MD

Heated Breathing Tube

User’s Manual

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The website of Electronic manual is http://www.rescomf.com/en/pro_show.asp?cid=240&id=2821

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1.Understanding the Heated Breathing Tube

1.1 Intended Use

Heated breathing tube is intended to be combined with a respiratory therapy devices and humidifiers to provide air connection between positive pressure ventilation and patient interface. It is intended for single-patient in homes, hospitals.

Indications: It is the same with the ventilators or humidifiers, please refer to the users' manual of ventilators or humidifiers connected to heated breathing tube.

Intended patient: It is used by adult patients receiving respiratory support via positive pressure ventilation.

Contraindications:

Studies have shown that the following pre-existing conditions may contraindicate the use of this device for some patients:

I. Absolute Contraindications

- High Risk of Airway Thermal Injury，such as recent airway surgery (≤72 hours) or mucosal damage (e.g., post-aspiration pneumonia), compromised mucosal barrier;
- Congenital Thermosensory Disorders, such as Hereditary Sensory Autonomic Neuropathy (HSAN Type IV), syringomyelia with impaired temperature perception;

II. Relative Contraindications

- Humidity-Sensitive Pathologies, such as acute pulmonary edema, alveolar proteinosis (PAP) during mechanical ventilation;

Refer to the users' manual of ventilators or humidifiers connected to heated breathing tube for any additional contraindications that may be specific to the use of that device.

Intended user: The intended users are adults who are capable of understanding general operation of the device and the content of instruction manual, and can be either doctors or lay persons.(Intended delivered volume ≥300ml).

1.2 Warnings and Cautions

Warning：

a. This product is intended for use by a single patient only, cross-use by different patients may lead to infection.
b. Use limitations please refer to the user's manual of the ventilator or humidifier which is used to connect with this product.
c. If the connection with other combined use device is not good, and air leakage happen, please stop use.
d. If the product is used when the voltage is out of range, it will cause the product to not work properly.
e. The plug (or appliance inlet) is used as disconnect device to the mains supply, do not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.
f. These devices should be inspected before each use. Visually examine the devices for obvious physical damage including:
   - Cracked, broken or otherwise distorted plastic parts.
   - Broken or significantly bent connector contacts.
   - Damage including cuts, punctures, nicks, abrasions, unusual lumps, significant discoloration.
   - Tips for damage, corrosion or misalignment.
   - On hand-switching, cable contacts for corrosion, discoloration and flatness.
g. Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
h. 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.
i. Use of 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.

j. 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

k. If the device intended for use by lay persons, the circumstances in which the user should consult a healthcare professional.

- Discontinue using the heated breathing tube if you have ANY adverse reaction to the use of tubes, and consult your physician or healthcare professional or distributor.

-This heated breathing tube is intended for the purposes described in this manual only, please contact your physician or healthcare professional or distributor if in doubt.

Warning statement：

Unauthorized modification of the device may result in product damage. If not followed may result in a range of harms, some of which are severe.

Please refer to the Warnings and Cautions within this guide. Failure to follow the operating instructions may compromise the performance and safety of the heated breathing tube. Only use your heated breathing tube for its intended use as directed in this guide.

When the heating breathing tube is used in combination with the ventilation equipment, the temperature of the air outlet at the patient's end shall be controlled by the ventilation equipment.

Cautions:

(1) Please read the instruction before use;

(2) Please stop using if the tube is damaged (having holes, kinks, tears, exposed heating wires, etc) or not functional;

(3) Inspect the product regularly and replace the product immediately if it is found to be contaminated or no longer suitable for its intended use;

(4) This product is sale on the order of physician or respiratory therapist;

(5) Please avoid foreign matter entering the tube;

(6) Do not block the airflow in the heated breathing tube;

(7) Please do not touch the heated breathing tube with skin for long time which may cause burning.

(8) Do not add extra temperature to any part of the heated breathing tube, for example, by covering it with a quilt, or using it in an incubator for newborns, or under the heating head of an insulation rescue table, as this may cause serious injury;

(9) This product should not be soaked or sterilized when used in hospital. It is recommended to use it for no more than 14 days;

(10) Keep the product away from high temperature environment or heating source and avoid using in places with open flame;

(11) This product is non-sterile. It need to be clean and disinfected before use. If the tube is not disinfected according to cleaning and disinfection instruction, it might cause patient infection when other patient use or reuse.

