# *Given Imaging Ltd.*

## EMC EMISSION REPORT

# Evaluation of the electromagnetic emission of the *Given® Video Capsule*

**January 2001**

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# 1.0 INTRODUCTION

## 1.1 GENERAL INFORMATION

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## 1.2 BACKGROUND

This report summarizes the results of the study of the ***Given® Video Capsule*** for compliance with FCC Part 15 Subpart C, § 15.209 and Part 15 Subpart B, § 15.109.

The Given capsule is part of ***Given® Diagnostic Imaging System***, developed and manufactured by Given Imaging Ltd. The system is designed to aid gastroenterologists in diagnosing small bowel diseases. The system is essentially based on the technology of swallowable devices, which have been marketed for many years, and video imaging which has also been utilized in medicine for quite some time. The ***Given® Diagnostic Imaging System*** merges these existing technologies into a miniaturized video system for acquiring images of the small bowel.

The testing was conducted at Hermon Laboratories Ltd. (Binyamina, Israel). The laboratory is accredited by American Association for Laboratory Accreditation (USA) according to ISO GUIDE 25/EN 45001 for EMC, Telecommunications and Product Safety Information Technology Equipment (Certificate No. 839.01). Dr. E. Usoskin, C.E.O. of Hermon Laboratories, approved the test reports.

# 2.0 PURPOSE

The purpose of this study was to verify that the Given capsule complies with the requirements of the applicable parts of the FCC Rules, including:

1. Field strength of emission according to § 15.209(a) for the EUT (Equipment Under Test) while located inside human body, Recorder belt worn.

2. Radiated emissions from the incorporated digital device caused by the Given Capsule, and also to verify compliance with §§ 15.109, 15.209.

## 3.0 SPECIFICATION REFERENCES

| | |
|---|---|
| 47 CFR Part 15: October 1999 | Radio Frequency Devices. |
| ANSI C63.2:06/1996 | American National Standard for Instrumentation-Electromagnetic Noise and Field Strength, 10 KHz to 40 GHz – Specifications. |
| ANSI C63.4:1992 | American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz. |

## 4.0 TEST ARTICLE

The equipment tested in this study (EUT) is a low power image transmitter enclosed in a capsule and intended for gastrointestinal imaging. The transmitter operates at a frequency in the 432-434 MHz range (either 432.13 or 433.94 MHz) with MSK modulation and is powered by two 1.5V internal batteries.

The EUT is part of the Given Diagnostic Imaging System, which is comprised of three subsystems (Figure 1):

A. The EUT: a disposable, swallowable capsule that acquires the video images during natural propulsion through the digestive system. The capsule transmits the acquired images via digital RF communication to the Data receiving/recording system located outside the body.

B. An external portable data receiving/recording unit worn in a waist belt that receives the data transmitted by the capsule. The portable data receiving/recording unit consists of an antenna array carried in proximity to the body, a receiver, and a memory medium for accumulation of the data during the examination. The waist belt also contains shielding that ensures

that the Capsule, when ingested and moving through the body, remains within the limits of the FCC rules.

