

# User

# Manual

MOWoOT  
II



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**CE**  
**2797**

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## IMPORTANT BEFORE YOU START

read this entire manual before setting up and operating the MOWOOT II system and retain it to solve doubts that may arise in the future.



We recommend recycling the device in legally established collection points.

## INDICATIONS FOR USE

- Due to neurogenic bowel disease: as in spinal cord injuries, spina bifida (meningomyelocele), multiple sclerosis, Parkinson's disease, and others,
- As side effects of medications, for example, medication for neurological disorders, opioids, anticholinergics, diuretics, analgesics, calcium supplements, and others,
- Due to endocrine disorders, for example, hypothyroidism, hypercalcemia, and others,
- Due to systemic diseases, for example, collagenosis, amyloidosis, and others,
- Due to other disorders of the colonic passage (idiopathic)

MOWOOT II can be used in two persons simultaneously, both by patients at home and by medical practitioners in clinics.

## CONTRAINDICATIONS

Pregnancy, acute active abdominal tumour disease, unstable vertebral fracture, acute inflammatory processes in the abdomen, an intra-abdominal implant (e.g., pump, catheter, SARS implant) when located between the colon and the pneumatically operated actuators of the MOWOOT II belt, abdominal stoma, cerebral shunt, abdominal, umbilical or inguinal hernias, vaginal – or rectal – prolapse.

## SIDE EFFECTS

In a controlled clinical study, the following undesirable effects, which could possibly be related to MOWOOT treatment, were observed in 1-2% of the treated patients: bloated stomach, abdominal pain, diarrhea, back pain, urinary tract infection and skin redness (erythema).

## SAFETY WARNINGS











**Electric Shock Hazard.** Do not immerse in liquid or allow liquid to enter any part of the console. To clean following instructions in sections 8.1 and 8.2. Do not open the console. Do not attempt to service the console yourself. Connect to the console only parts of the MOWOOT II system.







Do not use MOWOOT II if it has become wet neither in the presence of flammable material. Stop treatment in case of any change of the MOWOOT II system performance. **Close supervision is necessary at all times when MOWOOT system is used with children or in the case of mental disability.** Danger choking due to small parts.

## SAFETY PRECAUTIONS

Keep away from pets, sources of heat or moisture: dust, lint and dirt; Do not use, store or transport the console beyond the temp. range: 10°C to 30°C (50° to 86F), or beyond the humidity range: 30% to 85% rH (section 8.3). Do not operate the device during transit. Do not use above 3000 m from sea level. While in use, place the console on horizontal firm surface. Do not cover the console.

## LABELS

Symbol	Description	Location
	CE label showing compliance with European Directive 2007/47/EC amending Directive 93/42/EEC, concerning medical devices.	Desktop Device Belt Packaging
	Read Instructions before use.	Desktop Device Packaging
	Read Instructions before use.	Desktop Device Packaging
	Level of protection type BF equipment.	Desktop Device Packaging
	Double insulation.	Desktop Device Packaging
	Date of manufacture.	Desktop Device Packaging
	Serial Number. The symbol must be accompanied by the serial number of the device.	Desktop Device Belt Packaging
	Degree of protection against ingress of water.	Desktop Device Packaging
	humidity limitation. The limitation should be indicated next to the horizontal lines.	Desktop Device Packaging
	Manufacturer's name and address.	Desktop Device Belt Packaging

Symbol	Description	Location
	Non-sterile product.	Desktop Device Packaging
	Hand wash	Belt
	Do not wash	Belt
	Do not squeeze	Belt
	Do not iron	Belt
	Do not tumble dry	Belt



## 1. INTRODUCTION – THE MOWOOT II SYSTEM


MOWOOT II is a sequential pneumatic compression therapy system for the treatment and management of chronic constipation and has been designed and manufactured considering all legal regulations applicable to medical devices following the highest quality standard, and thus guaranteeing the maximum safety.

MOWOOT II does not interfere neither is affected by other electronic devices.

