Operator's Manual

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Revision Level History

Date	CO	Revision	Description
11/04/16	1274	00	Initial release of the operator's manual.
2/15/17	1341	01	Update to Cannula Description
3/10/16	1356	02	Replace Consult Symbol
6/19/17	1447	03	Add IP Rating Codes, Update Cannula Nomogram
06/26/17	1458	04	Add 5 Year Life Expectancy to Preface, add part number
06/26/17	1463	05	Add WARNING: Don't use on children or pregnant or nursing women
8/1/17	1483	06	Update equipment storage conditions
3/13/18	1634	07	Update Machinery Directive Health & Safety Requirements & Add Additional Cannulas
6/5/18	1673	08	Implement new catalog numbers for Cannulas
6/20/18	1685	09	Update Cannulas, update symbols in appendix
8/15/18	1694	10	Update Cannulas, Instructions for Settings & Operations Screens
8/20/18	1701	11	Update Instructions for Settings & Operations Screens,
10/9/18	1719	12	Add WARNING for use of Lens Removal & Cortical Removal modules
3/8/19	1757	13	Update Cannula Options
3/8/19	1809	14	Update Lens Removal Duty Cycle to include 40%, Ant. Vitrectomy Cut Rate to 2,500 Max Cuts
11/15/19	1937	15	Update EU and UK representatives and addresses for Brexit change
12/17/19	1957	16	Update units from pulses per minute to mmHg for Pulse Activation settings on Table 15; added coaxial cannula catalog number diagram
10/27/20	2110	17	Update UK address
9/8/21	2258	18	Added additional symbols from most recent standards
10/9/23	2479	19	Match CER exclusionary population in WARNING.

TABLE OF CONTENTS

PREFACE

The Operator's manual is a guide to the CataPulse® Lens Removal & Anterior Vitrectomy System and describes all options available to the user.

Please read the entire manual carefully before operating the system. Default settings are set by the manufacturer. It is recommended that each user, after training, decide on their preferential settings and save them under their user profile.

Use of accessories not designated by MED-LOGICS for use with the CataPulse may result in serious permanent patient injury, adverse surgical outcomes, or damage to the equipment.

Pay close attention to WARNING, CAUTION, and NOTE in this manual. A WARNING statement is written to protect individuals from bodily harm. A CAUTION statement is written to protect the system from damage. A NOTE is written to bring attention to highlighted information.

If you have any questions, or want additional information, please contact your local MED-LOGICS representative or the MED-LOGICS Technical Support at:

Lifetime testing at MED-LOGICS supports a minimum of a 5 year life expectancy for the CataPulse.

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WARNING: Do not attempt to use the CataPulse® without having adequate understanding of all its components, functions, controls, and limitations. MED-LOGICS requires that all CataPulse® users participate in a training session provided by a representative of MED-LOGICS before using the CataPulse®. Contact MED-LOGICS at (949) 582-3891 or email info@mlogics.com to schedule a training session.

WARNING: This device is not intended to be used on patients under the age of 21 or who are pregnant or nursing. This device is not intended to be used on patients presenting ocular infection, previous serious corneal disease, or acute or chronic systemic disease, i.e. immunocompromised patients. Providers should discuss recent medication usage with the patient before performing a procedure with this device.

Note: Federal (U.S.) law restricts this device to sale by, or on the order of, a physician.

INTENDED USE/INDICATIONS FOR USE

The CataPulse® is an ophthalmic surgical system intended to be used in a sterile operating room for the applications in the removal of the crystalline lens and also vitreous matter from the anterior chamber, when needed.

The CataPulse® is designed to be a minimally invasive, low energy device where the primary function is to dissect and extract the crystalline lens (cataract) through the use of high frequency pulsating vacuum. This system allows the surgeon to dissect and aspirate the lens in the eye, while replacing aspirated fluid and lens material with balanced salt solution (BSS) under a user controlled hydrostatic pressure. This process maintains a stable anterior chamber. Using the touch screen controls, the surgeon can adjust the maximum vacuum available, the pulse rate, the pulse duty cycle and the irrigation bottle height which controls the flow of BSS. Using the Footswitch, the surgeon can adjust the maximum vacuum available, the pulse rate, the irrigation bottle height, the flow of BSS solution, and the level of applied vacuum. Supportive of the surgical procedure to remove the cataract, the CataPulse® additionally provides an Anterior Vitrectomy function, to be used if necessary, to remove any vitreous that has migrated into the anterior chamber of the eye.

Figure 1: CataPulse® System

NOTE: The CataPulse® is intended to be used on a crystalline lens (cataract) that is grade 3 (LOCS II) or less, unless a femtosecond laser is used to break up the grade 4 cataract.

COMPONENT DESCRIPTION

CONSOLE

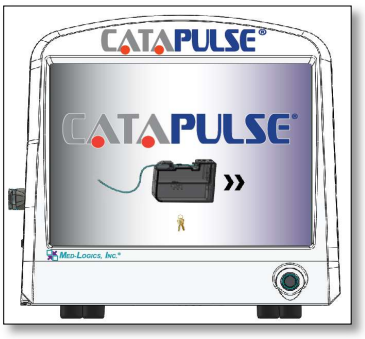


Figure 2a: CataPulse® Console. Front View

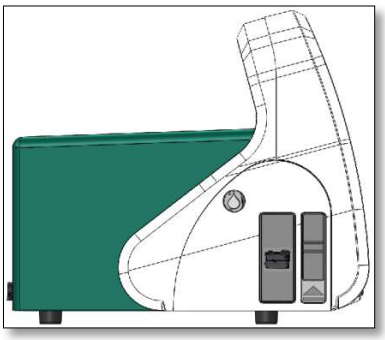


Figure 2b: CataPulse® Console. Side View

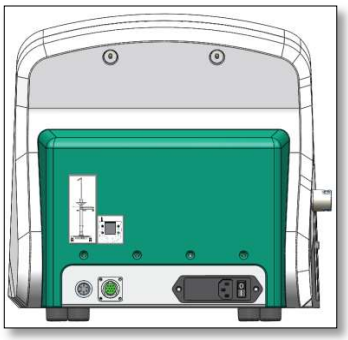


Figure 2c: CataPulse® Console. Rear View

The CataPulse® Console, featured in figures 2a through 2c above, is a software controlled device that provides the user the ability to change modes and performance values either from the LCD touch screen or the Footswitch. The graphics also allow the user to identify the parameter values and make changes when desired. The Main Power switch is located in the back of the Console, on the lower right corner. The Standby Power button is conveniently located on the front of the Console, on the lower right corner. The Cart, Footswitch, and Power cables are connected at the rear panel in the back of the Console. The Disposable Cassette is inserted through a hinged door in the Cassette Receiver, located on the left side of the Console. The irrigation line is attached to the Irrigation Pinch Valve located on the left side of the Console, above and behind the Cassette Receiver. The Cassette Eject lever is located on the left side of the Console, just in front of the Cassette Receiver.

CONSOLE SPECIFICATIONS		
Part Number	CP1700	
Dimensions	Width	15” (381 mm)
	Length	15.5” (394 mm)
	Height	14” (356 mm)
Weight	35 lbs. (16 Kg.)	
Features	Front Power Standby Button w/ LED indicator, Irrigation Pinch Valve, Cassette Receiver, Cassette Eject Lever, fits securely to the Cart Shelf.	
Environmental Limitations	Max Altitude	6562 Ft above sea level (2000 m)
	Temperature	50°F (10°C) - 80°F (26°C)
	Relative Humidity	10%-90% without condensation
Ingress Protection	IP12	
Power	100-240 VAC, 50/60 Hz (Fuse: Time Delay, 2A/250V, 5X20mm)	
End of Life	Return component to MED-LOGICS for disposal	
Packaging Configuration	Shipped in CP2000, re-usable shipping case	

Table 1: CataPulse® Console Specifications

FOOTSWITCH

The CataPulse® Footswitch, featured in figures 3a through 3c, is an extension of the Console operation to provide user control of the actual vacuum level and basic user adjustable parameters. The Footswitch will only be functional when an operation screen is open and will not operate in any other screen. The CataPulse® Footswitch features a centrally located linear pedal and four colored buttons, two on each side of the Footswitch. Each colored button has an image below it to represent the button's function.

- The blue colored button, with a water droplet image below it, located on the upper left area of the Footswitch, is the irrigation hold button which opens and closes the Irrigation Pinch Valve.
- The Green colored button, with the 1 to 3 dots separated by 4 cyclical arrows image below it, located in the lower left area of the Footswitch is the mode button and allows the user to scroll through the Max Vacuum, Vacuum Pulse Rate, and Bottle Height parameters.
- The Copper colored button, with the arrow pointed up, located in the upper right area of the footswitch is the increase button which increases the selected parameter's value.
- The Silver colored button, with the arrow pointed down, located in the lower right area of the Footswitch is the decrease button which decreases the selected parameter's value. The increase and decrease buttons, when held down, will scroll through the parameter values at the parameter defined increments as identified in the Operational User Adjustable Parameters Section of this manual.

