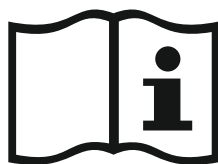




# PROPULSE<sup>®</sup>

## GS IRRIGATOR<sup>™</sup>



CE  
0086

**mirage<sup>®</sup>**  
Health Group

# Propulse<sup>®</sup>



Propulse<sup>®</sup> ProScoop<sup>™</sup>  
INS0028



Propulse<sup>®</sup> Noots Ear Tank  
INS0021



Propulse<sup>®</sup> ProTect<sup>™</sup> Cape  
KIT1012

# PROPULSE<sup>®</sup>

Propulse<sup>®</sup> Cleaning Tablets  
(x200 per pack)  
CL0001



Propulse<sup>®</sup> QrX<sup>™</sup> Single Use  
Tip (x100 per pack)  
KIT5002



Propulse<sup>®</sup> Carry Case  
KIT1005



Propulse<sup>®</sup> Head Lamp  
INS0036



## INTENDED PURPOSE

The Propulse® G5 Electronic Ear Irrigation System is intended to:

- a) Facilitate the removal of cerumen and foreign bodies that are not hygroscopic from the auditory meatus.
- b) Remove discharge, keratin or debris from the external auditory meatus by irrigation with warm water.

Reasons for using this procedure are to:

- a) Correctly treat otitis externa where the meatus is obscured by debris.
- b) Improve conduction of sound into the ear, where impacted wax is believed to be the cause of a hearing defect.
- c) Examine the external auditory meatus and the tympanic membrane.
- d) Remove a cause of discomfort.

This procedure should ONLY be carried out by a suitably qualified healthcare professional.

## WARNINGS AND CAUTIONS

- This manual must be read and understood before the Propulse® G5 Electronic Ear Irrigation System is used.
- Only suitably trained staff should use the device. Mirage can advise on the availability of training courses offered by relevant organisations.
- The Propulse® QrX™ Tip is “Single Use” and should be disposed of in accordance with local authority guidelines after use.
- The Propulse® G5 Electronic Ear Irrigation System must not be immersed in water.
- Only clean the device as specified in this manual (See page 10).
- If any changes in performance occur, turn off the Propulse® G5 Electronic Ear Irrigation System, disconnect from the mains electricity supply and DO NOT use (See page 11).
- The device has no user serviceable parts (See page 16).
- Use recommended Propulse® accessories only.
- Do not use Propulse® accessories with other devices.
- If the device is to be used for domestic visits, it is strongly recommended that a Propulse® Carry Case is used to prevent damage and contamination.
- The Propulse® G5 Electronic Ear Irrigation System is not user repairable and should be returned to your Propulse® supplier or Mirage Health Group (UK customers only) for service and/or repair. It is recommended that the Propulse® G5 Electronic Ear Irrigation System is serviced annually.

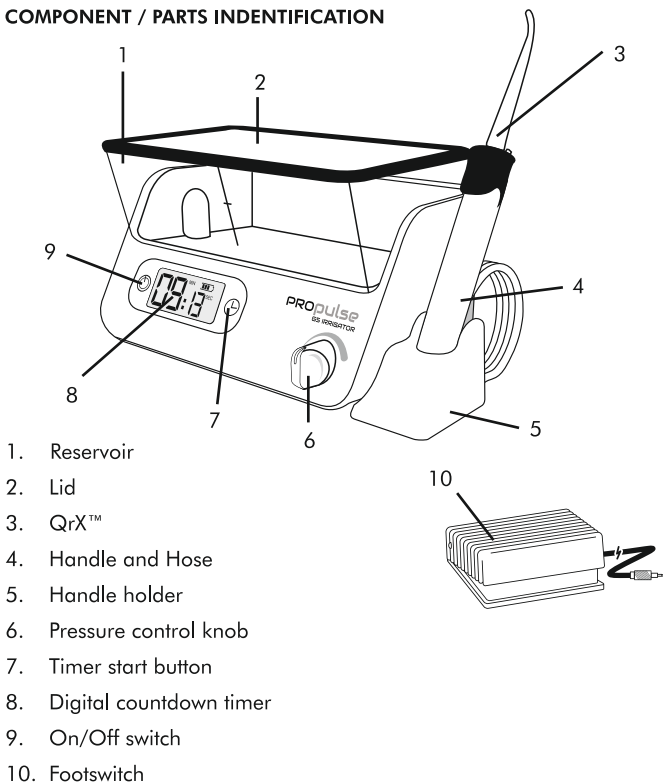
**Please note:** Damage caused to your Propulse® G5 Electronic Ear Irrigation System by the use of accessories, consumables or service agents not recommended by Mirage Health Group, will invalidate your warranty.

