** window appears.

Set the desired speed for the Slow mode

3. Under **Slow** select the desired speed rate for the Slow mode.

Set the desired speed for the Fast mode

4. Under **Fast** select the desired speed rate for the Fast mode.

E:\rdata

The default speed mode of the movie is Automatic. You can easily switch between the modes of speed.
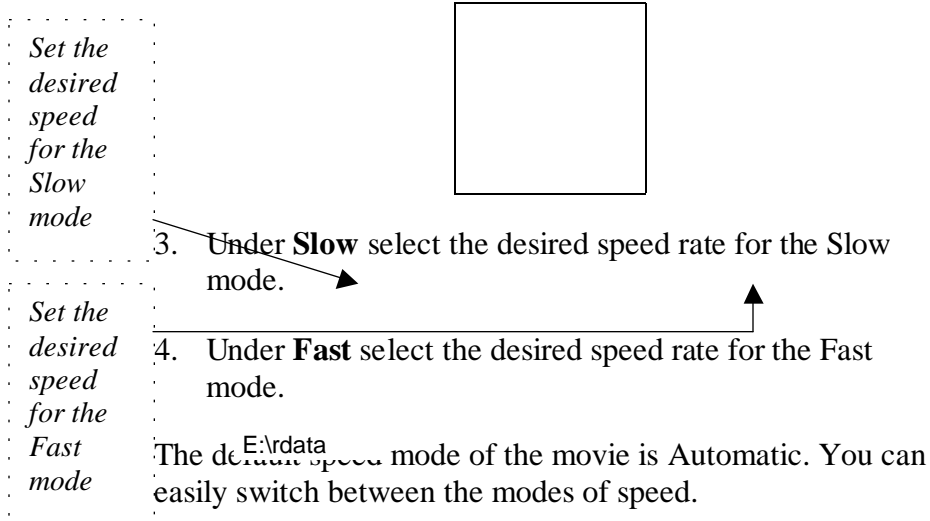
➢ **To select a speed mode**

E:\trials

• Click the **Video Speed** button to select the desired speed mode. The letter that appears on the **Video Speed** button indicates the selected speed.

Automatic

Restarting the Movie

When you restart the movie, the time and frame indications are automatically updated along with the Timebar.

➢ **To restart the movie**

- Click the **Restart** button.
  The PRR movie starts from the beginning and the related features such as the Time and Frame indications at the bottom of the **Video** section automatically resets to zero.

Moving by Frames

You can move along the movie one frame forward or backward, or to the last frame. While moving along the movie, the related features are updated accordingly.

➢ **To move by frames**

- To move one frame forward, click the **Forwards Step** button.
  The movie moves one frame forward.

- To move one frame backward, click the Back Step button.
  The movie moves one frame backward.

- To move to the last frame in the PRR movie, click the **End** button. The movie moves to the last frame and the time indication at the bottom of the **Video** section representing the end of the study, is automatically updated.

Moving by Time Indication

You can move to a certain section of the movie by indicating a time unit in the **Time** text box at the bottom of the **Video** section. The movie automatically moves to the related section of the movie.

➢ **To move by time indication**

1. In the **Time** text box at the bottom of the **Video** section, type in the desired time in the following format: HH:MM:SS.

2. Press the <**Enter**> key on your keyboard. The movie automatically scrolls to the desired video section and the **Timebar** is updated accordingly.

Playing and Pausing

When you watch the movie and you would like to have a longer look at one of the frames, you can temporarily stop the projection of the movie.

➢ **To Play/Pause the PRR Movie**

To play the movie, click the **Play forward** button. The movie is on. The **Play backward** button changes to the **Pause** button.

To play the movie, click the **Play backward** button. The movie is on. The **Play forward** button changes to the **Pause** button.

To pause the movie, click the **Play** button. The movie stops playing, the current frame appears as a still picture and the **Pause** button changes to **Play**.

Capturing an Image

When you capture a frame the following occurs:

- The captured frame immediately appears at the bottom of the **Thumbnail** section. The time indication derived from the Recorder appears next to the captured frame in the **Thumbnail** section.

- An indication of the thumbnail appears in the **Timebar** section of the **RAPID™ Main** screen.

➢ **To capture a frame**

1. 1. While the movie is playing, click **Pause.**

2. While the movie is still, click **Capture Picture.**

The selected frame appears with a time indication in the **Thumbnail** section. An indication that a thumbnail was created appears in the **Timebar** section.

Thumbnail Section

The **Thumbnail** section displays images captured from the PRR movie. Each reproduction appears in the **Thumbnail** section with a time indication derived from the Recorder and the first few words of the attached comment.