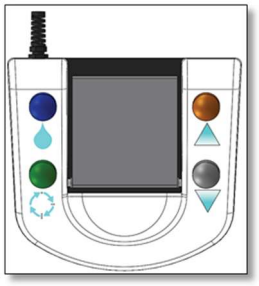


Figure 3a: CataPulse® Footswitch. Top View

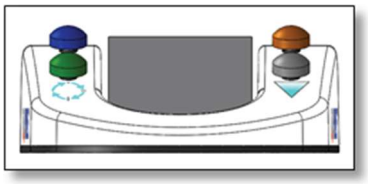


Figure 3b: CataPulse® Footswitch. Front View

Figure 3c: CataPulse® Footswitch. Side View

FOOTSWITCH SPECIFICATIONS		
Part Number	CP1800	
Dimensions	Width	11.8" (299.7 mm)
	Length	10.7" (271.8 mm)
	Height	4" (101.6 mm)
Weight	13 lbs. (5.9 Kg.)	
Features	Variable Vacuum Control Pedal, Irrigation Hold Button, parameter selection Mode Button, Increase and Decrease Buttons, Carrying Handle.	
Environmental Limitations	Temperature	50°F (10°C) - 80°F (26°C)
	Relative Humidity	10%-90%
Ingress Protection	IP46	
End of Life	Return component to MED-LOGICS for disposal	
Packaging Configuration	Shipped in CP2001, re-usable shipping case	

Table 2: CataPulse® Footswitch Specifications

CART

The CataPulse® Cart, featured in figures 4a and 4b, is an optional extension of the Console operation to provide user control of the hydrostatic pressure of BSS by way of increasing and decreasing the pole height. If the choice is not to use the CataPulse® Cart, means of control of hydrostatic pressure is at the discretion of the user. The CataPulse® Cart has been designed to connect to the CataPulse® Console to operate the automated IV Pole. The CataPulse® Cart features a retractable IV hook for a sleek design and convenient storage. The CataPulse® Cart also features a Medical Tray with an articulating arm for convenient accessibility. The CataPulse® Cart has been designed to securely support the CataPulse® Console and avoid introducing noise or vibrations, all while reducing the clutter of a separate manual IV pole. The CataPulse® Cart has a set of hooks to support the CataPulse® Footswitch for transport and storage. This component also features 4 wheels, 2 of which are locking and a handle for ease in maneuvering. When moving the CataPulse® Cart, it is necessary to push and pull using the handle to avoid tipping.

WARNING: Do not manually modify or force the CataPulse Cart pole height because this could cause incorrect indication of bottle height and Patient Injury.

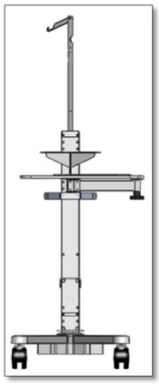


Figure 4a: CataPulse® Cart. Front View

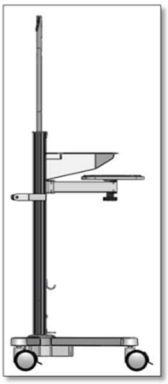


Figure 4b: CataPulse® Cart. Side View

CART SPECIFICATIONS			
Part Number	CP1900		
Dimensions		**Pole Down**	**Pole Up**
	Width	21.25” (540 mm)	21.25” (540 mm)
	Length	22.83” (580 mm)	22.83” (580 mm)
	Height	65” (1651 mm)	97” (2464 mm)
Weight	Cart Mass: 40 lbs. (18 Kg.)	Mass at safe working load: 100 lbs. (45 Kg.)	
Cable Length	16” (406.4 mm)		
Features	Adjustable and Automated Pole (ranging from 32 cm to 102 cm above patient eye level), Sleek and Retractable IV Bag Hook, 4- 3” Wheels (4 locking), Shelf for Console Attachment, Medical Tray w/ Articulating Arm for Adjustability To User Position, Hooks for Footswitch Storage, Wide Base for Stability.		
Environmental Limitations	Temperature	50°F (10°C) - 80°F (26°C)	
	Relative Humidity	10%-90%	
Ingress Protection	IP21		
Irrigation Bottle Size	Use with 250mL or 500mL Irrigation Bottles		
End of Life	Return component to MED-LOGICS for disposal		

Table 3: CataPulse® Cart Specifications

SYSTEM

Figure 5a: CataPulse® System for Transport/Storage. Front View

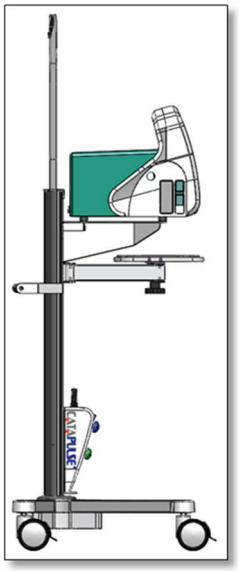


Figure 5b: CataPulse® System for Transport/Storage. Side View

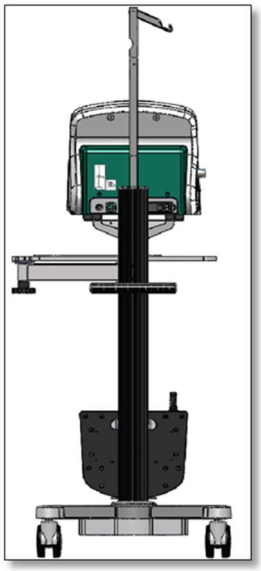


Figure 5c: CataPulse® System for Transport/Storage. Rear View

The fully assembled CataPulse® system, featured in figures 5a through 5c shows the assembled configuration for transport and storage. These images display the location and attachment of the CataPulse® Console on the shelf of the CataPulse® Cart, as well as, the CataPulse® Footswitch to the hooks near the bottom of the CataPulse® Cart.

ENVIRONMENTAL CONDITIONS	
Transportation & Storage	Temperature: 50°F to 104°F (10°C to +40°C) Humidity: 0 to 90% (non-condensation)
Use	Temperature: +59°F to +80°F (+15°C to +26°C) Humidity: 0 to 70% (non-condensation)

Table 4: CataPulse® System Specifications

LENS REMOVAL HANDPIECE SET

Figure 7a: CataPulse® Lens Removal Handpiece Set. Printed Side

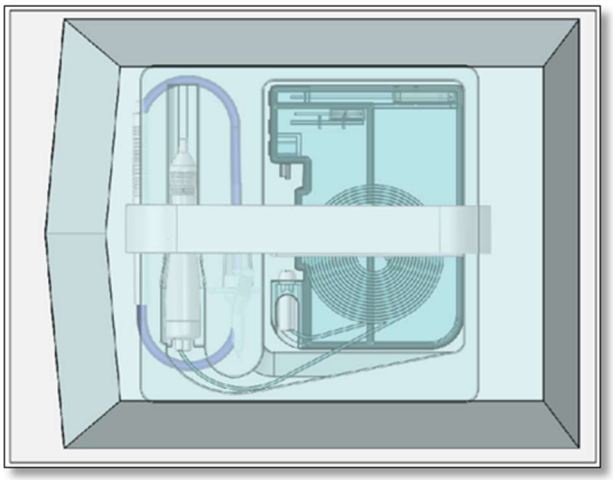


Figure 7b: CataPulse® Lens Removal Handpiece Set. Clear Side

The CataPulse® Lens Removal Handpiece Set contains the Lens Removal Handpiece attached to the Lens Removal Cassette with six feet of twin bore tubing, an Irrigation Set, and the Touch Screen Cover assembled in a containment tray. The Lens Removal Handpiece is made of plastic and has a male luer tapered tip for easy connection to any female luer tapered hub for a variety of cannula options. The twin bore tubing has one blue tube and one clear tube. The blue tube identifies the vacuum line as it will contain fluid during operation. The clear tube identifies the pressure line as it will contain pressurized air during operation. The Lens Removal Cassette is made of clear plastic and features two chambers. The top chamber is smaller and assists with quick vacuum response. The bottom chamber is larger and functions as a reservoir for the fluid collected during the operation. The fluid from the top chamber drains to the bottom chamber when the user fully releases the Footswitch.

WARNING: Never intentionally modify Handpieces or Tips (e.g. do not bend, cut, or engrave) as they can break or malfunction.

The Irrigation Set consists of a Spiker/Drip Chamber, ten feet of Irrigation Tubing, a 6 inch section of Pinch Valve Tubing, and a plastic Irrigation Handpiece. The Irrigation Handpiece has a male luer taper tip for easy connection to any female luer tapered hub for a variety of cannula options. Both the CataPulse® Lens Removal Set and Irrigation Set are preassembled for convenience and efficiency.

WARNING: Only use recommended Irrigation Tubing Set.

Below the containment tray is a clear folded Touch Screen Cover. This cover has two tabs to open and hold the cover while slipping it over the CataPulse® Console.

WARNING: End of Life, The Lens Removal Handpiece Set and items contained in the set are labeled and marketed as “Single-Use” and should never be used multiple times or used if the Tyvek® pouch is compromised. Contact MED-LOGICS for any questions or concerns.

CAUTION: If the user does not fully release the Footswitch periodically during the procedure and the top chamber of the Lens Removal Cassette reaches a certain level of fluid in it, the Console will automatically trigger a Fault 103 message on screen and cease supplying vacuum and the vacuum pulse at the handpiece. The Console will also automatically drain the top chamber of the cassette. See Troubleshooting 100 Level Faults on Page 37 for more details.

NOTE: The CataPulse® is intended to be used on a crystalline lens (cataract) that is grade 3 (LOCS II) or less, unless a femtosecond laser is used to break up the grade 4 cataract.