(12) This product is single patient can be reused after disinfection, repeated use of different patients may cause the spread of infectious substances.

(13) Be careful to strangulation due to cables and hoses, particularly due to excessive length.

(14) Keep the heated breathing tube and the controller out of the reach of young children / pets to avoid touch or chew. The wire or tube can cause strangulation.

1.3 Structural & compatible device

Model	Structural composition of Heated Breathing Tube		Compatible device		
	Heated tube	Heated tube controller	Device name	Brand	Model

HCT001	1	1	Ventilator and humidifier	Suitable for most ventilators or humidifiters which connector shall be comply to ISO 5356 standard.	No model limitation
HCT002	1	1			
HCT003	1	1			
HCT004	1	1			
HCT005	1	1			
HT001	1	0	Ventilator	BYOND	S1
HT002	1	0	Ventilator	VENTMED	DF-20A
HT003	1	0	Ventilator	hypnus	HFO-60/HF0-60M/HFO-80/HFO-80M
HT004	1	0	Ventilator	BYOND	S1
HT005	1	0	Ventilator	VENTMED	DF-20A
HFT001	1	0	Ventilator	Yuwell	HF-80AP
HFT002	1	0	Ventilator	Fisher&Paykel	AIRVO2
HFT003	1	0	Ventilator	Micomme	OH-60A
HFT004	1	0	Ventilator	RESPIRCARE	HUMID-BHR

Combined use device information:

The heated breathing tube only can used with approved respiratory therapy equipment (such as ventilator) and the patient interface (Mask or cannula) according to Medical device directive 93/42/EEC or Medical device regulation 2017/745. The heated breathing tube is not coaxial breathing set. Their connector size shall be comply with ISO standard, so that the breathing tube can be attached to their connector socket with good connection.

1.4 Product Specifications

1) Length: 1.8m
2) Internal diameter of cuff: 19mm （or 15mm）
3) Flow Resistance: R@30 l/min < 0.06 hPa/l/min
4) Compliance: C@60 hPa < 5ml/hPa
5) Leakage: @ 60 hPa＜10ml/min
6) Power input: AC100~240V, 50-60Hz, 1.2A max（Only for HCT001/HCT002/HCT003/HCT004/HCT005）Power of heated tube:≤48W（for HCT001/HCT002/HCT003/HCT004）Power of heated tube:≤18W（Only for HCT005）
7) Power input: DC24V, 2.5Amax Power of heated tube:≤60W (for HT001,HT002,HT003,HT004,HT005,HFT001,HFT002,HFT003,HFT004)
8) Electrical safety standard: EN IEC 60601-1
9) Electrical Safety Class IEC 60950: Class II
10) Water resistance: IP21（It means the device could protected against solid foreign objects of 12.5mm Φ and greater, and protect against vertically falling water drops.）
11) Shelf life time: 5 years
12) Respiratory humidification therapy instrument which supplies power for HT001, HT002, HT003, HT004, HT005, HFT001, HFT002, HFT003 and HFT004 should meet the following conditions, output voltage: DC 24V, Current:≥2.5A , output comply with IEC 60601-1, provide at least two MOOP insulation between ac input and dc output. Class II equipment.
13) The gas pathway is applied part. The heating wire temperature will be less than 41 degree C. It is used for avoid condensation of the therapy air in the tube and reduce the generation of condensed water.

1.5 Terms and definitions

Flow resistance:difference in pressure between two points in an airflow system at specified conditions, especially when measured across the filter element.

Compliance:change in volume of gas per unit pressure change within an enclosed space.