C. A standard workstation, which is used for the off-line storage, interpretation and analysis of the acquired data.

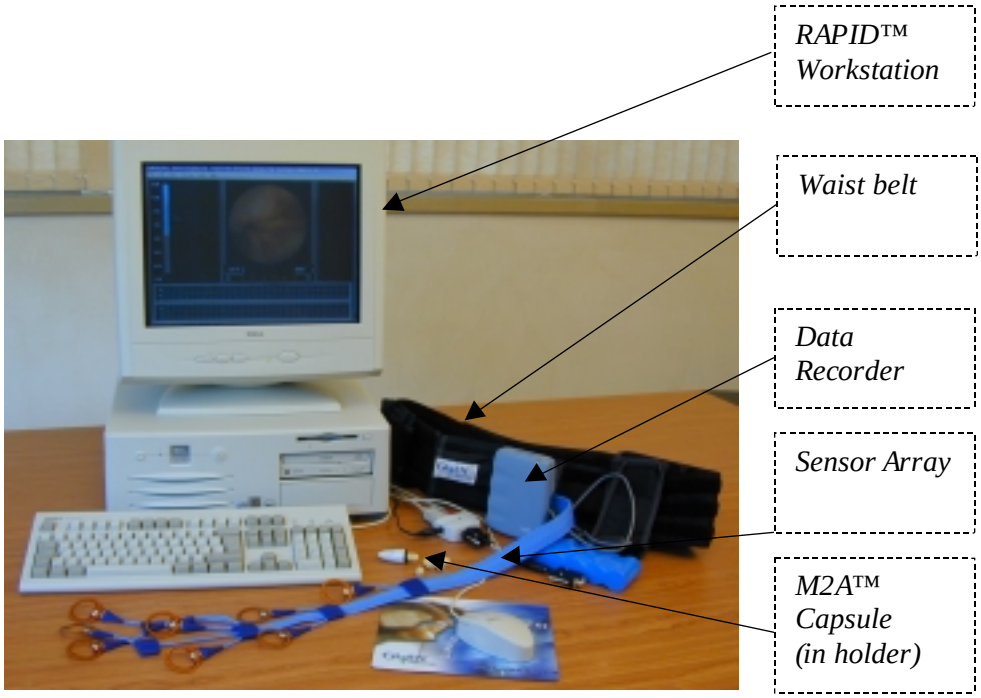


**Figure 1. Given Diagnostic Imaging System.**

# 5.0 TEST OBJECTIVE

## 5.1 OBJECTIVE

The main performance objective of the study was to measure the radiated emission from the capsule and to verify that it is within the permitted standard levels required by the FCC. A total of 4 subjects were tested in this study.

## 5.2 OPERATIONAL SEQUENCE

During the normal test procedure, the sensor array is attached to the patient's body, and the Data Recorder is attached on the Waist belt worn around the patient's abdomen (see Manual for more detailed description).

The Capsule is then taken out of the blister package, which contains a magnet, thereby activating the Capsule by an internal magnetic reed switch. After validation of the Capsule operation (Capsule illumination lights blinking, and Recorder receiving indicator blinking correspondingly), the Capsule is swallowed by the patient, starting natural passage through the digestive system.

Time between activation of the Capsule and swallowing under normal circumstances does not exceed 1 minute.

The Capsule passes through the esophagus (passage time of 2-3 seconds), and enters the stomach.

The Capsule resides in the stomach for about 1 hour (range 15 min – 3 hours), and then enters the small intestine.

Small intestine passage time is about 3 hours (range 2 – 4 hours). After passage through the small intestine the capsule enters the large intestine, and is naturally excreted, completing the process.

The total passage time of the capsule through the digestive tract is on average 24 hours (range of 12 hours – 72 hours).

The Capsule operation time is 7-8 hours. Therefore, the Capsule is no longer actively transmitting when it is excreted from the body. Because active transmission occurs only while the Capsule is within the body (apart from the momentary delay between opening the package and swallowing the Capsule), the Company believes that the appropriate test environment is use of the Capsule within the body.

In order to minimize emissions from the Capsule while it is in the body, a special shielding layer was inserted in the Waist belt, which is worn throughout the entire duration of the Capsule's active transmission mode - Table 1. Additional information regarding tests of the Waist belt with a phantom is in Appendix A.

| Location of the capsule | Capsule operational mode | Typical time | Shielded by Waist belt |
|---|---|---|---|
| Storage | Not operational | N/A | N/A |
| In the open air (package opened) | Operational | Less than 1 min. | No |

| | | | |
|---|---|---|---|
| In the body<br>- mouth<br>- esophagus<br>- stomach<br>- small intestine<br>- large intestine | Operational<br>Operational<br>Operational<br>Operational<br>Not operational after 7-8 hours (after initial activation) | Several seconds<br>2-3 seconds<br>1 hour<br>3 hours<br>20 hours | No<br>Partially<br>Yes<br>Yes<br>Yes |
| Excreted | Not operational | N/A | N/A |

Table 1. Summary of the Capsule operational sequence.

## 6.0 METHODS AND PROCEDURES

The study procedure included 2 principal tests:

1. Measurements of field strength of emission for EUT located inside the human body while subject wore a Waist belt;

2. Measuring of radiated emissions from the incorporated digital device and verification that the EUT complies with the FCC limits.

A secondary measurement was also taken of the field strength of emission in open space. This was not a primary endpoint of the study because the capsule will only actively transmit in open space for a brief period after the package is opened and before the patient swallows the device, an interval of less than one minute during which the physician tests the capsule to ensure that it is functioning.

