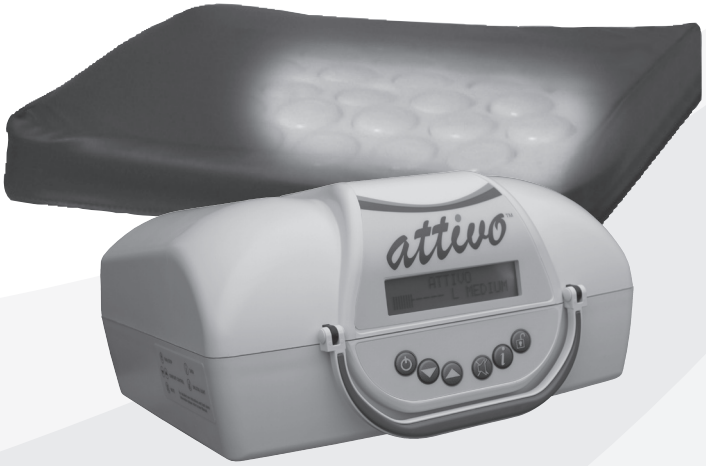
Talley

...reducing avoidable harms

ATTIVO™

Dynamic Seating System



User Guidelines

Explanation of Label Symbols and Statements


Caution


Refer to instructions of use / booklet

Medical Devices Directive 93/42/ EEC

North America ETL listed


Class II Equipment (Double Insulated)


Do not dispose of with the normal household waste *(please refer to www.talleygroup.com for further details)*


Manufacturer


Date of Manufacture


Fragile, handle with care


Suitable for connection to type BF applied parts


Keep dry


Temperature limitation


Humidity limitation


Atmospheric pressure limitation


Protect from heat and radioactive sources


Operating Instructions

WARNING This is a statement that alerts the user to the possibility of serious injury or other adverse reactions with the use or misuse of the device

CAUTION This is a statement that alerts the user to the possibility of a problem with the system associated with its use or misuse

IP22

IP: Ingress Protection (**Pump only**)
2: Protection against fingers or other object not greater than 80mm in length and 12mm in diameter
2: Protection from vertically dripping water when tilted to 15°)

Contents

Introduction

Thank you for choosing to use the Talley ATTIVO™ seating system. In doing so you have selected an effective product for the prevention and management of pressure ulcers which is suitable for seated patients with reduced mobility who are at high risk of pressure damage.

Suitable for use within all care environments, the ATTIVO™ seating system features an alternating air pressure cycle to provide a continuous pressure-relieving wave, helping to promote circulation to areas normally occluded during prolonged seated periods. Dual power technology offers both mains and battery operation, enabling at least 24 hours of continuous running time on a full battery charge.

The system will benefit from careful installation and use, providing a long and effective service life. Please read this user manual in order to achieve the best possible results.

List of Components and Accessories

Your ATTIVO™ seating system should comprise the following items - please ensure you have all of these before installation.

- ATTIVO™ power unit
- Mains lead with integral power supply (15V Mains adapter FW7362M/15)
- Power unit carry case
- TS209 B.A.S.E.® SEQUENTIAL cushion *or* B.A.S.E. ® Recliner Mat

The following accessories/spares are also available:-

- 12V Vehicle adaptor / charger
- Spare mains lead with integral power supply (15V Mains adapter FW7362M/15)

Cautions and Warnings

CONTRAINDICATIONS FOR USE

Alternating pressure therapy should not be used for patients with unstable fractures, gross oedema, burns or an intolerance to motion.

- There are no special skills required to operate the system.
- The medical professional is responsible for applying his/her best medical judgment when using this system.
- Select correct setting for therapy required. Care should be taken not to accidently change pressures once set as the efficiency of the therapy may be reduced. This could also be caused by pets, pests or children.
- The electricity supply is of the type indicated on the power unit
- Check the mains lead is free from damage and is positioned so as not to cause an obstruction, or injury, e.g. strangulation.
- Ensure the mains lead or pump cannot become trapped or crushed, e.g. via raising or lowering of bed or bed rails or any other moving object.
- The power unit must only be used with a suitable approved cord and plug set as supplied by Talley.
- The system is not used in the presence of flammable anaesthetics.

