



M2A[®] Patency System

User Manual Rev. 1.0

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TRADEMARKS

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WARRANTY

Given® Imaging Limited warrants that the components of the Given M2A® Patency 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 Patency 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 merchantability or fitness.

FCC ID: O8PPATENCYSCANNER

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.

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 radio or television antenna.
- Increase the separation between the M2A Patency Scanner and receiver.
- Consult the dealer or an experienced radio/TV technician for help.



Note

Changes or modifications not expressly approved by Given Imaging Limited could void authority to operate the M2A® Patency System.



Caution

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

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Chapter One

Introduction

Introduction

The M2A Patency System is a simple and easy to use device for verifying the patency of the GI tract.

It may assist you in various situations such as the use of the M2A[®] Capsule in patients with suspected strictures.

The M2A Patency System consists of the following components:

- M2A Patency Capsule
- M2A Patency Scanner
- TesTag (interference tester)

Once the patient ingests the M2A Patency Capsule it is propelled through the GI tract by normal peristalsis. If after 2 days (48–72 hours) the M2A Patency Scanner does not detect a signal retransmitted by the capsule, it indicates the following:

- Patency of the GI tract
- The M2A Patency Capsule was excreted naturally

The M2A Patency Scanner is used to detect the presence of the M2A Patency Capsule.

If after 2 days (48–72 hours) the M2A Patency Scanner detects the M2A Patency Capsule in the GI tract, this may indicate some problems with the patency of the GI tract. Eventually, the capsule dissolves into small fragments and is naturally excreted.

About this Manual

This manual describes the M2A Patency System and instructs the user on how to use the system.

The manual is comprised of the following chapters:

Chapter 1: Introduction	Describes the conventions of the user manual and how to contact Given Imaging Ltd.
Chapter 2: M2A Patency System Overview	Describes the system, provides the indications and contraindications, and the system specifications.
Chapter 3: System Setup	Describes how to setup the system.
Chapter 4: Using the M2A Patency System	Describes how to use the system and perform the M2A Patency Examination.

Related Documents

For further information about other components of the M2A Patency System, refer to the following related documents:

- M2A[®] Patency Examination—Patient Instructions
- M2A[®] Patency Capsule Package Insert

Conventions

Convention	Explanation
Bulleted List	One step procedure or a list of items.
Numbered List	A multi step procedure. You need to perform the procedure step by step according to the order of the steps.
	Warning
	Note
	Caution

Contacting Given® Imaging

Information and Technical Support for the M2A Patency System are available from:

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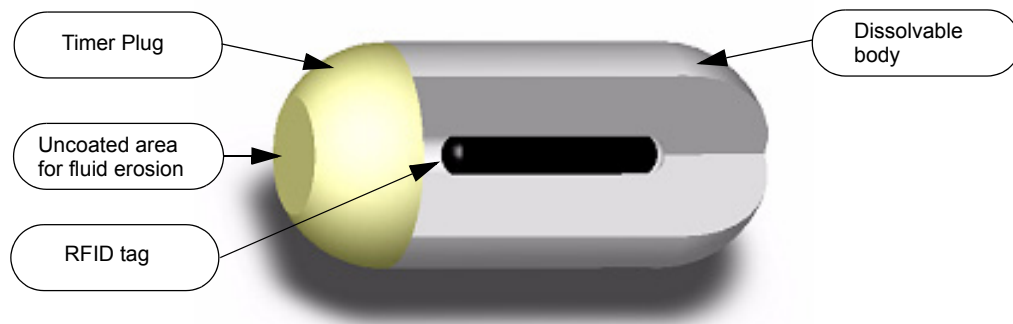
M2A[®] Patency System Overview

Overview

M2A Patency Capsule

The M2A Patency Capsule is an ingestible and dissolvable capsule comprised of a body that surrounds a small inner Radio Frequency Identification (RFID) tag. It is the same size of the M2A Capsule (26 mm long, 11 mm wide). The body is coated with an impermeable membrane, except for a small window on the Timer Plug.

The Timer plug seals the capsule's body. If the capsule is retained in the GI tract, the Timer Plug erodes, allowing the penetration of body fluids into the capsule and the dissolution of the body. The remaining fragments of the capsule can pass even small orifices.



The tag retransmits an RF signal once it is excited by an appropriate RF signal from the Patency Scanner. The latter detects the signal that indicates the presence of the capsule in the GI tract.

