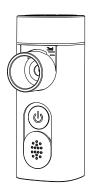


Instruction Manual

Handheld Mesh Nebulizer

NEB402



Manufactured for Sunset Healthcare Solutions 180 N Michigan Ave Ste 2000 Chicago, IL 60601

Thank you very much for choosing our Handheld Mesh Nebulizer. Please read this user manual carefully before using, so that you can use it safely and correctly. Keep this user manual properly in place for future reading.

Table of Contents

2. Intended Use	5
3. Contraindications	
4. Package Contents & Overview	5
5. Product Technical Parameters	6
6. User Instructions	7
7. Cleaning & Disinfection	.10
8. Storage Conditions	12
9. Trouble Shooting	12
10. Note & Warning	13
11. EMC Declarations	14
12. Signs & Symbols	21
13. After-Sales Service	23
14. Disclaimer Clause	24
15. Warranty Card	25
16. Certificate Of Inspection	26
17. FCC Statement	27

1. Important Safety Notes

- a. For the type, dose and regimen of the medication, please follow the instruction from your medical doctor.
- b. Operate the device as intended.
- c. This unit is only used for nebulization.
- d. Clean and disinfect the medication cup and accessories before using for the first time. Clean the medication cup and accessories after each use.
- e. Stop using the device if it is damaged or becomes wet.

2. Intended Use

The device is a Vibrating Mesh Nebulizer System designed to aerosolize liquid medication for inhalation therapy by the patient. The device may be used with pediatric patients older than 5 years of age and adult patients in home healthcare facility environment. Pentamidine is not permitted.

3. Contraindications

None.

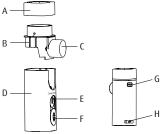
4. Package Contents & Overview

4.1 Package Contents



Figure 1 Package Contents

4.2 Product Contents



- A Medication Cover
- B. Medication Cup
- C. Spray Nozzle
- D. Main Unit
- E. Power Button
- F. Slide
- G. Cup Release Button
- H. Micro USB Cable

Figure 2 Product Contents

5. Product Technical Parameters

Device Name	Handheld Mesh Nebulizer	
Power Supply	DC 4.8V (2×2.4V rechargeable Li-ion batteries) or DC 5.0V 1.0A with AC adapter	
Power Consumption	<3.0W	
Nebulization Rate	0.25ml/min~0.9ml/min	
Particle Size MMAD < 5μm		
Medication Cup Capacity	10ml (Max)	
Vibration Frequency	110kHz±10kHz	
Weight	100g with batteries	
Size Length 38.5mm × Width 53.4mm × High 97.7		
Working Environment	Temperature: +41°F to +104°F (+5°C to +40°C) Relative Humidity: 30%~80%R.H. Atmospheric pressure: (86.0~106.0) kPa	

Storage Environment	Temperature: +14 °F to +122°F (-10°C to +50°C) Relative Humidity: 30%~80%R.H. Atmospheric pressure: (86.0~106.0) kPa
Time Auto-off	Power on, operate 10 mins, then auto-off

Table 1 Technical Parameters

Expected Longevity

Expected longevity of product follows, provided the product is used to nebulize medication 3 times a day for 10 minutes each time at temperature $+77 \, ^{\circ}F$ (25 $^{\circ}C$).

Durable period may vary depending on usage environment.

Main Unit 2 years

Top Cover 2 years

Medication Cup 2 years

Medication Cover 2 years

Mask (PVC) 1 year

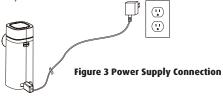
6. User Instructions

6.1 Power Supply

The nebulizer has a USB cable for charging, it does not include a power adapter. If using an alternate charger, please use an IEC 60601-1 approved AC adapter (output: DC 5.0V 1.0A).

The power system of the device runs on a rechargeable lithium battery.

When the device indicates low power, please charge it via USB cable (As shown in **Figure 3** below).



6.2 Battery Charging

The battery group can supply power up to 60 minutes continually after full charging.