- Suitable for continuous use.
- Not suitable for sterilisation.
- Do not position the power unit to make it difficult to disconnect the power supply, plug or cushion.
- Do not place device on or near a heat source.
- Do not use with hot water bottles or electric blankets.
- The materials used in the manufacture of all components of the system comply with the required fire safety regulations.
- Talley advice against smoking whilst the system is in use, to prevent the accidental secondary ignition of associated items which may be flammable, such as bed linen.
- Do not allow sharp objects to penetrate the cushion material.
- Do not modify the cushion or power unit in any way.
- Do not store in damp conditions.
- Not for use in an oxygen enriched environment.
- Always use the specified carry bag when using in an outdoor environment.
- Intended for home healthcare use and professional healthcare facility environments where operators with medical training are continually available when patients are present.
- The device is intended to be placed on a flat surface or placed in the carry bag supplied and hung by the straps over a suitable support, e.g. wheelechair handles.
- Wireless equipment such as mobile phones should be kept at least 10 feet or 3.3 meters away from the equipment.
- Do not connect to any other medical device or equipment.
- Risk of fire if incorrect fuse used.
- The cushion, power unit and power adapter should be cleaned between patient use, please refer to Care and Maintenance section for all warnings and cautions.
- The power unit battery is installed inside the unit and is not accessible by users. Battery replacement should only be carried out by qualified Talley service personnel.
- The power unit must only be used with the approved power adapter supplied by Talley (see Specification on page 9).
- The cushion must be properly set up as directed.
- All hoses must be free of kinks, twists, properly connected and positioned so as not to cause an obstruction or injury.
- In order for alternating cushion to operate effectively, please avoid placing objects on the surface that may obstruct the movement of air between the cells.
- Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline, as these may destroy the cover materials.
- Do not place heavy objects on the surface of the cushion when not in use.
- Check periodically to ensure patient support and comfort. The system is used as part of a pressure ulcer prevention program, not solely relied upon for this purpose.
- It should be noted that the use of a cushion will increase the patient's seated height by approximately 5cm, and care should be taken to ensure the patient's comfort and security regarding height of foot and arm rests.
- The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.

Installation and User Guidelines

1. Remove all packaging from the cushion and power unit.
2. Place the cushion on the chair, ensuring that the cushion is placed the correct way up with the BACK labelling facing the back of the chair. Secure cushion to chair using adjustable straps if applicable.
3. Suspend power unit from chair in a convenient position using the carry case provided, or place on a flat surface in the correct orientation.
4. Attach cushion air supply hose to power unit by matching up the alignment notch and groove on the ATTIVO™ power unit connection port and cushion hose connector and pushing together (Fig. 1). Ensure that this has been correctly clicked into place, otherwise a leak may occur.

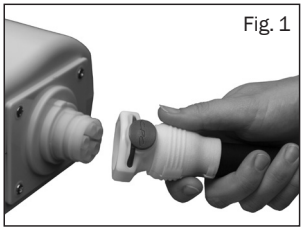


Fig. 1

5. If using mains power, insert the mains adapter DC outlet cable plug into the side of the power unit, and the other end into a mains outlet and switch the outlet on. The mains adapter indicator should be illuminated. If using an the optional vehicle adapter, insert the DC outlet cable plug into the side of the power unit, and the vehicle plug into a vehicle 12V power outlet. The vehicle adapter indicator should be illuminated.

   NB. The battery will charge when the unit is connected to a mains or vehicle adapter (indicated by battery charge status icon on display screen scrolling from left to right) and provides automatic continued operation if the external power supply or adapter fails. It is recommended to use a mains adapter when convenient to do so as this will ensure the battery is fully charged when needed. A fully discharged battery will take a number of hours to fully charge.
6. Standby mode is automatically invoked when the power is switched on. Press the RUN/STOP button to initialise and run the seating system. When the power unit has finished initialising the pump screen will display ATTIVO together with the battery status and the comfort setting (Fig. 2)

Fig. 2

7. The default comfort setting is MEDIUM. The comfort setting can be adjusted using the up and down arrow buttons (see COMFORT CONTROL on page 5).
8. The power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by '🔒' on the display screen. Press and hold the UNLOCK button until power unit beeps if further button operation is needed.