After ingestion, the M2A Patency Capsule is propelled by peristalsis through the gastrointestinal tract. Detection of an RF signal three days following ingestion means that the capsule is still retained in the GI tract. This may indicate a problem with the patency of the GI tract. In case the capsule is retained in the GI tract even longer, a disintegration process begins, to enable normal excretion of the resulting small fragments.

The M2A Patency Capsule acts through the following two phases:

Intact – This phase lasts for 80 hours. During this phase the capsule maintains its dimensions and rigidity while traveling through the various sections of the GI tract by peristalsis. The capsule withstands the various chemical and physical conditions of the GI tract. In most cases it is naturally excreted while still in the intact phase.

Disintegration – This phase occurs only after the capsule stays in the GI tract more than 80 hours. During this phase, first the timer plug erodes, followed by the body. The remaining parts are excreted naturally.

The M2A Patency Capsule is provided ready for ingestion in a hermetically sealed blister. Prior to ingestion, the physician tests the functionality of the capsule. The patient ingests the capsule immediately after testing.

For specifications and technical parameters of the M2A Patency Capsule, refer to [*Specifications*](#) on page 14.

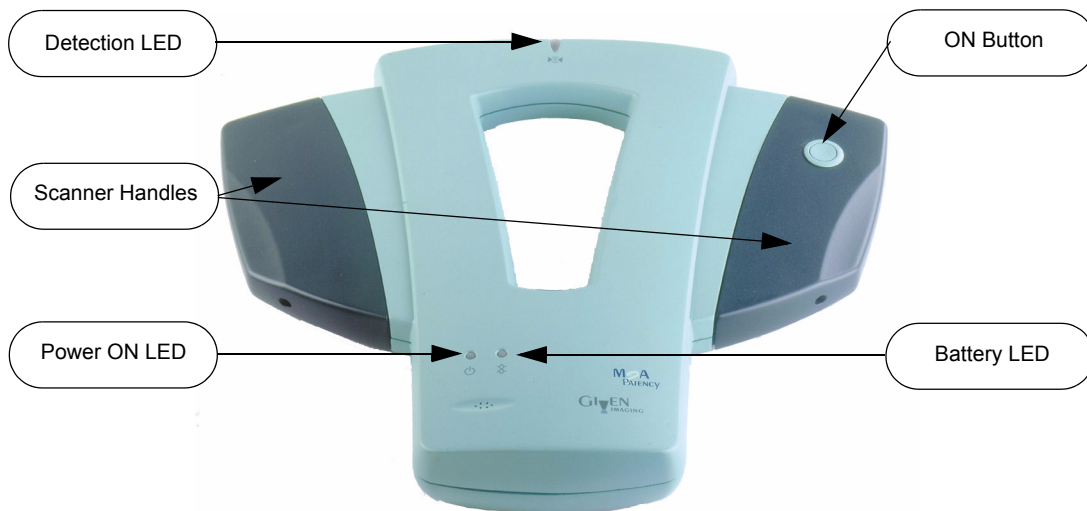
M2A Patency Scanner

The M2A Patency Scanner is an external transmitting/detecting unit that transmits and detects RF signals.

The M2A Patency Scanner is a hand-held, battery-operated device (eight 1.5v batteries) with a self-testing mechanism.

The Patency Scanner includes a processor, transmitter, receiver, an audible indicator and LEDs for indicating operation and detection of RF signal.

The Patency Scanner is used for transmitting the RF exciter signal to the Radio Frequency Identification (RFID) tag and for detecting the retransmitted signal from the tag.



TesTag

The TesTag is a plastic rod of 20 cm length. At one end it is equipped with an RFID tag similar to the one in the M2A Patency Capsules, at the other end a suction cap is attached.

The TesTag is used to verify the detection range of the Patency Scanner in a given environment.



Caution

Operating the Patency Scanner in the proximity of the following items might reduce the Scanner's range:

- **Operating monitors**—Use the Scanner at least 5 meters away from any operating monitors (Monitors in adjacent rooms should be turned off.).
- **Large metallic objects**—Use the Scanner at least 30 cm away from large metallic objects.
- **Electronic or magnetic cards/badges and remote controls**—Remove and put aside, at least 1 meter away, any electronic or magnetic cards/badges and remote controls which may contain RFID tags.

The TesTag tests the interference of the above within a given environment, and thus enables to select and validate the proper working environment for the M2A Patency Scanner.

A TesTag is supplied with each 10-Pak of M2A Patency Capsules.