When the battery power is below 3.8V, the green LED light will keep flashing, until the nebulizer powers off automatically. When low power is indicated, please recharge the battery for 1.5 hours. During charging, the green LED light flashes. When charging completes, the green LED light will display solid. When the device is on and nebulizing, the green LED light will display solid.

A Note:

We recommend charging the device every 2 days to ensure normal use.
Continue charging the device at least once per month when not in use for more than one month

The rechargeable battery should not be replaced by the user.

The device cannot nebulize while charging.

A Warning:

Please dispose of the device with the used batteries according to local environmental regulations.

6.3 Use Instructions

The light indicates the summary form

Green light displays solid	Working
Green light flashes 3 times	No liquid, shut down
Green light flashes 5 times	Battery low, shut down
Green light flashes 10 times	Set time for 10 minutes, shut down
Green light flashes	Charging
Green light displays solid	Fully charged

Step One:

Please refer to Section 7: Cleaning and Disinfection.

Step Two:

Open the medication cover by twisting it counter-clockwise, and fill the medication cup with liquid medication. Please see the Figure 4 Filling Procedure for reference.

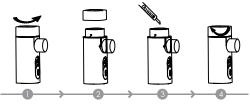


Figure 4 Filling Procedure

Step Three:

Connect mask or mouthpiece as in Figure 5 below, and click power button to power on.

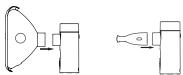


Figure 5 Connect Mask or Mouthpiece

Please hold the nebulizer to keep liquid medication in contact with the vibrating mesh, and the stream of inhalation, Please see Figure 6 below.

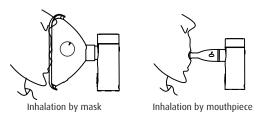


Figure 6 Inhalation

Step Four:

When finishing nebulization, press power button to power off. Pour out the residual liquid medication from the medication cup. Please see Figure 7 below.



Figure 7 Pouring out the Residual Liquid Medication

Step Five:

Clean after use:

Clean the main unit, medication cover, medication cup and mask or mouthpiece by the method detailed in Section 7: Cleaning.

A Note:

- a. Keep the device vertical and do not shake during operation.
- b. Holding inhaled breath for a short while can enhance the effectiveness of nebulization therapy.
- c. The medication liquid will sometimes congeal on spray connector and mesh disc, which will influence the nebulization rate. We recommended stopping nebulization, removing mask or mouthpiece, and using clean medical gauze to clean the residue.
- d. Contact provider with any additional questions for use.

7. Cleaning and Disinfection

Before first time use, follow disinfection and cleaning instructions. After each use, follow the cleaning instructions. The device should only be used and reused by a single person. The device is not provided sterile.

Continued on next page.

7.1 Cleaning

- 1. Remove the mask or mouthpiece from the main unit.
- Pour a small amount of clean water (or 3 parts clean water with 1 part white vinegar) into the medication cup and close the cover. Soak the medication cup for 5 minutes.
- 3. Turn on the device to nebulize the clean water or water/white vinegar for 1 to 2 minutes to remove residual medication from the mesh.
- Turn off the device, pour out any remaining water/vinegar, and disassemble the medication cover and medication cup from the main unit.
- Clean the casing of the main unit by moistening clean medical gauze with clean water and immediately dry using clean medical gauze. Also clean the electrodes with clean medical gauze.
- Rinse the mask or mouthpiece, medication cover and medication cup with clean water for at least 1 minute.
- 7. Use clean medical gauze to dry after rinsing.
- 8. Store the device in a clean and dry storage environment.

A Note:

The waterproof classification of main unit is IP22, it cannot be washed. Prevent water from entering unit.

Following the cleaning instructions after each use will prevent any remaining medication in the bottle from drying, adhering to the mesh cap, and resulting in the device not nebulizing effectively.