## 2. COMPONENTS OF THE MOWOOT II SYSTEM

### 2.1 Console and Accessories

Component	Illustration
The <b>console</b> supplies air to the exoperistaltic belt. There are two air outlets on the front of the unit. The console can operate one or two abdominal belts simultaneously.	
<b>Plug;</b> If using one abdominal belt only, you must seal the second air outlet located on the front of the console to keep air from escaping. Use the Plug to seal the unused outlet on the front of the console.	

Component	Illustration
<p><b>DC Power Adapter;</b> For indoor use only. Receives 100-240 VAC, 50-60 Hz and supplies 12 VDC 3A to the console. Use only the DC power adapter provided with the MOWOOT II.</p>	

## 2.2 Exoperistaltic Abdominal Belt

Is fastened around the area to be treated. Approx. height 110 mm. contains 4 actuators that fill up sequentially with air from the console completing 1 cycle. The cycles will be repeated until the treatment session is complete. It stops automatically once the treatment is finished.

The belt is connected to the console by four tubes connected to a plug, the plug must be placed with the logo facing up.

**Small Size (S):** Cyan border, perimeter 650-850 mm.

**Medium Size (M):** Green border, perimeter 800-1000 mm.

**Large Size (L):** Grey border, perimeter 950-1150 mm.

**Extra Large Size (XL):** Black border, perimeter 1100-1300 mm.

## 3. SETTING UP THE SYSTEM

Make sure to be able to reach the MOWOOT II System at any time during treatment.

### 3.1 Set up the Console



Place the console on a flat stable surface from where it will not slip or fall.

Plug the DC power adapter cable into the DC adapter socket on the console, and then plug the power cord into an appropriate 230-Volt wall outlet.

### 3.2 Put on Clothing that Covers the Treated Area

Wear light, loose, absorbent clothing over the area of your body that will be covered by the abdominal belt, to absorb perspiration, and to keep the belt clean.

### 3.3 Put on the Abdominal Belt

<p>a) Place the belt on the abdomen, between the last rib and the ischia (hip) and close the Velcro. The stitching should fit right in the centre of the abdomen. Tighten to the maximum without hurting. You should feel comfortable</p>	
<p>b) The tubes should exit through the left side of the belt.</p>	



### 3.4 Attach the Belt to the Console

**NOTE - Hold the console handle with one hand while connecting/disconnecting the belt with the other hand.**

Insert the belt connector into one of the two air outlets at the front of the console, making sure the MOWOOT II logo printed on the connector is facing UP. The belt connector will “click” into place. If you do not hear a click, move it gently to make sure it is secure.

- a) To remove belt connector, squeeze the release buttons at either side of the connector and pull out the connector.
- b) If using only one abdominal belt, plug the blocking connector into the unused air outlet.

If it is left open, air will escape, the console will stop working, the Status LED will turn on in red, and the alarm will beep.

### 3.5 Treatment Positions

Always make sure the controls on the console and the connection with the massage belt tubes can be reached easily from the treatment position.






The MOWOOT system can be used in a seated position or lying comfortably on a bed or couch.

## 4. USE OF THE DEVICE

Following is a description of the console operating panel.



#### 4.1 The Console Controls

Control	Función
	<b>Time knob.</b> used to set treatment time (1 to 20 min)
	<b>Speed Knob.</b> Used to set treatment speed (1 to 5 Speed, 4,5 to 7,5 seconds per cycle).
	<b>Start/Stop Button:</b> Used to start or stop treatment. Status LED: <ul style="list-style-type: none"> <li>· White - Power is on. Treatment has not started.</li> <li>· Green - Treatment is in progress.</li> <li>· Flashing green - Paused treatment</li> <li>· Red - indicates malfunction (Chapter 9 – Troubleshooting)</li> </ul>
	<b>Main Switch.</b> Used to turn on the console (located at the back side of the console, at lower right).
	<b>DC Adapter Socket.</b> Used for connecting the DC power adapter (located under the Main Switch).

## 5. SETTING TREATMENT FREQUENCY AND TIME

Set the Time Knob to the massage duration you want. We recommend a daily use time of 20 minutes. The minimum treatment time setting is 1 minute. The maximum treatment time setting is 20 minutes.