M2A Patency Scanner Operation

When not in use, the Scanner is stored hanging on a hook installed in your office. For further information, refer to [Specifications](#) on page 14.

To turn on the Scanner, press the ON button. A self-test mechanism checks the functionality of the Scanner. The Power ON LED indicates that the Scanner is ready for use. The Scanner is ON for 30 seconds, during which it transmits and receives signals. The Scanner turns off automatically after 30 seconds, unless you press the button again, in which case a new cycle of 30 seconds begins.

In case you turn the Scanner on and its self-test mechanism detects a malfunction, the Power ON LED blinks in red for a few seconds and the Scanner automatically turns off. If the batteries are low, the Battery LED blinks shortly and the Scanner automatically turns off. In this case, change the batteries as described on [page 23](#).

Attach the TesTag to the indicated spot and press the ON button again. If the Scanner beeps, the environment is appropriate for the Scanner's operation and you can proceed using it in this environment. If the Scanner does not beep, repeat the test at a different location, until you find a location that does not interfere with the proper functioning of the Scanner. Alternatively, you can turn off all monitors within a 5 meters radius.

This test must be performed each time before using the Scanner to detect the presence of an M2A Patency Capsule.

For specifications and technical parameters of the M2A Patency Scanner, refer to [Specifications](#) on page 15.

Indications and Contraindications

Indications

The M2A[®] Patency System is intended to verify patency of the GI tract.

Contraindications

The M2A Patency Capsule is contraindicated for use:

- in patients with cardiac pacemakers or other implanted electromedical devices
- in patients with swallowing disorders



Note

The main component of the capsule is Lactose (less than xx gr).

Warnings

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

- A negative or normal result obtained by the capsule does not exclude the presence of pathology.
- A thorough understanding of the technical principles, clinical applications and risks associated with the Given M2A Patency 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 Patency Capsule, make sure the patient thoroughly understands the procedure, and provide the patient with a copy of the *Patient Instructions*.
- If there is reasonable doubt concerning the integrity of the M2A Patency Capsule, do not use it.
- Instruct the patient to avoid biting or scratching the M2A Patency Capsule. After ingestion, query the patient concerning the smoothness of ingestion. If there is any doubt about the patient biting the capsule or about the integrity of the capsule after ingestion, no conclusions may be drawn from this examination regarding the patency of the GI tract. The examination must be repeated after verification of the extraction of the ingested capsule.
- Do not use a M2A Patency Capsule after its expiration date.
- Make sure that the patient has not ingested any other capsule or other ingestible diagnostic device before ingestion of the M2A Patency Capsule.
- After ingesting the M2A Patency Capsule and until it is excreted, the patient must avoid being near any source of powerful electromagnetic fields such as one created near an MRI device.
- Instruct the patient to contact the physician immediately if any abdominal pain, nausea or vomiting is experienced after ingesting the M2A Patency Capsule. It should be noted that patients with tight strictures may experience a mild abdominal pain.
- Store the M2A Patency Capsule in a safe place out of the reach of children and infants.
- The safety of this device has not been established in pregnancy.
- The safety of this device in patients with significant gastrointestinal diverticular disease is unknown.
- This device has not been tested in pediatric population (children 18 and below) and safety in young children is unknown.

Cautions

A caution indicates a condition that may damage the equipment.

- Make sure that only trained personnel familiar with the M2A Patency Capsule and Scanner use them.
- Use the M2A Patency Capsule and Scanner only if purchased from Given® Imaging Ltd. Use of other components may void the warranty and may damage it.
- Use the Scanner away from operating computer monitors, any large metallic objects and electronic or magnetic cards/badges and remote controls that may contain similar RFID tags. Use the TesTag to check the functionality of the Scanner in the environment you intent to use it.
- To ensure proper function of the Scanner, make sure that:
 - The battery LED is off.
 - When using the Scanner, it is at least 5 meters away from any operating monitors and 30 cm away from metallic objects.
 - Use the TesTag before each examination to verify that the environment is free of interference.
 - When using the Scanner, place it near the abdominal wall and operate according to the instructions.

