MICRODOC™
Micro Wound Therapy System

User's Manual and Patient Guide
Care and Use Instructions

The MicroDoc Micro Wound Therapy System Contents

The MicroDoc System consists of:

1. One MicroDoc NPWT Control Unit
2. Two MicroDoc ComforTech™ Dressings
3. Two Skin Prep Pads
4. One Velcro carrying strap that can be used to attach the control unit to an extremity near the wound
5. User's Manual

THIRD FOLD

MicroDoc ComforTech™ User Manual, Part # 84635503021
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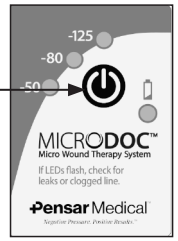
109 N Post Oak Ln., Suite 525, Houston, TX 77024
800.669.4757
www.pensarmedical.com

Pensar Medical™
Negative Pressure. Positive Results.™

Patient Operation of the MicroDoc Control Unit

Note: The patient or caregiver must be fully trained by a Healthcare Professional.



Turning the Unit Off

- Press and hold the blue ON/OFF button for approximately three (3) seconds to turn off the MicroDoc.
- All lights will turn off on the unit.

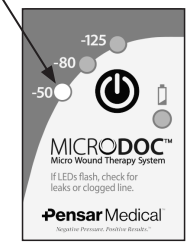
Disconnecting the Unit from the wound kit

- Disconnect the unit from the tubing with a half turn counterclockwise.

Turning the Unit On and Setting the Pressure

WARNING: ONLY SET THE DEVICE TO THE DOCTOR-PRESCRIBED PRESSURE.

- Ensure that the wound kit tubing is not connected to the MicroDoc.
- Press and hold the blue POWER button, the blue light will begin to flash at -50.
- The Battery power light will illuminate for 1 second.
- Press and release the blue POWER button to change between pressure settings to reach doctor-prescribed pressure.
- To start the therapy, connect the tubing and the pressure will be locked.
- While attempting to achieve the desired pressure, the blue light will remain solid.
- When the desired pressure is reached, the unit will lock into place and the blue light will flash intermittently.
- To unlock the unit and change the pressure setting, turn it off and then on to reach doctor-prescribed pressure.



MicroDoc Portability

- The MicroDoc can be attached to your arm or leg by using the Velcro strap that is included.
- Place the Velcro strap on top of clothing.
- The MicroDoc can also be attached to a belt or can be placed in a carrying case or a pocket.

MicroDoc Battery

- The GREEN battery light means the MicroDoc has full battery.
- If the LED changes to AMBER, there is approximately 2 days of battery life remaining.
- If there are no lights on the device and the blue light is not flashing, the unit is in deep sleep mode.

Visual Low-Pressure Indicator and AI Adaptive Functions

- If the blue light remains on, the unit is still attempting to achieve the desired pressure.
- After one minute of attempting to achieve the desired pressure, the unit will switch to one pressure setting lower or turn off if already set to –50mmHg; after another minute the unit will switch to a lower pressure level or turn off if –50mmHg is not achieved.
- During each sixty (60) second interval that MicroDoc tries to reach the proper set pressure level, if the pump motor runs for more than six cumulative seconds, this indicates a leak or blockage.
- If the pressure level cannot be maintained, the unit will turn off for 45 minutes before restarting at the previously desired set-pressure level.

Patient Operation of the MicroDoc Control Unit

If a Low-Pressure Indicator Occurs

- Check the tubing for an air-tight connection.
- Check the dressing for a proper seal around the wound.
- If the issue has been corrected, the unit may need to be turned Off and back On.
- If there are any issues, notify the healthcare professional or doctor.

Identifying a Blockage

During normal operations, the dressing should feel firm to the touch and have a textured appearance. It confirms that negative pressure is being applied to the wound. In a blockage condition, the dressing will have a loose appearance.

To resolve a blockage condition, perform the following:

- Check the tubing for any blockage or kinks in the line.
- Unkink the tubing or clear the line of the blockage (as appropriate) to correct the issue.
- Check if the dressing is saturated and/or needs to be changed.
- If the issue has been corrected, the unit may need to be turned Off and back On.
- If there are any issues, notify the healthcare professional or doctor.