7.2 Disinfection

To disinfect:

- Open the medication cover and pour a small amount of 2%-3% hydrogen peroxide solution into the medication cup.
- 2. Turn on the device to nebulize the 2%-3% hydrogen peroxide solution for 1 to 2 minutes.
- Soak the medication cup and cap in solution of 2%-3% hydrogen peroxide for 10 minutes at room temperature.
- 4. Rinse with distilled water for at least 1 minute.
- 5. Dry with clean medical gauze gently.
- 6. Assemble the device.
- 7. Store the device in a clean and dry storage environment.

A Note:

Never use the disinfectant benzalkonium bromide, household chlorine bleach, sodium hypochlorite, hypochlorous acid or quaternary ammonium compound to disinfect.

8. Storage Conditions

The device should be stored indoors. The environment temperature should be +14°F to +122°F (-10°C to +50°C), non-corrosive gas, good ventilation, avoid high temperature, humidity and direct sunlight. Keep the device out of the reach of unsupervised infants and children. The device may contain small parts that can be swallowed.

Prevent pets and pests from damaging equipment.

Dry the parts immediately after washing. Store the device and the components in the environment that meets the requirements, be careful to avoid collisions. Direct sunlight, lint, dust may cause vibrating mesh rusted and oxidized and decrease nebulization rate.

9. Trouble Shooting

Item	Trouble	Possible cause/solution
1	Does not work when turned on	Check if there is enough power; Check if there is enough medication; Check if the button is functioning well.
2	Nebulization rate is too low	Check if the medication cup has been filled with right medication, which should be water-soluble, non-corrosive medication; Check if the medication cup has been filled to the correct volume; Tilt main unit, so that the medication is in contact with the vibrating mesh; The vibrating mesh may be blocked, you can drop 2 or 3 drops of white vinegar into the medication cup with 3-6ml water, then clean with distilled water. Clean the medication cup to avoid disinfection for next use; The vibrating mesh may be rusted or oxidized and need to be replaced; The electrode contact pin may be rusted or oxidized.

	Please refer to a physician's advice. Viscous medication is not allowed.	
4	Please choose kid's mask to cover mouth and nose for better treatment effects. Kids are forbidden to use the nebulizer alone.	

10. Note & Warning

10.1 Note

- · Nebulizer is a medical device, please read the user manual before use.
- Please use required accessories, warranty service is not provided for damage caused by accessory beyond our list.
- Using a non-conforming adapter may cause equipment damage.
- Please refer to the user manual when problems appear, and contact the service center for maintenance.
- Please clean and disinfect the medication cup when using it for the first time. You can refer to the clean and disinfect chapter.
- The device is for medication nebulization, not for humidification.
- · Please keep the medical cup empty when storing it.
- · Please confirm all the accessories are correctly assembled before using it.
- Please use the accessory individually to avoid cross infection.
- · Please keep it vertical when nebulizing.
- Do not use the unit under inflammable gas environment or near heating device or open flame.

- · Do not use the unit near high frequency products or electronic products.
- Do not use a microwave oven, oven, blow dryer or other house applications to dry nebulizer and accessories.

10.2 Warning

- Please stop using it if you feel uncomfortable and please contact a doctor.
- Oily medication including volatile oil is not allowed, as it may cause damage to module.
- Water-soluble medication and saline dilution medication are allowed, but may cause Bronchospasm.
- · The device can't be used on an aircraft.
- One device is solely for single patient use and can be reused by a single patient. One device is used for single medication.
- Do not use mobile (cellular) telephones and other devices (such as MRI, diathermy, electrocautery, RFID and electromagnetic security systems) which generate strong electrical or electromagnetic fields, near the medical device.

11. EMC Declarations

- Handheld Mesh Nebulizer meets the requirement of electromagnetic compatibility in IEC60601-1-2.
- The user needs to install and use according to electromagnetism compatibility information which is attached with it.
- Portable and mobile RF communication device and some household appliances, such as mobile, interphone, microwave oven, dry blower, may influence nebulizer performance, so nebulizer should be kept away from them during using.
- Guidance and manufacture's declaration stated in the appendix.

