Portable Phlegm Suction Machine

Instruction Manual

Model No.: H-SM151

CE 1639

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1. Application

The Phlegm Suction Unit is a portable, AC-powered device intended to be used to remove phlegm from a patient's airway. Unfit thoracic drainage and gynecological drainage.

Intended patient population	Intended user
a) Age:3years to geriatric b) Weight: 10kg above c) Health: patient respiratory disorders. d) PATIENT state: The patient who is conscious and can spontaneously breathing.	It should only be used by persons trained in the use of medical suction equipment.

Indications：

The primary indication for suctioning the patient cared for at home is the patient's inability to adequately clear the airway by cough. The need for airway clearance is evidenced by:

1 more frequent or congested-sounding cough;

2 coarse rhonchi and expiratory wheezing audible to the patient and/or caregiver with or without auscultation;

3 visible secretions;

4 increased peak pressures during volume-cycled mechanical ventilation;

5 decreased tidal volumes during pressure-cycled ventilation;

6 indication by the patient that suctioning is necessary;

7 suspected aspiration of gastric or upper airway secretions;

8 otherwise unexplained increase in shortness of breath, respiratory rate, or heart rate;

9 decreases in vital capacity and/or oxygen saturation (as indicated by pulse oximetry), thought to be related to mucus plugging.

Complication/Side effects:

1. Blockage: secretions or debris may block the tubing and device malfunction can occur.

2. Trauma: vigorous or blind suctioning can cause damage to lips, teeth, tongue or pharyngeal tissues.

3. Stimulation：locally, suctioning can cause an increase in secretions secondary to tactile stimulation. Stimulation of sensitive tissues can result in a reflex arc such as sneezing (nasal cavity), gagging (posterior tongue), coughing (trachea), or bronchospasm (bronchi). Additional reflexes include vagal stimulation with bradycardia and hypotension, and tachycardia. Elevations in intracranial pressure can also occur. Hypoxia may result from coughing, bronchospasm, reflex hypopnea, the direct effect of the cannula (airway obstruction), or the evacuation of therapeutically hyper-oxygenated air and its replacement with room air.

4. Others: for an awake patient, suctioning can range from mildly uncomfortable to painful. Catheter stiffness, force applied, and suction strength are among the factors that determine the degree of patient discomfort.

Contraindications:

NO.

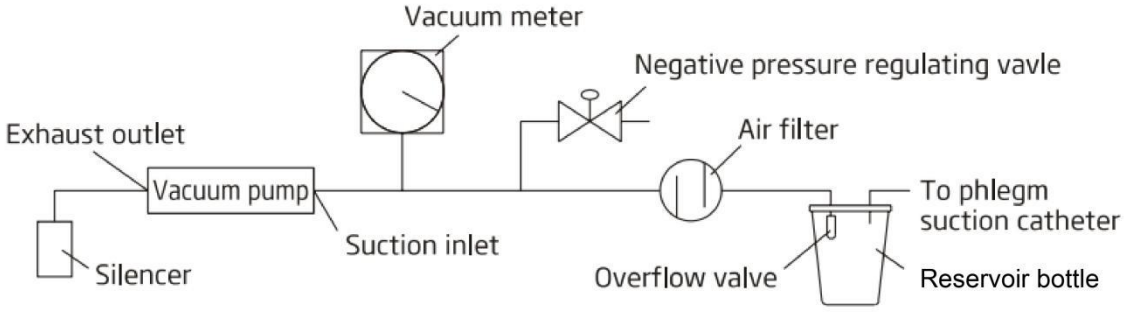
*Warnings:

Infection: an aseptic technique must be used to avoid intro- duction of infection into the airway.

2 .Structural characteristics and working principle

The main structure of suction device includes vacuum pumps, vacuum gauge, pressure regulating valve, air filter, and the reservoir bottles.