Wound Dressing

The dressing should be changed when:

- Physicians' orders require.
- Fluid accumulates around the dome.
- Fluid saturates towards the edges of the dressing/absorbent dressing is full.

Dressing changes may need to be more frequent based on wound such as when wound is infected, levels of exudate, dressing compromised, wound type, or other patient situations assessed.

WARNING: For use near common household electrical devices

The following common household devices and appliances could potentially have an effect on the MicroDoc which might cause degradation of its performance. If used closer than 12 inches from one of these, the MicroDoc should be observed to verify normal operation.

- Computers, TVs, stereos, cell phones, e-readers
- Hairdryers and electric shavers
- Refrigerators, toaster ovens
- Electric blankets, alarm clock radios

Call Your Nurse or Doctor Immediately If:

- There is a big change in the color or amount of the fluid in the dressing.
- If the fluid changes from clear to cloudy or bright red.
- You see the dressing fill rapidly with blood.
- You experience pain.

The MicroD**oc™**
Micro Wound Therapy System

Indications for use

MicroDoc Micro Wound Therapy System is indicated for patients who may benefit from a suction device as it may promote wound healing through the removal of low to moderate levels of exudate and infectious material.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

The MicroDoc Micro Wound Therapy System is suitable for use in both a healthcare and homecare setting.

Product Description

The MicroDoc Micro Wound Therapy System is a negative pressure wound therapy system (NPWT) that is specifically designed for shallow wounds with low to moderate amounts of exudate (~10 ml/day) that no longer or never required a collection canister. The system consists of a disposable, small, lightweight, battery operated, portable suction device containing an electric motor driven vacuum pump, two absorbent dressings with built-in polyvinylchloride (PVC) tubing to connect the dressing to the suction device. The dressing is applied over the wound and the provided adhesive materials provide additional stability. The dome on top of the drape is connected to the MicroDoc suction device via the tubing. The dressings and adhesive materials are provided sterile and are designed for single patient use. The negative pressure Control Unit is for single patient use, but is not provided sterile. The MicroDoc Micro Wound Therapy System is suitable for use in hospital, acute, non-acute, clinics, physician offices, and homecare settings. The portable suction device can be placed in a pocket, a carrier or attached to the body with an arm/leg Velcro strap which is provided.

The MicroDoc Micro Wound Therapy System consists of the following:

- MicroDoc Negative Pressure Wound Therapy (NPWT) Control Unit
- Two ComforTech™ dressings
- Two skin prep wipes
- Velcro carrying strap
- User's manual and quick reference guide

Principle of Operation

The MicroDoc control unit, which is powered by two AA alkaline batteries, maintains negative pressure wound therapy (NPWT) to the wound surface at three different healthcare professional prescribed settings (-50, -80 and -125mmHg). The system is intended to be used for a maximum of 7 days on low to moderately (~10 ml/day) exuding wounds.

Contraindications

The use of MicroDoc is contraindicated in the presence of:

1. Patients with malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life).
2. Previously confirmed and untreated osteomyelitis.
3. Non-enteric and unexplored fistulas.
4. Necrotic tissue with eschar present.
5. Exposed arteries, veins, nerves or organs.
6. Exposed bone or tendons
7. Anastomotic sites.
8. Emergency airway aspiration.
9. Pleural, mediastinal or chest tube drainage.
10. Surgical suction.

