

Electronic Ear Irrigation

Announcing
the arrival of
the ProJet 101
in Australia



ProJet

The New Standard in Electronic Ear Irrigation

Outstanding
value



Features:

- Power/ water pressure control button
- Water pressure indicator

Ear Irrigation kit consists of:

- Irrigator machine
- Water dispensing handle
- Water reservoir
- 10 ear irrigation tips
- Tip/ instrument storage
- Mains power cable and plug
- Foot switch

Specifications:

- Power: 230V, 50Hz
- Static pressure: 0.25 - 3 bar maximum
- Working time: 2 - 3 mins for 500cc
- Continuous usage: 8 mins
- Reservoir: 500ml
- Temp range: 5°C - 35°C
- Pressure: 860 - 1060 hpa
- HxWxD: 180x175x145mm

Utilising the most modern production methods the Guardian Projet 101 was designed to fulfil the most demanding surgeries and hospital ward requirements for a reliable, leak free and easy to use machine that is not expensive to run and does not require constant maintenance and subsequent down time.

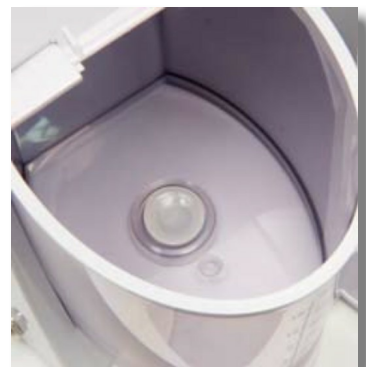
The P101 has many unique features designed to help the busy surgery such as:

- 1 Extra long mains lead and handle hose so machine can be sited where it is most convenient
- 2 Integral wall mount frees up valuable work space by wall mounting the Projet™ however easily removed for cleaning etc
- 3 Sliding flow regulator conveniently mounted in handle. Water flow can be temporarily stopped by sliding regulator to off position or flow regulated by sliding control to desired position
- 4 Ultra thin atraumatic tips help visualisation and direction of water flow
- 5 Digital control of water pressure and flow is easy to operate and remains constant and reproducible
- 6 Flat control panel is easy to keep clean
- 7 Tips held securely yet very easy to remove and replace
- 8 On board tip and/or instrument storage
- 9 Quiet operation
- 10 Oversize water reservoir silicone washer to reduce incidence of leaks
- 11 Economically priced

Water dispensing handle



Water reservoir



Proj^{et}

ProJet101

PULSATILE EAR IRRIGATOR

Designed by medical doctor
With innovative
pulsatile irrigation



User's Manual
Model: ProJet101



•Please read this user's manual carefully before performing ear irrigation.

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ProJet Electronic Ear Irrigator

Thank you for purchasing the Guardian ProJet Electronic Ear Irrigator. We are sure you will appreciate its ease of use and reliability. Given the proper care and maintenance, your ProJet will provide many years of reliable and efficient service.

Please familiarise yourself with the workings of the ProJet by reading this manual and practising with the machine before using on patients.

ProJet tip is designed for single patient use only and should be discarded after use by the appropriate method. We also recommend using one ProJet tip per ear to avoid the risk of cross contamination between ears.

Please note that all procedures using the ProJet should be carried out by a suitably trained nurse, doctor or audiologist.

IMPORTANT SAFEGUARDS

When using electrical appliances, especially when children are present, basic safety precautions should always be followed, including the following.

READ ALL INSTRUCTIONS BEFORE USING

DANGER -To reduce the risk of electrocution:

- Always unplug this product immediately after using.
- Do not use while bathing.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place in or drop into water or other liquid.
- Do not reach for a product that has fallen into water, unplug it immediately.

WARNING-To reduce the risk of burns, electrocution, fire, or injury to persons:

- A product should never be left unattended when plugged in.
- Close supervision is necessary when this product is used by, on, or near children or invalids.
- Use this product only for its intended use as described in this manual.
- Do not use attachments not recommended by the manufacturer.
- Never operate the product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service center for examination and repair.
- Keep the cord away from heated surfaces.
- Never block the air openings of the product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and the like.
- Never use while sleeping or drowsy.
- Never drop or insert any object into any opening or hose.
- Do not use outdoors or operate where aerosol(spray) products are being used or where oxygen is being administered.
- Unplug this product before filling. Fill reservoir with water only unless otherwise specified by manufacturer. Do not overfill.
- The motor in our Guardian ProJet has a temperature-over-heat control. If it overheats, the power will be switched off automatically. After cooling down, it will resume as usual.
- To avoid the risk of electric shock, do not remove cover(or back). Refer servicing to qualified service personnel.
- The machine may only be used with foot-switch model: CN1, manufactured by Yiin Wang Industrial Co., Ltd.