A picture captured from the movie

Drag the scroll bar to scroll through the thumbnails

Time indication derived from the Recorder

ured three images, a scroll bar appears
of the **Thumbnail** section. Use this scrollbar to scroll through the captured images.

The first word of the attached comment

gh the thumbnails, save, delete and edit
s attached to the picture. You can also move from a thumbnail to its exact location in the movie and view the adjacent pictures. Any of these operations requires the selection of a thumbnail.

Selecting a Thumbnail

You can select one, a few or all thumbnails. Follow the provided instructions according to your needs.

➢ **To select a thumbnail**

• Move the mouse pointer to the desired thumbnail and click.

A blue square appears over the thumbnail.

> **To select several thumbnails**

1. Select a thumbnail.

2. Move the mouse pointer to another frame you wish to select and simultaneously click the mouse and the <**Ctrl**> key of your keyboard; both selected thumbnails are covered by a blue square.

3. Repeat step 2 until you selected all the desired pictures.

➢ **To select all thumbnails**

1. Select the thumbnail at the top of the **Thumbnail** section.

2. Scroll to the last thumbnail and simultaneously click the mouse and the <**Shift**> key of your keyboard; all thumbnails are selected.

Scrolling through the Thumbnails

To scroll through the thumbnails, use the scroll bar located on the right side of the **Thumbnail** section. The thumbnails are arranged according to the sequence of capturing. The last thumbnail appears at the bottom of the **Thumbnail** section. Scrolling up reveals the more recent Thumbnails and scrolling down reveals the previous ones.

➢ **To scroll through the thumbnails**

• To observe a thumbnail previously captured, drag the scroll bar toward the top of the main screen.

• To view the most recently captured thumbnail, drag the scroll bar toward the bottom of the main screen.

Saving a Thumbnail

When you save a thumbnail, you actually save the thumbnail AND a short movie. The movie is comprised of 100 adjacent frames, 50 frames before and 50 frames after the selected frame. To watch this short movie, use any Windows media player, which is already installed on the Workstation.

The thumbnail is saved as a JPEG file and the short movie as an AVI file. You need to select only the location for saving the thumbnail. The RAPID™ Application automatically saves the thumbnail as a *.jpg and an *.avi file in the selected location.

The file name of the *.jpg and the *.avi file contains the same components as the PRR movie they were captured from. For further information, see *PRR Movie Name* on page *50*.

➢ **To save a thumbnail**

1. Click a thumbnail to select it.

   A blue square appears over the thumbnail.

2. Click the right mouse button.

   A popup menu appears.

3. Select **Save.**

   A window appears.

4. Select a folder for saving the thumbnail.

5. Click **OK.**

The thumbnail is stored in the location of your choice as a JPEG and an AVI file, and a message appears notifying you that the operation is complete.

➢ **To watch a the AVI movie**

1. Open the Windows media player.

2. Navigate to the *.avi file of the thumbnail you wish to examine.

3. Select the file.

4. Click **OK**.

   The short movie of 100 images is running.

Saving a Group of Thumbnails

You can save a group of thumbnails as an independent file. This file name contains all of the components of the PRR movie file name with the extension tn.grml, i.e., GI_(patient initials_examination date_patient number_tn.grml.

➢ **To save a group of thumbnails**

1. From the File menu, select File > Save As Thumbnails option.

   The **Save As** window appears.

2. Select a folder for saving the thumbnails.

3. Click **Save**.

   The group of thumbnails is saved as a file that its name is identical to the PRR movie file name with the extension tn.gml.

Removing a Thumbnail

1. Select a thumbnail.

   A blue square appears over the thumbnail.

2. Click the right mouse button.

   A popup menu appears.

3. Select **Delete**; the reproduction disappears from the
   Thumbnail section.

Creating or Editing a Comment

If you want to annotate a Thumbnail by entering a comment
or to edit a comment, do the following:

➢ **To edit a comment**

1. In the **Thumbnail** section, select a thumbnail.

2. Click the right mouse button; a menu appears.

3. Select **Comment**.

   The **Enter Comment** window appears:

*Enter here
your
comment*

4. Type in a comment, or edit the existing comment.

5. Click **OK** to save the changes and to close the **Comment** window.

Reading the Comment

In the Thumbnail section, you can read the annotating comment of a thumbnail by placing the pointer of the mouse on the beginning of the comment that appears below the thumbnail.