LENS REMOVAL HANDPIECE SET SPECIFICATIONS			
Part Number	CP2100		
Handpiece Dimensions		Lens Removal Handpiece	Irrigation Handpiece
	Length	4.43” (112.5 mm)	4.27” (108.5 mm)
	Diameter	.433” (11 mm) - .745” (18.9 mm)	.375” (9.5 mm)
Cassette Dimensions	Lens Removal Cassette		
	Width	1.48” (37.6 mm)	
	Length	5.546” (140.9 mm)	
	Height	4.046” (102.8 mm)	
Cassette ID		3 Ribs	
Cassette Chamber Volume	Top	4.7 fl. oz. (139 mL)	
	Bottom	5.88 fl. oz. (174 mL)	
Dual Bore Tubing	Length	6’ (1828.8 mm)	
Irrigation Tubing	Length	10’ (3048 mm)	
Reusable		No (Single Use Set)	
Transportation & Storage		Protect from exposure to moisture, cold (<5°C) & heat (>40°C)	
End of Life		After use dispose of in medical waste bin	

Table 5: CataPulse® Lens Removal Set Specifications

ANTERIOR VITRECTOMY HANDPIECE SET

The CataPulse® Anterior Vitrectomy Disposable Set contains the Vitrectomy Handpiece attached to the Anterior Vitrectomy Cassette with six feet of twin bore tubing packaged in a containment tray. The Anterior Vitrectomy Handpiece is made of plastic and has a stainless steel guillotine cutter. The twin bore tubing has one blue tube and one clear tube. The blue tube identifies the vacuum line as it will contain fluid during operation. The clear tube identifies the pressure line as it will contain pressurized air during operation. The Anterior Vitrectomy Cassette is for fluid containment but also identifies the correct operation desired. The Anterior Vitrectomy Cassette is made of clear plastic and contains two chambers. The top chamber is smaller and assists with quick vacuum response. The bottom chamber is larger and functions as a reservoir for the fluid collected during operation. The fluid from the top chamber drains to the bottom chamber when the user fully releases the Footswitch.

WARNING: End of Life, The Anterior Vitrectomy Handpiece Set's are labeled and marketed as "Single-Use" and should never be used multiple times or used if the Tyvek® pouch is compromised. Contact MED-LOGICS for any questions or concerns.

CAUTION: If the user does not fully release the Footswitch periodically during the procedure and the top chamber of the Anterior Vitrectomy Cassette reaches a certain level of fluid in it, the Console will automatically trigger a Fault 103 message on screen and stop actuating the handpiece cutter and stop supplying vacuum to the handpiece. The Console will also automatically drain the top chamber of the cassette. See Troubleshooting 100 Level Faults on Page 37 for more details.

Figure 8a: CataPulse® Anterior Vitrectomy Handpiece Set. Printed Side.

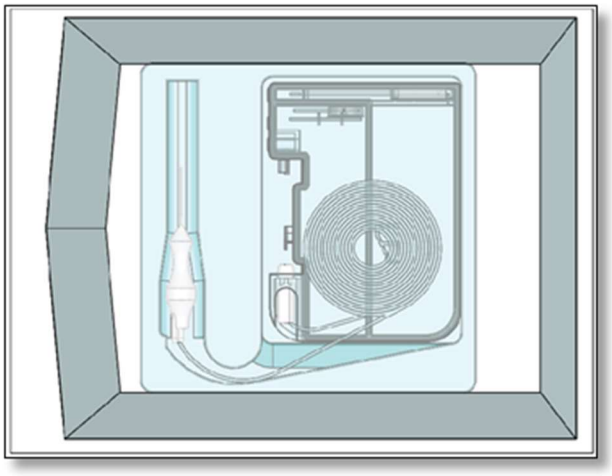


Figure 8b: CataPulse® Anterior Vitrectomy Handpiece Set. Clear Side.

ANTERIOR VITRECTOMY HANDPIECE SET SPECIFICATIONS		
Part Number	CP2200	
Handpiece Dimensions	Length	3.5” (88.9 mm)
	Diameter	.375” (9.5 mm) - .62” (15.7 mm)
	Cannula OD	.036” (.91 mm)
Cassette Dimensions	Anterior Vitrectomy Removal Cassette	
	Width	1.48” (37.6 mm)
	Length	5.546” (140.9 mm)
	Height	4.046” (102.8 mm)
Cassette ID		2 Ribs
Cassette Chamber Volume	Top	4.7 fl. oz. (139 mL)
	Bottom	5.88 fl. oz. (174 mL)
Dual Bore Tubing	Length	6’ (1828.8 mm)
Reusable		No (Single Use Set)
Transportation & Storage		Protect from exposure to moisture, cold (<5°C) & heat (>40°C)
End of Life		After use dispose of in medical waste bin
Applied Part		Type B, this part makes contact and/or penetrates the eye

Table 6: CataPulse® Anterior Vitrectomy Lens Removal Set Specifications

DISPOSABLE LENS REMOVAL CANNULAS

MED-LOGICS has developed straight and angled plastic and metal disposable cannulas to attach to the Lens Removal Handpiece and aid the surgeon in the removal of the crystalline lens (cataract). The cannulas are attached to a female luer taper hub for easy attachment and removal, and can come in several different configurations to suit surgeon preference. Lens Removal cannulas will be marked with an aspirating cannula symbol on the pouch and on the plastic cannula tray. Lens Removal Cannulas with a stainless steel hub will also be identified with a green colored silicone instrument marker.

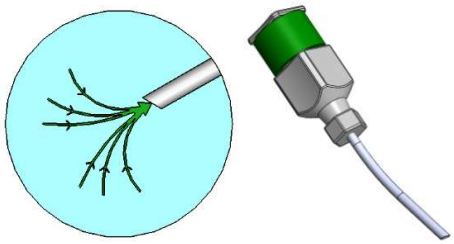
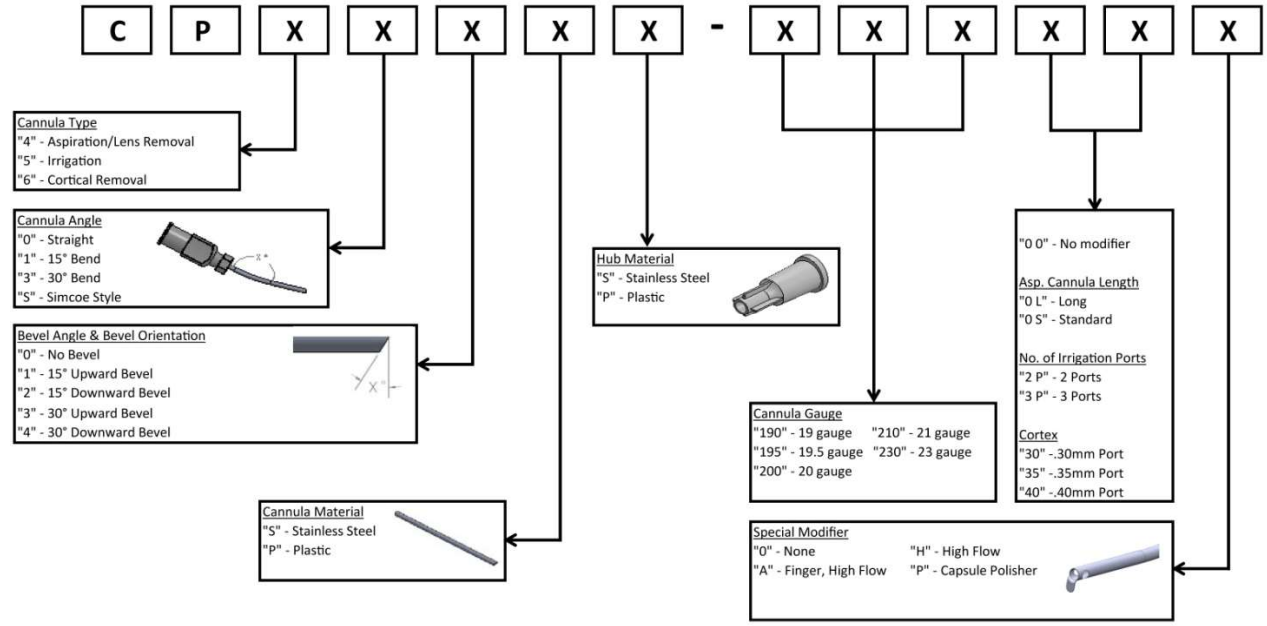


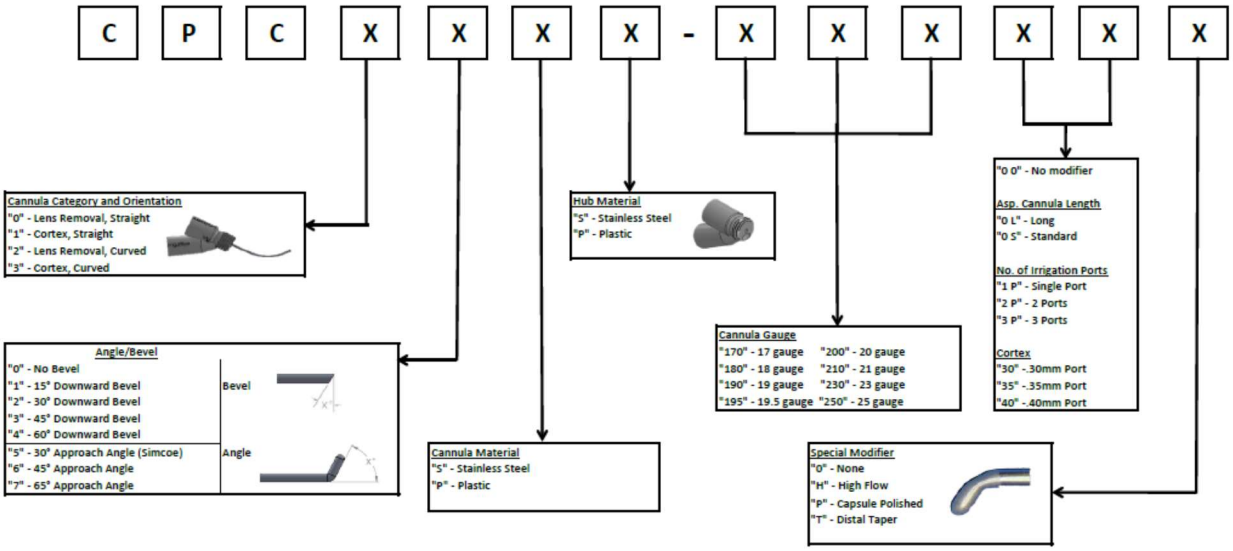
Figure 3: Lens Removal Cannula Symbol & Lens Removal Cannula with SS Hub and Silicone Marker

WARNING: The Disposable Cannulas are labeled and marketed as “Single-Use” and should never be used multiple times or used if the Tyvek® pouch is compromised. Contact MED-LOGICS with any questions or concerns.