System Labeling

The following table lists the labels attached to various components of the Given[®] Patency System:

Labeling	Explanation
	The M2A [®] Patency System must be used at a distance from any powerful magnetic fields such as the one created by an MRI.
	The M2A Patency Capsule is intended for single use only.
	Attention! Consult the documentation provided with the M2A Patency System.
	Type BF equipment
FCC ID	O8PPATENCYSCANNER
	CE mark
	C-Tick mark
	CSA mark
	Lot number
	Indoors use only

Specifications



Note

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

M2A Patency Capsule

Physical Dimensions	Length: 26 mm, Diameter: 11 mm
Weight	3.3gr $\pm$ 0.2gr
Material	Biocompatible, food grade (mostly dissolving) components: Body: Lactose anhydrous Barium sulphate Magnesium stearate Citric acid Sodium bicarbonate Maltodextrin Plug: Maltodextrin Glyceryl Monostearate Carnauba Wax Polysorbate 20
Operating Time (period)	2–3 days
Shelf Life	12 months
Operating Temperature	35–45°C
Storage Conditions	15–25°C, dry and out of direct sunlight

M2A Patency Scanner

Transmission frequency	128 ± 3 KHz
Transmission time	30 Sec. 25% Duty Cycle
Read cycle	24 ms
Read Range	≤ 30 cm
Weight	2.3 Kg ± 0.2 Kg
General Dimensions	497 mm × 442 mm
Housing material	ABS + PC (CYCOLOY C2800)
Power supply	12 V, 8 AA 1.5V batteries
Average Current	200 mA
Battery type	Lithium L91 from Energizer (or equivalent from other manufacturers)
Max Operation time	Up to 600 ON cycles
Operating temp.	5–50°C
Storage temp.	0–30°C
Classification	Internally powered

System Setup

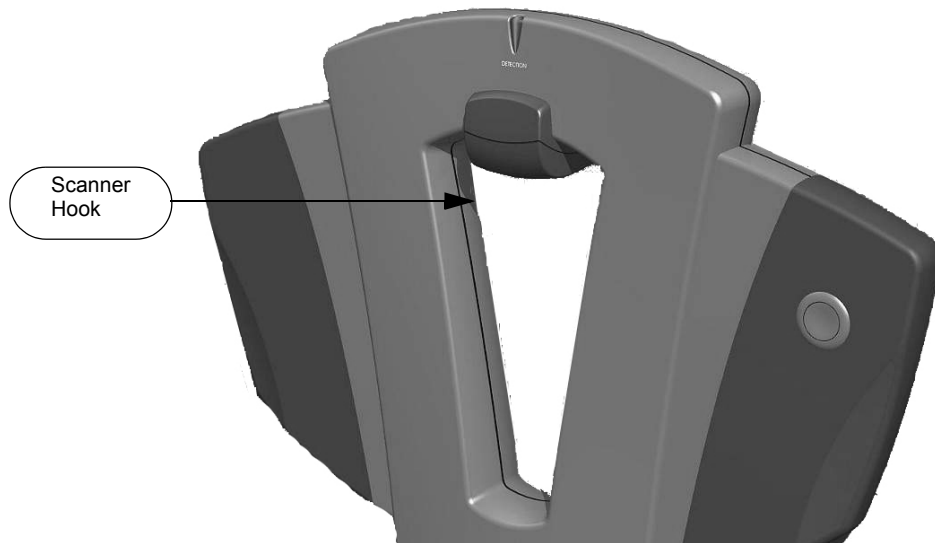
Before the System Arrives

Before the M2A Patency System arrives at your office, prepare the following:

- Storage place for the M2A Patency Capsule 10-Pak box.
- Space on the wall for hanging the Scanner away from any computer monitor and large metallic items.

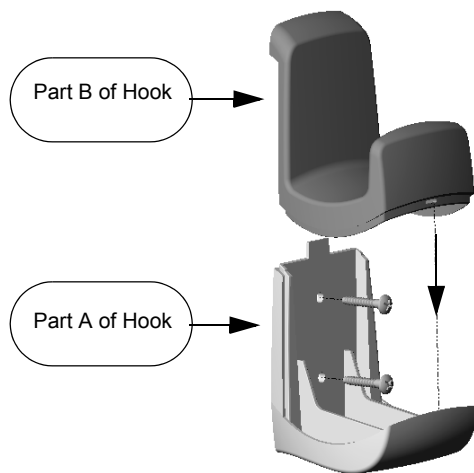
Hanging the Scanner

The Scanner is supplied with a hook to be attached to the wall with two screws. Prior or after using it, hang the Scanner on the hook.