After measuring the radiated emission of the capsule in open space, the testing procedure began and the subjects were requested to swallow the capsule.

The measurements started approximately 10 minutes after swallowing in order to ensure that the capsule was in place and that no side effects were recorded. The total duration of the procedure was about 2 hours. It was important to perform the inside-body measurements for as long a period as possible, with several repetitions, to permit evaluation of possible differences within the same test caused by the capsule's passage through the intestine.

During this test, subjects were sitting on the wooden turntable, as shown in Figure 2. The EUT was operated in continuous transmitting mode. The frequency range was investigated with a biconilog antenna from 30 MHz to the 5$^{th}$ harmonic only.

To find maximum radiation, the turntable was rotated 360°, the measuring antenna height was changed from 1 to 4 m, and the antenna polarization was changed from vertical to horizontal. Peak and quasi-peak detectors were used.

*Section 15.31 test procedures*: Tests of the EUT satisfies the requirement in 47 C.F.R. § 15.31(a)(6) that intentional radiators be tested under ANSI C63.4-1992 (C63.4) procedures. In that the EUT is a portable, small, lightweight device intended to be ingested and operated almost exclusively inside a human body, the on-site testing provisions of Section 8.3.2 of C63.4 and Section 15.31(d) of the Rules were used to demonstrate compliance, including use of a non-conducting platform, except that instead of testing at three different locations, the EUT was tested inside at least three different humans and inside a phantom. The procedure met the criteria in C63.4 for both tests using a phantom and tests using humans as follows:

(A) The testing using the phantom included at least three human subjects (actually, as indicated below, four were used) and met the C63.4 requirements of (i) conducting at least four scans at the same test distance where emissions were maximized by rotating the humans and phantom, (ii) raising and lowering the measurement antenna between 1 and 3 meters (as noted above, the antenna was actually raised between 1 and 4 meters), and (iii) measuring each emission with both horizontal and vertical polarization of the measurement antenna. The results obtained from the human testing (with shielded belt) contained in this report, and those obtained from the phantom (with shielded belt) as set forth in the Appendix to this report, all of which are based on measurements taken from an open area test site (OATS) at the limit distance while maximizing the fundamental and all harmonic emissions in accordance with C63.4, are comparable.

(B) Testing using at least three human subjects yielded results for the fundamental and all harmonic emissions measured while the EUT was inside each, with each emission being measured on an OATS at the limit distance. As indicated, each emission was maximized by rotating the human subjects, raising and lowering the measurement antenna between 1 and 3 meters, and measuring each emission with both horizontal and vertical polarization of the measurement antenna.

A description of each test and its results is presented below.

## 7.0 RESULTS

The test measurements of emissions from the capsule while inside the body are detailed in Table 2, and one example is shown in Figure 3.