Warnings

1. Certain patients are at high risk of bleeding complications which, if uncontrolled, could potentially be fatal. Patients must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately discontinue therapy, leave dressing in place, take appropriate measures to stop bleeding and seek immediate medical assistance.
2. The use of anticoagulants does not deem a patient inappropriate for treatment with MicroDoc however hemostasis must be achieved before applying the dressing. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that may increase the risk of bleeding, if disrupted. Frequent assessment must be maintained and considered throughout the therapy.
3. At all times care should be taken to ensure that the pump and tubing do not:
    - Lie in a position where it could cause pressure damage to the patient.
    - Trail across the floor where it could present a trip hazard or become contaminated.
    - Present a risk of strangulation or a tourniquet to patients.
    - Rest on or pass over a source of heat.
    - Become twisted or trapped under clothing or bandages so that the negative pressure is blocked.
4. Sharp edges or bone fragments in a wound must be covered or removed prior to using MicroDoc due to risk of puncturing organs or blood vessels while under negative pressure.
5. If defibrillation is required, disconnect the pump from the dressing prior to defibrillation.
    - Remove the dressing if it is positioned in a location that will interfere with defibrillation.
6. MRI Unsafe
    - MicroDoc is not MRI compatible.
    - Do not take MicroDoc into the MRI scan room.
    - MicroDoc presents a projectile hazard in the MRI scan room.
7. MicroDoc has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this therapy.
8. MicroDoc is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).
9. MicroDoc use is not appropriate for simple enteric fistulas (not within a wound) or recommended if enteric fistula management is the sole goal of therapy.

Warnings continued from page 5

10. With spinal cord injuries, if the patient experiences autonomic hyperreflexia (a sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), MicroDoc use should be discontinued to help minimize sensory stimulation.
11. To eliminate the risk of bradycardia, the MicroDoc should not be placed in proximity to the vagus nerve.
12. The MicroDoc should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked used is necessary, the MicroDoc should be observed to verify normal operation in the configuration in which it will be used.
13. Portable RF communications equipment (including antenna cables and external antennas) should be used no closer than 12 inches to any part of the MicroDoc. Otherwise, degradation of the performance of this equipment could result.

Precautions

1. Precautions should be taken in the following types of patients who are at high risk of bleeding complications:
    - Receiving anticoagulant therapy or platelet aggregation inhibitors or actively bleeding.
    - Having weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to; anastomoses, infection, trauma or radiation.
    - Suffering from difficult wound hemostasis.
    - Untreated for malnutrition.
    - Noncompliant or combative.
    - Suffering from wounds in close proximity to blood vessels or delicate fascia.
2. MicroDoc dressings should only be applied by a healthcare professional.
    - Dressings are not to be removed or changed by the patient.
3. Where MicroDoc is used on infected wounds, more frequent dressing changes may be required.
    - Regular monitoring of the wound should be maintained to check for signs of infection.
4. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing does not compromise circulation.
5. MicroDoc does not provide audible alarms.
    - The pump should be carried or worn so that it is visually accessible, and the patient/healthcare professional can check the status routinely.
6. Although MicroDoc can be used under clothing/bedding, it is important that occlusive materials, e.g. film dressings, are not applied over the pad area of the dressing as this will impair device performance.
7. Protect the periwound skin.
    - For patients with fragile skin, a skin protectant should be used on areas of skin where the adhesive drape is to be applied.
    - Inappropriate use or repeated application of the adhesive drape may otherwise result in skin stripping.
    - Do not pull or stretch the drape during application.
8. If reddening or sensitization occurs discontinue use and contact the treating healthcare professional.
9. Do not use MicroDoc with oil-based products such as petrolatum as it may compromise establishing an effective seal.
10. Do not use wound fillers such as foam or gauze. MicroDoc is designed for use on shallow wounds.

Precautions continued from page 6

11. The MicroDoc may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin.
    - Any surgical drain should be routed under the skin away from the edge of the dressing and function independently of the MicroDoc.
12. When showering, the MicroDoc pump should be disconnected from the dressing. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the top of the tube.
13. Do not take the pump apart.
14. The dressing should not be used with any other suction pump.
15. Do not alter or cut tubing configuration or pull on the tubing.
16. Do not cut the dressing as this may lead to loss of NPWT application.
17. Always ensure to place dressing centrally over the wound so that the port is positioned above the wound area. By ensuring the port is not placed directly over/or extends over the wound area, this will help avoid drainage collecting around the port.
18. CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible, move the device out of the x-ray or scanner range.
    - If the device has been taken into the CT scan or x-ray range, check that it is functioning correctly following the procedure.
19. This device is single-patient-use only.
    - Use of any part of this system on more than one patient may result in cross- contamination that may lead to infection.
20. High temperatures and humidity may reduce wear times of dressings.
21. During transport, there is a potential for radio frequency interference that could affect MicroDoc performance.
    - If the device malfunctions, replace the device.
    - MicroDoc is not intended for use aboard aircraft.
22. The potential for electromagnetic interference in all environments cannot be eliminated.
    - Use caution if MicroDoc is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.
    - RFID systems have the potential to influence the MicroDoc performance. Therefore, in a healthcare or hospital environment, the MicroDoc should be observed to verify normal operation.

