



PROFESSIONAL MEDICAL PRODUCTS

STAZIONE DIAGNOSTICA DA PARETE VISIO 5 PLUS

VISIO 5 PLUS WALL DIAGNOSTIC STATION

STATION MURALE DE DIAGNOSTIC VISIO 5 PLUS

ESTACIÓN DIAGNÓSTICO DE PARED VISIO 5 PLUS

Manuale d'uso - User manual
Manuel de l'utilisateur - Guía de uso

- È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.
- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.
- Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.
- Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

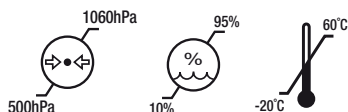
REF 805-900-01 (GIMA 31620)
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805-904-01 (GIMA 31624)
805-906-01 (GIMA 31625)



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Thank you for purchasing our product. This VISIO 5 Plus HQ Power Transformer meets the most stringent requirements regarding the selection of manufacturing material, performance, safety, and final control. These instructions must be followed to ensure the performance and durability of the VISIO 5 Plus HQ Power Transformer. The operator/user must read and understand this manual thoroughly to keep the product performance durable and reliable for a defined period.

After opening the package, it is necessary to check all the components, against the standard configuration. Check that these are all present and in perfect condition.

INTENDED USE:

The VISIO 5 Plus HQ Power Transformer is a wall-mounted diagnostic station that provides a constant 3.5V output voltage independent of AC mains voltage for MD standard diagnostic instruments. . It should only be operated by trained healthcare professionals in a professional healthcare facility.

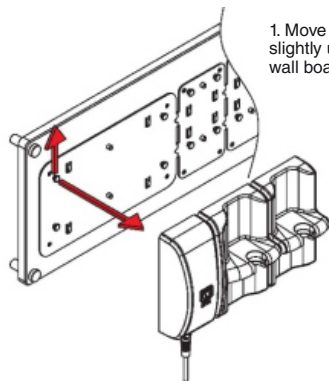
FEATURES:

1. Ergonomic design non-slip Handle.
2. Constant output voltage with integrated surge protection.
3. Soft start technology gently introduces voltage into the instrument's bulb/LED when turned on, eliminates cold-shock, and preserves bulb/LED life.
4. The unit provides a constant 3.5V output independent of the mains voltages.
5. The device switches ON and OFF automatically once removed or replaced in the cradle respectively.
6. The adjustable light intensity ensures that whenever the device is picked from the cradle, the brightness is at maximum and can be lowered/decreased by clicking the button down and can be increased by the clicking button up.
7. In case the device is not placed back in the cradle, the device turns Off after three minutes of Idle state preserving Bulb/LED life and power.
8. Very precise brightness control, between 3% and 100%.
9. The spiral cord stretched to 3 meters ensures the instrument to be used comfortably from different angles.
10. Low power consumption.
11. The Handle works optimally well with LED and/or Xenon-Halogen Heads.
12. The product is IEC 60601-1 Certified.

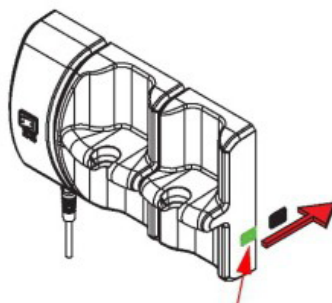
SPECIFICATIONS:

Input:	100-250V 50/60Hz
Input Power	34VA Max
Fast Fuse	2 x 250V/2A
Poly Fuse	8V /2.20A
Output 1:	5V/2000mA
Output 2:	3.5V/800mA X1 (For Unit with Single Handle) 3.5V/800mA X2 (For Unit with Two Handles)
Protection Class	I

PROCEDURE FOR CONNECTING & ATTACHING THE TRANSFORMER MODULE

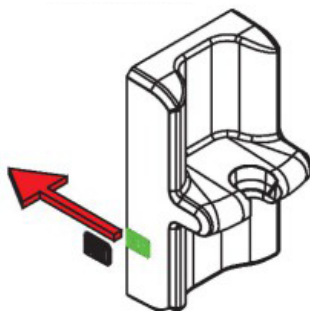


1. Move Power Transformer unit slightly upwards & pull it away from wall board.

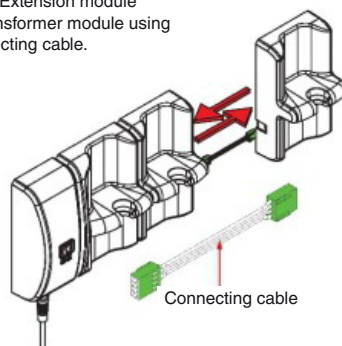


2. Remove the gate from the power Transformer Module.

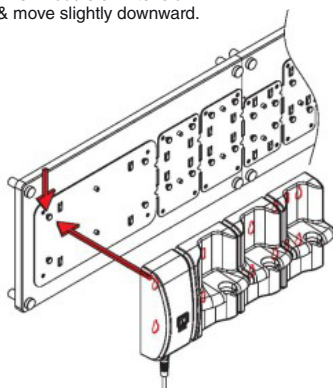
3. Remove the gate from the Extension Transformer module.