## 7.1 MEASUREMENTS INSIDE THE BODY

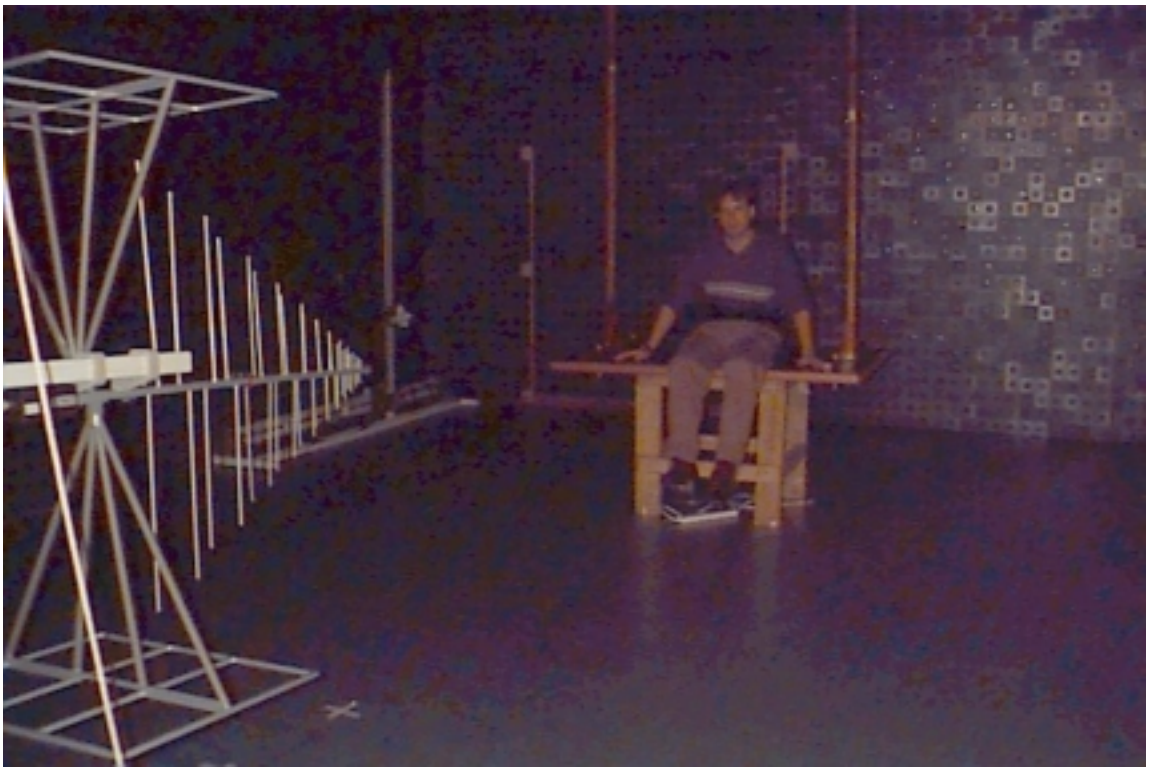

**Figure 2. Radiated Emission Test Setup**

| EUT | Initials | Frequency | Radiated Emission dB(µV/m) | Margin Below FCC Limit dB |
|---|---|---|---|---|
| 158 | SGA | 432.2 | 34.1 | 11.9 |
| 157 | OKO | 432.1 | 39.4 | 6.6 |
| 156 | MFR | 432.1 | 37.9 | 8.1 |
| FE7 | DGA | 434.0 | 39.9 | 6.1 |

**Table 2: Radiated Emission Measurements Test Results (EUT Inside Human Body, Wearing the Waist Belt)**

As can be seen from the table, all test measurements were well below the applicable limit of 46 dB. The range of observed radiated emission was from 34.1 dB up to 39.9 dB. The average maximum value of all reported observations was 37.8 dB, which is 8.2 dB below the limit.

Most of the subjects were tested twice, with a one-hour interval between the end of the first measurement and the start of the second, in order to find any significant changes that could indicate radiated emission changes during the procedure. No such changes were found.