HOW TO READ THE CANNULA PART NUMBER



HOW TO READ THE COAXIAL CANNULA CATALOG NUMBER



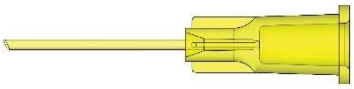
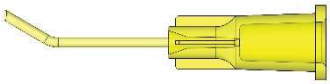
PLASTIC DISPOSABLE LENS REMOVAL CANNULAS		
Part Number CP404PP-1950L0	Asp. Cannula, Straight, 30° Downward Bevel, Plastic Cannula, Plastic Hub, 19.5G, Long	
Part Number CP434PP-1950S0	Asp. Cannula, 30° Bend, 30° Downward Bevel, Plastic Cannula, Plastic Hub, 19.5G, Standard Length	

Table 7: Plastic Disposable Lens Removal Cannula Specifications

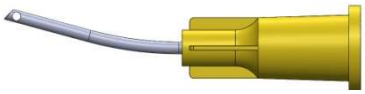
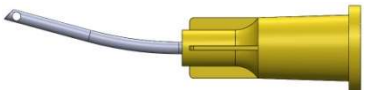
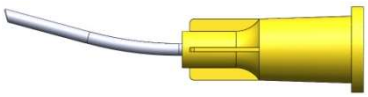
PLASTIC HUB, METAL DISPOSABLE LENS REMOVAL CANNULAS		
Part Number CP412SP-1900SH	Asp. Cannula, 15° Bend, 15° Downward Bevel, SS Cannula, Plastic Hub, 19G, Standard Length, High Flow	
Part Number CP412SP-2000SH	Asp. Cannula, 15° Bend, 15° Downward Bevel, SS Cannula, Plastic Hub, 20G, Standard Length, High Flow	
Part Number CP414SP-1900SH	Asp. Cannula, 15° Bend, 30° Downward Bevel, SS Cannula, Plastic Hub, 19G, Standard Length, High Flow	
Part Number CP414SP-2000SH	Asp. Cannula, 15° Bend, 30° Downward Bevel, SS Cannula, Plastic Hub, 20G, Standard Length, High Flow	

Table 8: Plastic Hub, Metal Disposable Lens Removal Cannula Specifications

*Note: Images provided are a graphical representation of the cannula and may not necessarily represent the exact physical features of the cannula

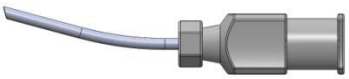
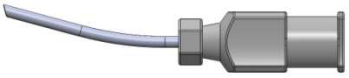
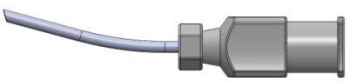
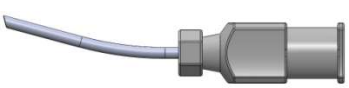
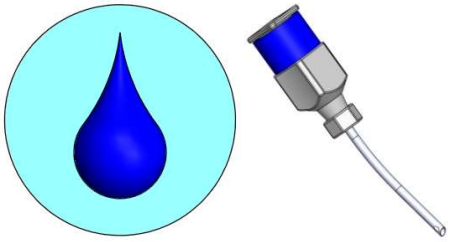
METAL DISPOSABLE LENS REMOVAL CANNULAS		
Part Number CP412SS-1900LH	Asp. Cannula, 15° Bend, 15° Downward Bevel, SS Cannula, SS Hub, 19G, Long, High Flow	
Part Number CP412SS-2000LH	Asp. Cannula, 15° Bend, 15° Downward Bevel, SS Cannula, SS Hub, 20G, Long, High Flow	
Part Number CP414SS-1900LH	Asp. Cannula, 15° Bend, 30° Downward Bevel, SS Cannula, SS Hub, 19G, Long, High Flow	
Part Number CP414SS-2000LH	Asp. Cannula, 15° Bend, 30° Downward Bevel, SS Cannula, SS Hub, 20G, Long, High Flow	
Transportation & Storage	Protect from exposure to moisture, cold (<5°C) & heat (>40°C)	
End of Life	After use dispose of in medical waste sharps bin	
Applied Part	Type B, this part makes contact and/or penetrates the eye	

Table 9: Metal Disposable Lens Removal Cannulas

*Note: Images provided are a graphical representation of the cannula and may not necessarily represent the exact physical features of the cannula

DISPOSABLE IRRIGATION CANNULAS

The Metal Disposable Irrigation Cannulas have several available options for the Irrigation Cannula Handpiece. This is a stainless steel cannula attached to a stainless steel or plastic female luer taper hub. The tips of the cannulas come in several different geometries. Some are beveled and have 2 ports on either side of the cannula for irrigation. This is a built-in safety precaution that provides irrigation flow and hydrostatic pressure in the event that one of the ports is obstructed. Angled distal tips assist in maneuvering the cannula within the anterior chamber, which is especially helpful in manipulating the lens segments. Irrigation cannulas will be marked with a water droplet symbol on the pouch and on the plastic cannula tray. Irrigation Cannulas with a stainless steel hub will also be identified with a blue colored silicone instrument marker.



Irrigation Cannula Symbol & Irrigation Cannula with SS Hub and Silicone Marker

WARNING: The Disposable Cannulas are labeled and marketed as “Single-Use” and should never be used multiple times or used if the Tyvek® pouch is compromised. Contact MED-LOGICS with any questions or concerns.

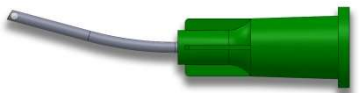
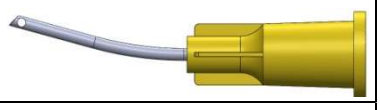
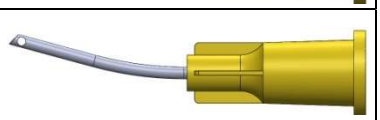
PLASTIC HUB, METAL DISPOSABLE IRRIGATION CANNULAS		
Part Number CP530SP-1703PO	Irr. Cannula, 15° Bend, 30° Upward Bevel, SS Cannula, PP Hub, 17G, 3-Port,High Flow	
Part Number CP530SP-1803PO	Irr. Cannula, 15° Bend, 30° Upward Bevel, SS Cannula, PP Hub, 18G, 3-Port,High Flow	
Part Number CP513SP-1903PH	Irr. Cannula, 15° Bend, 30° Upward Bevel, SS Cannula, PP Hub, 19G, 3-Port,High Flow	
Part Number CP513SP-2003PH	Irr. Cannula, 15° Bend, 30° Upward Bevel, SS Cannula, PP Hub, 20G, 3-Port,High Flow	

Table 10: Plastic Hub, Metal Disposable Irrigation Cannulas

*Note: Images provided are a graphical representation of the cannula and may not necessarily represent the exact physical features of the cannula

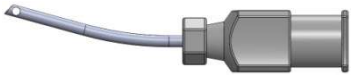
METAL DISPOSABLE IRRIGATION CANNULAS		
Part Number CP513SS-1903PH	Irr. Cannula, 15° Bend, 30° Upward Bevel, SS Cannula, SS Hub, 19G, 3-Port, High Flow	
Part Number CP513SS-2003PH	Irr. Cannula, 15° Bend, 30° Upward Bevel, SS Cannula, SS Hub, 20G, 3-Port, High Flow	
Part Number CP510SS-1903PA	Irr. Cannula, 15° Bend, SS Cannula, SS Hub, 19G, 3-Port, High Flow, Finger	
Part Number CP510SS-2003PA	Irr. Cannula, 15° Bend, SS Cannula, SS Hub, 20G, 3-Port, High Flow, Finger	
Transportation & Storage	Protect from exposure to moisture, cold (<5°C) & heat (>40°C)	
End of Life	After use dispose of in medical waste sharps bin	
Applied Part	Type B, this part makes contact and/or penetrates the eye	

Table 11: Metal Disposable Irrigation Cannulas

*Note: Images provided are a graphical representation of the cannula and may not necessarily represent the exact physical features of the cannula

CANNULA SELECTION NOMOGRAM

Irrigation Cannula		
Model	**Pole Height**	**Flow (mL/s)**
CP513SS-1903PH, CP513SP-1903PH, & CP510SS-1903PA	32 cm	0.79
	62 cm	1.12
	92 cm	1.48
CP513SS-2003PH, CP513SP-2003PH, & CP510SS-2003PA	32 cm	0.57
	62 cm	0.82
	92 cm	1.05

Lens Removal Cannula			
Model	**Applied Vacuum**	**Pulse Rate / Duty Cycle**	**Flow (mL/s)**
CP412SS-1900LH, CP412SP-1900SH, CP414SS-1900LH, & CP414SP-1900SH	650 mmHg	800 PPM/60%	1.27
	400 mmHg	600PPM/50%	0.75
	250 mmHg	600 PPM/50%	0.45
CP412SS-2000LH, CP412SP-2000SH, CP414SS-2000LH, & CP414SP-2000SH	650 mmHg	800 PPM/60%	1.07
	400 mmHg	600PPM/50%	0.61
	250 mmHg	600 PPM/50%	0.49
CP404PP-1950L0 & CP434PP-1950S0	650 mmHg	800 PPM/60%	1.51
	400 mmHg	600PPM/50%	0.62
	250 mmHg	600 PPM/50%	0.46

WARNING: Never remove the irrigation cannula from the eye or stop irrigation flow while the aspiration/lens removal cannula is also present in the eye and applying vacuum. Removal of the irrigation cannula or cessation of irrigation while vacuum is being applied can result in fluidic imbalance in the eye and patient injury.