EMC Information

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible

to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by Sunset Healthcare Solutions (Sunset) conform to this IEC60601-1-2 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

1.NOTE The EMISSIONS characteristics of this equipment make it suitable for use in a residential environment (for which CISPR 11 class B is normally required).

2.WARNING:The use of accessories and cables other than those specified by Sunset, with the exception of cables sold by Sunset as replacement parts for internal components, may result in increased emission or decreased immunity of the device.

3.WARNING:The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.

4.WARNING: PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of [ME QUIPMENT or ME SYSTEM], including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.

5.WARNING:Do not use mobile (cellular) telephones and other devices(such as MRI,diathermy, electrocautery, RFID and electromagnetic security systems) which generate strong electrical or electromagnetic fields, near the medical device. This may result in incorrect operation of the unit and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 7m. Verify correct operation of the device in case the distance is shorter.

Cables	Length (m)	Whether to block	Note
USB Cable	1	No	-

Guidance and Manufacturer's declaration – electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.

Electromagnetic emission IEC 60601-1-2

Emissions test	Compliance	Electromagnetic environment – guidance		
RF emissions CISPR 11 Group 1		This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
RF emissions CISPR 11	Class B			
Harmonic emissions IEC 61000-3-2	Class A	This device is suitable for use in all establishments, including domestic establishments and those directly		
Voltage fluctuations/flicker- emissions IEC 61000-3-3	Complies	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Guidance and Manufacturer's declaration – electromagnetic immunity
The device is intended for use in the electromagnetic environment
specified below. The customer or the user of the device should assure
that it is used in such an environment.

	Compliance level	Electromagnetic environment – guidance
	±6 kV 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 power supply lines ±1 kV for input/output lines	±2 kV for power supply lines*1)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000- 4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4- 11	<5 % U T (>95 % dip in U T) for 0.5 cycle 40 % U T (60 % dip in U T) for 5 cycles	<5 % U T (>95 % dip in U T) for 0.5 cycle 40 % U T (60 % dip in U T) for 5 cycles	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of this device requires continued operation during power mains interruptions, it
	70 % U T (30 70 % U T (3		is recommended that the device be powered from an uninterruptible power supply or battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
--	-------	-------	---

NOTE UT is the A.C. mains voltage prior to application of the test level. The test of input/output lines is not applicable since they are shorter than 3.0m.

Guidance and manufacturer's declaration – electromagnetic immunity – for device that is not LIFE- SUPPORTING.

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

it is used in such an environment.				
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment – guidance	
Conducted RF IEC 61000 -4-6 Radiated RF IEC 61000-4-3	3 V/m 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V rms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{p}$ 80 MHz to 800 MHz $d=2.3\sqrt{p}$ 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, "2) should be less than the compliance level in each frequency range." 3) Interference may occur in the vicinity of equipment marked with the following symbol: ((**)*)	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device – for device that is not IHF-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter (m)			
output power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
(W)	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{p}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12. Signs & Symbols

Label	Explanation	Label	Explanation
LOT	Batch code	0	General mandatory action sign
SN	Serial number	\Diamond	General prohibited sign
	Manufacturer	©	Indicates the product does not contain toxic and harmful substances and element.
	Date of manufacture	IP22	Protected against solid foreign objects of 12.5 mm and greater; Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
11	This way up	涔	Keep away from sunlight
\triangle	Caution	((<u>*</u>)))	LF electromagnetic radiation
A	General warning sign	T	Keep away from rain
		Z	Disposal of Electrical & Electronic Equipment (WEEE): Do not treat this product as household waste.

		1	,
1	Warning, electricity	NON STERILE	Non-sterile
İ	TYPE BF APPLIED PART		Refer to instruction manual/ booklet
	Prohibited	I	Fragile, handle with care
	"ON" / "OFF" (press / press)	\	Operation indicator
1	Storage and delivery temperature limits	<u>%</u>	Storage and delivery humidity limitations
***	Storage and delivery atmospheric pressure limitations	o √ 0	Micro-USB plug interface
PRESS	Press button to remove the medication cup.	Max.	Maximum identification of the volume of the medication cup.
MR	MR Unsafe. Don't use the device in MR environment.		