It used oil-free lubrication pump to stop environmental pollution by oil mist. It has low noise. Reservoir bottle is hidden in a submerged novel structure, and it has an overall plastic enclosure design. The operation of the device will not produce positive pressure to ensure reliability and safety. The vacuum conditioning system can be adjusted by non-polar voltage as needed. It is small size, light weight and easy to carry, and is suitable for a variety of emergency situations and out-clinics in particular.
Operation principle diagram:



3. Main Technical Specifications

Input rating	AC 220V, 50Hz ， 0.7A
Max. negative pressure	87 KPa
Negative pressure regulating range	20KPa~Max. negative pressure
Pumping flow rate	≥16L/min
Fuse	AC250V, F2 AL, Φ5.2 X 20
Reservoir bottle	1100mL
Noise	≤60dB(A)
Vacuum gauge	0~100KPa, 2.5 grade
Equipment Type	Medium vacuum/low flow
Working mode	30 min ON,30min off
Electrical requirements	Class II, type BF
Life of products	5years
Accessory use times(Reservoir bottle and tubing)	30 times
Note: It is not suitable for use in environment with flammable and explosive gases; Electromagnetic interference source: the minimum separation distance of ≥1.1m when it is close to power lines and electrical equipment with the voltage less than 500V	

4. Operating and storage conditions

Operating temperature range	+5℃~+40℃
Operating humidity range	30% to 85%RH
Atmospheric pressure range	700hPa~1060hPa
Transport and storage temperature range	-20℃~+70℃
Storage humidity range	10% to 95%RH
Note: When storage temperature is below 5℃,please keep the device in normal working condition for at least 2 hours before using.	

5. Installing and Commissioning

5.1 Open Package Inspection

The customer shall carefully inspect if the appearance of product is good,and the varieties &quantities of the attachments are in conformity with those as indicated in the attached list before installing and commissioning.Also ,the customer shall timely notify the supplier or manufacturer of damage(s) if any.

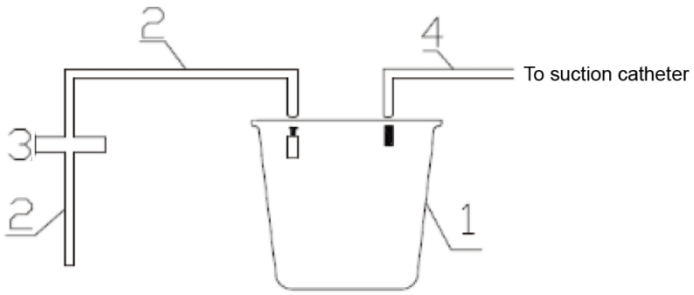
5.2 Power line Connection

Connect the plug with the power source.Turn on the power supply,and the power indicator will illuminate.

Note:The power plug is used for power shut-off,and the power socket shall be grounded reliably.

5.3 Tubing Connections

Please refer to tubing connection diagram, and suction catheter temporarily not connected



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1) Reservoir bottle； 2) Intermediate tubing； 3) air filter ； 4) Suction tubing

Tubing Connection Diagram

5.4 Connector inspection

Turn tightly the negative pressure regulating calve clockwise,and block the air suction inlet with finger or the rubber head of dropper,or fold up and hold the suction tubing.

Start the aspirator for running with no strange sound; the pointer of the vacuum meter will quickly reach up to the limit negative pressure, Release the air suction inlet, the pointer will return below 0.02Mpa, If so, the connector can be regarded as being in good connection.
Attech the suction catheter. The negative pressure in the negative pressure system shall be less than 0.06MPa at the time of attaching F6 suction catheter, less than 0.04MPa when attaching F8 suction catheter and less than 0.03 MPa when attaching F12 suction catheter. If so, the phlegm suction machine is considered as being in normal condition.
Note 1: If the suction catheter is blocked as per the following method: Bend the suction tubing in "V" form (with no liquid in the bottle), and release it to the original status when the negative pressure reaches up to the maximum value. Repeat this procedure several times till the catheter is no blocked.

5.5 Negative pressure regulating

‣ Block suction inlet, turn on the suction device switch, and regulate the negative pressure valve, and the reading on vacuum meter shall be within 0.02MPa~limit negative pressure.

‣Control the negative pressure as required for suction by means of the negative pressure valve at the time of clinical practice.

‣Increase the negative pressure by turning the valve clockwise.

‣Reduce the negative pressure below 0.02Mpa prior to power shut-off

5.6 Inspection & testing of overflow device

‣Open the bottle lid, clean up the valve mouth, and leveling the rubber valve clack on the float, the valve clack shall not be warped, bent and broken, but well connected with float. The float shall be able to move freely in its support without any blockage, lift the bottle lid with hand to make the float contact the water surface perpendicularly gradually lower the holder cover to let the float rise. Tighten the bottle lid, attach the suction tubing at the inlet, and screw firmly the regulating valve, then, actuate the aspirator.