General Guidance

The MicroDoc System should be used on wounds which fit comfortably within the area of the dressing pad, observing precautions on port positioning.

- It is intended for use on shallow wounds with low to moderate levels of exudate (~10 ml/day).
- It is not intended for use on complex wounds with extensive undermining or tunneling.
- This dressing is intended for wounds that can be adequately accommodated within the pad's dimensions. If the wound has moderate drainage, then the size of the wound should generally be no more than 25% of the dressing pad area.
- Larger dressings can be purchased separately.

For use on closed surgical incisions

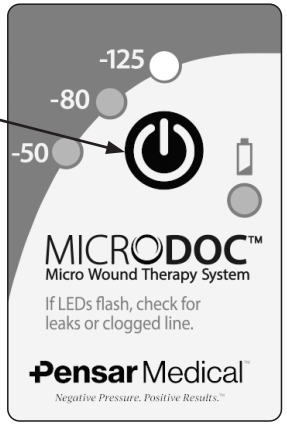
- NPWT is indicated for patients considered to be at risk for surgical site complications.
- If high volume exudate is present and/or large volume incisional drainage is anticipated, use traditional NPWT with a canister until fluid noted is low to moderate and then transition the patient to MicroDoc.
- Use a skin prep wipe on intact skin surrounding the incision. It is important to allow the skin prep to dry completely before dressing application.

For use on split thickness skin graft/skin substitutes

- Generally, a non-adherent layer is applied over the graft prior to applying the MicroDoc dressing.
- Depending on the contour of the graft site, additional filler may be utilized to stabilize the graft.
- Monitor dressing and pump functionality frequently.

Operation of the MicroDoc Control Unit

While the MicroDoc is a very sophisticated system, the beauty is the simplicity of its design. It is very easy to use, and one button controls the entire system.



1. To begin therapy, press the blue POWER button.
2. Repeated pressings of the POWER button will toggle between the three pressure settings.
3. When the Healthcare Professional prescribed pressure is attained, release the POWER button and the control unit will begin to attain that pressure level.
4. To turn off the unit, press and hold the POWER button until all the lights go off.

MicroDoc Portability

The MicroDoc can then be attached to the closest extremity (arm or leg) by using the included Velcro strap placed on top of clothing or attached to a belt to hold it at the patient's waist. As an alternative it can also be placed in a carrying case.

Dressing Application

Caution: The dressing must only be applied by a healthcare professional.

The healthcare professional must wear sterile gloves. The MicroDoc comes standard with the MicroDoc ComforTech™ dressings. The goal is to get a secure dressing that does not leak and enables the negative pressure control unit to remove any excess exudate away from the wound and contain it in the dressing.