"SAVE THESE INSTRUCTIONS"

WARNINGS OF SAFETY

- This product is for ear irrigation only. Please do not apply to any other area.
- Equipment not intended for use in oxygen rich environment.
- Equipment not intended for use with flammable anaesthetics.
- Do not position the unit so that it is difficult to operate power plug as disconnecting device from supply mains.
- No modification of this equipment is allowed.

- Please read carefully before use.
- We separate the severe risk and notice according to the potential risk.



caution

The Incorrect operation may cause serious injury or death.



caution

The Incorrect operation may cause injury or serious product damage.

caution

- Plug out: Please plug out the outlet before cleansing and maintaining the machine. Do not pull the plug with wet hands to avoid "electric shock" or any hurt.
- Please do not put the machine into water to cleanse, or use it during the shower. Meanwhile, do not use with wet hands to avoid the possibility of electric shock.
- When the plug is covered with dust, please cleanse it to avoid the cause of fire.
- Please do not use in case the cord or plug is damaged, and when universal plug is not tight. It will cause temporary electric shock or fire.
- Do not use when you are not in good spirit.
- Do not put the blocking material into water container.
- Please bundle the cord up not to use if the cord is damaged, distorted during processing, and tangled during pulling.
- Prohibit to take apart the machine to repair and assemble by yourself.
- Use 230V power voltage only, and prohibit to use other power voltage, otherwise it will cause fire, electric shock and damage.
- Please hold tightly the plug head to pull the plug, and don't pull the cord to plug out to prevent electric shock as well as fire.
- Please use single user ear tip to irrigate ear only.
- Do not re-use the ear tip to avoid the risk of cross infection.
- Do not use outdoors to avoid electric shock and disorder.
- Keep the water jet away from hot or high temperature place.
- Please do not drop any article to the intake and nozzle of water jet.
- Only suitable trained medical professionals should operate this device.
- Ensure that warnings and cautions are observed.
- Ensure that patients do not exhibit any contra indications for use.

caution

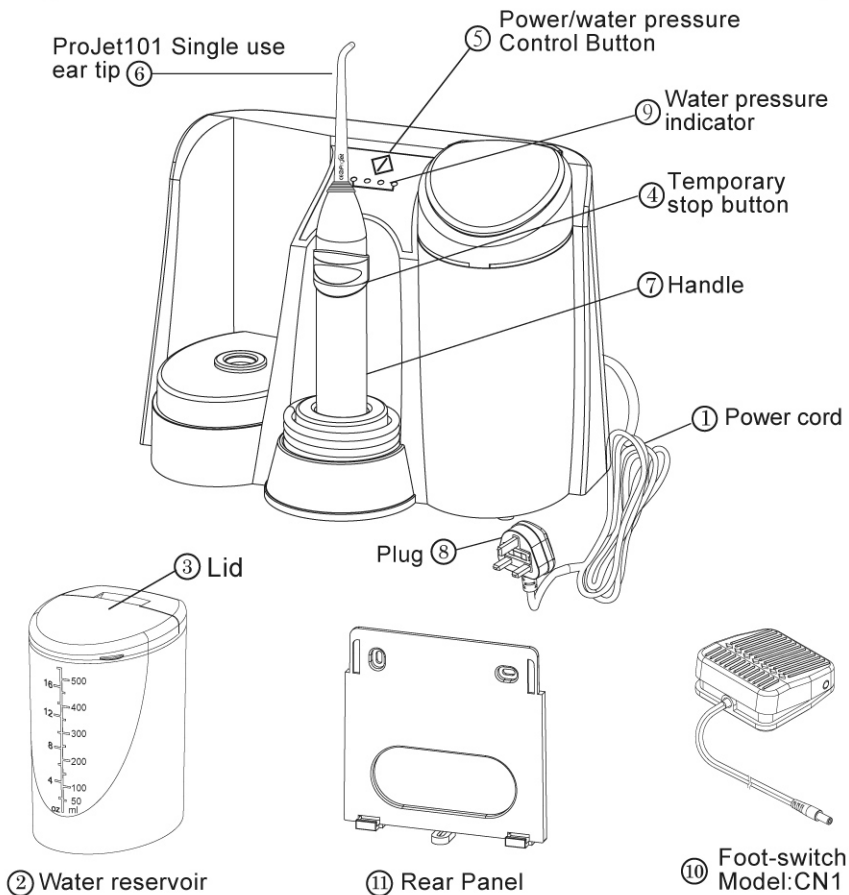
- You must install the machine on the wall according to wall mounting installation steps in the manual, in order not to fall or drop into water to cause accident.
- Please pull out the plug after use to avoid electric shock or leakage.
- Upon request, manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist service personnel to repair parts.
- Prohibit to operate continuously over 8 minutes.
- Prohibit to operate without water in tank.