It can be used at any time of the day, although we advise doing it in the morning, as soon as you wake up, before getting up. We recommend not doing the treatment right after eating.

Adjust the Speed Knob according to your feeling and your needs. Low speed 4,5 sec. /cycle (position 1) a 7,5 sec/cycle (position 5).

## 6. STARTING THE TREATMENT SESSION

1. Verify the main switch (back side of the console) is in OFF position.
2. Connect the DC power adapter cable to the DC adapter socket (located under the Main Switch).
3. Connect the power cord to the electrical outlet.
4. Put on the abdominal belt, following the instructions in Section 3.3 above and get into a comfortable seated, reclining, or lying position from where you can easily reach the console controls.
5. Connect the belt to the desktop device and make sure that the hoses are properly connected (3.4).
6. Turn on the Main Switch to the ON position.
7. Press the Start/Pause button. - Treatment begins.

## 7. ENDING THE TREATMENT SESSION

When your treatment time is complete, MOWOOT II system will stop. If you need to pause the massage during the treatment session, press Start/Pause button. If you need to definitely stop the treatment before massage is finished, press Stop button. At the end of treatment, turn OFF the console using the Main Switch.

**NOTE - When immediate abdominal belt deflation is necessary, disconnect the belt from the console to immediately deflate the air pressure in the belt actuators.**

## 8. MAINTENANCE & STORAGE

### 8.1 Cleaning

Gently wipe the external surfaces using a soft cloth, warm water and a mild detergent. Wipe with clear water. Wipe dry using a soft towel only. When dry, the external surfaces may be wiped down with alcohol. When using alcohol, wear gloves and work in a well-ventilated area. Allow the device to air dry completely before use.

### 8.2 Console Cautions

Disconnect the console from electrical outlet before cleaning. Let it dry completely before reconnecting it to the electrical outlet. Do not allow any moisture or liquids to enter the console.

### 8.3 Belt Cautions

Never submerge the belt in liquid. Do not hand or machine wash. Do not use bleach. Do not wring, iron, tumble, do not dry mechanically or dry with dry heat. Do not allow liquid to get into the air inlets.

### 8.4 Storage & Transportation

Keep the device away from direct sunlight, store in a dry, shaded place, do not twist or fold the connector tubes and store the power cord lightly wrapped and secured.

The components of the MOWOOT II system should only be transported in their original packaging.

## 9. TROUBLESHOOTING

Problem	Root Cause and Corrective Action
The console is working in a low pressure regardless of the pressure set.	<ol style="list-style-type: none"> <li><b>1.</b> No electricity. Check the electrical wall outlet.</li> <li><b>2.</b> Verify that the power supply is properly connected to DC adapter socket to the 220-Volt Wall outlet.</li> <li><b>3.</b> Power cord. Check the power cord visually for any defects.</li> <li><b>4.</b> Defective belt. Replace belt and check again.</li> <li><b>5.</b> An internal problem. Contact usMIMA S.L..</li> </ol>
Red LED is ON	<ol style="list-style-type: none"> <li><b>1.</b> Malfunction. Contact to usMIMA S.L..</li> </ol>
The console starts working and stops immediately.	<ol style="list-style-type: none"> <li><b>1.</b> The air cannot move through the belt tubes.</li> <li><b>2.</b> Check belt tubes for kinks, twists and folds.</li> </ol>
One actuator inflates but the following one does not.	<ol style="list-style-type: none"> <li><b>1.</b> The actuator does not receive air.</li> <li><b>2.</b> Check its tube for kinks, twists and folds.</li> </ol>
The console stops working, the Status LED turns on in red, and the buzzer beeps.	<ol style="list-style-type: none"> <li><b>1.</b> Abdominal belt is not connected properly to console.</li> <li><b>2.</b> Additional plug is not inserted into unused air outlet.</li> <li><b>3.</b> Always plug the unused air outlet with the prong plug provided with the console. If all connections are OK and problem persists, contact usMIMA S.L.</li> </ol>
Irregular noise.	<ol style="list-style-type: none"> <li><b>1.</b> Transferring of vibrations. Make sure the console is standing firmly on all four of its bumpers.</li> <li><b>2.</b> Internal problem. Contact usMIMA S.L.</li> </ol>

## 10. ASSISTANCE

The only authorized to perform technical assistance interventions on the device will be the manufacturer. For any technical assistance intervention, contact usMIMA S.L.

