VISTA APEX

Syringe Warmer™

REF 404301 REF 240301 **Rx ONLY**

REF 404302 REF 240302

Reorder REF	Description
404301-2	6cc 110V Syringe Warmer Kit
404302-2	12CC 110V Syringe Warmer Kit
240301-2	6cc 220V Syringe Warmer Kit
240302-2	12cc 220V Syringe Warmer Kit
404317-2	Warmer Base Inserts Reorder

Inter-Med, Inc.
2200 South St.
Racine, WI 53404 USA
Tel: +1-262-636-9755

Made in USA

404300-I-V-ENG (5)

VISTA APEX PRODUCTS TERMS AND CONDITIONS OF WARRANTY:

The operator assumes all risk and liability for damages arising out of the improper use of Vista Apex's product. In the event of a defect in material or workmanship, Vista Apex's liability is limited, at Vista Apex's option, to replacement of the defective product, or part thereof, or reimbursement of the actual cost of the defective product. In order to take advantage of this limited warranty, the defective product must be returned to Vista Apex.

The Vista Sryinge Warmer Kit is warranted to be free from defects under normal usage conditions for 6 months from its date of delivery. There is no warranty, expressed or implied, of merchantability or fitness. The manufacturer's sole obligation under this warranty is to opt to either repair or replace the defective part of the product. If service must be performed to correct a defect, then the manufacturer will provide the service at its factory according to the mutual agreement made in advance. The manufacturer and its distributors will not accept the return of product unless the return is authorized and shipped in accordance with the distributor's instructions. Contact the local representative of the distributor from which the product was purchased for shipping instructions, a return authorization number, and an ARS shipping label.

There is no warranty, remedy or condition, expressed or implied, except as provided herein. The warranty and remedies contained herein are made by the manufacturer to the first buyer for dental use and are in lieu of all other agreements (expressed or implied), liabilities or remedies for breach of warranty. Vista Apex shall not be liable for consequential or incidental damages. No person or distributor is authorized to modify the terms of this warranty.

This warranty is void if any defect is caused by conditions beyond the manufacturer's control, including acts of God, damage resulting from mishandling, neglect, misuse, improper maintenance, accident or alteration/ repair by anyone other than the manufacturer. The buyer assumes all liability for any damage caused by improper use of the product. The manufacturer assumes no liability for the user's failure to follow the instructions contained in this manual.

RETURN POLICY

Vista Apex will accept for return previously purchased merchandise which is suitable for resale or that which was shipped in error by Vista Apex. Merchandise suitable for resale requires current labeling and unopened non-soiled packaging.

All returns must have prior approval and must be shipped "prepaid" along with a return authorization form and a copy of the original invoice. Any products returned that are discontinued, dated, damaged, or opened could be denied credit or assessed a higher return fee.

Merchandise returned for credit must be received by Vista Apex within 60 days of the original invoice date. Returns made within 30 days will be subject to a 15% restocking fee. Any returns made 31-60 days after the original invoice date will be subject to a 25% restocking fee.

Equipment cannot be returned without written authorization from Vista Apex. Any equipment returned within 30 days from the date of the original shipment from Vista Apex may not be assessed a restocking fee as long as the merchandise has current labeling and unopened non-soiled packaging. Unopened equipment returned within 31 to 60 days from the date of the original shipment from Vista Apex requires a restocking fee of 25% of the purchase price, including shipping and handling charges. Any equipment returned after 60 days from date of original shipment from Vista Apex will not be restockable for credit. Installation, if required, must be initiated with an outside party, and is the sole responsibility of the customer.

- Special orders are not suitable for resale and therefore not returnable for credit.
- Claims for lost or damaged shipments should be filed immediately with the carrier.

tel: +1-262-636-9755 **toll free:** +1-877-418-4782 **fax:** +1-262-636-9760 **www.vistaapex.com**

EMS Compliance Table (Table 2-4)

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle and 70% U_T; 30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 300 cycles

Guidance and Manufacturer's Declaration

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
AC Power Line	1.8m	Unshielded	1 Set	AC Power

Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The equipment with the following ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for 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. ESSENTIAL PERFORMANCE: Device heats to specific temperature.
- 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".
- The 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.
- 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."
- WARNING: If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

EMI Compliance Table (Table 1)

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment

Technical Data

Transit, Storage, and Operating Conditions	Temperature	10°C - 40°C (50°F - 104°F)
	Pressure	500hPa - 1400hPa
	Altitude	-100m - 3000m
Electrical Properties	Input	110-120VAC ~50/60Hz 0.5A max (110V Kits) 220-240VAC ~50/60Hz 0.3A max (110V Kits)
	Fuse information	Thermal fuse: non-replaceable, contact manufacturer Electrical Fuse: 2A 250V 0.25" x 1.25"

Composite Warmer Kit

Contents

A. Syringe Warmer (1)
   A1. Power Indication Light
   A2. 6cc or 12cc Dome (1)
B. Disposable Warmer Bowl Inserts (5)
   Reorder packs contain Qty: 30
C. Power Cord

Instructions For Use:

Please read completely before operating unit

1. Warnings and Precautions

- This system has been designed and manufactured to assure personal safety. Please read all safety and operating instructions carefully before installation and use.
- Handle system with care at all times.
- The Vista Syringe Warmer kit operates at a high temperature and may be hot to the touch. Caution should be taken to avoid touching hot surfaces.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- HAZARD: Do not modify this equipment without authorization of the manufacturer. Damage to equipment or harm may result.

2. Indications

The Vista Syringe Warmer is designed to heat dental irrigating solutions up to 120˚F (49˚C).

3. Operating your Therma-Flo™ Composite Warming Kit

- Gently unpack the contents of your Syringe Warmer Kit.
- Confirm that all components and accessories are included:
  Syringe Warmer Kit:
  (1) Syringe Warmer Unit, (1) Power cord, (1) 6cc or 12cc Dome, (5) Warmer Base Inserts
- Connect power cord into the power connector making sure that it is fully seated.
- Place a Warmer Base Insert onto the Warmer Base followed by the Dome.
- Turn system on by switching the green ON/OFF switch on the front of the Composite Warmer base to the "On' position. **The switch will illuminate when the unit is on.**
- Heat Syringe Warmer base for a minimun of 20 minutes prior to inserting filled syringes. The unit should be turned on at the beginning of the day and off at the end of the day.
- Fill syringes with solution of choice. Place syringe into the openions on teh syringe dome.
- Syringe Warmer will regulate between 110˚F and 120˚F.

4. System Care

- It is recommended that the unit is turned off when not in use.
- **It is recommended that you wipe the system down at the end of each day with isopropyl alcohol, do not spray device directly or use medical disinfectants. Wipe dry when finished.**
- Sterilize included compule dispensing guns using an autoclave at 132˚C for 3 minutes unwrapped. If using a different dispensing gun, follow manufacturer's sterilization specifications.
- Do NOT attempt to autoclave the base or dome of warming unit.
- No special disposal requirements.

Technical Support

For questions regarding your Syringe Warmer unit, please call Vista Apex toll free at (877) 418-4782 Monday thru Friday 8:00 AM to 5:00 PM (Central Standard Time).

Product Symbol Definitions

	Manufacturer
REF	Catalogue number
Rx ONLY	Prescription only: US federal law restricts this device to sale by or on the order of dental professionals
	Operator's manual; Operating instructions
	Do not use if package is damaged
	Fragile; handle with care
	Keep dry
	Caution
	Humidity limitations
	Pressure limitations
	Temperature limitations
	Warning; Hot surface