Attaching the Hook to the Wall

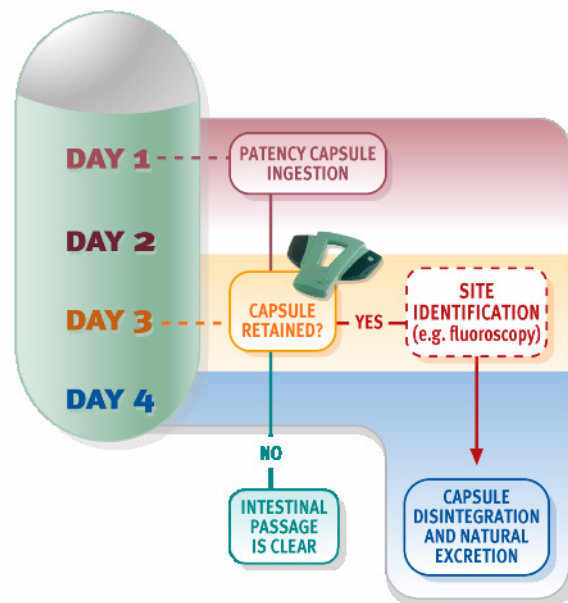
1. Select a location on the wall (approx. 40 x 40 cm) suitable for hanging the Scanner.
2. Mark required holes using Part A as a template.
3. Drill two holes.
4. Secure part A of the hook to the wall.
5. Mount part B on top of part A.



Using the M2A[®] Patency System

Overview

On the first day of the M2A Patency Examination, the patient ingests the M2A Patency Capsule. Two days later (48–72 hours), the patient returns to the clinic to check whether or not the M2A Patency Capsule was retained. If the Scanner does not detect the Capsule, the GI tract is patent. If the capsule is retained and the Scanner detects it, the physician may consider performing a fluoroscopy or X-ray the same day, in order to locate the capsule. Eventually, the capsule disintegrates into small fragments and is naturally excreted.



The M2A Patency Examination includes the following:

- Preparing the patient
- Preparing the system components
- Detection/functionality test
- Dispensing the capsule
- Releasing the patient
- Interference testing
- Scanning of the abdominal area with the Scanner

Preparing the Patient

Once it is decided that the patient should undergo M2A Patency Examination, verify that the patient does not have any contraindications and obtain the patient's informed consent.

Inform the patient that the M2A Patency examination involves the following:

- Ingesting the M2A Patency Capsule. The capsule will pass naturally through the patient's digestive system.
- Recording the time of bowel movements following the ingestion of the M2A Patency Capsule.
- Returning to your office after 2 days (48–72 hours) to check whether capsule was excreted.
- If required, undergoing an X-ray or fluoroscopy to detect the location of the M2A Patency Capsule or RFID tag.

Inform the patient in writing and verbally that the following is required to achieve accurate results:

A week before M2A Patency Examination

- During check-in, the patient will be asked about the pattern of his/her bowel movements. Therefore, it is important to make note of the frequency of the bowel movements about a week before the examination.
- The patient must prepare a list of currently taken medication.
- After lunch one day before the examination, the patient must start a liquid diet prescribed by the physician. From 10 p.m. on, the patient is to abstain from eating or drinking except for necessary medication with a sip of water.

- The patient is expected to abstain from smoking 24 hours before the examination.

The day of M2A Patency Examination

- The patient should not take any medication as of two hours before the examination.
- When arriving at the clinic, the patient is asked to give his/her informed consent and to go through the patient check-in procedure.

After Ingestion

- The patient may continue with his/her regular eating habits.
- The patient must immediately contact the physician's office, if any abdominal pain, nausea or vomiting occur.
- The patient must fill in the Bowel Movement Activity Form in the Patient Instructions booklet until instructed by the physician to discontinue due to capsule excretion.
- After 2 days (48–72 hours), the patient returns to the office to check whether the M2A Patency Capsule was excreted.
- Undergoing an MRI while the capsule is inside the patient's body may result in serious damage to the intestinal tract or abdominal cavity. If the excretion of the M2A Patency Capsule was not positively verified, the patient must contact the physician for evaluation and possible abdominal X-ray before undergoing an MRI examination.



Note

Before the patient leaves the clinic, verify that:

- the ingestion was smooth and the coating of the M2A Patency Capsule was not compromised by the patient's teeth
- the patient has given his/her informed consent
- the patient has the Patient Instructions and a new appointment for 2 days (48–72 hours) later.

Preparing for the Examination

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

- M2A Patency Capsule
- M2A Patency Scanner
- TesTag
- Glass of water

Preparing the Scanner

If this is the first time you are using the Scanner, place 8 batteries in their bay. Beware of the correct polarity.