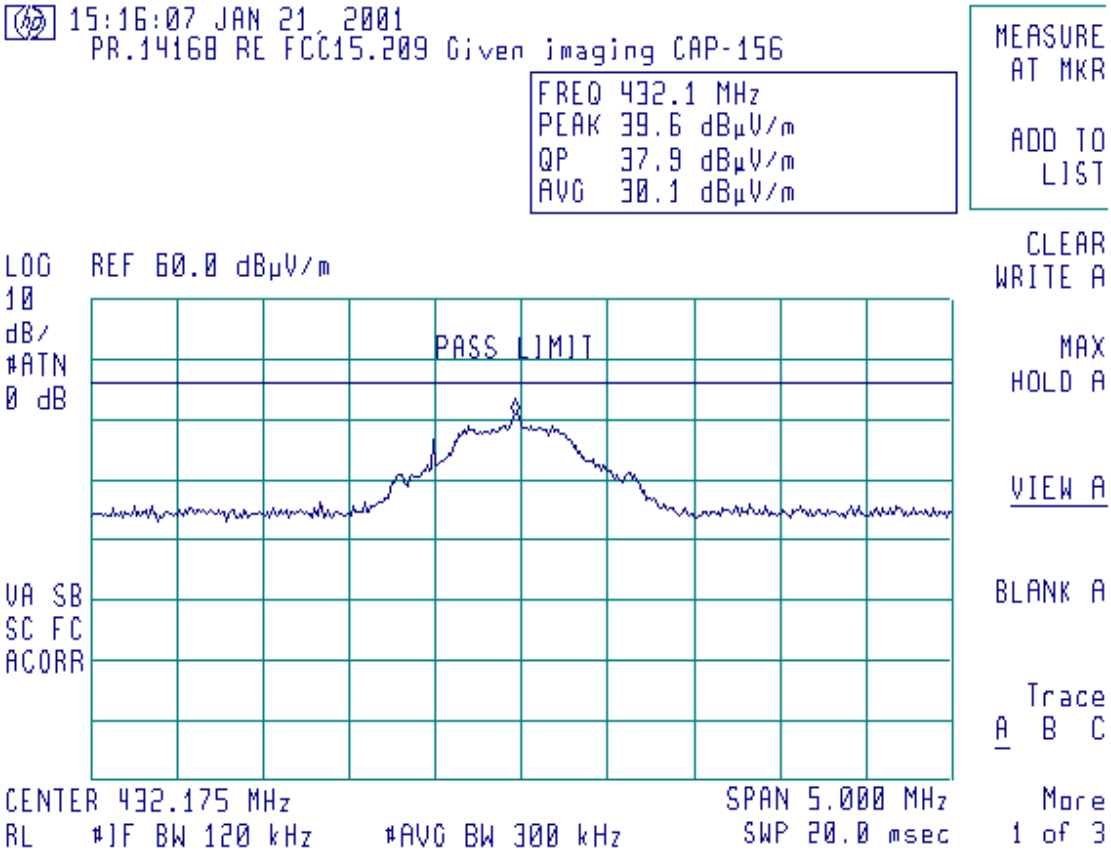


**Figure 3. Sample of**
**Carrier Frequency Measurements**

Copies of the lab report for each of the subjects are provided with this summary.

## 7.2 MEASUREMENTS IN OPEN SPACE

In addition to measuring emissions from the capsule while inside the body, an open space capsule measurement was performed as shown in Figure 4, according to FCC Part 15 Subpart C §15.209. As noted above, however, in practical use, the capsule will be operating outside the body for less than a minute (just the time period from opening the wrapping on the capsule and checking it to ensure that it is operational to when it is swallowed). Thus, these measurements are not representative of the typical emissions from the capsule in clinical use.

All the listed results were obtained throughout the testing with a quasi-peak detector, resolution bandwidth=120 kHz, and biconilog antenna in vertical polarization @ 1 meter height.

Margins=dB below (negative if above) specification limit (46 dB).

The test measurement results are listed in Table 3.

MEASUREMENTS PERFORMED AT 3 METER DISTANCE

| EUT | Frequency MHz | Radiated emission dB(µV/m) | Margin Above FCC Limit dB |
|---|---|---|---|
| 158 | 432.1 | 55.7 | 9.7 |
| 157 | 432.1 | 53.6 | 7.6 |
| 156 | 432.1 | 54.7 | 8.7 |
| FE7 | 434.0 | 54.7 | 8.7 |

**Table 3. Radiation Emission Measurements Test Results (EUT in Open Space)**

As anticipated and shown in the table, all the measurements exceeded the limit of 46 dB during open space tests, with emissions ranging from 53.6-55.7dB. However, the expected higher duration of these emission levels outside the body is less than a minute, as noted above. The user manual and instructions all inform physicians that testing the Capsule should take less than one minute, and all Capsules will be given by trained physicians.