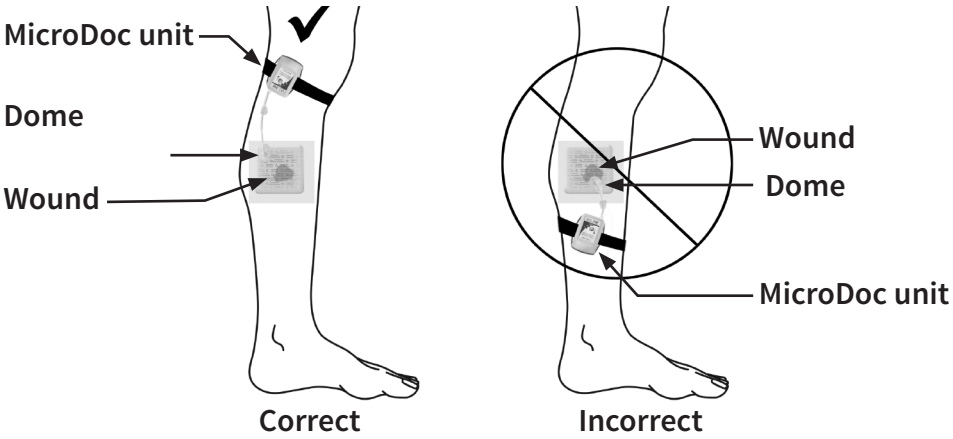
Site Preparation

1. To create an effective dressing seal, you may need to clip hairs (if facility permits) at wound dressing site when hair may prevent a proper seal.
2. Cleanse and prepare wound and peri-wound area per facility protocol, and be sure any oils, debris, are removed gently to improve drape adhesion.
3. Apply skin protectant to peri wound and let thoroughly dry before placing dressing. Prepare wound for treatment per facility protocols and patient's wound care orders.

Operation of the MicroDoc Control Unit continued

MicroDoc Dressing Application

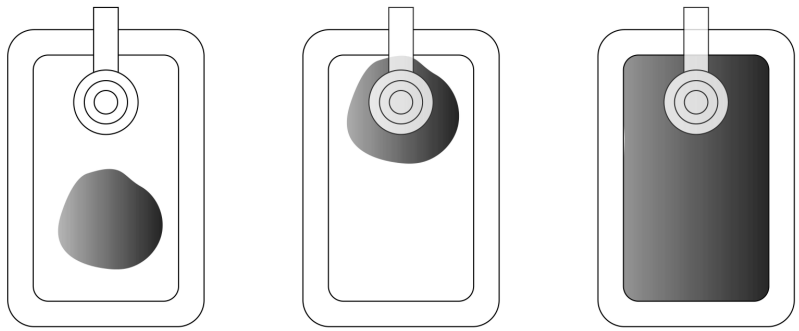
1. A new wound dressing must be applied by a healthcare professional. Check orders before beginning and assess if wound is appropriate for sNPWT use with MicroDoc ComforTech™ Dressing.
2. See wound site preparation notes. (Page 8)
3. Use a clean technique per facility protocol.
4. Peel off the dressing backing from one side to expose adhesive and place dressing centrally over the wound so that the dome is positioned above the wound area and not directly over the wound area. This will help avoid drainage from collecting around the dome.
5. Remove the other back layer of the dressing and gently apply the dressing around the wound for a smooth seal, avoiding creases when possible.
6. Window-panning transparent strips are provided for clinical convenience if the clinician would like an added layer around the perimeter of the dressing. Skin protectant may be used in this area to protect the patient's skin integrity based on the facility protocols.
7. Connect the dressing tubing to the fixture on the MicroDoc control unit with a half turn clockwise or until tight connection.



Dressing Removal

The absorbance of exudate by the dressing is enhanced by the negative pressure of the MicroDoc. The dressing should be changed midway through the 7-day treatment (3 days) or sooner if needed depending on the exudate volume. The dressing should be changed before the fluid reaches the edges of the dressing. This will prevent any exudate leakage. If a dressing is removed for any reason, DO NOT re-apply the same dressing. A new dressing must be applied by a healthcare professional or doctor.

1. Turn off the MicroDoc control unit by pressing and holding the POWER button and all lights will turn off.
2. Disconnect the MicroDoc from the dressing by twisting the connector counterclockwise.
3. If drape strips were used around the perimeter of the dressing, gently and slowly brace the skin while stretching the strips to remove.
4. Remove the dressing by gently lifting at a corner and slowly peeling the dressing back. Bracing the skin while removing the dressing can also protect its integrity.
5. If removing a dressing from a surgical incision, remove the dressing in-line with the sutures and not across the sutures.
6. Dispose of used dressing per facility protocols.
7. Clean as the physician has ordered.