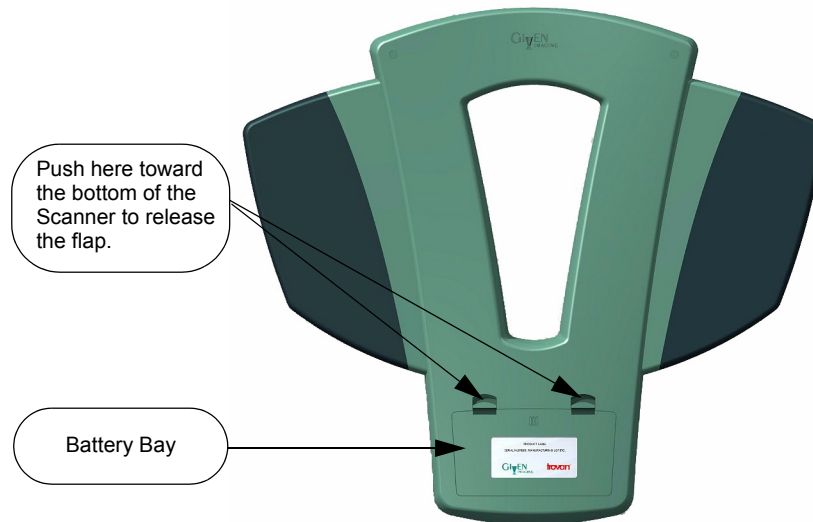


Note

It is recommended to use 1.5v lithium L91 energizer batteries. Other batteries last for less time and may leak and damage the Scanner.

To place the batteries in the Scanner

1. Open the battery bay by pushing the flaps toward the bottom of the Scanner.



2. Insert 1.5V batteries into the battery bay according to the sketch inside.
3. Verify that you placed the batteries according to the correct polarity and that the batteries are fully seated in their place.
4. Close the battery bay and make sure the flap is closed and secured by its clasps.



Note

It is recommended to remove the batteries when you know that you are not going to use the M2A Patency Scanner for a long period of time.

Testing the Environment for Interference



Caution

Operating the Scanner in the proximity of the following items might reduce the Scanner's detection range:

- **Operating monitors** - Use the Scanner at least 5 meters away from any operating monitors (Monitors in adjacent rooms, should be turned off.)
- **Large Metallic objects** - Use the Scanner at least 30 cm away from large metallic objects.
- **Electronic or Magnetic cards/badges and Remote Controls** - Remove and put aside, at least 1 meter away, any electronic or magnetic cards/badges and remote controls which may contain RFID tags.

Use the TesTag to test the Scanner's functionality in the room you are planning to work with it. In case of doubt, move to another room and repeat the test.

1. Take the Scanner off its hook.
2. Attach the suction cap of the tester to the designated spot on the Scanner.

3. Hold the Scanner by its handles, with the TesTag pointing forwards.

4. Press the Power button and make sure that:

- The Power LED is ON.

If the Power LED turns on, blinks in red for 5 seconds and the Scanner turns off, the Scanner is faulty.