13. After-sales Service

Changes or modifications by users are not allowed. Any such behavior will void the user's warranty right.

- 1. The device is warranted to be free from defects materials and workmanship appearing within 1 year from the date of purchase, when used in accordance with the instructions provided with the device. We will, at our option, repair or replace without charge. On the Any repair service out of the scope of warranty will be charged accordingly.
- 2. Please contact us to obtain warranty service. Warranty conditions:

To obtain the warranty service, please present this warranty card and fill out the related content. The company provides 12 months' warranty from the date of purchase.

With following conditions, the warranty shall not apply:

- a. Failure or damage caused by improper use.
- b.Failure or damage caused by the dismantle movement of a non-our-company authorized maintainer.
- c.Failure or damage caused by accidental falling, pressing, dropping, immersion etc

The Company reserves the right of final interpretation of the warranty card, which may be subject to change without prior notice.

14. Disclaimer Clause

Please read the user manual before using the product. We will not take any responsibility in case of damage caused by improper use of the product.

Please use or purchase original parts or accessories. The manufacturer does not take responsibility for the buyer or third parties for any damage or loss intentionally or unintentionally caused by improper use.

On the request for warranty service, please present your warranty card filled with purchase date and seal (with the store and address). Any repair service out of the scope of warranty will be charged accordingly.

Warranty card

NFR402

The warranty period for the unit is 1 year.
 The warranty for the medication cup is 6 months.

During the warranty period, Sunset will decide to Warranty Card repair or replace the unit and/or medication cup according to your case. When exceeding the warranty Distributor copy period, relevant charges must be taken according to your Type of product : _____ The warranty does not extend to accessories, as they Serial No.: are consumable items. •The warranty does not cover the following cases: Name of Customer : Damage caused by misuse of product, such as impact, Date of purchase :_____ soaking or wetting and other irregular operation. Contact number : Damage caused by incorrect operation of the product Address : as detailed in the manual. Damage caused by accident. Sales company :_____ Unauthorized disassembly or modification. Contact number : Missing invoice, warranty card or unidentifiable Address of sales company: product serial number E-Mail: customerservice@sunsethcs.com Attention: please contact your place of purchase with FIRST COPY the customer copy of the warranty card in the event This warranty card is a duplicate. that the machine needs maintenance. Please keep This copy is kept by the distributor. product packaging so that it may be used if returning machine. ×-----× The warranty period for the unit is 1 year. NFR402 The warranty for the medication cup is 6 months. Warranty Card During the warranty period, Sunset will decide to repair or replace the unit and/or medication cup Customer copy according to your case. When exceeding the warranty Type of product : period, relevant charges must be taken according to your case. Serial No.: •The warranty does not extend to accessories, as they Name of Customer: are consumable items. Date of purchase : •The warranty does not cover the following cases: Damage caused by misuse of product, such as impact, Contact number :_____ soaking or wetting and other irregular operation. Address : Damage caused by incorrect operation of the product Sales company : as detailed in the manual Contact number : Damage caused by accident. Unauthorized disassembly or modification. Address of sales company: Missing invoice, warranty card or unidentifiable E-Mail: customerservice@sunsethcs.com product serial number SECOND COPY Attention: please contact your place of purchase with This warranty card is a duplicate. the customer copy of the warranty card in the event This copy should be properly kept by that the machine needs maintenance. Please keep the user and shown as proof of warranty product packaging so that it may be used if returning if necessary. machine

FCC STATEMENT

FCC Caution

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference;
- (2) This device must accept any interference received, including interference that may cause undesired operation.

A Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the 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, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- · Reorient or relocate the receiving antenna.
- · Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- · Consult the dealer or an experienced radio/TV technician for help.