WARNING: Med-Logics recommends a minimum 50% factor of safety on irrigation flow. To select the appropriate IV Pole Height for the Irrigation & Lens Removal Cannulas selected, apply the following formula:

Minimum Safe Irrigation Flow Rate = 1.5(Lens Removal Flow Rate)

Failure to provide Minimum Safe Irrigation Flow as defined by Med-Logics can result in fluidic imbalance in the eye and patient injury. Using a cannula that is not referenced on the chart or using a cannula outside of the safe working parameters listed above is risky and unwise. Please contact a surgical specialist from MED-LOGICS for advice.

WARNING: The use of accessories not designated by MED-LOGICS for use with the CataPulse may result in serious permanent patient injury, adverse surgical outcomes, or damage to the equipment.

Table 12: Cannula Selection Nomogram

METAL DISPOSABLE CORTICAL REMOVAL CANNULA

The Metal Disposable Cortical Removal Cannula is an available option for the Lens Removal Handpiece. This is a stainless steel cannula attached to a stainless steel female luer taper hub. The tip of the cannula is beveled and has a 0.3 mm port located on the side of the cannula. Different angle options assist with maneuvering inside the anterior chamber. Cortical cannulas will be marked with an image of a cannula with a side port on the pouch and on the plastic cannula tray. Cortical Removal Cannulas with a stainless steel hub will also be identified with a mauve colored silicone instrument marker.

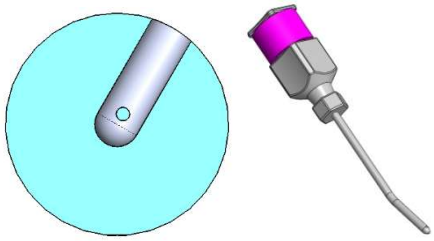


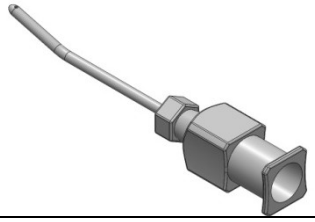
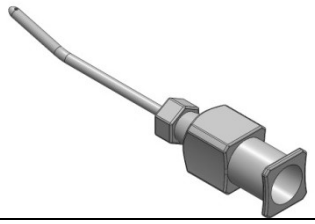
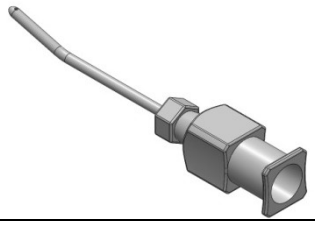
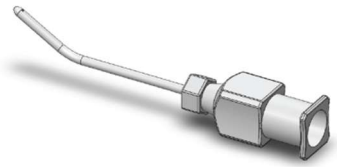
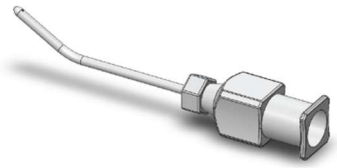
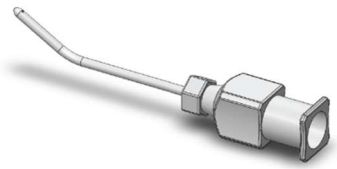
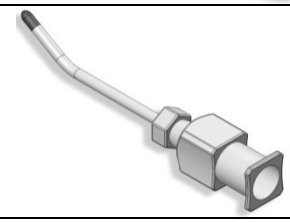
Figure 4: Cortical Removal Cannula Symbol & Cortical Removal Cannula with SS Hub and Silicone Marker

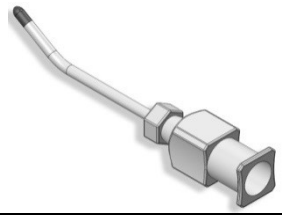
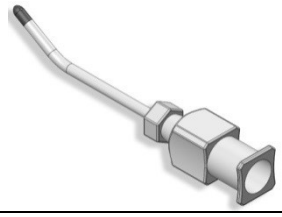
WARNING: The Disposable Cannulas are labeled and marketed as “Single-Use” and should never be used multiple times or used if the Tyvek® pouch is compromised. Contact MED-LOGICS with any questions or concerns.

PLASTIC HUB, METAL DISPOSABLE CORTICAL CANNULAS		
Part Number CP6S0SP-21040S	Cort. Removal Cannula, 30° Bend, SS Cannula, Plastic Hub, 21G, .40mm Side Port, Silicon Sleeve	
Part Number CP6S0SP-23030S	Cort. Removal Cannula, Simcoe Style, SS Cannula, Plastic Hub, 23G, .30mm Side Port, Silicon Sleeve	

Table 13: Plastic Hub, Metal Disposable Cortical Cannulas

*Note: Images provided are a graphical representation of the cannula and may not necessarily represent the exact physical features of the cannula

METAL DISPOSABLE CORTICAL CANNULAS		
Part Number CP610SS-190350	Cort. Removal Cannula, 15° Bend, SS Cannula, SS Hub, 19G, .35mm Side Port	
Part Number CP610SS-200350	Cort. Removal Cannula, 15° Bend, SS Cannula, SS Hub, 20G, .35mm Side Port	
Part Number CP610SS-210350	Cort. Removal Cannula, 15° Bend, SS Cannula, SS Hub, 21G, .35mm Side Port	
Part Number CP630SS-190300	Cort. Removal Cannula, 30° Bend, SS Cannula, SS Hub, 19G, .30mm Side Port	
Part Number CP630SS-200300	Cort. Removal Cannula, 30° Bend, SS Cannula, SS Hub, 20G, .30mm Side Port	
Part Number CP630SS-210300	Cort. Removal Cannula, 30° Bend, SS Cannula, SS Hub, 21G, .30mm Side Port	
Part Number CP630SS-19030P	Cort. Removal Cannula, 30° Bend, SS Cannula, SS Hub, 19G, .30mm Side Port, Capsule Polisher	

Part Number CP630SS-20030P	Cort. Removal Cannula, 30° Bend, SS Cannula, SS Hub, 20G, .30mm Side Port, Capsule Polisher	
Part Number CP630SS-21030P	Cort. Removal Cannula, 30° Bend, SS Cannula, SS Hub, 21G, .30mm Side Port, Capsule Polisher	

Transportation & Storage	Protect from exposure to moisture, cold (<5°C) & heat (>40°C)
End of Life	After use dispose of in medical waste sharps bin
Applied Part	Type B, this part makes contact and/or penetrates the eye

Table 14: Metal Disposable Cortical Cannula Specifications

*Note: Images provided are a graphical representation of the cannula and may not necessarily represent the exact physical features of the cannula

INSTALLATION

NOTE: Don't position the equipment to make it difficult to operate the disconnection device.
CAUTION: Do not attempt to use the CataPulse® Lens Removal System without having a clear understanding of all its components, functions, controls, and limitations.

CART INSTALLATION

1. Cart assembly instructions are included in the Cart shipping container.
2. Place the assembled CataPulse® Cart on a firm, level surface.
3. Lock the cart wheels to prevent the cart from rolling.
4. With a person holding the Console in place on the Cart Shelf, bolt the CataPulse® Console to the Cart shelf with the 4 Barrel Bolts provided (See Figure 9a below).

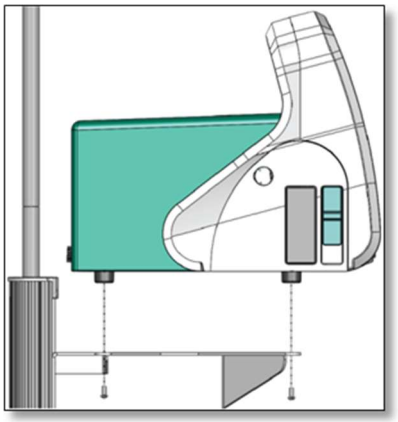


Figure 9a: Secure CataPulse® Console to Cart Shelf with Barrel Bolts. Side View

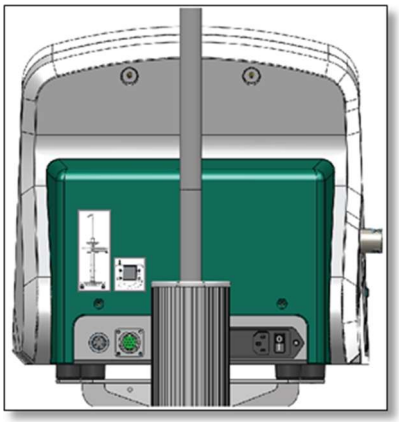


Figure9b: CataPulse® Console Rear Panel. Connection Port Identification

CART CONNECTION PORT

The Cart connection port is located on the left side of the rear panel, just left of the Footswitch connection port. The Cart connection port has a symbol of a cart next to it. Firmly attach the Cart cable to the Console by inserting the connector into the receptacle and rotate the knurled locking ring clockwise to secure in place.

FOOTSWITCH CONNECTION PORT

1. Place the CataPulse® Footswitch on the CataPulse® Cart hooks located near the bottom front of the cart (As shown in Figures 5a-5c).
2. The Footswitch connection port is located on the left side of the rear panel of the CataPulse® Console, between the power inlet and the Cart connection port. The Footswitch connection port has a symbol of a Footswitch next to it. Firmly attach the Footswitch cable to the Console by inserting the connector into the receptacle and rotating the knurled locking ring in a clockwise manner to secure in place.