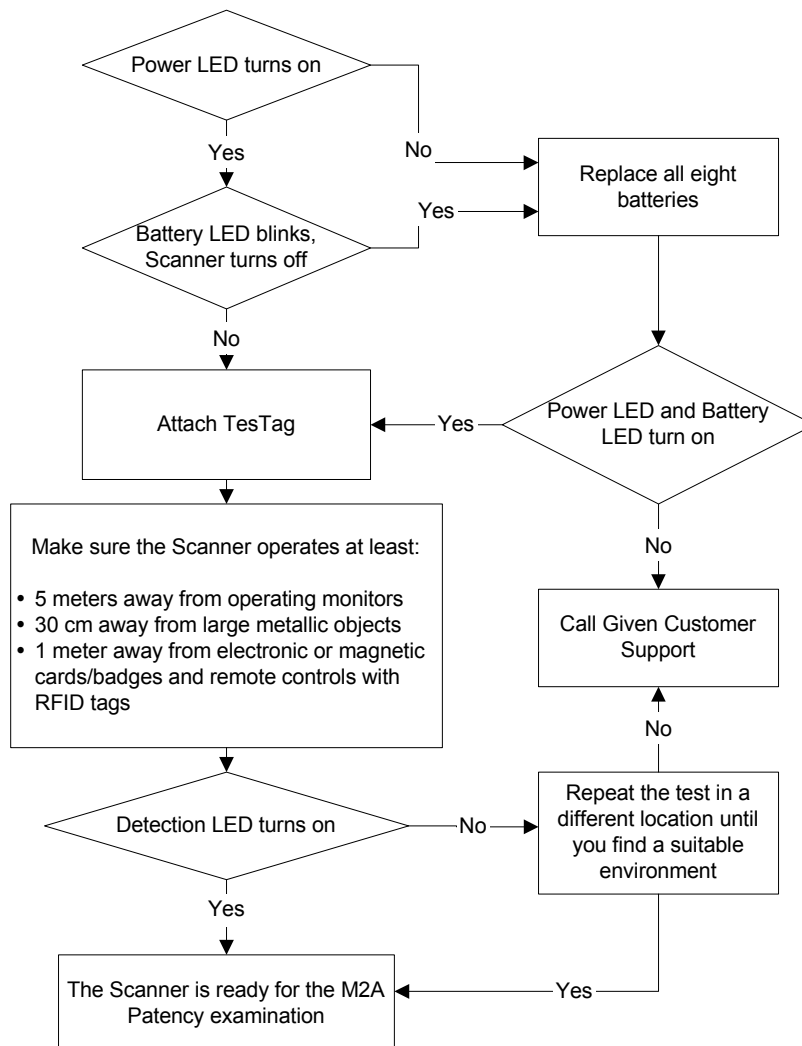
- The Battery LED is off.

If the Battery LED turns on, blinks for 5 seconds and the Scanner turns off, replace batteries.

5. If the blue Detection LED turns on, the Scanner operates correctly in this environment.

If the blue Detection LED does not turn on, repeat the test at a different location, until you find a location that does not interfere with the proper functioning of the Scanner.

Testing for Interference



Checking-In a Patient

Make sure the patient has followed the preparation instructions, as discussed on [page 20](#). During this procedure we recommend to obtain and retain the following information:

- Patient data – First and Last name, ID number, and physique (Thin, Normal, Stocky or Protuberant Abdomen).
- Bowel movement regularities
 - How often does the patient have a bowel movement:
At least once a day
At least once every 2 days
At least once every 3 or more days.
- Bowel movement irregularities - Any irregularities in the last week prior to the ingestion.

Dispensing the Patency Capsule

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



Note

Read the Indications, Warnings and Cautions in the Package Insert of the Patency Capsule or in Chapter Two prior to dispensing the M2A Patency Capsule.



Caution

During the following procedure you perform a detection test. Failure to carefully observe the following steps may adversely affect the examination.

1. Take an M2A Patency Capsule out of the 10-Pak box and place it in its blister on a table, at least 1 meter away from all other capsules. Make sure the table is not made of metal.

2. Take the Scanner off the hook and turn it on.
3. Hold the Scanner by its handles with its back facing the capsule, bring it near the capsule, (up to 20 cm) and test detection.

If the Detection LED does not turn on, take another M2A Patency Capsule and repeat step 3. If the Scanner detects the new capsule, write down on the back label of the faulty capsule the date and return it to its box. If the Scanner does not detect the second capsule either, contact Given Customer Support.
4. If the capsule is detected, return Scanner to its hook and open the blister carefully.
5. Ask the patient to take the capsule out of its blister.
6. Ask the patient to put the capsule in his/her mouth and to hold it under the tongue WITHOUT INGESTING. Instruct the patient not to bite the capsule.
7. After a short adjustment period, with the capsule in the patient's mouth, ask the patient to ingest the capsule with a sip of water.
8. In the Patient Instructions booklet, write down the ingestion time of the capsule.
9. Ask the patient about the smoothness of the ingestion. If there is any doubt about the patient biting the capsule or about the integrity of the capsule after ingestion write it down in the Patient Instructions booklet.

No conclusions may be drawn from this examination regarding the patency of the GI tract. The examination will have to be repeated after verification of the extraction of the ingested capsule.



Note

If for any reason, after taking the capsule out of its blister, the patient does not ingest it, or if for some reason you suspect that the capsule is defective, return the capsule to its blister, mark on the back label the date and contact Given Customer Support.

Releasing the Patient

Once the patient has ingested the M2A Patency Capsule, the patient may leave the office. Verify that the patient knows how to fill in the Bowel Movement Activity Form in the Patient Instructions booklet.