‣Put the suction tubing into one clean water pail or attempt to simulate actual application to suction the liquid into the holder of the overflow device, as a result The float will rise as the liquid level ascends until the valve is closed and suction stops automatically. The final position of liquid level depends on the suction process adopted.

‣Release the regulating valve, set the aspirator switch off, Open the holder plug and empty the liquid in the bottle, the float shall be at the bottom of the support and the valve is in open status in case of re-screwing firmly the hold plug. If so, the overflow device is considered as being in normal condition, which can be used for clinical practice.
Note:
1. The liquid level still continuously ascends after the overflow device has been shut off, possibly due to:
(1) Residual negative pressure still in the bottle;
(2) Valve mouth not fully closed.

For item(1), the liquid level in bottle will not ascend when the suction tubing is placed again into the liquid as suctioned, and for item (2), the liquid level still ascends. Thus, it is required to observe carefully, and lift immediately the tubing out of the suctioned liquid when the holder to close to full, then, switch off the aspirator to stop suction, and examine the possible reason of the valve fault.

2. The float is still adhered on the valve mouth as already closed by the float, possibly due to the negative pressure in the line. At this moment, release the regulating valve or shut off the aspirator(to release the negative pressure in the line),the float will descends from the valve mouth under the action of gravity.(it is forbidden to pull the float with hand, in order to avoid the rubber valve clack being separated from the float)

‣After shut-off, release the negative pressure then open the bottle lid;

Note 1: Never use the aspirator under the condition of the overflow device &the conductor dismantled

5.7 Stop running

Turn off the aspirator switch, and pull the power plug out of the socket to shut off the power supply.

5.8 Cleaning and Disinfection

5.8.1 Basic information

The Phlegm Suction Machine is for patient care . It may share use with others, but the Suction catheter single use only. Except the Phlegm Suction Machine and air filter, the accessories can be washed and sanitized.

The accessories use time is 30 times, the air filter need to change when turn yellow.

5.8.2First use and once daily

. Disassemble all accessories to pieces and flush each piece by tap water. (All accessories mean the all parts except the Phlegm Suction Machine and air filter).

. Connected the tube to the machine;.

5.8.3 After each use

5.8.3.1 Accessories (Include reservoir bottle, Suction tubing, Intermediate tubing) should be cleaning and disinfection as follows:

1).Reservoir bottle cleaning: first empty the reservoir bottle, remove the dirt in the bottle and on the bottle cap with a soft brush or soft cloth, clean it with hot water or mild detergent, and then rinse it repeatedly with clean hot water, including flushing overflow parts, seals and various tubes. Unscrew the overflow unit if necessary and clean the float and float jacket separately. (Avoid sharp objects and drop when cleaning or using reservoir bottle)

2).Tube cleaning: suction a small amount of water, clean the inner wall of the tube.

3)Accessories Disinfection: After washing, disinfect using the following methods:

Soak in 1 part vinegar (>=5% acetic acid concentration) to 3 parts water (131ºF-149ºF/55ºC-65ºC) solution for 60 minutes. Rinse with clean, warm water and air dry in a clean environment. (The vinegar solution should not be reused).

Note: The accessories only for single patient use.

5.8.3.2 Phlegm suction machine body cleaning: wipe the outer surface of the machine with a damp cloth soaked in alcohol. To avoid liquid infiltration, do not wipe on cracks and words.

Note: Alcohol is highly flammable. Do not use alcohol within the vicinity of open fire or smoke.

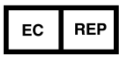
5.8.4 Keeping care

. To care the accessories a good hygiene, suggest to put the accessories in a container or a plastic bag with seal until

5.8.5 About Phlegm Suction Machine

. Do not pour water onto Phlegm Suction Machine. Do not immerse the Phlegm Suction Machine into water. If there are some water drops onto Phlegm Suction Machine, use a wet towel to clean surfaces.