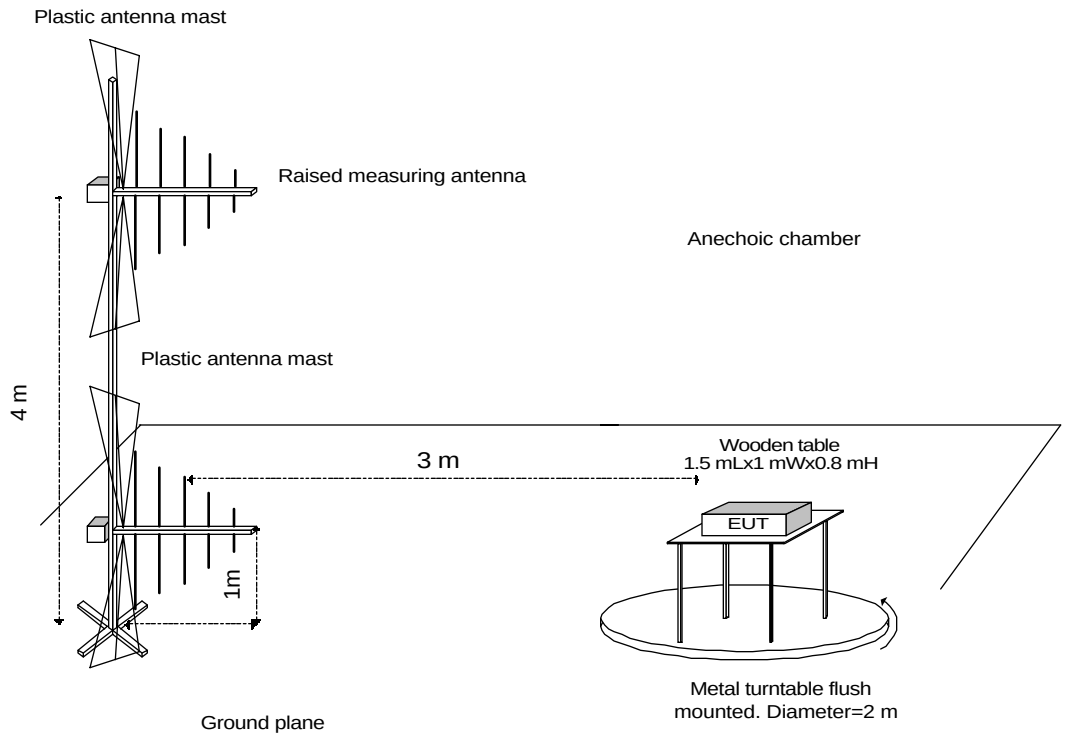


**Figure 4.**
**Radiated Emission Test Setup**

## 7.3 UNINTENTIONAL RADIATED EMISSIONS TEST

This test was performed in order to measure radiated emission from the incorporated digital device of the EUT and to verify the transmitter's compliance with §15.109 and §15.209.

The radiated emissions measurements of the capsule's incorporated digital device were performed in the anechoic chamber at 3 meters measuring distance in the frequency range of 30 MHz to 5 GHz. The EUT was placed on the wooden table as shown in Figures 3-5. The biconilog antenna was used.

To find maximum radiation, the turntable was rotated 360°, the measuring antenna height was changed from 1 to 4 m, and the antenna polarization was changed from vertical to horizontal. The measurements were performed with EMI receiver setting: RBW=120 kHz, peak and quasi peak detectors.