Guidance and manufacturer's declaration - electromagnetic emissions

ProJet101 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	ProJet101 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	ProJet101 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

PARTS LIST



1. Power cord
2. Water reservoir
3. Lid
4. Temporary stop button
5. Power/water pressure Control Button

6. ProJet101 Single use ear tip
7. Handle
8. Plug
9. Water pressure indicator
10. Foot-switch Model:CN1
11. Rear Panel

INTENDED PURPOSE

The ProJet is designed to:

- Aid the removal of cerumen and foreign bodies from the external auditory canal.
- Aid the removal of discharge, keratin and/or debris from the auditory canal.

Reasons for using this procedure are to:

- Remove a cause of discomfort.
- Remove non hydrophobic objects from the external auditory meatus.
- Examine the external auditory meatus and the tympanic membrane.
- Assist in removing impacted wax and so improve sound conduction.
- Clear debris where the meatus is obscured.

IMPORTANT INFORMATION

- Please read and understand this manual before using your ProJet.
- Please do not immerse your ProJet in water.
- Clean the device as per our recommendations.
- The device has no user serviceable parts and should be returned to your distributor or direct to us for repair and/or service.
- ProJet tips are single use only and should be discarded in accordance with local authority or PCT requirements.
- If any changes occur in the performance of the ProJet, please turn off the machine and remove from the mains supply.
- The device should be serviced annually.
- DO NOT USE UNTIL THE MACHINE HAS BEEN CHECKED BY AN AUTHORISED SERVICE ENGINEER.
- ONLY SUITABLE TRAINED MEDICAL PROFESSIONALS SHOULD OPERATE THIS DEVICE.
- ENSURE THAT WARNINGS AND CAUTIONS ARE OBSERVED.
- ENSURE THAT PATIENTS DO NOT EXHIBIT ANY CONTRA INDICATIONS FOR USE.

Contra-indications for ear irrigation:

Whilst the ProJet101 is suitable for ear irrigation there may be instances when the use of such a machine is not recommended and the following are some circumstances:

1. Difficult, restless or uncooperative patients.
2. The patient has experienced complications following ear irrigation in the past.
3. Where consent has not been given for the machine to be used.
4. Where there is a history of middle ear infections in the last 6 weeks.
5. The patient has undergone ear surgery (Apart from grommets that have extruded at least 18 months previously and the patient has been discharged from the ENT department).
6. The patient has tympanic membrane perforation.
7. The patient has inner ear disorders especially if characterized by severe dizziness or vertigo.
8. Where the patient has a history of mucous discharge in the last year.
9. The patient has a cleft palate (whether repaired or not).
10. In the presence of acute otitis externa or oedematous ear canal combined with pain and tenderness of the pinna.
11. If patient complains of pain – **STOP IMMEDIATELY.**

DIRECTIONS

IRRIGATION PROCEDURES:

1. Explain to the patient the procedures of the ear irrigation. Informed consent should be obtained before ear irrigation. The patient should be informed of the probable risks of the procedure.
2. Examine both ears by regular ear examination procedure. Use otoscope to check if ear irrigation is still indicated, or if any contra-indication for ear irrigation exists. Stop the procedures if any contra-indication exists, and refer to a medical doctor.
3. Connect the footswitch to ProJet main unit, plug the power cord into the correct voltage wall outlet. The indicator light on the front panel will illuminate at the right of the power scale (the minimum water pressure light).
4. Press the power switch ONCE to turn on the motor.
5. Ask patient to sit in a chair and tilt their head towards the affected ear to be irrigated. Check that the headlight is working normally.
6. Place the protective cape on the patient's shoulder and under the ear to be irrigated. Ask the patient to hold a suitable receptacle (Noots ear tank or similar device) on the neck approximately a few centimeters below the ear.
7. Fill the water reservoir with 500cc warm water at $39^{\circ}\text{C}\sim 40^{\circ}\text{C}$, so the temperature of water irrigated into the ear canal will be at body temperature ($37^{\circ}\text{C}\sim 38^{\circ}\text{C}$).
8. Connect a new ProJet single use ear tip to the handle of ProJet main unit.
9. Hold the handle with tip connected over the suitable receptacle (Noots ear tank or similar device) and press the footswitch for about 10 seconds to purge any trapped air or cold water that is in the delivery system. Irrigate warm water onto the hand of the practicing professional to check and confirm the warm water temperature. Once warm water is delivered from the tip, the machine is ready to be used on the patient. This procedure allows the patient to become accustomed to the noise of the machine too.
10. Gently pull the auricle upwards and backwards to straighten the ear canal.

11. Warn the patient that you are going to start the ear irrigation and ask them to alert you if they feel dizzy or experience ear pain. The procedure must be discontinued immediately if the patient feels dizzy or experience any ear pain during the irrigation procedure.
12. Place the ear tip at the entrance of the external auditory meatus and direct the water stream towards the posterior-superior wall of the ear canal (11 o'clock in the right ear and 1 o'clock in the left ear) under illumination via headlight. Press footswitch to start ear irrigation. Always start with two short applications of water to determine if the patient is sensing water in the nose or throat, which signifies tympanic membrane perforation. The procedure should be terminated and medical advice sought if the patient experiences such problems. The procedure can be continued if the patient does not experience such problems.
13. Always start any treatment at the minimum setting.
14. If the minimum setting is not sufficient, gradually increase pressure/flow by pressing the on/off switch on the front panel until the desired setting is reached. The setting is shown by the indicator lights moving up the scale from the right to the left. It is recommended that a maximum of two reservoirs of water (1000cc) is used in any one irrigating procedure.
15. The water stream should swing to and fro gradually, and should not stay at any fixed point of the external auditory meatus.
16. Release the footswitch to inspect the external auditory meatus and tympanic membrane with the otoscope when necessary, and check the solution running out closely.
17. After removal of earwax or debris, dry mop excess water from the meatus under direct vision using the Jobson Horne probe or similar device and best quality cotton wool. Stagnation of water and any abrasion of skin during the procedure can predispose to infection. Removing the water with the cotton wool and tipped probe reduces the risk of infection.
18. Remove and discard disposable single use ProJet ear tip.
19. Examine bilateral ears, including meatus and tympanic membrane. Document what was seen in examination, the procedure carried out, the condition of the tympanic membrane and external auditory meatus and treatment given. If any abnormality is found, a referral should be made to the medical doctor.
20. Give advice regarding ear care and any relevant information and provide leaflet.

MACHINE OPERATION:

1. Plug in the power cord

- Insert the footswitch plug into the footswitch socket.
- Plug the power cord into the correct voltage wall outlet.
- The power indicator on the front panel lights when the machine is enabled (ready to be started).
- The indicator light on the front panel will illuminate at the right of the power scale (the minimum water pressure light) when you plug in the power cord.

2. Fill the water reservoir

- Open the lid of the water reservoir and fill it with 500cc warm water at 39°C-40°C, so the temperature of water irrigated into the ear canal will be at body temperature (37°C-38°C).
- Always use warm water at body temperature to irrigate the ear to avoid dizziness or vertigo.

3. Attach the ear irrigator tip to the handle

- Slide the rim on the irrigator tip into the groove on the handle until it locks in place, and slide up the pause button on the handle (slide down the pause button will pause water flow). Do not twist the irrigator tip in the handle.



- To turn on, slide up the pause button.
- To turn off, slide down the pause button.

● **Water pressure
Pause button**

4. Adjust water pressure

- Press the control button on the front panel to adjust water pressure (please see figure 1).