   NB. The display screen is only illuminated for a short period after button operation in battery mode.
9. To stop the power unit, press and hold the UNLOCK button until power unit beeps and '🔒' clears from display screen. Then press and hold the RUN/STOP button until power unit beeps three times to return to stand-by mode (if using the power adapter, disconnect it from the power unit and unplug from the power source). The power unit will then power off automatically after one minute of inactivity or may be forced off by pressing the MUTE key.
10. Place the user manual in a safe place for future use.

It should be noted that the use of an alternating air pressure cushion will increase the patient's seated height by approximately 5cm, and care should be taken to ensure the patient's comfort and security regarding height of foot and arm rests.

OPERATION BUTTONS

The operation buttons on the face of the power unit provide the following functions.

RUN/STOP

Press to invoke stand-by mode prior to running power unit. Press again to run power unit. Press and hold whilst power unit is running (and unlocked) to cease operation and return to stand-by mode. In battery operation the power unit will then power off after 1 minute of inactivity. If using mains power, switch off by disconnecting power cable from power unit or turning off mains power.

COMFORT CONTROL

The automatic default comfort setting is MEDIUM. However, if the patient prefers a firmer or softer cushion, increase or decrease the comfort control setting accordingly using the UP and DOWN arrow buttons (SOFT/MEDIUM/FIRM). The comfort setting is shown on the display screen. Check periodically to ensure patient support and comfort.

MUTE

Press to silence the sounder and to clear the message from the display screen. The MUTE button can also be used to force power-off in stand-by mode.

DATA

The information menu can be activated by pressing the DATA button for 5 or more seconds while pressing the RUN/STOP button, then releasing the RUN/STOP button while continuing to press the DATA button for a few seconds. Press the DATA button when ready to exit the information menu.

NB. Used for accessing information only, does not affect mode of operation.

UNLOCK / LIGHT

The power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by '🔒' on the display screen. Press and hold the UNLOCK button until power unit beeps if further button operation is needed (i.e. change of comfort setting, or returning power unit to stand-by mode). The power unit will lock again 1 minute after last button operation. Pressing this button will also illuminate the display screen for 10 seconds if power unit is in battery operation (screen will always be illuminated in mains operation).

MAXIMUM USER WEIGHT GUIDELINES

127kg (20 stone) max.

Battery Information

- A fully charged battery should operate the power unit continuously for at least 24 hours.
- Charge status is shown on the display of the power unit when it is in stand-by and run mode.
- As the batteries are automatically charged as required when the system is operating on mains power, the battery module should not require removing or changing in normal use.
- Use only the mains adapter or optional vehicle adaptor supplied with the system.
- When power unit operation times when running from the internal battery are noticeably shorter than normal, it is time to replace the battery pack. Contact Talley or authorised dealer for battery replacement service.
- Never use any battery pack that is damaged or worn out. Use the battery pack only for its intended purpose.
- The battery pack is not serviceable and should be replaced if faulty (indicated by applicable battery faults displayed in place of battery charge status icon). Contact Talley or authorised dealer for battery replacement service.

CHARGING THE BATTERY

If not fully charged, the battery will automatically charge when the power unit is plugged into a power source via the power adapter. The battery will charge whilst the vacuum power unit is in standby or in run mode.

REPLACING THE BATTERY

The battery is installed inside the unit and is not accessible by users. Battery replacement should only be carried out by qualified service personnel. Contact Talley or authorised dealer for battery replacement service.

Care and Maintenance

COVER

Always keep the cushion cover as clean as is practicable. The material is waterproof and vapour permeable.