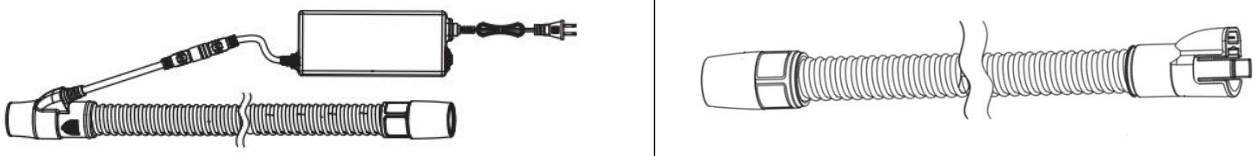
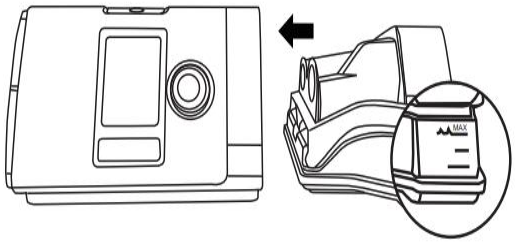
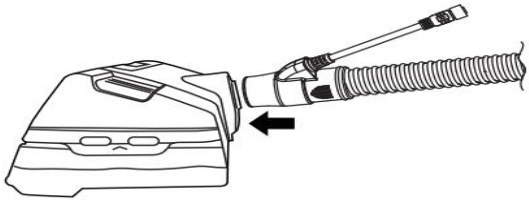
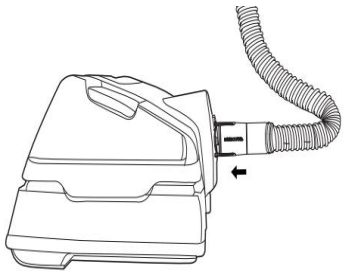
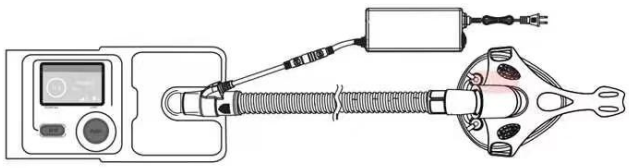
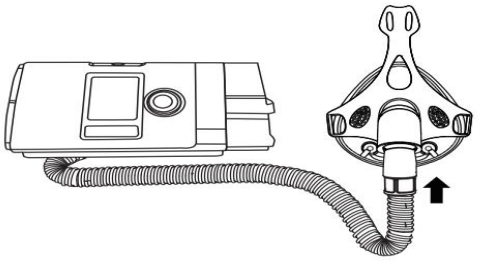
Leakage rate:quantity of gases passing through leaks per unit time.

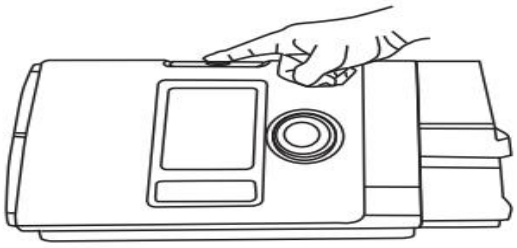
1.6 Clinical benefit

- Provide air connection to assist in completing non-invasive respiratory therapy；
- Support on gas delivery for respiratory care with good flow resistance and compliance meet with ISO 5367 Standard requirement.

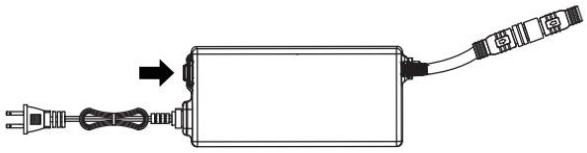
2.Use and Care

2.1 Use Instruction

<table>
<tr><th>HCT Series</th><th>HT & HFT Series</th></tr>
<tr><td colspan="2">  </td></tr>
<tr><td colspan="2">Step 1: Before installation, check the whole heated breathing tube unit for damage.</td></tr>
<tr><td colspan="2">  </td></tr>
<tr><td colspan="2">Step 2: Install and connect the humidifier, ensuring that the water level of the humidifier does not exceed the maximum water level.</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td colspan="2">Step 3: Connect the machine-end cuff of the heated breathing tube to the air outlet of humidifier.</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td colspan="2">Step 4: Connect the user-end cuff of the heated breathing tube to the ventilation mask, nasal cannula, trachea cannula or other products.</td></tr>
</table>



Step 5: Turn on the humidifier or the ventilator.



N.A

Step 6: Plug the power plug of the heating tube control unit into a power socket, turn on the power switch of the control unit. The green power indicator is ON, and the product starts to work.