Move the mouse pointer to here to view the complete comment
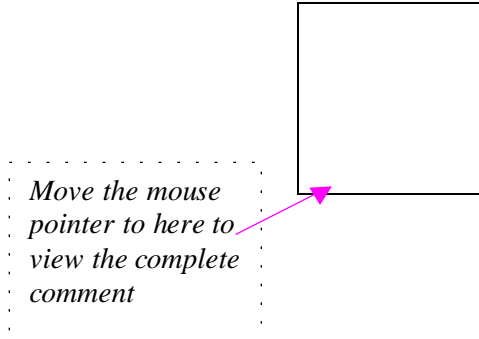
➢ **To read the comment**

• Position the mouse pointer on the first word of the comment located under the thumbnail.

The full comment appears and you can read it.

Moving from a Thumbnail to the Movie

If you wish to look at the images adjacent to the captured one, you can move from the **Thumbnail** section to the **Video** section. The PRR movie automatically displays the captured frame to enable you to look at what preceded or followed the captured frame.

➢ **To move from a thumbnail to the movie**

1. Select the desired thumbnail.

   A blue square appears over the thumbnail.

2. Click the right mouse button.

   A popup menu appears.

3. Select **Go To**; the movie automatically updates to display the desired frame. Use the **Forward and Backward Step** buttons to view the adjacent pictures.

Timebar

The **Timebar** indicates the time as derived from the Recorder during the movie projection. The **Timebar** is synchronized with the movie and it moves along indicating the elapsed time by changing the moving bar into light blue.

When you create a thumbnail, the **Timebar** section presents the first word of the thumbnail annotation as the following figure shows:

The section of the movie you have already watched

The section of the movie you did not watch

Thumbnails that were captured
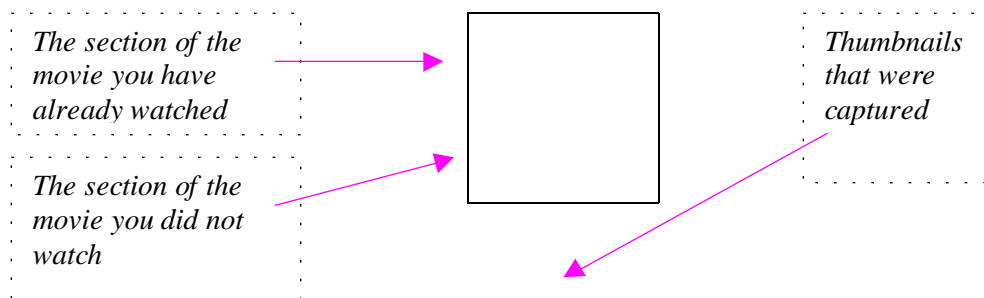
Scrolling Through the Movie

You can scroll through the movie by dragging the **Timeba**r up or down. The movie presentation is updated accordingly.

➢ **To scroll through the movie**

- Drag the gray area of the Timebar up, to view the first section of the movie and down to view the last section of the movie.

  The displayed PRR movie is updated accordingly.

Moving from Comment Indication to Frame

If you select a comment indication in the Timebar section the movie automatically moves to the frame belonging to the selected comment.

➢ **To move from comment to frame**

- In the **Timebar** section, select a comment.

  The comment indication appears in red, the mouse pointer changes to red and the frame that the comment refers to appears in the **Video** section.

Performing Capsule Endoscopy

Once the Given® Diagnostic Imaging System is connected and ready for use and you are familiar with the system and the RAPID™ Application, you can perform a Capsule Endoscopy.

Performing a Capsule Endoscopy consists of the following:

- Preparing the patient.

- Preparing the examination set for the patient.

- Checking in the patient.

- Deploying the Data Recorder Set.

- Dispensing the M2A™ Capsule.

- Discharging the patient.

- Receiving from the patient the Data Recorder, Sensor Array, Battery Pack and Waist Belt.

- Downloading data from the Data Recorder to the Workstation and processing it to a PRR movie.

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Preparing the Patient

Once you have decided that the patient should undergo the Capsule Endoscopy, inform the patient that the Capsule Endoscopy involves the following:

- Ingesting a small (the size of a large vitamin pill) Given® Imaging M2A™ Capsule which will pass naturally through the patient's digestive system while taking pictures of the intestine.

- Attaching to the abdomen a Sensor Array. The images captured by the M2A™ Capsule are transmitted to the Sensor Array.

- Wearing a belt around the waist during the examination, which lasts approximately 8 hours. The belt contains a Walkman®-like Given® Data Recorder which saves all the images and shielding that ensures FCC compliance. The belt must be worn at all times throughout the procedure, a minimum of 8 hours.

- Returning the Data Recorder set for further processing.