6. Explanation of Symbols

Symbols	Meaning	Symbols	Meaning
	Consult User Guide		ON
	Type BF applied part		OFF
	Class II equipment	IP21	Protection against solid foreign objects and harmful effects due to the ingress of water
	Serial number		Authorized representative in the European Community Caution
	Manufacturer		Warning/Caution
	CE Marking of Conformity	~	Alternating Current
	This appliance is marked according to the European directive 2012/19/EC on Waste Electrical and Electronic Equipment (WEEE). The symbol on the product, or on the docu ments accompanying the product, indicates that this appliance may not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment		Indoor use only

7 .Operations and Maintenance

7.1 Operation and Maintenance

Prior to operation, check the suction device according to the installation and commissioning procedures to ensure it is in good working order, and once sterilized suction catheter and tube is connected, the device may be put into use.

Note: please read the packaging description before using the attached suction tube.

During operation, pressure regulating valve is used to adjust the pressure to desired level, and turned the switch on or off as per requirement. Always pay attention to liquid level in the reservoir bottle. When the liquid level rises to the calibration capacity of the reservoir bottle (the device remain operational when tilted 10 degrees), suction operation should stop to empty and clean reservoir bottle before use again, otherwise the liquid level will drive the floater up to the level that closes off valve port, forcing suction operation to stop automatically.

Note: When liquid level continues to rise after overflow component is shut off, Please refer to inspection and testing of overflow component procedure for handling.

Emergency measures in use:

1) In case when purulent sputum or mucus obstructs suction tube, the pressure regulating valve should be loosen promptly to release pressure, and suction tube should be replaced before used again;
2) In case where the suction tube difficult to pull out after suction or sucked on human tissues, please apply the method above by loosening the pressure regulating valve.（Operating time must not exceed 30 minute）

⚠ Suction volume must not exceed the maximum liquid level warning mark

Tightened cap and tube joints when pressure is insufficient

Note 1: Prior to suction, bend the suction catheter into a V shape to boost that pressure to the required range on turning on the device, then insert the suction tube into patients Phlegm site, and then release the suction catheter to suck for better result.

Note 2: The specification and size of suction tube is determined by the medical staff according to clinical requirements

Note 3: During operation, if there is presence of bubble in the reservoir bottle, liquid level of the reservoir battle should be monitored to prevent overflow device failure.

Note 4: The suction devices should be used under the guidance of medical personnel, and in strict accordance to operation procedures outline in the Manual, and in case of doubt please contact the supplier or manufacturer.

Note 5: The diameter of the sputum suction catheter should be appropriate, the action should be gentle in the process of sputum suction, not to stimulate back and forth, negative pressure suction should not be too high, the adult is generally 0.04MPa, too high pressure may damage the air to the mucosa, sputum suction should not exceed 15s.

7.2Replace air filter

When air filters sucked or filled with dust would result in colour change of membrane from light to dark, and also caused significant reduction and even disappearance of inhalation capacity at the tube mouth, and pressure on the vacuum gauge will continue to rise to more than 0.04MPa. In such case, please replace the air filter replacement from our company.

Note 1: When the overflow component is shut off or the suction tube is blocked, suction force may also

decrease or disappear, and pressure values would also increased. Please refer to “Common Troubleshooting”.
Note 2: The air filter should be changed regularly and destroyed in a centralized method.

7.3 Changing fuse

Fuse is located in the bottom of base, when replacement is required, cut off the power supply first, use flat or cross screwdriver counter-clockwise to open the base to replace.

7.4 Maintenance

Prior to shut down, Wash in a hot water/dishwashing detergent solution and rinse with clean, hot tap water. Then wash with a commercial (bacterial-germicidal) disinfectant, follow disinfectant manufacture’s recommended instructions and dilution rates carefully.
It is recommended to suck small amount of clean water using suction tube to clean the tube internal wall. After shut down, empty reservoir bottle, use soft brush or cloth to remove dirt on bottle and the cap, then wash again with water (including the overflow component, seals and various tubes). If necessary, unscrew the overflow component, separate float planes and floater for a through cleaning (Note: rubber valve shall not be separated and floater).

Used suction tube should be cleaned by saline to remove remnants of purulent sputum and mucus within the tube. If the suction tube is blocked, it should be replaced.

Reservoir bottles, caps and various tubes should be soaked and disinfect followed:
60-minute soak in a solution of vinegar and water with an acetic acid content ≥ 1.25% (The vinegar solution should not be reused.);

Note: Reservoir bottle is made of plastic, avoid sharp items when clean or in use, and also prevent it from falling

The outer surface should be wiped by wet cloth pre-soaked with disinfectant. To avoid the infiltration of liquid, do not wipe on crack, words and artworks
Devices not in use should be placed in dry and clean place, and operate the device on a regular basis (typically every six months).
Note: Before the next use of the device, overflow component and other tubing should be fitted according to tube connection method.