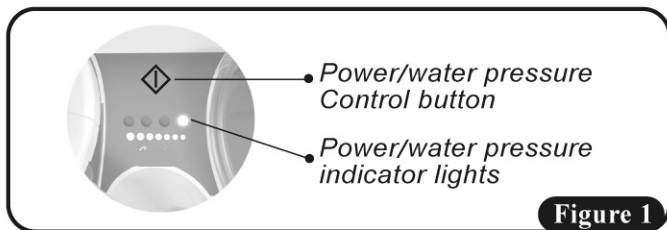
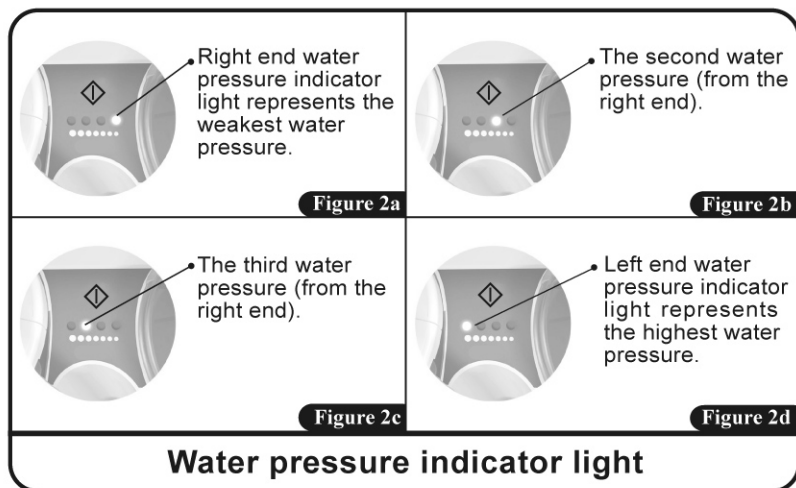


Figure 1

- The adjoining left water pressure indicator lights if you press the control button for 2 seconds before releasing it.

- The adjoining water pressure indicator lights gradually, from right to left, if you press the control button continuously. Release the control button when the desired water pressure indicator lights. The machine is now ready to be used.
- The right end water pressure indicator lights when the weakest water pressure is enabled or activated (Figure 2a). The water pressure is higher when the indicator light turns on from right side toward left side (Figure 2b, 2c). The left end water pressure indicator lights when the highest water pressure is enabled or activated (Figure 2d).



- Always use the weakest water pressure initially, and then increase the water pressure if necessary.

5. Activate machine

- Press the control button on the front panel ONCE to turn on the motor (Press the control button again will turn off the motor). Press the foot pedal switch will start the warm water irrigation.
- To turn on/off the motor, press and release immediately the control button on the front panel. The water pressure light will not shift.

6. Stop machine temporarily

- Releasing the footswitch will stop the machine. You can slide down the pause button on the handle to pause water flow temporarily too. Sliding up the pause button on the handle will re-start irrigation.

7. Finish ear irrigation

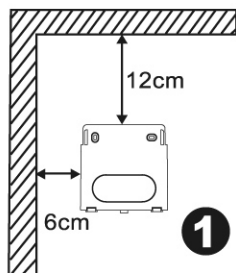
- After treatment, empty the reservoir and purge any water remaining in the system by using the machine empty for a few seconds.
- Turn the motor off by pressing the control button on the front panel again.
- Disconnect the power cord from the wall outlet, and disconnect the foot pedal switch.

8. Discard the single use ear tip

- Disconnect and discard the single use ear tip after ear irrigation.

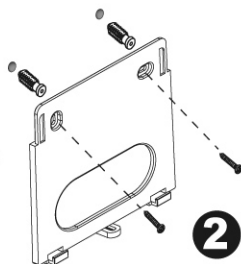
OPTIONAL WALL MOUNTING

- 1** Unit should be mounted with 6 inches (15cm), for the ceiling, and 3 inches (7.5cm) from the wall.

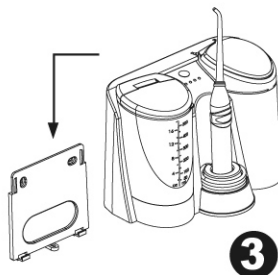
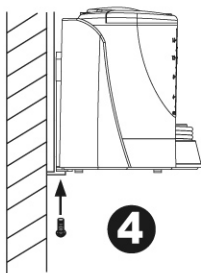


- 2** Drill two holes of 0.8cm and 2.5cm deep (The distance between two holes is 8.3cm). Hammer two plastic plugs into these two holes till level with the wall.