## **DO NOT IRRIGATE** the ears if:

- a) Consent is not given and/or the patient is uncooperative.
- b) Previous complications occurred following this procedure.
- c) There is a history of a middle ear infection in the last six weeks.
- d) 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 dept).
- e) The patient has a perforation or there is a history of a mucous discharge in the last year.
- f) The patient has a cleft palate (repaired or not).
- g) In the presence of acute otitis externa; an oedematous ear canal combined with pain and tenderness of the pinna.
- h) If patient complains of pain - **STOP IMMEDIATELY**.

*\*Please refer to Contraindications on page 15.*

## **COMPONENT / PARTS IDENTIFICATION**



The Propulse® G5 Electronic Ear Irrigation System consists of:

a) The main unit with integral battery and the following user controls:

- A footswitch which (when pressed) starts the flow of water. The water stops when the footswitch is released.
- An LCD display with countdown start button (to facilitate a 10 minute cleaning cycle)
- Water pressure/control flow knob
- Battery level indication meter (when charging, this will cycle through from min to max and repeat until fully charged)
- A mains power indicator
- An on / off switch

b) Water container/reservoir (1) is removable to facilitate filling and cleaning. Graduation mark to indicate correct level of water required to dissolve cleaning tablet.

Mushroom Valve – to retain the water in the reservoir when it is removed from the Propulse® machine.

c) Handle and non-detachable hose. The Handle accommodates the Propulse® QrX™ Single Use Tips.

d) The footswitch - is connected to the main body via a jack plug/socket connection. The device will only function if the footswitch is connected.








**Please note:** Residual water in the handle and hose will continue to flow if the handle is not held in the vertical position or, if the handle is held in a position that is lower than the machine. To prevent residual flow, it is recommended that the handle be returned to its holder on the machine.

# TECHNICAL DATA

**Performance:**

Static pressure between:	0.27 bar (minimum setting) 3.45 bar (maximum setting)
Water jet pulses:	1200 per minute (approximately)
Maximum operating time:	10 minutes continuous use (with a recommended rest time of 2 hours)
Storage temperature range:	-5°C to 65°C
Storage relative humidity:	up to 80%
Rechargeable battery:	6v Ni-MH 1300mAh
Power adaptor:	Input 100-240v ~ 50/60Hz Max 0.45A Output 9v DC2A
Electrical Safety:	EN6061-1
EMC Compliance:	EN60601-1-2

# GUIDE TO SYMBOLS

-  Attention - Consult Accompanying Documents
-  Type BF Electrical safety
-  Protected against water droplets
-  Single use item
-  Conforms to the Medical Device Directive 93/42/EEC
-  Must be disposed of in accordance with European waste electrical and electronic equipment directive 2002/96/EC
-  Manufactured by

## GUIDANCE & MANUFACTURERS DECLARATION

The Propulse® G5 is intended for use in the electromagnetic environment specified below. The customer or the user of the Propulse® G5 should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 6$ kV contact $\pm 8$ kV air	$\pm 6$ kV contact $\pm 8$ kV air
Electrical fast transient/burst IEC 61000-4-4		$\pm 2$ kV for power supply lines $\pm 1$ kV for input /output lines
Surge IEC 61000-4-5		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11		$<5\% U_T$ ( $>95\%$ dip in $U_T$ )
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8		
Conducted RF IEC 61000-4-6  Radiated RF IEC 61000-4-3		

**Note 1:**  $U_T$  is the a.c. mains voltage prior to application of the test level.

**Note 2:** At 80 MHz and 800 MHz, the higher frequency range applies.

**Note 3:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) 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.



## GUIDANCE & MANUFACTURERS DECLARATION

## Electromagnetic environment - guidance

Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Mains power quality should be that of a typical commercial or

separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol:



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 Propulse® G5 is used exceeds the applicable RF compliance level above, the Propulse® G5 should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Propulse® G5.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## Cleaning Cycle Timer

The Propulse® G5 has been fitted with a 10 minute timer to help facilitate the correct cleaning method prior to using the Propulse® for the day's ear irrigation procedures. Failure to clean the machine prior to the day's clinic may lead to ear infection.