7.5 Periodic Safety Checks

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- Inspect the equipment and accessories for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.
- Inspect the fuse to verify compliance with rated current and breaking characteristics.
- Verity that the device functions properly as described in the instructions for use.
- The leakage current should never exceed the limit defined in EN/IEC 60601-1. The data should be

recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

8 .Common Trouble shooting

Failure	Cause analysis	Remedy	Note
Negative Pressure limit is less than 0.07MPa	1)mouth leakage 2)Leakage on connecting points 3)regulating valve loose or released	1)clean bottle mouth, tighten or replace the cork, seals or joints 2)re-tightly each connection point 3)turn tightly the regulating valve	1)maintenance of cabin parts should be conducted by qualified personnel; 2)split tube should be replaced
Negative value is greater than 0.04MPa, but the suction power at mouth of the suction tube is significantly reduced or disappeared	1)Overflow component is shut off 2)Tubing is blocked 3)Air filter is blocked	1)turn off the device, turn the regulating valve counter-clock wise to release the pressure in the tube, then tighten the valve 2)Dredge, clean or replace the tube 3)Replace the air filter from Our company	1)empty the reservoir bottle promptly 2)blue mark on the air filter is the inhaling mouth
Power supply voltage is normal, but indicator light is not on	1)power plug is loosen 2)fuse is fused 3)indicator light is damaged	1)repair or replace power plug 2)replace fuse 3)replace indicator light	1)specification:AC250V, F2AL, Φ5X20
Fuse is fused	1)voltage oversupplied 2)internal line fault 3)rolling resistance of pump and resulted in current increase	1)adjust voltage 2)check and repair line fault 3)check pump and motor	Must be conducted by qualified technician (refer to electrical Theory flow Chart)

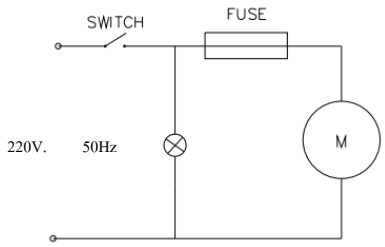
Note: If pump fails, demolition and repair should be operated by qualified personnel, please contact the manufacturer if necessary (power should be cut off before inspection of lines or opening up the box)

9 .Additional Notes

9.1 Restriction on transportation and storage conditions

Portable suction device should be stored well-ventilated room without corrosive gases, and should avoid sever vibration or shock.

9.2 Electrical Theory Flow Chart



Electrical maintenance should be conducted by qualified personnel

9.3 After sales service

The company will accept return, replace or repair for product with quality issues that was not caused by artificial factor and occurred within one week from the date of sales. The company will provide maintenance free of charge for product with quality issues which occurred within one and a half from the date of manufacturing (one year from use commence date) under standard use and storage conditions. For products with quality issues which occurred after one and a half from the date of manufacturing (one year from use commence date), the customer should take invoice and warranty card to our after-sales service department, representative office or dealer office, and the company will provide parts for maintenance at a reasonable charge. Where user is not able to provide invoice, the company will extend the free warrantee period by one month calculated based on device reference or date of manufacturing. Warranty does not extend to the following circumstances: 1. machine damage or deformation caused by collision; 2. machine exposed to water or rain; 3. infiltration of water, blood or sputum, or suction of viscous liquid into the pump by customer and resulted in machine failure; 4. vulnerable and consumables items including: air filters, suction tube and fuse.

When product and accessories are reaching the end of their expiry dates, these products and accessories should be disinfected then be delivered to qualified companies or individuals for recycling.

9.4 Included in delivery

Suction tubing (length 2.0 m)	1 PC	Intermediate tubing (length 0.2m)	2 PCS
Manual	1 PC	Air filter	3 PCS
Reservoir bottle	1 PC	Suction catheter (12Fr/8Fr)	2 PCS
Connector	1 PC	float (overflow valve)	1 PC

10.Important information regarding Electro Magnetic Compatibility (EMC)

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3* 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 ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines	± 0.5kV, ± 1 kV line(s) to lines
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

11. Disposal statement

Correct Disposal of this product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of , with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling .

This product does not contain any hazardous substances

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