Inform the patient in writing and verbally that he/she needs to do the following to achieve accurate results:

- Abstain from food and drink for 8 hours prior to undergoing the Capsule Endoscopy.

- Male patients should shave their abdomen 6 inches above and below the navel.

- After ingesting the M2A™ Capsule, the patient should not eat or drink for 2 hours. After 2 hours the patient may drink water. After four hours the patient may have a light snack. After the completion of the study, the patient may return to his/her normal diet.

- After ingesting the M2A™ Capsule, the patient should immediately contact the physician's office if he/she has any abdominal pain, nausea or vomiting.

- After ingesting the M2A™ Capsule and until it is excreted, the patient should not be near any source of powerful electromagnetic fields such as one created near an MRI device

- During the examination, the patient should avoid any strenuous physical activity. He/she should not bend or stoop during the Capsule Endoscopy.

- During the examination, the patient should check every 15 minutes that the green light at the top of the Data Recorder is blinking. If it stops blinking during the first 6 hours of the examination, the patient should write down the time and contact the physician's office.

- During the examination, the patient should not remove the Data Recorder belt.

- In the Event Form, the patient should write down the time and the nature of any event such as eating, drinking and unusual sensations. The patient will have to return this form along with the examination set.

Note:

	Before the patient leaves the clinic, you should give the patient the Event Form along with a copy of the *Patient Instructions for Undergoing Capsule Endoscopy*.

Preparing Patient Examination Set

Verify that the Given® Diagnostic System is set up according to the instructions provided in the *Connecting the System* on page *21*, and that you have the following equipment and accessories:

- M2A™ Capsule

- Data Recorder

- Sensor Array

- Charged Battery Pack

- Belt with belt extension, pouches and suspenders.

- Application kit (10 adhesive sleeves, a Sensor Template, two adhesive pads).

- Marker

- Razor

- Disinfectant

- Measuring tape

- Scale

Checking In a Patient

The Check-In procedure is done through the RAPID™ Application. The procedure includes entering the patient's details and initializing the Data Recorder. Before you start checking in the patient, verify the following:

- The RAPID™ Workstation has a shared \rdata directory.

- The \rdata directory is defined as the Data Recorder directory.

- The RAPID™ Application is configured according to your convenience, i.e., the language, screen settings and measurement system.

- The patient abstained from eating or drinking for the last 8 hours.

- The patient did not take any medication in the last 2 hours.

- The patient (if male) shaved the area of the abdomen 6 inches above and below the navel.

For further information, on how to check in, refer to the *Patient* chapter on page *41*.

Deploying the Data Recorder Set

Deploying the Data Recorder Set includes the following:

- Adjusting the Recorder-Battery belt.

- Connecting belt components.

- Attaching the Sensor Array to the patient.

- Putting the belt on the patient.

Adjusting the Recorder Battery Belt

The Recorder-Battery belt is an external belt that the patient wears during the examination. It contains two pouches for holding the Recorder and the Battery pack. It is important that the belt fits the patient and the patient is comfortable wearing the belt.

➢ **To fit the Recorder-Battery belt**

1. Ask the patient to stand up.

2. Place the belt around the patient's waist.

3. Adjust the belt to fit the patient. For shorter patients, it will be necessary to add the belt extension.

4. Make sure that the Battery Pack and the Recorder pouch are at the patient's waist as the following figure shows:
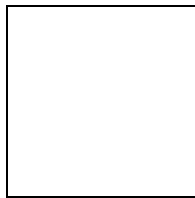
5. Adjust the suspenders to fit the patient.
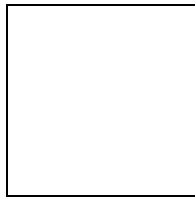
6. Remove the belt.

7. Place the belt next to the Battery Pack and the Recorder.

Connecting Belt Components

This section instructs you on how to connect the Battery Pack to the Recorder and how to secure both Battery Pack and the Data Recorder in their pouches.

Note:

Since fully charged batteries slowly discharge, use only a Battery Pack you have just charged. For information on how to charge the Battery Pack, refer to *Charging the Battery Pack* on page *88*.

➢ **To connect belt components**

1. Place a recently fully charged Battery Pack in the battery belt pouch.

2. To connect the Battery Pack to the Data Recorder, connect the 9-pin Female connector of the Battery Pack cable to the 9-pin Male connector of the Data Recorder.

3. Secure with the securing screws.

Note:

While connecting the Battery Pack to the Data Recorder, hold the Data Recorder.

The Data Recorder green LED blinks, turns on and then off. Once the recording starts the LED blinks at the receiving rate.