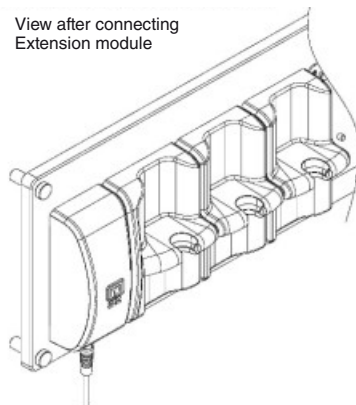
4. Connect the Extension module with Power Transformer module using provided connecting cable.

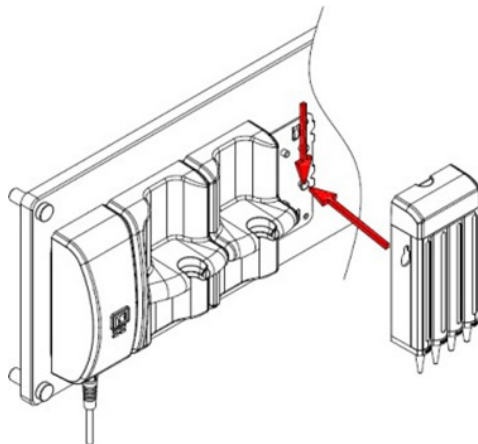


5. Fix the power Transformer module & Extension module with wall board & move slightly downward.

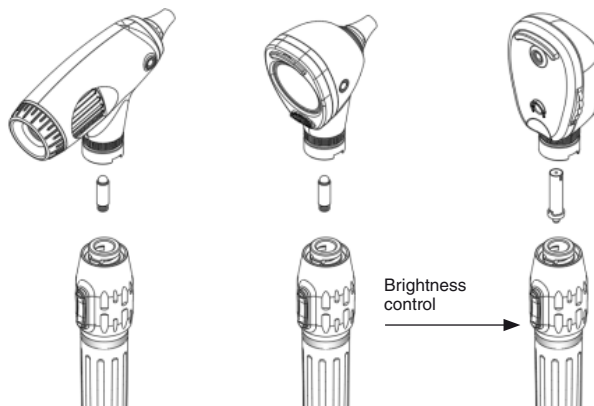


View after connecting Extension module



VISIO 5 EAR TIP DISPENSER**OPERATING INSTRUCTIONS**

1. Attach the required plug i.e., EU/US or AUS to the power cable and insert it into the wall socket.
2. Do not switch ON the Unit until the Head is properly attached to the Handle.
3. Hold the Handle and Head in each hand, insert the head into Handle and match the bayonet grooves on the Handle and Head, push the head down and turn it clock wise.
4. Ensure that the head and handle are attached properly.
5. Turn the power switch to "I", the Indication LEDs will glow Green making sure that the unit is in working condition now.
6. The handle will automatically light up when it is removed from the cradle.
7. The brightness of the handle can be increased or decreased by pressing the Adjustment button on the '+' and the '-' positions respectively on the handle.
8. The handle can be simultaneously used independent of each other because of galvanic isolation.
9. The Adjustment button does not turn OFF the handle completely. Placing the handle on the cradle will turn the handle completely off.
10. Kindly switch off the unit from the Power switch (i.e., at the '0' position) in case it is not in operation in order to ensure long operation.

FOR EAR TIP DISPENSER:

Ear Tip Dispenser has the capacity to hold up to 100 cannulas of two different sizes i.e., 2.5mm and

4.0mm.

1. Insert the cannulas from the top by removing the cover cap.
2. 2.5mm cannula can be taken out from the first two slots present on the lower side of the dispenser. The next two slots are for 4.0mm cannulas
3. Only one cannula can be taken out at a time from the cannula holder.

Note:

The Otoscope/Ophthalmoscope is intended for Transient examination < 1 minute with a break of 10 minutes between applications. The maximum temperature at the application point, at an ambient temperature of 40°C, is 48°C for 3.5V Oscopes. The ear tip of the otoscope is an Applied part.

 Use medical devices provided plugs only.

 Before removing the head, make sure that switch is off.

 Unplug the power cord of power transformer module before connecting the extension transformer module

 Do not use the equipment in case it is damaged. Avoid precarious repairs. Repairs shall be carried out with original spare parts only, which shall be installed according to the intended use. For any other repair/replacement apply to your retailer.

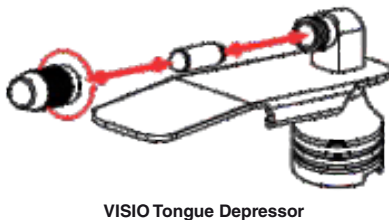
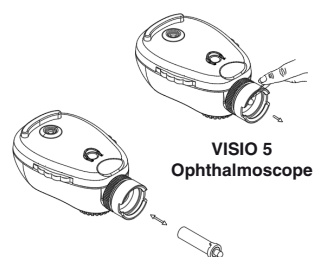
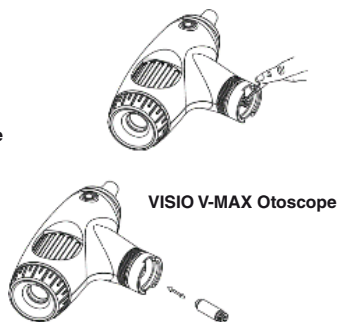
REPLACEMENT PROCEDURES:

- Bulb/LED replacement procedure:

The VISIO 5 Otoscope and Ophthalmoscopes (5GE, 5SE, 5XE) models come up with Xenon/Halogen Bulbs and LEDs.