A
Dressing properly positioned and is acceptable to be left in place.

B
Dressing requires change, port may block with fluid.

C
Dressing requires change, pad area is full.

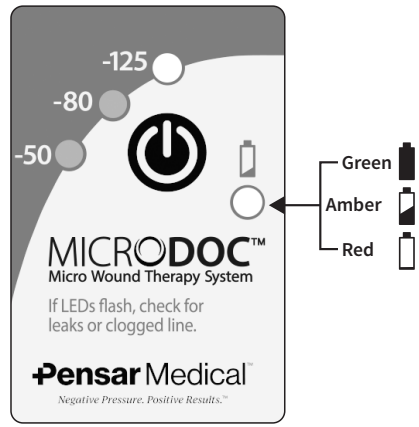
Remaining Battery Life Feature

The MicroDoc control unit clearly displays a battery icon and LED.

a. When first powered on the LED will be green. After a short time, this light will stop illuminating and remain off as a battery saving feature.

b. The LED color will light up and be amber-colored when there is approximately 2 days or 20% of battery life remaining.

c. If the LED changes to RED, battery life is about to expire, and therapy will cease.



Addressing a Low-Pressure Condition or Blockage

If there is a gross leak that affects the normal operation of the unit, after one minute the unit will attempt to achieve pressure at one pressure setting lower (or turn off if already set to –50mmHg). If the leak continues and pressure cannot be achieved the unit will rest for 45 minutes before turning back on automatically to resume therapy at original set-point.

To resolve the low-pressure condition, check for the following.

1. Check for any leaks in the dressing seal or tubing.
2. Check to make sure the connection of the tubing is secure and fastened correctly.
3. Check the dressing for any leaks.
4. If there are any issues, notify the healthcare professional or doctor.

If leak persists, a dressing change may be required.

If the unit is in deep-sleep (no lights illuminated or flashing), press and hold the POWER button to resume operation.

Therapy Guidelines

As a general guideline please follow all physicians' orders regarding the use of this system. The MicroDoc is designed to be used for a maximum of 7 days. After 7 days of use, please plan to dispose of the unit. Please follow all applicable guidelines for disposing of this unit.

Specifications

Environmental Conditions			
Storage Conditions		Operating Conditions	
Temperature Range	-4°F (-20°C) to 140°F (60°C)	Temperature Range	41°F (5°C) to 104°F (40°C)
Relative Humidity Range	0-95%, non-condensing	Altitude Range for Optimum Performance	-50 to 8,000 feet (-15.24m to 2438 m)

Cleaning Instructions

1. The ComforTech™ Dressing is sterile and designed for single use; it does not require cleaning.
2. If the MicroDoc becomes contaminated during use, follow the instructions below:
   a. DO NOT SPRAY ANY LIQUID DIRECTLY ONTO the MICRODOC CONTROL UNIT
   b. Spray enough Isopropyl Alcohol 70% (or above) to moisten a soft terry cloth
   c. Use the cloth to wipe down the unit
   d. BE CAREFUL NOT TO ALLOW MOISTURE BUILDUP ON THE UNIT

Warning against service and maintenance

The MicroDoc is designed as a single patient use device and to be used for a maximum of 7 days. DO NOT ATTEMPT TO SERVICE THE UNIT. If the unit is defective upon opening the sealed box, contact Pensar Medical.

Parts requiring preventative inspection and maintenance

- The unit undergoes a final quality inspection on the pump, sensors and software to ensure it is functioning as intended prior to release.

The MicroDoc Applied Parts

- The MicroDoc is a Type BF applied part.

Patient and Caregiver Maintenance

- The MicroDoc is a single use product designed to be used for a maximum of 7 days, therefore no patient or caregiver maintenance is required.

