

The label on the side of the M2A™ 10-Pak is as follows:



The sealing blister on each Capsule also contains the following label to ensure that the Capsule is not removed from its packaging – and thereby activated – except in the moment before the Capsule is ingested.



TECHNICAL SPECIFICATIONS GIVEN® DIAGNOSTIC IMAGING SYSTEM

M2A™ CAPSULE

Physical Properties

Dimensions:

Length:	26 mm
Diameter:	11 mm
Weight:	3.7 gr
Material:	Biocompatible plastic

Optical Properties

Illumination:	4 white light emitting diodes
Field of view:	140°
Effective Visibility Distance:	3 cm
Magnification:	1:8
Min. Detectable Object:	less than 0.1 mm

Operational properties

Sampling Rate:	2 fps
Operating Time:	7-8 hours
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 - 45°C
Storage Temperature:	0 - 50°C

DATA RECORDER

Software:	Proprietary Firmware
Recording time:	Up to 10 hours
Weight:	305 gr
Battery type:	External, Nickel-Metal, 6V, 6500 mAH
Battery pack weight:	912 gr
Sensor Array:	8 flat 40 mm diameter flexible PCB
Operating Temperature:	5 - 50°C
Storage Temperature:	-40 - 70°C

Waist Belt

Belt Performance:	Shielding 7-10dB (measured in phantom)
Fabric:	Inner layer of Shieldex® Supra fabric
	Shielding more than 80dB @ 432-434MHz

RAPID™ APPLICATION SOFTWARE

Software:	RAPID™ proprietary
Languages:	EN/FR/GM/IT/SP
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

RAPID™ WORKSTATION

Hardware:	Custom DELL Workstation
Operating system:	WIN 2000
Data memory capacity:	20 GB
Memory type:	Internal disk
Regulatory and standards	FCC/FDA/MDD, CSA, CE

INDEX OF ATTACHMENTS

EMC Emission Report

Appendix A
Lab Reports

User's Manual

Patient Instructions

Package Insert

Sales and Use Projections Letter