## Cleaning Instructions

The importance of using the correct strength cleaning solution cannot be overstated. A solution that is too strong will in time damage the Propulse® G5 Irrigation System. A solution that is too weak will fail to provide the correct level of cleaning and decontamination. Mirage Health Group recommends the use of Propulse® CHLOR-CLEAN® Tablets. They are easy and effective to use and provide a measured / specific strength of cleaning solution that is safe and kind to the Propulse® internal components.

- 1 Place warm tap water into the reservoir to the "Fill Line".
- 2 Place one Propulse® CHLOR-CLEAN® tablet into the reservoir and allow it to dissolve completely.
- 3 Once dissolved run the machine until the cleaning solution leaves the handle. This ensures that the cleaning solution has reached all of the internal components.
- 4 Press the start button on the timer on the front display panel of the Propulse® G5
- 5 After the countdown is complete, the Propulse® will "beep" indicating the end of the cleaning cycle.
- 6 Remove the reservoir with the remaining cleaning solution and discard.
- 7 Fill the reservoir with clean, well run, cold tap water and return to the Propulse®
- 8 Run the Propulse® ensuring that all remaining cleaning solution has been flushed through.
- 9 Remove reservoir, discard water and dry reservoir thoroughly with a paper towel
- 10 Return reservoir to the Propulse® - it is now ready for use.

## OPERATING INSTRUCTIONS

These instructions are for general use. When required, refer to the detailed information in the second half of this manual.

- Ensure that ONLY suitably trained clinicians operate the device.
- Ensure that the warnings and cautions are observed.
- Ensure that the patient exhibits no contra indications.
- Ensure the unit has been cleaned prior to first use (refer to page 10 for detailed cleaning guidance).
- Mains electrical power is not necessary if the battery is adequately charged.
- The device may be operated whilst connected to the mains electrical supply using the Power Adaptor provided.
- Ensure that the footswitch is connected.
- The reservoir should be removed prior to filling.
- The water reservoir must be filled to within approximately 1cm with warm water at 40°C. Monitor temperature regularly to ensure that patient comfort and safety is maintained. Refill as necessary.
- Fit a new Propulse® QrX™ Single Use Tip to the Handle.
- Set Pressure/Flow switch (6) to minimum (by turning anti-clockwise).
- Turn on the Power Switch (9) (marked "I").
- Adjust the water pressure/flow to an appropriate value that is compatible with the treatment requirements and patient comfort.
- Direct the irrigator tip into the noots tank and switch on the machine for 10-20 seconds in order to circulate the water through the system and eliminate any trapped air or cold water.

### **Ensure the water is warm before presentation to the patient.**

- During treatment you can pause the flow by releasing the footswitch
- After treatment empty the reservoir and operate the device to purge any residual water.
- Remove the Propulse® QrX™ Tip and dispose of in accordance with local authority guidelines.
- Turn off Power Switch after use and connect to the Power Adaptor to recharge the battery (if required).
- Clean the Propulse® G5 Irrigator unit every morning prior to use, with a Propulse cleaning tablet (See page 10).
- The Propulse® G5 Irrigator should only be transported in a Propulse® approved carry case to prevent damage or contamination.
- If any changes in performance occur, turn off the Propulse® G5 Irrigator, disconnect from the mains electricity supply and DO NOT use. Please refer the machine to the Mirage.

## DETAILED INFORMATION

### Fitting the Footswitch

The Propulse® footswitch is connected to the main unit by a socket in the side of the device. The Propulse® G5 Irrigator will NOT operate unless the footswitch is connected.

### Filling the water reservoir

It is recommended that:

- i) The water reservoir is removed from the device for filling and that the lid is always in place when the water container is in-situ on the device.
- ii) The water reservoir must be filled to within approximately 1 cm of the top of the reservoir. This helps to eliminate the risk of spillage.
- iii) Water above 40°C should NOT be used in order to avoid the risk of scalding and burns to the user and patient. Water below 40°C should NOT be used in order to avoid the risk of patient discomfort and dizziness.

### Fitting the Propulse® QrX™ Tip

The Propulse® G5 Irrigator System is supplied with 100 x Propulse® QrX™ Single Use Tips. Use One Propulse® QrX™ Tip per treatment.

#### To fit a Propulse® QrX™ Tip

- 1) Remove tip from packaging - Tips are non-sterile.
- 2) Push Tip into Handle until a click can be heard.