WARNING: Do not lift, pull, or carry the Footswitch by the connector cable.

POWER CONNECTION SUPPLY

1. The power inlet is located on the right hand side of the rear panel of the CataPulse® Console. Insert the female end of the main power cord firmly into the female receptacle.
2. Insert the male end of the main power cord firmly into the main power source or wall outlet.
   WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
   NOTE: Confirm that the power supplied is 100/240 VAC and 50/60 Hz.
3. The 'ON/OFF' switch (is identified with an 'I/O' symbol) located adjacent to the power inlet on the rear panel of the CataPulse® Console provides power to the Console. Switch the inlet power "ON" or "I".
   NOTE: An illuminated blue LED will begin to flash (on the Standby Power Button on the front panel) at a rate of ½ second ON for every 4 seconds OFF.
4. The Standby Power Button located on the lower right corner of the front panel of the CataPulse® Console provides power to the computer processor. Turn the standby power "ON" by pushing the button.
   NOTE: The illuminated blue LED will begin to flash (on the Standby Power Button on the front panel) at a rate of ½ second ON for every 1 second OFF.
5. The CataPulse® Console will now display the Splash Screen, shown in (figure 10), which will lead into the Default Home Screen after 25 seconds.
   NOTE: Once the Default Home Screen is displayed the Standby Power Button LED will remain a consistent illuminated blue.
6. The CataPulse® Lens Removal System is now ready to either navigate to a user's profile, the settings screen, or have a Disposable Set inserted into the Console.

SCREEN NAVIGATION

The screen will communicate prompts, messages, parameter selection, parameter values, and their changes to the user. The device will allow up to 5 users to set up a profile of personal parameter settings. To adjust those parameter settings as desired and to select between the desired user profiles, see the section of the User Profile Window. The device will instinctively bring the user to the correct operational screen based on the type of disposable set inserted into the Cassette Receiver located on the left side of the CataPulse® Console. For questions about the graphics icons see the Graphics Identification Key section.

SPLASH SCREEEN

The Splash Screen will be used as a transition screen that is visible upon startup of the device while the device is going through the boot-up process. This screen does not have any touch screen capabilities and will always lead directly into the Home Screen.

Figure 10: Splash Screen

HOME SCREEN

The Home Screen is presented to the user as soon as the application begins. This screen is accessed several different ways depending on which screen is currently in use:

- on start-up of the CataPulse® application,
- by touching the Close Icon on the User Profile Window (when not currently logged in),
- by touching the Refresh Icon on the Surgeons Home Screen,
- by exiting the Operation Screens, (when not currently logged in),
- by removing a Cassette from the Console.

The Home Screen has an image of a Cassette and two arrows to visually indicate what the next steps are, (inserting the Cassette), in order to be transferred to an Operation Screen if the user chooses to operate with default parameters.

The Home Screen also has a Key Icon located at the bottom center of the screen. Touching this Key Icon transports the user to the User Profile Window where they can choose a user profile if they desire.

Figure 11: Home Screen

USER PROFILE WINDOW

The User Profile Window can be intentionally accessed from the Home Screen or the Surgeons Home Screen by selecting the Key Icon. It will be automatically accessed by exiting the Settings Screen if the Settings Screen was accessed from the User Profile Window by selecting the Close Icon.
The User Profile Window will allow a list of 5 user profiles to select from. Each user profile will have a Check Icon that will indicate the selection of that user profile. Selection of the Check Icon will bring the user to that Surgeons Home Screen.
Similarly, each user profile will have a Gears Icon to indicate a desire to adjust user specific settings. Selection of the Gears Icon will bring the user to that surgeon's Settings Screen.
At the bottom of the screen there is an outline of a person with a Plus Sign Icon. This is the 'add a new user profile' Icon. Touching this Icon brings the user to a blank Settings Screen from which they can create a new profile. A new profile can be created only if the maximum of 5 profiles has not been reached.
At the top of the User Profile Window there will be a Close Icon. Selection of this button will close the User Profile Window and take them back to either the Home Screen or the Surgeons Home Screen.

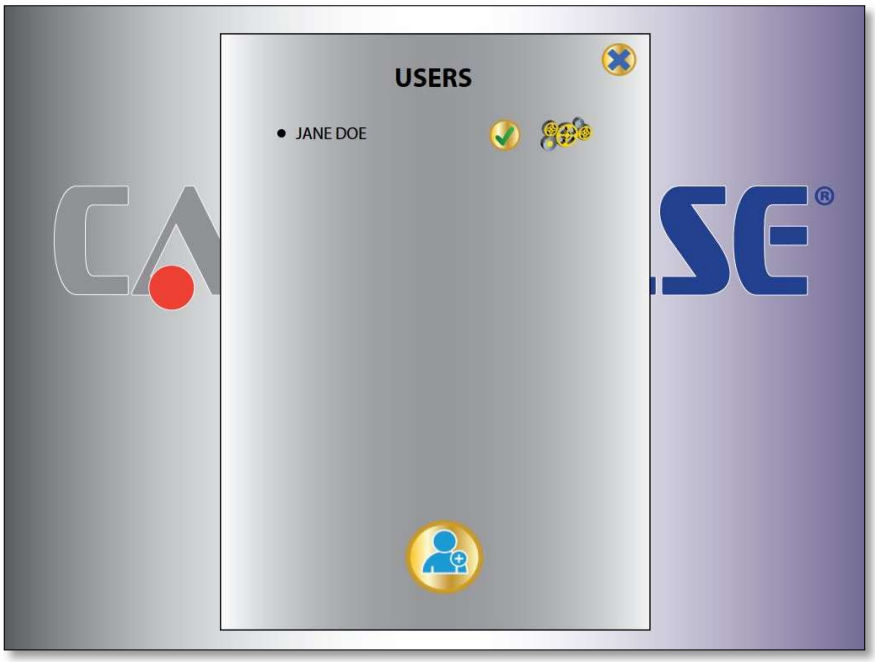


Figure 12: User Profile Window

SETTINGS SCREEN

The Settings Screen can be intentionally accessed from the User Profile Window, either by selecting the Gears Icon or the 'add a New User Profile' Icon.
The Settings Screen will be automatically accessed by selecting a language from the Language Screen or by declining to delete the user profile in the Delete Profile Window.
The Settings Screen has two textboxes on the upper left side of the screen for the User Name and Facility. By tapping in the User Name or Facility textbox, a keyboard in the selected language will appear on the bottom half of the screen.
Below the Facility textbox is the Language selection. Language selection is done in the Language Screen which is accessed by touching the Globe Icon located to the right of the language selection box. All other parameters (Brightness, Volume, Max Vacuum, Bottle Height, Pulse Activation, Pulse and Cut Rate, and Duty Cycle) are adjusted by tapping in the textbox to the right of the parameter name. Once the desired parameter is selected, an Up and Down Arrow will appear below that parameter in place of the keyboard. The parameter will be adjusted by use of the Up and Down Arrows within the allowable range of that parameter (See Operational User Adjustable Parameters section below). Whenever a textbox, parameter, arrow or keyboard key is selected, the outline of the texted box will be highlighted blue as an indication of its intended selection. These parameters can be adjusted individually for each of 3 operational modules which are indicated by symbols for Lens Removal , Cortex Removal , and Capsule Polishing .There are 3 Icons at the top right of the Settings Screen; an outline of a person with a minus sign , a Floppy Disc and Close Icon. The outline of a person with a minus sign is the Delete Profile Icon which will transfer the user to the Delete Profile Window (See Figure 23). The Floppy Disc Icon will save the profile and transfer the user back to where they entered the Settings Screen from, either the User Profile Window or the Operation Screen. If the user is transported back to the Operation Screen, the adjusted and saved settings will be applied automatically. The Close Icon will exit the user from the Settings Screen and return the user to the Screen they accessed the Settings Screen from without saving any changes.

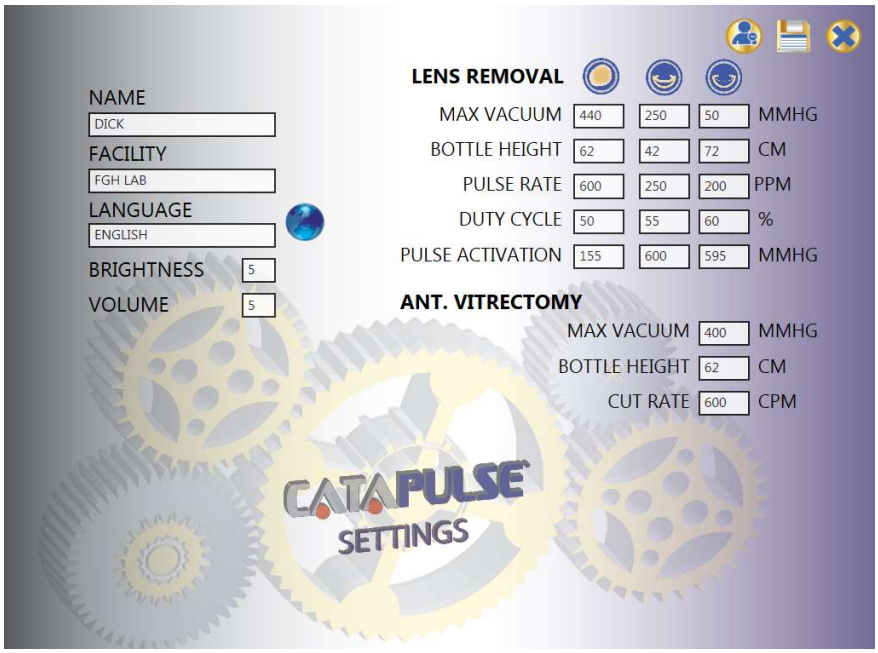


Figure 13: Settings Screen

LANGUAGE SCREEN

The Language Screen can be accessed through the Settings Screen by selecting the Globe Icon  .The user will leave the Language Screen and be transported back to the Settings Screen by selecting the Flag Icon or name of the origin of that language. When a Language is selected, the user is returned to the Settings Screen. The selected Language will be applied to all text while in that user's profile. The keyboard will also be updated to the keyboard of that language.