- Inspect top cover for signs of damage or wear which could result in the contamination of the interior, e.g. tears, holes, damage to seams or zips, underside staining, etc. The frequency of these checks should be at each decontamination process, i.e. between patients or patient occupancy (or weekly for longer term patients).
- Care should be taken to avoid puncturing cover with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- The cover may be removed and cleaned in accordance with The Revised Healthcare Cleaning Manual June 2009 subject to the following action: Following the use of a detergent and or disinfectant solution the cushion cover should be rinsed with clean water using a clean cloth and allowed to dry.
- Frequent or prolonged exposure to high concentrations of aggressive disinfectant solutions will reduce the useful life of the cushion cover.
- Where high concentration disinfectants e.g. $\geq$ 10,000ppm chlorine releasing agent (e.g. Haztab or bleach) or combined cleaning/chlorine releasing agent (e.g. Chlorcleam, Actichlor) and detergent solutions are used to remove blood or other body fluids, cushions should be thoroughly rinsed with clean water to remove any residues. This will help prevent any possible long term compatibility issues associated with disinfectant residues.*

- Alternatively disinfection may be achieved by laundering the cover at temperatures not exceeding 65°C for 10 minutes or 73°C for 3 minutes which may include a chlorine rinse.
- Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline, as these may destroy the cover materials.
- Do not iron.
- Ensure that the cushion is thoroughly dried before placing in storage.

INTERIOR COMPONENTS

- Check air bellows and cushion interior for signs of damage or contamination, e.g. staining or evidence of fluid ingress. The frequency of these checks should be at each decontamination process, i.e. between patients or patient occupancy (or weekly for longer term patients)
- Care should be taken to avoid puncturing air bellows with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- The individual bellows strips can also be wiped clean with a mild antiseptic solution*.
- All cushion components are replaceable and can be obtained easily from Talley.
- Do not immerse the cushion in water. The interior components of the cushion (base, foam and bellows) are wipe clean only.

POWER UNIT

Always disconnect the power unit from the power adapter and the power adapter from the power source before carrying out maintenance, repairs, servicing or cleaning. Check all electrical connections and power lead for signs of excessive wear. The power unit / power adapter can be wiped down with detergent or disinfectant solution or wipe*. Do not use solvents. Unsuitable for sterilisation. Dispose of the power unit / power adapter in accordance with the local regulations including WEEE requirements. The power unit / power adapter should be cleaned between patient use as a minimum.

***** In line with the MHRA Medical Device Alert (MDA/2013/019), Talley advises customers to use pH neutral, high level disinfectant cleaning products to sanitise reusable medical devices to prevent damage to materials and the degradation of plastic surfaces after prolonged use. The use of inappropriate cleaning and detergent materials on medical equipment could damage surfaces and may compromise the ability to decontaminate medical devices adequately or may interfere with device function. Talley recommends the use of TECcare® CONTROL antimicrobial wipes and fluid to clean and decontaminate all products it supplies to health and social care facilities. TECcare® CONTROL products provide class leading broad spectrum, high level disinfection with an exceptional safety profile. Being pH neutral TECcare® CONTROL can be universally used on all hard and soft surfaces without any detrimental effect. TECcare® CONTROL is CE marked for cleaning medical equipment.

SERVICING

Once the initial guarantee period expires, Talley recommend that all power units should be serviced annually or as indicated by the 'hours to service' display. The unit contains no user serviceable parts and should only be serviced by either Talley or an authorised dealer. Talley will make available on request service manuals, component parts lists and other information necessary for Talley, an authorised dealer or a competent electrical engineer to repair or service the system. Talley's standard terms and conditions apply to all sales. A copy is available on request. For service, maintenance and any questions regarding this, or any other product, please contact Talley.

It is the customer's responsibility to ensure the following prior to collection:

- the system is cleaned of any obvious contaminants.
- contamination status is documented.
- assistance is given to Talley personnel to bag the equipment if the mattress has been in a known or suspected infectious environment.

TRANSPORT AND STORAGE

Handle with care. Please report instances of damage or impact to Talley Service Department.
Transport
–25 °C without relative humidity control; and
+70 °C at a relative humidity up to 93 %, non-condensing.
An atmospheric pressure range of 700 hPa to 1 060 hPa.
Suitable for all standard modes of transport when in the correct packaging.