To discharge the patient

1. Verify that the patient has the Patient Instructions.
2. Schedule another appointment for 2 days later (minimum 48 hours) to check whether the capsule is retained or excreted.



Note

It is important to perform the test 2 whole days (48–72 hours) after ingestion.

3. In the Patient Instructions, fill in the relevant information and instructions, i.e. who to contact in case of emergency and the following appointment.
4. Release the patient.

Checking Whether Capsule is Retained

The patient returns to your office after 2 days with the Bowel Movement Activity Form to assess whether capsule is retained in the GI tract.

1. Attach the TesTag and perform the test as described on [page 24](#).
2. Ask the patient to hand in the Bowel Movement Activity Form and check the patient's bowel movement log to verify regular bowel movements.
3. Ask the patient to put aside all items with RFID and verify that you are not carrying any such items.



Note

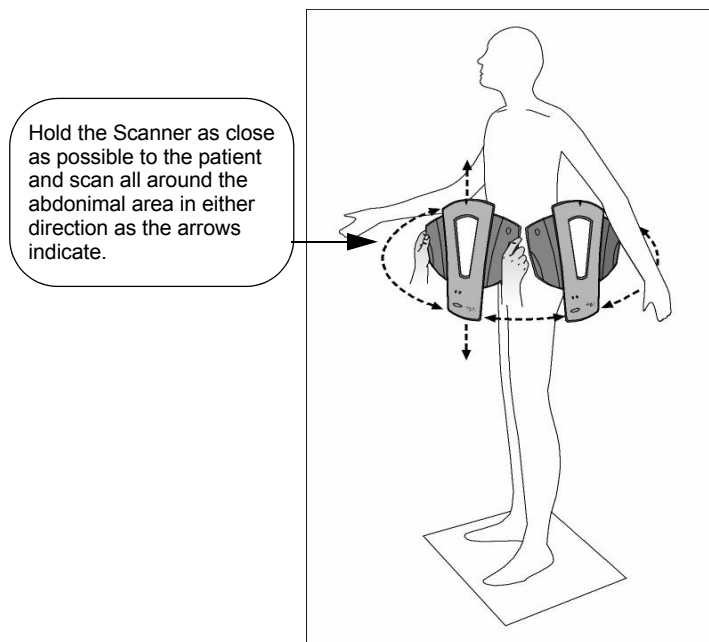
Some personal items contain RFID tags, which may lower the reading range (i.e. car remote control, electronic and magnetic cards/badges).

4. Ask the patient to take off heavy clothes such as jackets, coats or sweaters.
5. Ask the patient to stand up.
6. Take Scanner off the hook.
7. Verify that the Scanner is at least 5 meters away from an operating monitor (monitor in adjacent rooms should be turned off) or any metallic objects and turn it on.
8. Verify the following:
Power On LED is on.
Battery LED is off.
9. While the back of the Scanner faces the patient, bring the Scanner close to the patient and scan his/her abdomen by moving the Scanner up and down and sideways.
If capsule is not detected scan also the patient's back and flanks by moving the Scanner up and down and sideways.

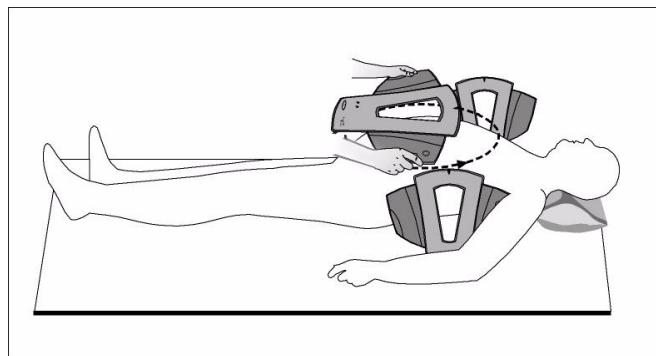


Note

Maximum receiving is at the handles of the Scanner. To use the maximum reading range, move the Scanner along the required scanning area including the handles of the Scanner.



In case the patient has a protuberant abdomen, ask the patient to lie down and scan the abdomen cavity front and back. Make sure the patient does not lie down on a metal table.



In case the patient is very large and the Scanner did not pick up a signal, it may be indicated to perform an X-ray to make sure the capsule has left the body.



Note

If the test lasts longer than 30 seconds, the Scanner turns off automatically. Press the ON button again to resume the operation of the Scanner.

- 10.** At the end of the M2A Patency Examination, discuss the outcome with the patient.

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