- 3** Remove the power cord from the storage box and fit main body back onto the panel. (Fix the power cord through the hole below the panel, and do not press heavily to damage the power cord).



- 4** Please make sure to fix the Water Jet and rear panel tightly with attached safety screw.



CLEAN AND MAINTENANCE



caution

- Do not immerse ProJet ear irrigator in water to wash.
- Always disconnect the plug from the MAINS prior to cleansing and maintaining the ProJet ear irrigator.
- Please cleanse the plug periodically to avoid electric shock, hurt and bad connection.

Clean and maintenance

- Before cleaning and maintaining the ProJet101 ear irrigator, always unplug the cord from electrical socket first.
- Clean the machine with a damp cloth regularly. The water reservoir and single use ear tip are removable. When cleaning, please do not use any rough tool or utensil (such as scrubbing pad) to wash the unit to prevent the machine from getting damaged.
- Always keep the ProJet101 ear irrigator sanitized and dry.

Miscellaneous notice

- Do not wash main body with above 50°C water.
- Please do not use the dilution and gasoline to fade the color.
- Clean the plug once a year to prevent a poor connection.

CLEANING AND DISINFECTION OF THE MAIN BODY

Internal cleaning of the ProJet101

1. Please prepare 500cc warm water with adequate concentration of chlorine solution according to the manufacturer (NaDCC---Sodium Dichloroisocyanurate 0.1% or HOCL 0.5%).
 2. Run the ProJet ear irrigator for a few seconds to allow the chlorine solution to fill the pump and internal flexible tubing and handle.
 3. Leave to stand for about 10 minutes. Empty the water reservoir, and rinse the system through with tap water to ensure no cleaning solution is left in the internal part of the machine before use.
 4. This cleansing and disinfecting procedure should be done before ear irrigation everyday.
 5. **DO NOT** leave the cleaning solution in the unit longer than recommended to avoid machine damage.
 6. **DO NOT** use too strong or higher concentration of cleaning substance to avoid damage of the machine.
- **ALWAYS USE THE SINGLE USE PROJET EAR TIP FOR EACH EAR IRRIGATION TO AVOID PROBABLE CROSS INFECTION.**

GUIDE TO SYMBOLS



Conforms to the Medical Device Directive 93/42/EEC



Applied part of the type BF



Class II Equipment

IPX1 Protected against water droplets



Single use item



Must be disposed of in accordance with European waste electrical and electronic equipment directive 2002/96/EC



Consult the accompanying documents.



Symbol for temperature limitation (Use 39°C-40°C warm water only).



Symbol for manufacturer



Symbol for authorised representative in the European community

SN

Symbol for serial number

TROUBLE-SHOOTING GUIDE

Please try the below trouble-shooting guide before returning for repair.

Problem	Cause	Corrective Action
<i>The ear irrigator is not functioning</i>	<i>Improper connection with the power source</i>	<i>Unplug and plug it again</i>
	<i>There is no electricity in the socket</i>	<i>Try other sockets and plug it again</i>
<i>Motor is not working</i>	<i>Motor may have overheated causing the auto-safety system to be turned on</i>	<i>Wait for 20 minutes until the motor is cooled down, It will revert to normal function.</i>
<i>Pump is functioning but water was not sprayed out</i>	<i>The water reservoir is empty</i>	<i>Refill the water reservoir with water</i>
<i>Water pressure is too low</i>	<i>Inadequate water pressure</i>	<i>Adjust the control button to the most adequate water pressure.</i>
		<i>Check the water reservoir to see if it is placed in the correct position</i>

- If the power cord is damaged, it must be replaced by the manufacturer or its service agent or a similarly qualified person in order to avoid hazard.



caution

Please do not take the appliance apart yourself for repair. If you want to replace a part such as the spray tube, water reservoir etc., please contact your dealer or our authorized maintenance centre.