4. Insert Data Recorder into the Data Recorder pouch, and bring the Battery Pack cable out from the top opening of the pouch. (See the following picture).

5. Use the Velcro straps to secure the Data Recorder and Battery Pack cable.

6. Fold the remaining length of the Battery Pack cable and secure it with the Velcro flap along the back of the belt.

7. Put the belt aside until the patient is ready to wear it.
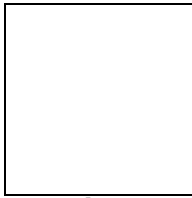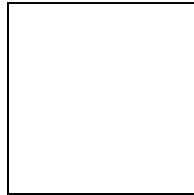
Warning

⚠	Do not connect the Data Recorder to the RAPID™ Workstation while Data Recorder is connected to the Sensor Array that is worn by the patient or while the Waist Belt is in the belt being worn by the patient.

Attaching the Sensor Array to the Patient

The Sensor Array is attached to the patient's abdomen.

Use the Sensor Template to place each one to the eight sensors of the Sensor Array in its correct location.

Necessary equipment and accessories

The M2A™ Capsule 10-Pak of the Given® Diagnostic Imaging System also includes the Sensor Application kit. The kit contains the following items which are necessary for deploying the Sensor Array:

Item	Explanation
Sensor Template	Helps you position each one of the eight sensors in their proper location.
Marker	Enables to mark the location of each sensor.
Adhesive Sleeves	Holds each one of the eight sensors and securely attaches each one of the sensors to its place.
Adhesive Pads	Enables secure attachment the Sensor Array cable to the patient's hip.
Disposable Razor	Removes any hair from the abdomen.

Warning

⚠️	Do not use the Sensor Array if it is torn or damaged.
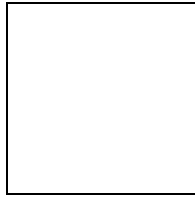
The template has 9 holes. Eight holes indicate the recommended location of each one of the eight sensors and the additional hole indicates the navel as a reference point.

Place the template on the patient's abdomen and use the marker to make a small dot at each location.

Remove the template and locate each sensor over the dot. Securely attach the eight sensors to the patient's body with the adhesive sleeves. The adhesive sleeves are supplied with the Sensor Application kit.

To secure the Sensor Array cable to the patient's hip, use the adhesive pads. The adhesive pads are supplied with the Sensor Application kit.

Note:

Any object which comes in between the patient's body and the sensors, including hair or air, and any changes in the sensors arrangement may interfere with the quality of the data.

➢ **To attach the Sensor Array**

1. Insert each sensor into an adhesive sleeve. The sensor markings (dots or "THIS SIDE UP") should face away from the patient and the adhesive side of the sleeve should face the patient's abdomen.

2. To secure the sensor in the sleeve, remove the liner from the adhesive line at the opening of the adhesive sleeve and press both lips together.
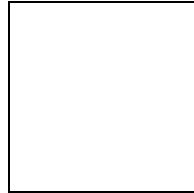
3. Ask the patient to lie down and to expose his/her stomach area down to the pubic bone.

4. If a male patient arrives unshaven, wipe the patient's abdomen with disinfectant and shave the abdomen 6 inches above and below the umbilicus (navel).

5. To mark the location of each sensor, place the Sensor Template on the patient's stomach with the drawing facing up while using the navel as a reference point and insert the marker into the holes. Mark the location of each sensor.

6. Remove the Sensor Array Template from the patient and keep it for reference until you complete the procedure.

7. Place the Sensor Array on the patient's abdomen using as a guideline the numbers on each sensor wire and the numbers on the Sensor template. The Sensor Array connector should be at the LEFT SIDE of the patient.

8. To attach each sensor, start with the rightmost sensor. Remove the protective backing from its Adhesive Sleeve. Secure the sensor to the patient's abdomen so that the hole at the center of the sleeve approximately overlaps the marking on the patient's abdomen.

9. Repeat step 1 - 8 for all sensors.

10. To secure the Sensor Array cable to the left side of the patient's body, use the remaining adhesive pads as the following scheme shows:
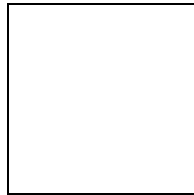
11. Instruct the patient to get dressed. The Sensor Array connector and approximately 10 inches of cable should remain outside of the patient's clothes.

Putting the Belt on the Patient

Since you adjusted the belt, putting it on the patient is very quick and simple.