OPERATIONAL CONDITIONS

A temperature range of +5 °C to +40 °C;
A relative humidity range of 15% to 93%, non-condensing; and
Operational Atmospheric Pressure: 700 hPa to 1060 hPa
Suitable for pollution degree 2
Operational altitude ≤ 2 000 m
IP Rating: IP22 pump only

MANUFACTURER'S GUARANTEE

The power unit and cushion are covered by a 24 month manufacturer's guarantee. The intended design life is 5 years if fully serviced.

Fault Finding

All sounders can be silenced and messages cleared by pressing the MUTE button once. Should any fault occur, press the MUTE button to reset the power unit. If fault remains/ re-occurs, contact Talley.

WARNING INDICATORS

NO BATTERY – indicates battery is not correctly fitted. The power unit will only operate using the power adapter whilst this message is displayed. Contact Talley or authorised dealer to check battery and installation.

LOW BATTERY (only appears during battery operation) – the power unit will continue to run whilst this warning is displayed. Press the MUTE button to silence the sounder and clear the message. Note that the system will automatically shut down when the battery is fully discharged. Plug into a power source to charge.

LOW PRESSURE – indicates pressure has fallen below minimum allowable levels. Power unit will continue to run whilst these messages is displayed. Check that the hose is connected to the power unit correctly. Check that the internal tubing and bellows are connected and that there are no punctures. Press the MUTE button to clear the message and to silence the sounder. If the fault re-occurs, contact Talley.

EMI fault – indicates that the unit detects the pressure sensor amplifier is adversely affected by external RF fields. The power unit will continue to run whilst this message is displayed. Press the MUTE button to silence the sounder. This indicator will clear when interference ceases.

O/C BATT *or* CCT FAIL (will appear instead of battery charge status icon) – indicates that the battery is not functioning correctly and cannot be used. The power unit will only operate using mains power whilst this message is displayed. Contact Talley to order a replacement battery.

UNCALIBRATED – contact Talley for recalibration (the power unit will continue to run whilst this message is displayed).

If any of the following faults are displayed the power unit will cease to operate:- PUMP OPEN; PUMP SHORT; RELEASE KEY; ROTOR FAULT. Should any of these faults occur, press the MUTE button to reset the power unit. If fault remains/re-occurs, contact Talley.

Specification

CE 0120

POWER UNIT (Medical Device Classification: Class IIa)

Model Ref:	ATTIVO TG600/07
Construction:	Flame retardant ABS
Dimensions:	210mm x 205mm x 105mm
Weight:	2.2 kg
Cycle Type / Time:	Active 1-in-4 cell cycle / 16 minutes
DC Input Voltage:	15V Nominal
Pressure Range:	30 / 50 / 70mmHg (SOFT / MEDIUM / FIRM)
Fixed Internal Battery:	6V 2.5Ah NiMH

POWER ADAPTER

Mains Adapter Type:	FW7362M/15 (supplied)
Input:	100-240V / 50-60Hz / 700mA
Output:	15V dc / 2A
Cable Length:	4 metres
Part Number:	34-26-05-103

CE 0120

CUSHION (Medical Device Classification: Class IIa)

Model Ref:	**TS209 B.A.S.E. SEQUENTIAL**	**B.A.S.E. RECLINER MAT**
Construction:	PVC bellows within punched CMHR foam surround	
Dimensions:	430mm x 430mm x 70mm	1080mm x 430mm x 70mm
Weight:	1.9 kg	3.9 kg

The above mains adapter is considered part of the ME equipment

12V vehicle power adapter is available as an optional accessory (99-01-14-05)

The ATTIVO™ power unit must only be used with the specific external power adapters as supplied by Talley.

Talley products are manufactured to comply with International and National safety standards. Talley design and manufacture products to conform to the requirements of ISO9001, ISO13485 and Directive (93/42/EEC). Talley reserves the right to modify the specification of any product without prior notice in line with a policy of continual product development. Our standard terms and conditions apply.

EMI/EMC Statement and Manufacturer's Declaration

This equipment has been tested and found to comply with the limits of EN 60601-1-2.

These limits are designed to provide reasonable protection against harmful interference in both a medical and residential environment. This equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with manufacturer's 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 or other equipment, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the receiver or equipment was connected.