Figure 14: Language Screen

DELETE PROFILE WINDOW

The Delete Profile Window can be accessed by selecting the Delete Profile Icon at the top of the Settings Screen. The Delete Profile Window will provide 2 options: “YES” (Delete Profile) and ‘NO’ (do not Delete Profile). After making a selection, the user will be transported back to the Settings Screen.

Figure 15: Delete Profile Window

SURGEON HOME SCREEN

The Surgeon's Home Screen is very similar to the Home Screen except that it has the Refresh Icon located at the bottom center of the screen. It has the Name of the Surgeon in the bottom left corner of the screen and the Facility in the bottom right corner of the screen. The Refresh Icon will transport the user to the Home Screen. The Key Icon will transport the user to the User Profile Window. The purpose of the Surgeon's Home Screen is to identify which user's parameters will be present when the surgeon inserts a Cassette and is transported to an Operational Screen.

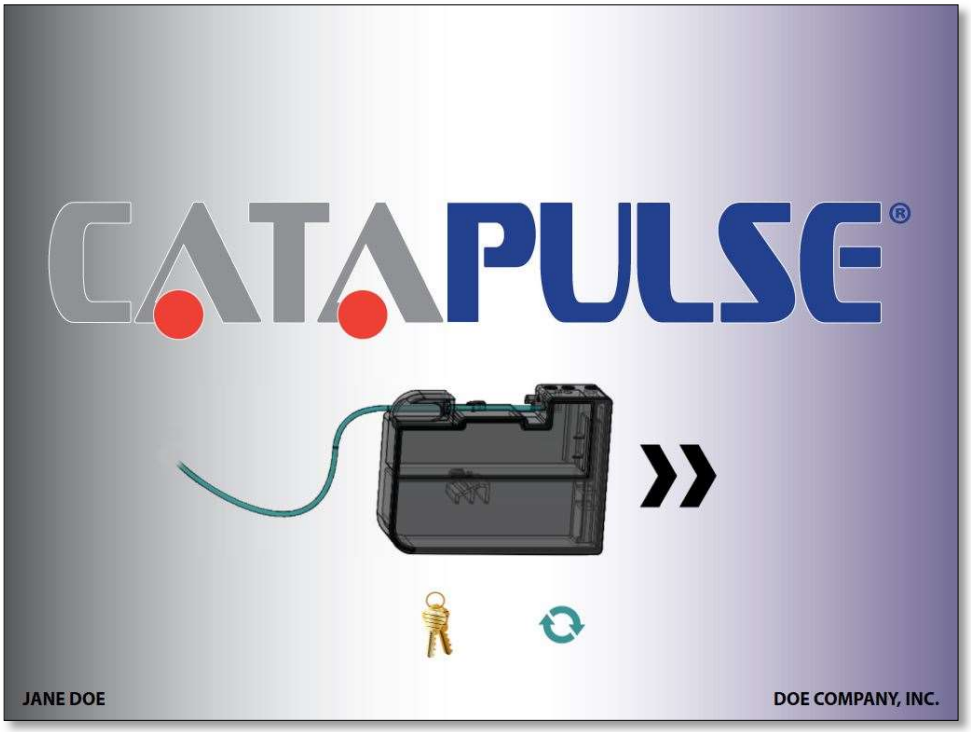


Figure 16: Surgeon Home Screen

LENS REMOVAL OPERATIONAL SCREEN

The Lens Removal Screen is accessed by inserting a Lens Removal Cassette into the Cassette Receiver (See Figure 17). The Cassette must be completely inserted into the Cassette Receiver for the Lens Removal Operation Screen to be displayed. Once the Cassette is inserted and the Operational Screen is displayed, the Vacuum and Pressure pumps will start and build pressure in preparation for operation. At any time before or after Cassette insertion the surgeon can attach the Irrigation Pinch Tube Section, a 6" clear tubing section, into the pinch valve located just above and behind the Cassette Receiver.

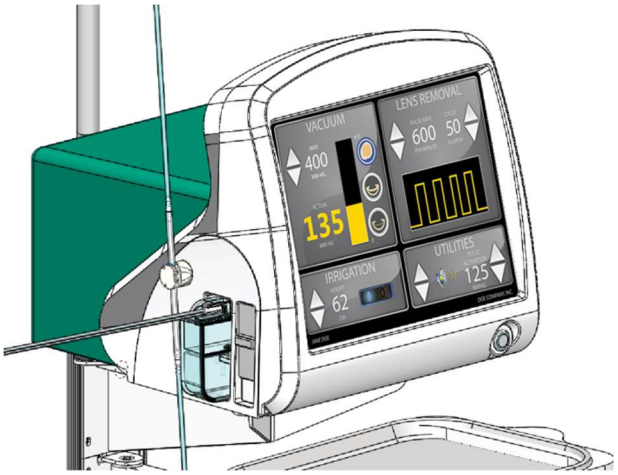


Figure 17: Insertion of a CataPulse® Lens Removal Cassette into the CataPulse® Console

At this point, the user can adjust operational parameters as necessary. Adjacent to each adjustable parameter are a set of Up and Down Arrows to allow the surgeon to increase or decrease that parameter by its incremental value within the allowable parameter range (See Operational User Adjustable Parameters section below). As each parameter is adjusted by the touch screen, the parameter along with the adjustment arrow will be illuminated blue. When a parameter is adjusted with the Footswitch, the parameter must first be selected with the Footswitch mode button and will illuminate blue. At this point, either the increase or decrease arrow will illuminate blue when the corresponding Footswitch Button is selected. There are six parameters that can be adjusted on the touch screen, four of which can also be adjusted by the Footswitch Buttons. Four of the on-screen parameters are identified by text. Two parameters are identified with Icons, and a third Icon is used as a navigation button.

The Irrigation Hold Icon is in the shape of a switch which can display an 'OFF' or 'CLOSED' position in which an orange illuminated circle is displayed on the switch. This Switch can also display an 'ON' or 'OPEN' position in which a blue illuminated line is displayed on the switch.

The Volume Icon is identified with a speaker. This Icon can be displayed in 6 levels, depending on the user preference. Five of these levels are represented with sound waves emanating from the speaker. One of these levels is the 'OFF,' or mute state, and is represented with a Red circle with a Red diagonal line through it covering the speaker.

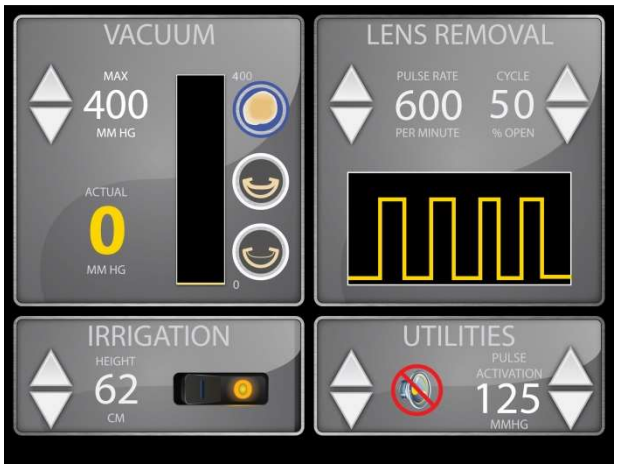


Figure 18a: Lens Removal Display Irrigation OFF.

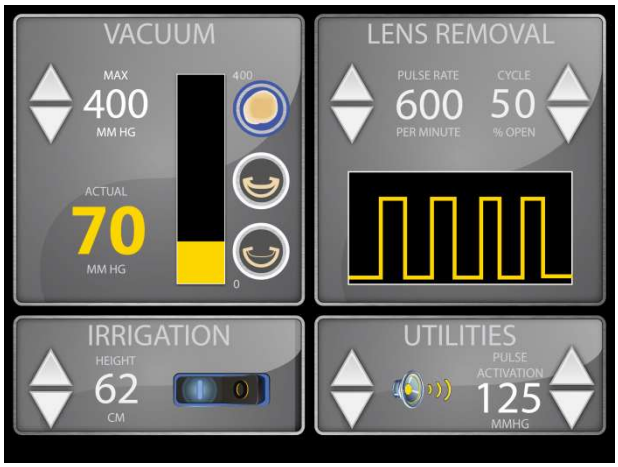


Figure 18b: Lens Removal Display Irrigation ON. Low Vacuum

When the Cassette is first inserted, there will be no vacuum applied. The vacuum bar graphic will be blacked out, and the Actual Vacuum will be zero. The Irrigation Pinch Valve will be closed upon entering the Operational Screen and the Irrigation Hold Switch will be in the 'OFF' position until irrigation is turned on by the user.

The user may also choose between three unique operational modules by selecting one of three distinct icons using the touch screen. The top icon, located next to the bar depicting the vacuum level, represents the lens removal portion of the procedure. The middle icon represents the cortical removal portion of the procedure, and the bottom icon represents the capsule polishing portion of the procedure. The icon for the active module will be highlighted blue, while the icons for inactive profiles will remain gray. This allows the user to quickly and easily switch between different setting preferences while in the operations screen for different parts of the procedure. While in these modules, the user can still change settings using either the touch screen or Footswitch controls. Any settings changes may be saved while in the operations screen by holding the respective icon for three seconds or more. Any changes saved using this method will automatically populate in the Settings screen for the respective profile.