➢ **To put the belt on the patient**

1. While the patient is standing, place the Recorder-Battery Pack belt around the patient's waist.

Note:

	The Sensor Array connector and wire should dangle from above the belt.

2. To connect the Sensor Array to the Recorder, insert the Sensor Array 8-pins male connector to the 8-pins Female connector at the top of the Recorder. Verify that the protrusion of the Sensor Array connector is facing outwards.

3. Instruct the patient that the belt should not be removed during the course of the examination for any reason, at least 8 hours.

Dispensing the M2A™ Capsule

Before dispensing the capsule ascertain that there is no other M2A™ Capsule or other diagnostic capsule in the patient's gastrointestinal tract.

Note:

Verify that you read the Indications and Contraindications, Warnings and Precautions in the Package Insert of the M2A™ Capsule or in chapter one prior to dispensing the M2A™ Capsule.

➢ **To dispense the M2A™ Capsule**

1. Prepare a glass of water for the patient.

2. To activate the M2A™ Capsule, open the blister containing the M2A™ Capsule.

3. Take the capsule with its holder out of the blister.

    The capsule should start blinking

Note:

If for any reason, after activating the M2A™ Capsule by removing it from it's blister, the patient is not taking the M2A™ Capsule, it should be deactivated by replacing it, in its holder, to the blister. The capsule should stop blinking. If it does not stop on your first attempt, turn the capsule in its holder and replace in blister until blinking stops.

4. To verify that the capsule is operating, hold it in front of the patient's abdomen, close to the sensors.

The Data Recorder LED starts blinking in green.

5. Instruct the patient to take the M2A™ Capsule out of its holder.

6. Ask the patient to put the M2A™ Capsule in his/her mouth, and to hold it under the tongue WITHOUT INGESTING.

7. If after a short adjustment period, with the M2A™ Capsule in the patient's mouth, the green light keeps on blinking, ask the patient to ingest the capsule with a sip of water.

Note:

	The time elapsed between capsule activation and ingestion should usually not exceed 1 minutes.

8. In the Event Form, write down the ingestion time of the M2A™ Capsule.

Discharging the Patient

Once the patient has ingested the M2A™ Capsule, the patient may leave the clinic. The examination lasts as long as the Data Recorder LED is blinking but not less than 6 hours unless the M2A™ Capsule was excreted. Verify that the patient knows how to behave during the examination.

➢ **To discharge the patient**

1. Verify that the patient has the *Patient Instructions for Undergoing Capsule Endoscopy*, and a Capsule Endoscopy Event Form.

2. Verify that the patient knows how to behave during the examination:

   • The patient should avoid any physical activity that involves sweating, bending or stooping.

   • The patient should avoid any source of powerful electromagnetic fields such as one created near an MRI device

   • The patient needs to abstain food for another 2 hours after capsule ingestion. After 2 hours the patient may drink water. Four hours after ingesting the capsule, the patient may eat a light snack.

   • The patient may take usual prescribed medication 2 hours after ingesting the capsule.

   • The patient must not remove the Data Recorder Waist Belt until 8 hours after the procedure has begun.

3. Ask the patient to check that the green LED of the Data Recorder is blinking. If it stops blinking, the patient should write down the time the patient noticed it. If it is less than 6 hours since the ingestion of the Capsule, the patient should immediately call your office.

4. Ask the patient to return to the clinic with the Data Recorder, belt and Sensor Array after approximately 8 hours.

5. Instruct the patient whether, at the end of the examination, he/she should take off the Data Recorder and Sensor Array by him/her self or should return to the clinic for removing the equipment.

6. If the patient should take off the Recorder and Sensor Array by him/her self, verify that the patient understands the instructions provided in the *Patient Instructions for Undergoing Capsule Endoscopy*.

7. Discharge the patient.

Receiving the Examination Set

At the end of the examination, the patient should return to your clinic and you may take off the examination set unless the patient has already done this.

It is recommended to recharge the Battery Pack immediately after return.

Note:

	The Battery Pack should be charged only with the charger supplied by Given® Diagnostic Imaging System.

After removing the sensors from the adhesive sleeves, clean them before storing.

➢ **To receive the examination set**

1. Disconnect the Data Recorder from the Battery Pack.

2. Take the Data Recorder and the Battery Pack out of the belt.

   Recharge the Battery Pack. For instructions refer to *Charging the Battery Pack* on page *88*.

3. Carefully remove adhesive sleeves from sensors. This can be done easily by tearing them in the middle along the perforation.