The equipment having been tested to operate within the limits of electromagnetic compatibility. (Immunity to interference from nearby sources radiating radio frequency energy). Sources exceeding these limits may give rise to operation faults. Where possible the system will sense the interference and if it is of short duration transparently take countermeasures whilst operating near normally, or failing this will issue a warning and take measures for the continued safely of the user. Further increased levels of energy may cause the system to stop operating, continuously generate random faults or continuous resets.

Try to ascertain the source of the interference by turning nearby or suspect equipment off, and see if the interference effects stop. In any such event the user is encouraged to try to correct the interference by one of the following measures:

- Have the interfering equipment repaired or replaced.
- Reorient or relocate the interfering equipment.
- Increase the separation between the equipment and the possible source of the interference.
- Connect the equipment to an outlet on a circuit different from that to which the interfering equipment was connected.

Information regarding Electro Magnetic Compatibility (EMC) according to IEC60601-1-2
With the increased number of electronic devices such as PC's and mobile telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. The EMC (Electro Magnetic Compatibility) standard IEC60601-1-2 defines the levels of immunity to these electromagnetic interferences. From the other hand, medical devices must not interfere with other devices. IEC60601-1-2 also defines the maximum levels of emissions for these medical devices. The ATTIVO™ conforms to this IEC60601-1-2 standard for immunity and emission. Nevertheless, special precautions need to be observed:

- The ATTIVO™ needs to be installed and put into service according to the EMC information below.
- The ATTIVO™ is intended for use in the electromagnetic environment specified in the tables below. The user of the ATTIVO™ should assure that it is used in such environment.
- In general, although the ATTIVO™ complies too the EMC standards, it can be affected by portable and mobile RF communications equipment (such as mobile telephones).
- The ATTIVO™ should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the ATTIVO™ should be observed to verify normal operation.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions (IEC 60601-1-2)		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Class B	The ATTIVO™ systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage pump supply network that supplies buildings used for domestic purposes.
Harmonics emissions 61000-3-2	Class A	
Voltage fluctuations / flicker emissions 61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV For mains supply lines ± 1kV For input/output lines	± 2 kV For mains supply lines ± 1kV For input/output lines	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Surge IEC61000-4-5	± 1kV line(s) to line	± 1kV line(s) to line	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on mains supply IEC 61000-4-11	<5%Ur (>95%Ur) for 0.5 cycle	<5%Ur (>95%Ur) for 0.5 cycle	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment. In the event of a mains interruption the ATTIVO™ system will automatically use internal battery power, unless the battery is exhausted.
	40%Ur (60% dip in Ur) for 5 cycles	40%Ur (60% dip in Ur) for 5 cycles	
	70%Ur (30% dip in Ur) for 25 cycles	70%Ur (30% dip in Ur) for 25 cycles	
	>5%Ur (>95% dip in Ur) for 5 secs	>5%Ur (>95% dip in Ur) for 5 secs	
Mains frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Note: Ur is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V rms 150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.5 GHz	3 V rms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ATTIVO™ including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz 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). 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note1: At 80 MHz and 800 MHz, the higher frequency range applies. Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 ATTIVO™ is used exceeds the applicable RF compliance level above, the ATTIVO™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ATTIVO™. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the ATTIVO™			
The ATTIVO™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ATTIVO™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ATTIVO™ as recommended below, according to the maximum output power of the communications equipment.			
Output Power of Transmitter in Watts (W)	**Separation distance according to frequency of transmitter in Meters (m)**		
	150 kHz to 80 MHz d = 1.2 √P	**80 MHz to 800 MHz d = 1.2 √P**	**800 MHz to 2.5GHz d = 2.3 √P**
0.01	0.01	0.01	0.01
0.12	0.12	0.12	0.12
0.12	0.12	0.12	0.12
0.23	0.23	0.23	0.23
0.1	0.1	0.1	0.1
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: At 80MHz and 800MHz, the separation distance for the higher frequency range applies. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

This medical device is compliant with:
IEC 60601.1 3rd edition Medical electrical equipment safety and essential performance
IEC 60601.1.11 Home healthcare environment

USER MANUAL PART NUMBER 50-02-07-212/5

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