SPECIFICATION

Power	AC230V, 50Hz
Capacity	0.1A
Static pressure	0.25 bar Mimimun ~ 3.00 bar Maximun
Pulsation	From 450 to 1200 Rpm
Fuse	T 1.6A/250V
Working time	About 2-3 minutes for 500cc
Dimension	180(H)X175(W)X145(L)
Reservoir	500ml
Footswitch	Model:CN1 Manufactured by Yiin Wang Industrial Co., Ltd.
Irrigator tip	Model:ProJet101 Manufactured by Suit Way Precision Molding Co., Ltd.

TRANSPORT AND STORAGE

	Transport/Storage	Operation
Temp. range	-10°C~55°C	5°C~35°C
Relative Humidity	10%up to 90%	10%up to 90%
Pressure	860 to 1060 hpa	860 to 1060 hpa

OPERATION TIME

The maximum duration of continuous usage should not exceed 8 minutes. Have a rest period of at least 10 minutes after ear irrigation.

ABANDONMENT


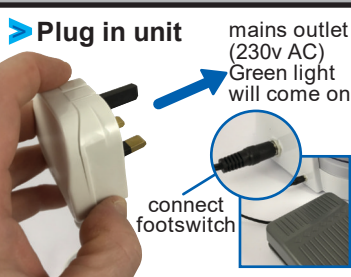
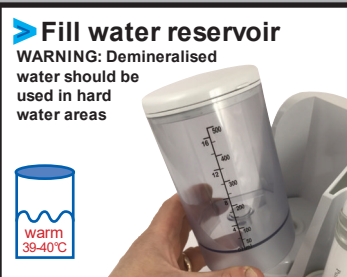
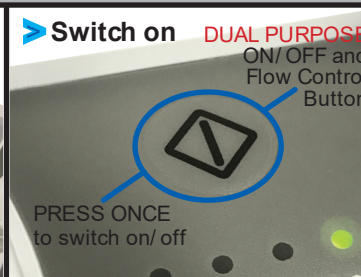
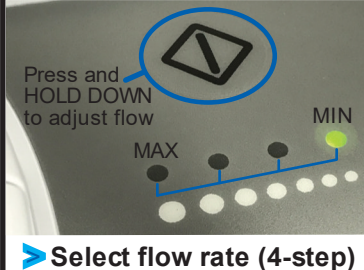
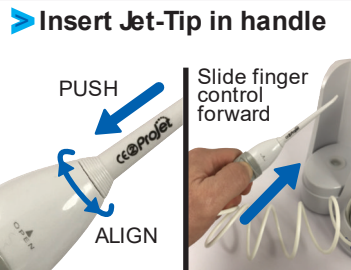


If you want to throw away the waste appliance, please abandon according to trash separating of environment protecting Dept. regulation.



GUARDIAN[®]

CE
0598

Projet 101 Quick Start Guide

 <p>> Unpack and check</p>	<p>> Plug in unit</p> <p>mains outlet (230v AC) Green light will come on</p> <p>connect footswitch</p> 	<p>> Fill water reservoir</p> <p>WARNING: Demineralised water should be used in hard water areas</p>  <p>warm 39-40°C</p>	<p>> Switch on</p> <p>DUAL PURPOSE ON/OFF and Flow Control Button</p> <p>PRESS ONCE to switch on/off</p> 
<p>Press and HOLD DOWN to adjust flow</p> <p>MAX MIN</p>  <p>> Select flow rate (4-step)</p>	<p>> Insert Jet-Tip in handle</p> <p>PUSH</p> <p>ALIGN</p> <p>Slide finger control forward</p> 	<p>Press down to operate</p> <p>> Press</p> 	<p>> Clean after use</p> <p>Clean as per operating instructions, using Chlor-Clean (or equivalent) tablets.</p>  <p>Replenish tips in caddy</p>

Spares and accessories. Available from your medical equipment supplier:

- Projet 101 single-use tips, pack 100
- Projet 101 shoulder capes, pack 100
- Super absorbent ear canal water wicks, dispenser of 50
- Single-use Jobson Horne wool carrier/probe with loop, x100
- Replacement mushroom valve for water reservoir, each

- Order code: 190.60.100
- Order code: 190.60.000/9
- Order code: 190.60.000/10
- Order code: GD.200.15/100
- Order code: 190.60.000/1

Information on the complete range of Projet 101 spares and accessories is available on request.

TECHNICAL SUPPORT HELPLINE: 1300 884 612

ATTENTION
If unit doesn't operate when footswitch is pressed, press on/off button once and make sure finger control is pushed forward