4. To clean the Sensor Array, wipe it lavishly with 90% alcohol and let it air-dry for 20 minutes.

5. When the Sensor Array is dry, return it to the Carrying Case in which they were supplied.

6. To download the data from the Data Recorder, refer to *Creating a PRR Movie* on pate *46*.

Charging the Battery Pack

Use only a fully charged Battery Pack. Since even fully charged batteries discharge slowly, recharge the Battery Pack

just before use. If a patient returns a Battery Pack at the end of an examination and on the following day another examination will take place, immediately recharge the Battery Pack. Recharging a Battery Pack is an overnight process.

Note:

	The rechargeable Battery Pack lasts at least 2 years. After two years of daily use or after 500 rechargings, it is recommended to replace it.

Warning:

⚠	For charging the Battery Pack use only the Charger supplied with the Given® Diagnostic Imaging System

➢ **To recharge the Battery Pack**

1. Connect the Charger male 9-pin connector to the Battery Pack 9-pin Female connector.

2. Connect the Charger to the electric socket.

   The Charger indicator is on.

   When the Charger indicator blinks, the Battery Pack is fully charged.

3. Unplug the Charger from the socket and from the Battery Pack.

4. Use the charged Battery Pack.

Troubleshooting

This section describes common problems you may encounter when performing the Capsule Endoscopy, and instructs you on how to cope and overcome these problems.

Note:

	If you encountered a problem that is not mentioned in this section, or you followed each step as advised in this section and the problem persists, call Given® Imaging Limited technical support Tel: +972-4-909-7706 .

Electrical Outage

PROBLEM

An electrical outage occurred during patient Check-In, Recorder Initialization, or during download.

SOLUTION

Once electrical power has returned, restart the process.

Data Recorder

The following section describes common problems you might encounter while using the Data Recorder during the Capsule Endoscopy.

Recorder Initialization

PROBLEM

During the Check-In process, after clicking **Check-In**, the message *Initializing Recorder* stays on and the message *Initialization is complete* does not appear.

SOLUTION

- Check the Connection Box connection to the mains and verify that the Connection Box LED is on.

- Check the Recorder data directory:

  - Verify that the Recorder data directory is E:\rdata.

  - Verify that the \rdata directory is a shared directory. Use Windows Explorer or My computer to do that. If it is not a shared directory, select the E:\rdata directory, right-click it and use the sharing sub-menu.

- Check the Connection Box-Workstation connection:

  - Verify that the LAN cable is properly connected.

  - Check the connection of the 9-pin female-female cable to the Workstation and to the Connection Box.

- Verify computer name:

My computer\properties\Network Identification\Full computer name=RAPID. If not, change to RAPID and restart the computer.

Data Recorder Operation

To check the Data Recorder operation, always verify that the Data Recorder LED blinks as soon as you connect it to the Battery Pack in the following blinking sequence:

The Data Recorder green LED blinks, turns on and then off. Once the recording starts the LED blinks at the receiving rate.

PROBLEM #1

The LED of the Data Recorder does not blink upon connecting the Battery Pack to the Data Recorder.

SOLUTION

- Change the Battery Pack. If the problem persists:

- Change the Data Recorder and repeat the Recorder Initialization process.

- Call technical support to report the faulty Data Recorder.

PROBLEM # 2

The Data Recorder LED does not blink while the M2A™
Capsule is held near the Sensor Array.

SOLUTION

1. Move the M2A™ Capsule away from the Sensor Array.

2. Disconnect the Battery Pack from the Data Recorder and
    then reconnect them.

3. Verify that the Data Recorder LED blinks and then turns
    off.

    If it blinks and then turns off, bring the M2A™
    Capsule close to the Sensor Array.

    > **If the Data Recorder LED blinks**, you may
    > proceed with the procedure of dispensing the
    > M2A™ Capsule.

    > **If the Data Recorder LED does not blink**, use
    > another M2A™ Capsule. **Be sure to dispose of the
    > first capsule as per the instructions in this
    > manual.**

    If the Data Recorder LED does not blink, change the
    Battery Pack.

    > **If the Data Recorder LED blinks upon Battery
    > Pack connection**, you may proceed with the
    > procedure of dispensing the M2A™ Capsule.

    > **If the problem persists:**

    >   • Change the Data Recorder and repeat the
    >   Recorder Initialization process.

- Call technical support to report the faulty Data recorder

PROBLEM #3

Data Recorder LED does not blink when the M2A™ Capsule is in the patient's mouth.

SOLUTION

1. Tell the patient to keep the Data Record belt on, and instruct the patient to take the M2A™ Capsule out of his/her mouth.

2. Hold the M2A™ Capsule next to a sensor attached to the patient's abdomen.

   If the LED blinks, ask the patient to ingest the Capsule.