2.2 Processing instruction

Manufacturer: GuangDong EDA Technology Co., Ltd. Method:See in below table Symbol:N.A. Devices:This processing instruction is suitable for all models of Heated breathing Tube. Processing requirements for first and interval use: Have to clean and disinfect the tube before first use, or when no use over than one week.	
Limitations on processing	Reuse: 30 times ● These devices are designed for 30 repeated uses when in accordance with reprocessing instructions. These devices are supplied non-sterile as indicated on the packaging labels. Process through cleaning and disinfection after each use. Care in use and handling will help ensure the useful life. ● It is recommended to establish a procedural review (before and after each use) by which the heated breathing tube showing such damage or wear are either sent for refurbishing, discarded and/or replaced.
INSTRUCTIONS	
Initial treatment at the point of use	**Step 1:** For HCT001,HCT002,HCT003,HCT004,HCT005: Turn the I/O power switch of the controller to position “O” to turn off the heated breathing tube first, then press the Start/Stop button of the ventilator, after that turn off the power of ventilator. For HT001,HT002,HT003,HT004,HT005,HFT001,HFT002,HFT003,HFT004: Press the Start/Stop button of the ventilator to stop heated breathing tube and ventilator, then turn off the power of ventilator. **Step 2:** Remove the tube from the breathing machine, for HCT001, HCT002, HCT003 ,HCT004 and HCT005 which has the heated tube controller, it is necessary to disassemble the tube body and the control box(Disassembling method: terminal of nut loosening can be directly unplug after) before cleaning. For other models do not have heated tube controller. **Step 3:** Rinse the tube with clean water until no obvious soil stay in the tube when there is obvious soil or contamination in the tube after detaching the tube from ventilator.
Preparation before	**Step 1:** Please check the heated breathing tube for any damage before cleaning.

<table>
<tr><td colspan="2">cleaning</td><td>If there are any holes, tear or crack, the tube should be replaced after dissemble the tube.
Step 2：Please check if there is dirt, blood or sputum scab in the tube, it must be cleaned within half an hour.
Step 3: Prepare Liquid container which can accommodate the tube, Enzyme-containing cleaning solution (5mL cleaning solution /1L water) and an effective chlorine solution containing 500mg/L.</td></tr>
<tr><td rowspan="2">Cleaning:</td><td>Automated</td><td>N.A. The product cannot be automatically cleaned, which may cause product damage (it may case contact pins deformation, pipe wrinkles or damage, accelerate connector and tube aging et.,) and affect product performance.</td></tr>
<tr><td>Manual</td><td>Step 1：Please use clean water to wash the dirt, blood or sputum scab and other dirt in the tube firstly.
Step 2：Soak the tube in enzyme-containing cleaning solution (5mL cleaning solution /1L water) for 2-3 minutes, then rinse with clean water. Suggest using the clean enzymatic detergent from GETINGE.
Step 3：After cleaning, check that there is no dirt, blood or sputum scab inside the tube and other dirt can be disinfected. Otherwise, please repeat above Step 1 to Step 2.
Note:
● In the cleaning process, the terminals on the tube body of HCT001,HCT002, HCT003, HCT004, HCT005 can't soak into the water.
● Do not soak tube in hot water, alcohol, non-designated disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed one hours soaking in ANY solution.
● Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents to wash the tubes, they will damage the tubes.
● Manual cleaning effect has its instability, it is recommended to strictly follow the instructions when cleaning.</td></tr>
<tr><td rowspan="2">Disinfection:</td><td>Automated</td><td>N.A. The product cannot be automatically disinfected, which may cause product damage (it may case contact pins deformation, tube wrinkles/deformation or damage, accelerate connector and tube aging et.,) and affect product performance.</td></tr>
<tr><td>Manual</td><td>Step 1: Soak the cleaned tube with an effective chlorine solution containing 500mg/L for 30 minutes to disinfect it; The tube must be completely immersed in disinfectant during immersion disinfection.
Step 2: During the soaking process, the metallic terminals on the tubes' body of HCT001,HCT002, HCT003, HCT004 , HCT005 can't soak into the water. No special treatment is required for other models.
Step 3: After soaking, rinse with pure water or cold boiled water and soak for 30 minutes.
Note：Manual disinfection effect has its instability, it is recommended to strictly follow the instructions during disinfection.</td></tr>
<tr><td colspan="2">Drying</td><td>Step 1:Then hang the tubes vertically in a ventilated environment for more than 4 hours to air dry.
Step 2: After drying, check that the tubes are free from blood stains, stains, damage, aging and cracks.</td></tr>
<tr><td colspan="2">Maintenance, inspection and testing</td><td>Then install the heated breathing tube into the controller (for HCT001,HCT002, HCT003, HCT004, HCT005) or the ventilator to confirm it can work normally when you power on the controller or ventilator.</td></tr>
</table>

Packaging	The tubes after disinfection are stored in clean and dry containers or clean bags for use.Do not wear gloves with talcum powder when packing to prevent talcum powder from entering the tube inside; When packing, check whether the articles and heated tube controller(if it is HCT series) are complete to prevent missing parts.
Sterilization	N.A.
Storage	Storage temperature : -20℃～55℃; Relative humidity : ≤93%； Atmospheric pressure:70Kpa~106Kpa Storage conditions : Keep in the original packaging, protected from dust and avoid exposure to direct sunlight.