The VISIO Tongue Depressor and Operating Otoscope come up with Bulbs only. The replacement procedure for the bulb and LED is given below;

Turn OFF the unit and unmount the head from the handle. Pull the lamp downward/out from the Bulb/LED holder, as illustrated below:



 Always turn OFF the unit before unmounting the head from the handle and let the lamp cool down before touching it for replacement. Otherwise, there is a risk of severe burns by touching the hot lamp.

CLEANING AND DISINFECTION

OTOSCOPE HEAD & TONGUE DEPRESSOR:

Clean and disinfect the outer surface of the otoscope head with a soft cloth and the inner surface with a cotton wool bud soaked in 70% isopropyl alcohol or water.

Do not dip the chamber in any disinfection solution.

LENS:

The lens can be cleaned using a moistened cotton-tipped applicator with a solution of water and mild detergent.

OPHTHALMOSCOPE HEAD:

The Ophthalmoscope head/housing can be wiped/cleaned with a cloth moistened with alcohol. Use 70% isopropyl alcohol solution for cleaning the outer surface.

Glass Surfaces can be cleaned using a moistened cotton-tipped applicator with a water solution and mild detergent.

DIAGNOSTIC HANDLE:

The handle can be cleaned with a cloth soaked with disinfectant. However, it cannot be dipped into liquids.

EAR TIP DISPENSER

The Ear Tip Dispenser can be cleaned by using the following method:

Slightly moisten a cotton swab or cloth with isopropyl or ethyl alcohol and gently wipe the surface of the cover.

Wipe from side to side rather than in a circular motion.

 Do not use a rough cloth for cleaning the lens to avoid scratches.

 Autoclaving and flash sterilization of the handle is prohibited.

 Autoclaving and flash sterilization of the head is prohibited.

 Do not use abrasive Ultrasonic cleaner, alcohol, or other chemicals to clean the lenses as this degrades lens or mirror quality, as they will scratch the coated surface of the lenses.

MAINTENANCE:

The VISIO 5 Plus HQ Wall Transformer does not require regular maintenance.

SERVICE:

The devices have no components serviceable by the end user.

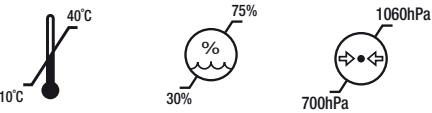
Cautions/General Warnings:

1. Read the label before unpacking.
2. Do not use the device in case it is damaged. Apply to your retailer/distributor.
3. Periodically check the battery conditions, making sure that no sign of corrosion or oxidation is present. In case of necessity, replace them with new ones.
4. Carefully handle the batteries as the liquids can irritate skin and eyes.
5. Before usage, thoroughly check the product. The same Operation shall be carried out after cleaning.
6. Check that the connection between the chamber and the handle is perfect and that the On/Off Button works correctly.
7. If the light is intermittent or, in case, it does not turn on, check the bulb/LED, the batteries and the electrical contacts.
8. This product is not allowed to enter or be used in areas with strong magnetic fields e.g. MRI scanners.
9. Any unauthorized modification/service is strictly prohibited at user end so, always contact the authorized person or send the unit back to the authorized agent.
10. Autoclaving and Flash sterilizing the Wall transfer, Otoscope/Ophthalmoscope head, tongue Depressor, and Diagnostic handle will result in severe electrical and mechanical damages, which are strictly

- prohibited.
- 11. Ultrasonic cleaning is not recommended.
 - 12. Store the device in a clean and recommended environment.

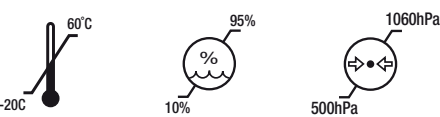
OPERATING ENVIRONMENT

Temperature Limitation Humidity Limitation Atmospheric Pressure Limitation



STORAGE ENVIRONMENT:

Temperature Limitation Humidity Limitation Atmospheric Pressure Limitation



SHELF-LIFE:

The shelf-life of these devices is 5 years.

WARRANTY:

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

EXPLANATION OF UTILIZED SYMBOLS:

	Caution: read instructions (warnings) carefully		Medical Device compliant with Regulation (EU) 2017/745		Product code
	Manufacturer		Date of manufacture		Lot number
	Keep away from sunlight		Keep in a cool, dry place		WEEE disposal
	Type BF applied part		Follow instructions for use		Medical device
	Serial number		Atmospheric pressure limit		Imported by
	Authorized representative in the European community		Humidity limit		Temperature limit
	Unique device identifier				



Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.