In the event of damage to the packaging upon receipt

- Contact your dealer or Pensar Medical

Mode of Operation

- Continuous
- Negative pressure settings: -50mmHg, -80mmHg, -125mmHg

Battery Type

- AA type battery
- Polarity: +/-

Service Life

- 7 days

UL Information

UL Classified Medical Equipment UL 60601-1 CSA C22.2
IEC 60601-1 (Edition 3.1)
IEC 60601-1-2 (Edition 4.0)

FIRST FOLD

Electromagnetic Compatibility Information

Electromagnetic Emissions

The following electromagnetic emissions information is provided for healthcare facilities and home care environments where the use of this device around other devices could result in electromagnetic interference.

Guidance and Manufacturer's Declaration- Electromagnetic Emission		
The MicroDoc is intended for use in the electromagnetic environment below. The customer or the user of the MicroDoc should assure that it is in such and environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment**
RF Emissions CISPR 11	Group 1	The MicroDoc uses energy from two alkaline batteries only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The RF emissions characteristic of the MicroDoc make it suitable for use in hospital and home use environments.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Electromagnetic Immunity

The following electromagnetic emissions information is provided for healthcare facilities and home care environments where the use of this device around other devices could result in electromagnetic interference.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity			
The MicroDoc is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroDoc should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment-Guidance
Electrostatic Discharge	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors can be any material (wood, tile, concrete, vinyl etc.)
Radiated RF EM fields	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	The device is designed to function in a home healthcare and healthcare environment. Devices in the environment should not interfere with the device performance.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity			
The MicroDoc is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroDoc should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment-Guidance
Proximity fields from RF wireless communications equipment.	See clause 8.10 of IEC 60601-1-2	2450 MHz Band: 2400-2570 Service: Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 Pulse Modulation 217Hz Maximum power: 2W Distance: 0.3 meters Immunity Test level: 28	The device is designed to function in a home healthcare and healthcare environment. It can be near Bluetooth, WLAN, RFID and LTE equipment.
RATED power frequency magnetic fields.	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	The device is designed to function in a home healthcare and healthcare environment. Devices in the environment should not interfere with the device performance.

WARNING: The MicroDoc should not be used adjacent to or stacked with other electrical equipment and that if adjacent or stacked used is necessary, the MicroDoc should be observed to verify normal operation in the configuration in which it will be used.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MicroDoc, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Symbols Glossary

Symbol	Standard	Number	Title	Description
	ISO 7010	W001	General warning sign	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself
	ISO 15223-1	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	ISO 7010	M002	Follow instructions for use	Indicates the need for the user to consult the instructions for use
	N/A	N/A	N/A	Indicates the device should not be disposed of in the regular trash

Symbols Glossary (continued)

Symbol	Standard	Number	Title	Description
	IEC 60417	5333	Type BF Applied Part	Indicates a medical device that has medium- or long-term conductive contact with the patient
	N/A	N/A	N/A	Indicates UL determined the medical device complies with ISO 60601=1
	ISO 15223-1	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	ISO 15223-1	5.3.4	Keep dry	Indicates the medical device needs to be protected from moisture
	ISO 15223-1	5.3.2	Keep away from sunlight	Indicates the medical device needs protection from light sources
	ISO 15223-1	5.2.3		Indicates the medical device has been sterilized using ethylene oxide
	ISO 15223-1	5.4.2	Do not re-use	Indicates the medical device is intended for one use, or for use on a single patient during a single procedure
	ISO 15223-1	5.2.8	Do not use if package is damaged	Indicates the medical device should not be used of the package has been damaged or opened
	ISO 15223-1	5.1.3	Date of manufacture	Indicates the date when medical device was manufactured
	ISO 15223-1	5.1.4	Use-by-date	Indicates the date after which the medical device is not to be used
	ISO 15223-1	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified
	ISO 15223-1	5.1.7	Serial number	Indicates the manufacturer's serial number so that the medical device can be identified
	N/A	N/A	Prescription only	Caution: Federal (USA) law restricts this device to sale by or on order of a physician
	ASTM F2503	N/A	MR Unsafe	The device is MR unsafe. Do not bring the device into the MRI scan room. The device presents a projectile hazard.
Caution: Federal (USA) law restricts this device to sale by or on order of a physician				

SECOND FOLD