## 11. SPARE PARTS

In order to maintain both the guarantee and the functions of the product and its safety, it is necessary to use only original spare parts supplied only by the manufacturer. Both the console, abdominal belt and power supply can be purchased separately. Contact usMIMA S.L ([www.mowoot.com](http://www.mowoot.com)).

## 12. DISPOSALS



Disused pneumatic desktop units and power supplies should be disposed of as electronic waste. The devices can be disposed of at appropriate collection points free of charge.

Disposable belts and sealing plugs should be disposed of as residual waste.

## 13. WARRANTY & CONTACT INFORMATION

### \_Manufacturer Warranty

This MOWOOT II Device has been subjected to the most rigorous quality controls. However, if any malfunction occurs due to defective materials, we encourage you to please read these warranty conditions carefully and contact our Customer Service on the telephone number +34 935 106 653 or by email [info@mowoot.com](mailto:info@mowoot.com) to UsMIMA, SL (Hereinafter referred to as "usMIMA"),

### \_Certificate of Warranty

For this certificate, usMIMA warrants that MOWOOT II Device, to which this warranty applies (hereinafter "Device") is free from defects in material and workmanship at the time of its original purchase by the consumer and for a period of 2 years from delivery or 244 hours of use (20 minutes per day for 2 years). If during this period of validity of the warranty, the Device presents any defect attributable to the manufacturing process, due to materials and/or labour, the consumer must inform usMIMA within 2 months after being aware of such defect and may choose to require the replacement of the Device.

The guarantee of the device subject to guarantee will be free for the consumer and user. Such gratuity shall comprise the necessary expenses incurred in order to remedy the lack of the Device under warranty, as well as the costs of shipping, and costs related to labour and materials.

### \_Warranty Conditions

In this document you will find the conditions of the warranty for purchasing the device.

### 1. Data and Documentation

To use the rights granted by this warranty, it is essential to prove the date of purchase of the Device, by means of an original purchase invoice, purchase receipt or delivery note of the Device.

MOWOOT II is warranted for two years from delivery. The delivery is understood to be made on the day that appears on the invoice or ticket of purchase, or in the corresponding delivery note if it was later.

The consumer must also provide the following information: **(a)** Name, surname, and address of buyer; and **(b)** Model and serial number of the purchased MOWOOT device.

## 2. Exclusions

The warranty covers all defects in materials or workmanship, with the following exceptions:

- 1.** Damage and damage caused by accident, improper use or negligence of the user including, but not limited to:
  - a.** Lack of reasonable and necessary maintenance;
  - b.** The use of the device for purposes other than normal, in accordance with the characteristics of MOWOOT II;
  - c.** Do not follow the instructions given by usMIMA for the correct use and maintenance of MOWOOT II;
  - d.** The installation or use of MOWOOT II in a manner not in accordance with the current technical or safety standards;
  - e.** Accidents, natural disasters or any other cause beyond the control of usMIMA.
- 2.** Damage caused by repairs performed by personnel not authorized by the service station of the device warranty;
- 3.** Damage or deterioration of any accessory or decorative surface of the device;
- 4.** Damage or damage to any unit or device in which the serial number has been erased, modified, withdrawn or manipulated;
- 5.** Damage caused by causes beyond the design or manufacture of the Device (e.g. power failure);
- 6.** Periodic reviews, maintenance and repair or replacement of parts due to normal wear and tear of the Device;
- 7.** Indirect damages and losses of any kind;
- 8.** Personal or material damages caused as a result of the user's failure to comply with the rules and instructions given by usMIMA for the installation, use and maintenance of the Device.