#### To remove a Propulse® QrX™ Tip

- 1) Retract the QrX™ Locking Collar using a thumb.
- 2) Grasp the used QrX™ Tip between forefinger and thumb and pull gently from the QrX™ Handle.
- 3) Dispose of used tip in accordance with local authority guidelines.

### DO NOT REUSE TIPS.

Propulse® QrX™ Tips are available to purchase in boxes of 100, individually wrapped (non-sterile) tips from your normal Propulse® supplier or from Mirage directly (UK only). Propulse® QrX™ Tips are clearly branded with the Propulse® logo on the tip and its packaging. Only branded Propulse® QrX™ Tips should be used with the Propulse® G5 Irrigator.

### Replacing the Mushroom Valve

The Mushroom Valve is specifically designed to prevent water flowing out of the reservoir whilst filling. Should a replacement Mushroom Valve be required, please follow the steps below -

This will help prevent possible damage to the water inlet valve.

- 1) Remove the reservoir from the Propulse® G5 Irrigator.
- 2) Remove the old Mushroom Valve from the reservoir and discard.
- 3) Insert a new Mushroom Valve into the reservoir.
- 4) Return the reservoir to the machine.

## **Power Adaptor**

The Power Adaptor can be used to charge the internal battery or to run the device from the mains electrical supply.

Connect the outlet lead of the Power Adaptor to the Power Adaptor socket marked on the end of the product and to the mains electrical supply. Make sure the cord and Power Adaptor are positioned so that they will not be subjected to damage or stress or present a trip hazard.

Only use a Propulse® branded Power Adaptor.

To reduce the risk of electric shock, unplug the unit from the power source before attempting to clean it externally.

The Power Adaptor must not be used outdoors or in damp areas.

The Propulse® Power Adaptor will have been supplied with a selection of international plugs. Please fit the appropriate plug for your region. If there are any problems connecting to the mains electrical supply consult a qualified electrician.

## **Battery Use And Care**

We recommend that the battery be fully charged for 24 hours before you using the Propulse® G5 Irrigator for the first time.

For subsequent use the battery will normally require 16 hours to fully charge.

A new battery or one that has not been used for a long time may have reduced capacity the first few times it is used.

The battery is integral and is only replaceable by Mirage Health Group. Refer to your Propulse® supplier or Mirage Health Group (UK customers only) for more information.

It is recommended that the battery is replaced after 400 charge cycles.

## Environmental Protection



This symbol on the products and/or accompanying documents means that used electrical and electronic products should not be mixed with general waste. Please return to Mirage Health Group. Penalties may be applicable for incorrect disposal of this waste, in accordance with national legislation.

Disposing of used Propulse® QrX™ Tips - Disposal should be in accordance with local authority guidelines and regulations for the disposal of clinical waste. Propulse® QrX™ Tips should not be disposed of in municipal waste.

## Transportation

Before the Propulse® G5 Electronic Ear Irrigation System is transported, the reservoir must be emptied and the machine should be operated until the handle and hose are empty of liquid. The reservoir should then be dried using a paper towel.

For safer transportation of Propulse® G5 Irrigator, Mirage recommends that the Propulse® carry case is used to prevent damage or contamination.

## Cleaning

Do not attempt to clean the Propulse® QrX™ Tip. Use one Propulse® QrX™ Tip per patient treatment and discard to clinical waste after use as this reduces the risk of cross infection between patients.

External cleaning of the Propulse® G5 Irrigator should be done by hand, wiping with a damp cloth only. Apply liquids to the cloth not the unit. Do not immerse the unit in water. Mild detergents and disinfectants may be used externally.

For internal cleaning, please refer to page 10.

<b>Contraindication to irrigation</b>	<b>Rationale</b>
If the patient has experienced any complications from a previous episode of irrigation with water.	If the patient did not tolerate a previous episode of irrigation it would be unwise to repeat the procedure in case the symptoms are exacerbated.
There has been evidence of a middle ear infection (Otitis Media) in the last 2 months.	The tympanic membrane may be vulnerable to damage due to the adverse effect infected fluid may have on the ear drum.
The patient has undergone any form of ear surgery apart from grommets which are documented to be extruded from the tympanic membrane for over 2 years and the patient is discharged from the ENT department.	There will be a weakness to the structure of the ear canal and tympanic membrane after surgery. This does not include cosmetic surgery to the pinna (for example repair of bat ears). If the tympanic membrane is intact 2 years post grommet extrusion there should not be an increased risk of damage to the tympanic membrane.
There is a suspected or actual perforation present or there is a history of mucous discharge from the ear in the last 2 years.	A mucous discharge would indicate a perforation and water entry under pressure could cause infection or damage the delicate middle ear structures.
If the patient has a cleft palate (regardless of whether it has been repaired or not).	A cleft palate indicates an underdeveloped facial skeleton and as such the tympanic membrane and middle ear structures could be more vulnerable to damage.
In the presence of acute otitis externa (pain, swollen ear canal and tenderness of the pinna).	Although it is essential to thoroughly clean the infected ear canal, when it is swollen debris should be removed by microsuction.
Profound hearing loss in one ear.	There is a risk associated with any intervention and when a patient completely relies on one ear for hearing (as the other ear has a profound hearing loss) any risk to this ear is unacceptable