Please record the number of uses in the following table after each use:

Number of uses	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Mark "√" after each use															
Number of uses	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Mark "√" after each use															

2.3 Troubleshooting

Malfunction	Possible Solutions
The green power indicator is not ON after turning on the power switch of the control unit.	1. Please check whether the power plug is pluged into the power socket. 2. Send it back to the manufacturer for repairing.
The green power indicator is ON after power on, but the heated breathing tube is not heating.	1. Check whether the connection ports of the control unit are properly connected. 2. Replace the heated breathing tube(Except the control unit). 3. If the heated breathing tube cannot be heated after replacement, send it back to the manufacturer for repairing.
Air leakage at the machine-end cuff of the heated breathing tube.	1. Check whether the machine-end cuff of the heated breathing tube is properly connected to the air outlet of the ventilator or humidifier. 2. Check whether the machine-end cuff of the heated breathing tube is damaged. 3. Check whether the ventilator or humidifier outlet is damaged.
Air leakage at the user-end cuff of the heated breathing tube.	1. Check whether the user-end cuff of the heated breathing tube is properly connected to the ventilation mask. 2. Check whether the user-end cuff of the heated breathing tube is damaged. 3. Check whether the ventilator mask is damaged.
There is a leak in the heated breathing tube.	Replace the heated breathing tube(Except the control unit).

Note： If you have any problems, refer to the troubleshooting section of your device user manual or www.rescomf.com.

Report incident:

Note: For any serious incidents that occur in relation to this device, these should be reported to distributor or Rescomf and the competent authority in your country.

3. Additional Requirements

3.1 Operating Conditions

Operating temperature: 5℃- 30℃；

Relative humidity : ≤93%；

Atmospheric pressure:70Kpa~106Kpa

Recommended maximum working temperature of breathing sets: 37° C

Recommend maximum working pressure of breathing sets：30cmH2O

3.2 Storage and Transport Conditions.

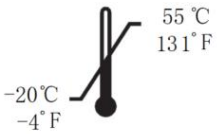
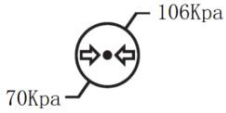
Storage temperature : -20℃～55℃;

Relative humidity : ≤93%；

Atmospheric pressure:70Kpa~106Kpa

Storage conditions : Keep in the original packaging, protected from dust and avoid exposure to direct sunlight.

3.3 Description of symbols

Caution! Refer to the attached documents	Latex Free	Batch code	Use-by date
			
WEEE Symbol	Non-sterile	Follow the user' manual	Date of manufacture
			
Manufacturer	Catalogue number	Temperature Limit	Humidity Limitation
			
Atmospheric pressure limitation	Type BF Applied part	Non-ionizing radiation	Read the instructions
			
II Class Device	Medical Device	Ingress Protection: Protected against solid objects over 12mm, e.g. fingers. Protected against vertically falling drops of water, e.g. condensation.	Authorized Representative in European Community.
			

The device is MR unsafe	Non-sterile	Unique device identifier	
			

3.4 Declaration on disposal of medical consumables

When the device reaches the end of its service life, snip off the device and packaging in accordance with local laws and regulations for safe disposal.

3.5 EMC statement

The heating breathing tubing meets the electromagnetic compatibility requirements of IEC60601.

Users should install and use them according to the EMC information provided with the attached files.

Portable and mobile RF communication equipment may affect the performance of heating breathing line, avoid strong electromagnetic interference when using, such as close to mobile phones, microwave ovens, etc. The heating breathing line should not be used close to or stacked with other equipment. If it must be used close to or stacked with other equipment, it should be observed to verify that it can work properly in the configuration used.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

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	Clause 5

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 ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°

and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	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 bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM 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.					