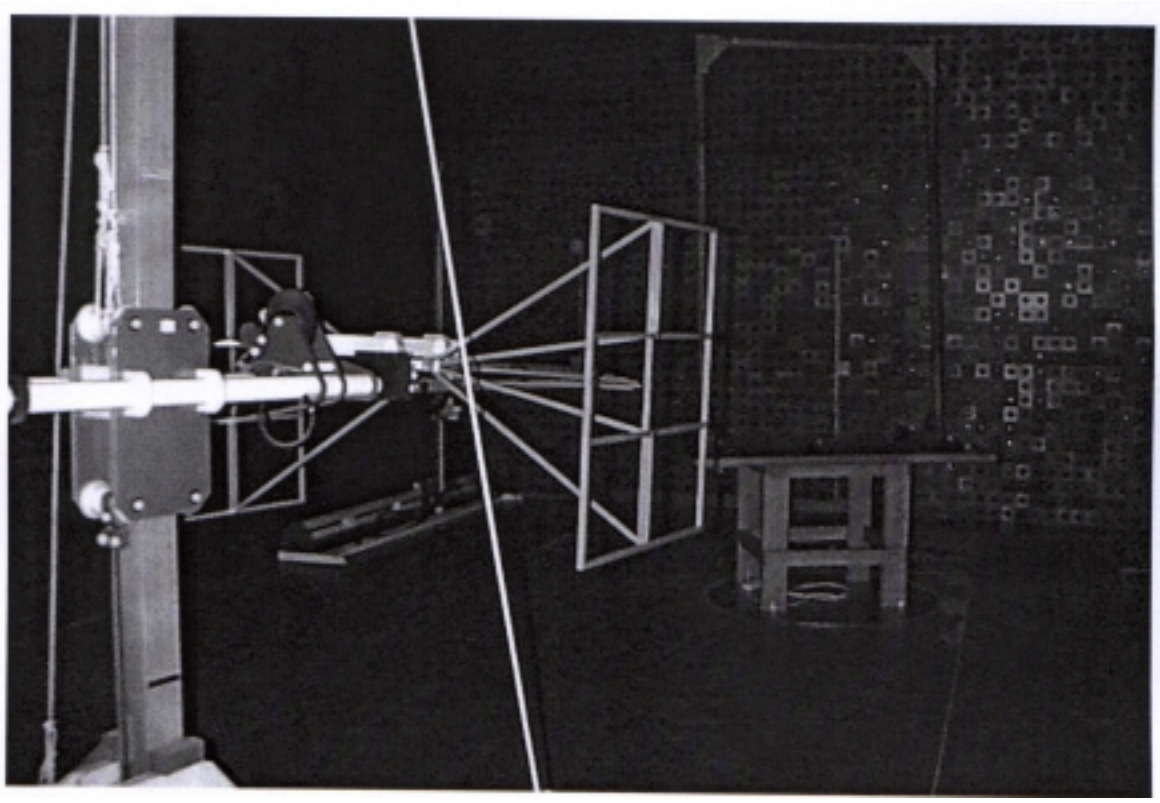

**FIGURE 5. UNINTENTIONAL RADIATED**
**Emission Test Setup**

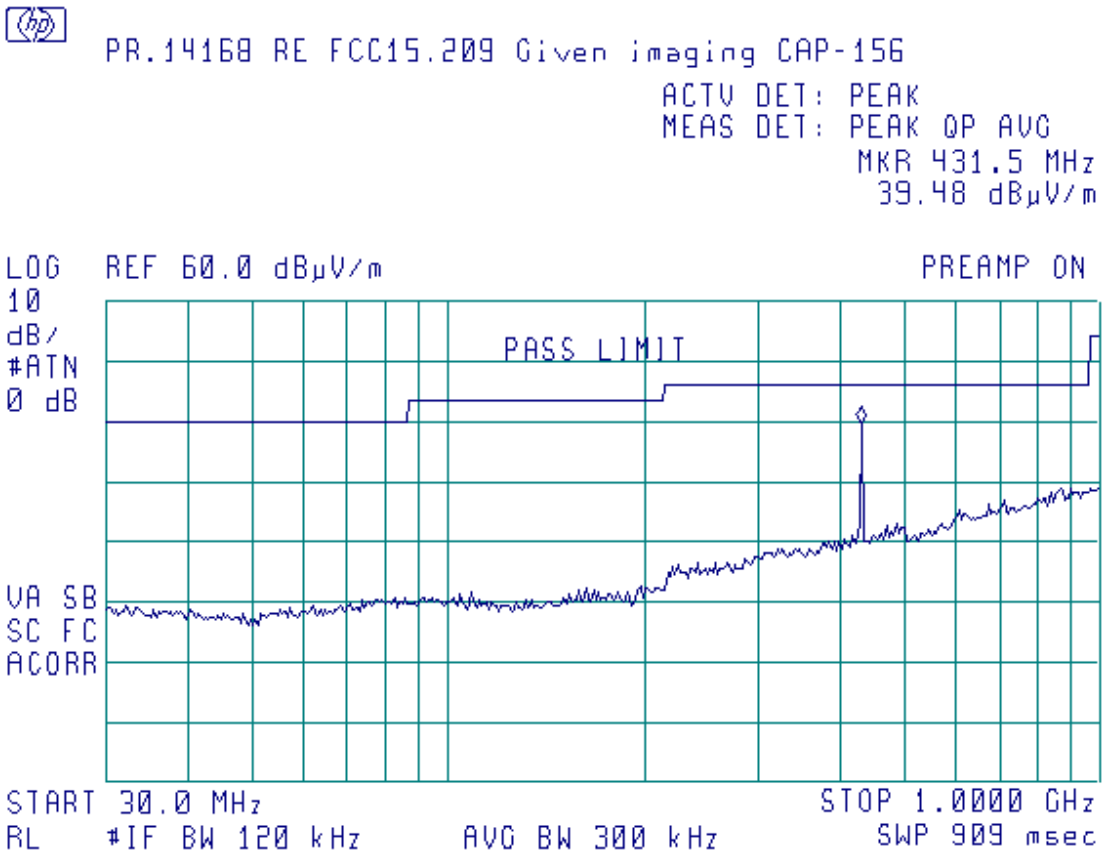


**Figure 6. Sample of Radiated Emission Measurement Results (30 MHz – 1 GHz)**

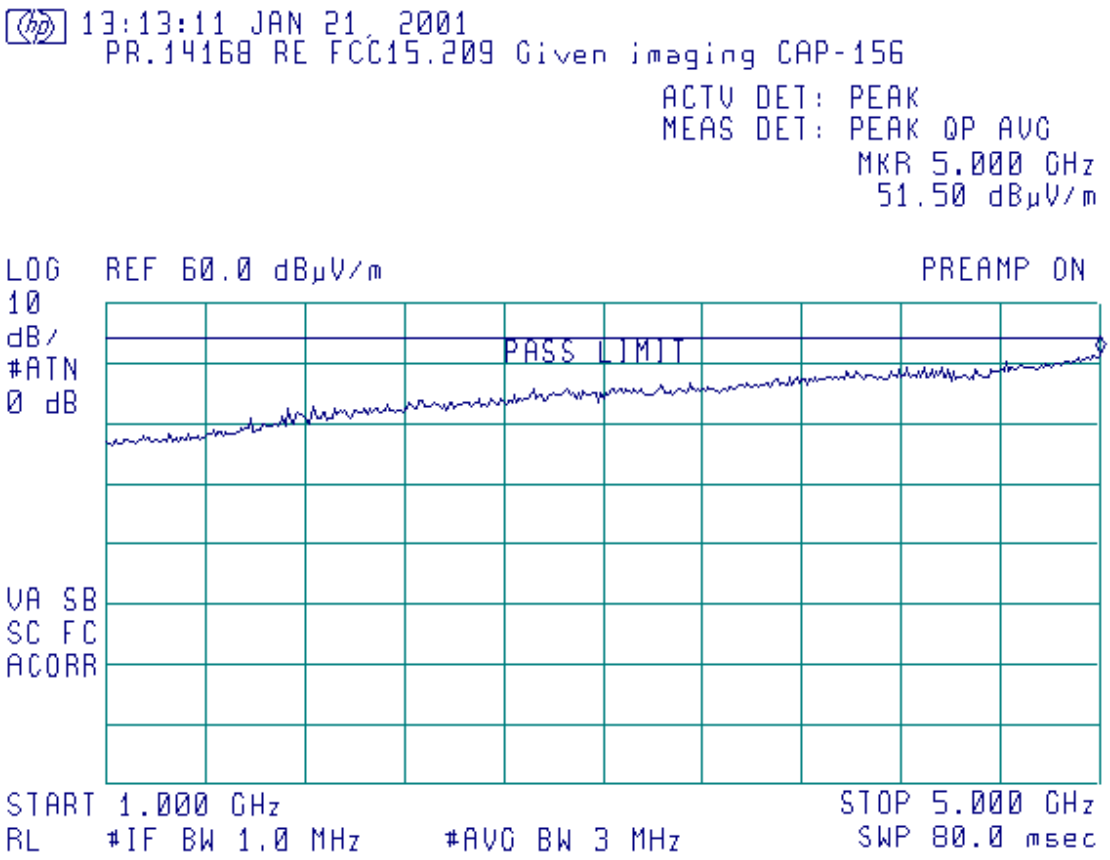


**Figure 7. Sample of Radiated Emission Measurement Results (1 GHz – 2 GHz)**

All the measured emissions were at least 10 dB below the specified limit of 46 dB, and the EUT was found to comply with the standard requirements. The test results were measured at 432/434 MHz, corresponding to the capsule carrier frequency.

## 8.0 STUDY CONCLUSIONS

The results of this study demonstrate the following:

1. During passage of the capsule through the human body (while wearing the Waist belt), all the tests produced emission measurements below the FCC limit of 46 dB throughout the entire test.

2. Although the Given Capsule exceeds the FCC's emission limits by approximately 7-10 dB when operated in open space rather than in its intended environment of use, *i.e.*, inside the human body, the device will only operate outside the body for less than a minute, thereby minimizing the impact of these higher emission levels. The medical imaging function of the capsule precludes lowering the transmitter power or otherwise reducing emission levels, which would compromise image quality and diagnostic accuracy.

3. As predicted by electromagnetic propagation theory - no significant differences in the behavior were observed between 432 and 434 MHz.

4. All Given Imaging Capsules were found to comply with the standard requirements of unintentional radiation according to § 15.109.

Based on the results obtained in the study, it can be concluded that the Capsule withstands the basic safety requirements of the FCC standard regarding both frequencies of transmission and unintentional radiated emission.