<b>Caution when irrigating with water in the following groups of patients</b>	<b>Rationale</b>
Patient is taking anti-coagulants.	The lining of the ear canal is delicate and there is a higher risk of bleeding so ensure trauma to the ear canal is avoided.
The patient is diabetic.	The pH of wax in patients who are diabetic is a higher pH than average increasing their vulnerability to infection.
Tinnitus	Although wax impaction can cause tinnitus, trauma to the tympanic membrane may exacerbate this.
Vertigo	This is also a symptom of wax impaction but irrigation can trigger an episode so ensure appropriate water temperature and patient safety.
Radiotherapy that has involved the ear canal	A radiated ear canal can develop bony necrosis so wax should be removed before it becomes hard and trauma to the canal should be avoided.

## **Maintenance & Safety Inspections**

To ensure optimum performance the Propulse® G5 Irrigator should be serviced every 12 months. Service or repairs conducted by unauthorised agencies/organisations invalidate any or implied warranties from Mirage.

The Propulse® G5 Irrigator should under-go routine electrical safety testing to ensure that it remains safe to use.

Users of the Propulse® G5 Irrigator should carry out regular inspections to ensure that the handle and hose, power adaptor and cable, reservoir and main body of the machine are free from damage prior to use. If any damage is evident, the Propulse® G5 Irrigator should NOT be used until replacement parts have been fitted.

Only Propulse® branded items should be used with the Propulse® G5 Irrigator.

The Propulse® G5 Irrigator is not user repairable and should be returned to your Propulse® supplier or Mirage Health Group (UK customers only) for service and/or repair:

### **Mirage Health Group**

1 Little Mundells, Welwyn Garden City, Hertfordshire AL7 1EW UK  
Tel - +44 (0) 845 130 5440

The clinical procedures relating to the use of ear irrigators can be found on the following websites:

[www.earcarecentre.com](http://www.earcarecentre.com)

[www.entnursing.com/earcare.htm](http://www.entnursing.com/earcare.htm)

Mirage is not responsible for the content or maintenance of third party internet sites.

Mirage can also advise on the availability of training courses offered by the relevant organisations.

Additional information on use of the Propulse® can be found at <http://www.youtube.com/user/MirageHealthGroup>



## Warranty

The Propulse® G5 Irrigator carries a twelve months warranty (\*subject to conditions) from the date of original purchase. Should any defect arise due to faulty material or workmanship, Mirage Health Group will provide a replacement unit upon receipt of the faulty Propulse® G5 Irrigator, proof of purchase, information relating to the nature of the fault and details of where the item was purchased.

Should any of the "Accessory" items (listed below) prove to be faulty as a result of defective material or workmanship, Mirage Health Group will provide a replacement "Accessory" item free of charge upon receipt of the faulty accessory (\*subject to conditions).

"Accessory" items are: Footswitch; Reservoir / Tank and Lid; Mushroom Valve and Washer; QrX™ Tip; Power Supply Lead and Power Transformer.

\*Conditions of Warranty (applicable to Propulse® G5 Irrigator and "Accessory" items).

### **The warranty does not cover:**

- Accidental damage or damaged caused by misuse.
- Faults caused due to lack of maintenance.
- Damaged caused by using the Propulse® G5 Irrigator for any use other than its intended use.
- Damage caused as a result of repair by any unauthorised agents - ONLY Mirage Health Group should undertake repairs.
- Damage caused by the use of accessories / cleaning products that have not been recommended by Mirage Health Group.

This warranty is in addition to, and does not diminish your statutory or legal rights.

Additional user manuals and other accessories are available from Mirage Health Group Ltd at:



### **Mirage Health Group**

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