   If not, replace the M2A™ Capsule and restart the M2A™ Capsule Dispensing procedure as described on page *84*. **Be sure to dispose of the first capsule as per the instructions in this manual.**

PROBLEM #4

The Data Recorder LED stops blinking during the examination and more than 6 hours have passed since the Capsule ingestion.

SOLUTION

A minimum of 6 hours is considered a successful examination. However, it is recommended to try and continue with the examination, and to check that the termination is not due to a connection fault or to a Battery Pack premature

depletion. (However, the belt must be worn in any event for a minimum of 8 hours.). To check the connection and the Battery Pack, perform the following:

- Battery Pack and Data Recorder Connection

    If there is a problem with the connection,

    1. Reconnect the Battery Pack to the Recorder

    2. Verify the blinking sequence of the Data Recorder LED:

    If the LED blinks upon Battery Pack connection and then blinks according to the rate of recording, continue with the examination.

    If the LED does not blink upon connection of the Battery Pack,, refer to Data Recorder Problem #1.

    If the LED blinks upon Battery Pack connection but does not start blinking according to the rate of recording with an active capsule, the capsule's battery is depleted. Consider completing the examination.

    If the connection is intact,

    1. Change Battery Pack.

    2. Verify the Data Recorder LED blinking sequence:

    If the LED blinks according to the sequence proceed with the examination.

    If the LED blinks upon Battery Pack connection but does not start blinking according to the rate of recording with an active capsule, the capsule's

battery is depleted. Consider completing the examination.

If the LED does not blink upon Battery Pack connection according to the blinking sequence, refer to Data Recorder Problem #1.

PROBLEM #5

The Data Recorder LED stops blinking during the examination and less than 6 hours have passed since the Capsule ingestion.

SOLUTION

- Tell the patient to keep the Data Record belt on, and heck the Battery Pack-Data Recorder connection.

  If there is a problem with the connection:

  1. Reconnect.

  2. Verify the blinking sequence of the Data Recorder LED:

     If the LED blinks upon Battery Pack connection and then blinks according to the rate of recording, continue with the examination.

     If the LED blinks upon Battery Pack connection but does not blink when receiving data, the M2A™ Capsule is defective.
     Reschedule for another examination at a different date after excretion of the M2A™ Capsule.

If the LED does not blink upon Battery Pack connection, refer to Data Recorder Problem #1. If problem persists, reschedule for another examination at a different date after excretion of the M2A™ Capsule, and contact Given® Imaging Limited technical support.

If connection is intact:

1. Change Battery Pack.

2. Check blinking sequence of the Data Recorder LED:

    If the blinking sequence is correct, proceed with the examination and discharge the patient.

    If the LED blinks, turns on and then off, but does not blink according to the receiving rate, reschedule for another examination at a different date after excretion of the M2A™ Capsule.

    If the LED does not blink upon Battery Pack connection, refer to Data Recorder Problem #1. If problem persists, reschedule for another examination at a different date after excretion of the M2A™ Capsule, and contact Given® Imaging Limited technical support.

Data Recorder Download

PROBLEM

The download does not start and the *Please Wait* message constantly appears.

SOLUTION

- Check the connection of the Connection Box to the electric socket and verify that the Connection Box LED is on.

- Check Data Recorder directory:

    - Verify that the Data Recorder directory is \rdata.

    - Verify that the \rdata directory is a shared directory. Use Windows Explorer or My computer.

- Check the Connection Box-Workstation connection:

    - Verify that the LAN cable is properly connected.

    - Check the connection of the 9-pin female cable to the Workstation and to the Connection Box.

    - If all above are OK and the problem persists, call Given® Diagnostic Imaging System technical support.

Sensor Array

Sensor Array Condition

PROBLEM

The Sensor Array you use is worn or torn.

SOLUTION

Use another Sensor Array supplied by Given® Imaging Limited. Do not use a torn or a worn Sensor Array.

Sensor Location

PROBLEM

You applied a sensor to the wrong location.

SOLUTION

1. Remove the sensor from its location.

2. Carefully, take the sensor out of the adhesive sleeve.

3. Insert the sensor in a new adhesive sleeve.

4. To secure the sensor in the adhesive sleeve, remove the liner from the adhesive area at the opening of the adhesive sleeve and press the two lips together.

5. Reapply to correct location.

M2A™ Capsule

PROBLEM

The M2A™ Capsule does not blink when removed from its blister.

SOLUTION

Replace the M2A™ Capsule with another M2A™ Capsule, and discard the defective capsule.

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