### \_Geographical Scope

This warranty is valid throughout Europe and will be valid only for MOWOOT II devices.

usMIMA will not offer any of the warranty services specified in this document outside that territory.

### \_Pieces

All parts or Devices replaced under warranty services shall become the property of usMIMA.

This warranty gives you specific legal rights. However, you may exercise your rights under the applicable legislation in force for that purpose.

**\_Cancellation of Warranty**

The warranty of the Device will be invalidated: **(a)** For damage produced and caused by repairs carried out by personnel not authorized by the service station of the MOWOOT II warranty, as well as if additional parts or accessories that are not original are replaced or used. **(b)** By manipulation of the data of the invoice, ticket of purchase or delivery note.

**\_Data Protection**

Your data will be included in an automated file owned by **usMIMA** for further communications regarding repairs. You may access this file in order to exercise your rights of access, rectification, cancellation and opposition with respect to your personal data, by means of a written communication addressed to usMIMA, S.L.

**ANNEX I - CLASSIFICATIONS**

Class IIa Medical Device, Standard 93/42 / EEC, Section IX, Rule 9. The protection against electric shock is Class A and DC. Degree of protection against electric shock of type BF (Clasif CEI EN 60601-1.). Degree of IP 21. EC 2797. The device is not protected against water penetration. The device is not subject to sterilization. Continuous operation device. The device is not suitable for outdoor use.

**ANEXO II – ESPECIFICACIONES TÉCNICAS**

Treatment time	1 - 20 min
Dimensions	220 x 170 x 130 mm
Weight	1,5 kg (3,3lbs.)
Electrical Requirements	100 - 240 VAC, 50 - 60 Hz
Number of actuators	4 units
Rated Voltage	12 VDC
Set pressure	0,65 ± 0,1 bar
Maximum Frequency of Treatment	4,5 Seconds/Cycle
Minimum Frequency of Treatment	7,5 Seconds/Cycle
Transport and Storage Temperatures Range	from -20 to 70° C
Relative Humidity of Transport and Storage	10 to 93% Hr
Operating Temperature Range	+10 to +30° C
Relative Operating Humidity	30 to 85% Hr
Atmospheric operating pressure	700 to 1060 hPa
MOWOOT II Warranty	limited 2 years or 244 hours
Classification	Class IIa (93/42/CEE)

### ANNEX III – EMC MANUFACTURER'S DECLARATION

Electromagnetic Compatibility (EMC) Statement for Home Healthcare Environment the Desktop Device System has been evaluated to international standard IEC 60601-1-2 "General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests".

1. The Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided here within the accompanying documents.
2. Portable and mobile RF communication can affect the Medical Electrical Equipment. See below recommended separation distances between portable and mobile RF communication equipment and the desktop device system.
3. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance  $d=3.3$  m way from the system.

Rated Maximum Output Power of Transmitter (W)	Separation Distance* according to Frequency of Transmitter (m)
0.01	0.23
0.1	0.73
1	2.3
10	7.3
100	23

**NOTE - The distance calculated from 800 MHZ to 2,5 GHZ**

Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

This system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe the device function to verify normal operation in the configuration in which it will be used.



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

MOWOOT II - Electromagnetic Immunity - Manufacturer's declaration			
MOWOOT II is intended for use in the electromagnetic environment specified below. The customer or the user of the MOWOOT II should assure that it is used in such an environment.			
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Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	Complies	
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines	Complies	Mains power quality should be that of a typical domestic or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line to line	Complies	Mains power quality should be that of a typical domestic or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip in Ut for 0.5 cycle 60% dip in Ut for 5 cycles 30% dip in Ut for 25 cycles >95% dip in Ut for 5 cycles	Complies	Mains power quality should be that of a typical domestic or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic I or hospital environment.
NOTE: Ut is the a.c. mains voltage prior to application of the test level.			

**Recommended separation distance between portable and mobile RF communications equipment and the MOWOOT II**


MOWOOT II is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The consumer or the user of the MOWOOT II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MOWOOT II as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d= 1.2 \sqrt{P}$	80 MHz to 800 MHz $d= 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d= 1.2 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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



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