Figure18c: Lens Removal Module Active

Figure 18d: Cortical Removal Module Active

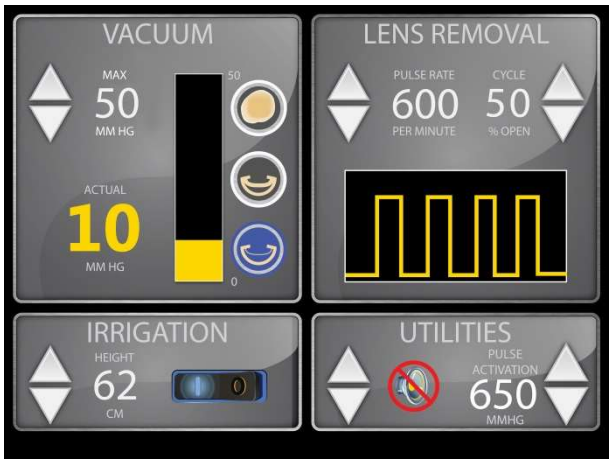


Figure 18f: Capsule Polisher Module Active

Vacuum should not be applied until irrigation is safely and properly supplied to the eye. By pressing the Footswitch, the surgeon will be able to control the actual vacuum level. This actual vacuum level will be displayed numerically in Yellow (in units of mmHg), as well as visually on the bar graph as a portion of the maximum vacuum.

When the actual vacuum level is elevated above the preselected Pulse Activation value, the Pulsed Vacuum will begin. If changes are made to the Pulse Rate and/or Duty Cycle parameters, the graphic below them will adjust to show changes in Pulse Rate and Duty Cycle. As the Pulse Rate increases or decreases, the pulses over a given period of time will increase or decrease. As the Duty Cycle increases or decreases the relation of the 'OPEN' vacuum (peak) to 'CLOSED' vacuum (trough) will increase or decrease. One full cycle, a peak and trough, is considered 100% of the operation, so if the duty cycle is set at 55% open, the peak will encompass 55% of the cycle and the trough will encompass 45% of the cycle.

To exit the Lens Removal Operational Screen and return to the Home Screen, the user must remove the Disposable Cassette from the Console. To remove the Disposable Cassette from the Cassette Receiver, the user must press the Cassette Eject Lever located in front of the Cassette Receiver and remove the Cassette from the Console. Once the Cassette is completely removed from the Console and the Cassette Receiver Door is closed, the user will be transported back to the Home Screen from which they entered.

NOTE: The CataPulse® is intended to be used on a crystalline lens (cataract) that is grade 3 (LOCS II) or less, unless a femtosecond laser is used to break up the grade 4 cataract.

WARNING: Do not switch between operational modules while applying vacuum or attempting to remove cortical tissue or while attempting to perform capsule polishing. Switching between operational modules under the listed conditions may change the maximum vacuum limit and allow a higher than expected amount of vacuum to be applied, and could potentially result in patient injury.

ANTERIOR VITRECTOMY OPERATIONAL SCREEN

The Anterior Vitrectomy Screen is accessed by inserting an Anterior Vitrectomy Cassette into the Cassette Receiver (See Figure 19). The Cassette must be completely inserted into the Cassette Receiver for the Anterior Vitrectomy Operation Screen to be displayed. When the Cassette is inserted and the Operational Screen is displayed, the vacuum and pressure pumps will start and build pressure in preparation for operation. The Irrigation Set should already be installed in the pinch valve located just above and behind the Cassette Receiver.

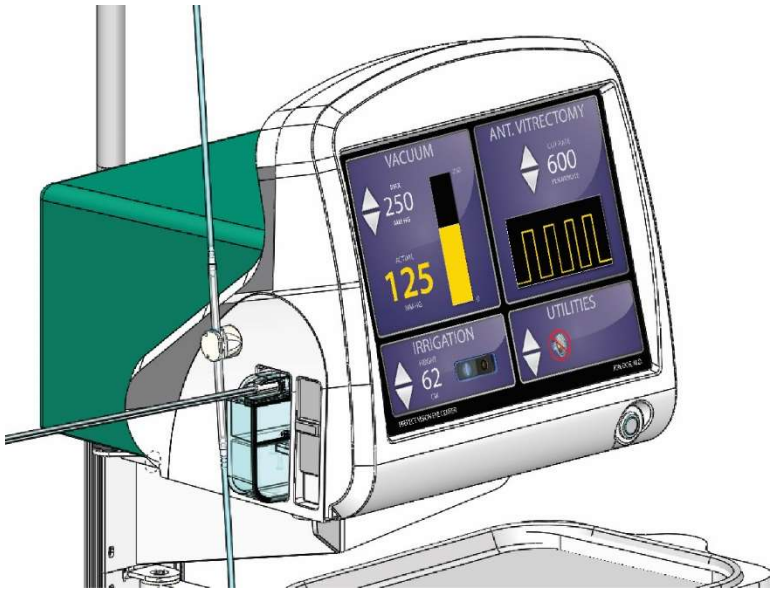


Figure 19: Vitrectomy Cassette Insertion

At this point, the user can adjust operational parameters, as necessary. Adjacent to each adjustable parameter are a set of Up and Down Arrows. The Arrows allow the user to increase or decrease parameters by the incremental value within the allowable parameter range (See Operational User Adjustable Parameters section below). As each parameter is adjusted from the touch screen, the parameter along with the adjustment arrow will be illuminated blue. When a parameter is adjusted with the Footswitch the parameter must first be selected with the Footswitch mode button and will illuminate blue. Either the increase or decrease arrow will illuminate blue when the corresponding Footswitch button is selected. There are five parameters that can be adjusted on the touch screen, four of which can also be adjusted by the Footswitch buttons. Three of the on screen parameters are identified by text, while two parameters are identified with Icons and a third Icon is used as a navigation button.

The Irrigation Hold Icon is in the shape of a switch which can display an 'OFF' or 'CLOSED' position in which an orange illuminated circle is displayed on the switch. This Switch can also display an 'ON' or 'OPEN' position in which a blue illuminated line is displayed on the switch.

The Volume  Icon is identified with a speaker. This Icon can be displayed at 6 levels, depending on the selected volume. Five of these levels are represented with sound waves emanating from the speaker. One of these levels is the 'OFF' or mute position and is represented with a Red circle with a Red diagonal line through it covering the speaker.

When the Cassette is first inserted, there will be no vacuum applied and the Actual Vacuum will read zero. The Irrigation Pinch Valve will be closed upon entering the Operational Screen, and the Irrigation Hold Switch will be in the 'OFF' position until irrigation is turned ON by the user.

When the irrigation is turned ON, vacuum can be applied. By pressing the Footswitch, the user will control the actual vacuum level. This actual vacuum level will be displayed numerically in Yellow as well as visually on the bar graph as a portion of the maximum vacuum. The Cut Rate graphic will show the graphical representation of guillotine cutter cutting speed. If changes are made to the Cut Rate value, the graphic will adjust to show changes in Cut Rate. The Duty Cycle will always remain at 50% and therefore is not an adjustable option.

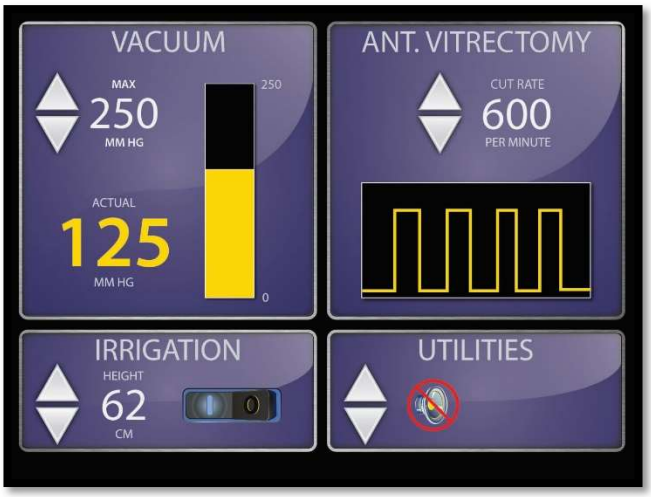


Figure 20: Anterior Vitrectomy Screen. Irrigation On and Vacuum Applied

To escape the Anterior Vitrectomy Operational Screen and return to the Home Screen, the user must remove the Disposable Cassette from the Console. To remove the Disposable Cassette from the Cassette Receiver, the user will press the Cassette Eject Lever located just in front of the Cassette Receiver and remove the Cassette. Once the Cassette is completely removed from the Console and the Cassette Receiver Door is closed, the user will be transported back to the Home Screen.

SURGICAL PROCEDURE SET-UP

1. Cover the CataPulse® Cart Arm or Medical Tray with the sterile cover.
2. Open the Lens Removal Handpiece Set and transfer to the surgical technician along with the cannulas to be used. The sterile clear terminal tray can be used to store the handpieces when they are not in use.
3. Find the strip of double sided tape on the bottom of the clear thermal tray and identify the one inch tab.
   3.1 Peel the protective cover off of the double sided tape.
   3.2 Place the clear thermal tray in a convenient location on the sterile cover.
4. Install the sterile Screen Cover. This allows the surgical technician to utilize the features on the Consoles touch screen under sterile conditions.
   4.1. Hold the two tabs of the Screen Cover.
   4.2. Pull the tabs apart from each other.
   4.3. If necessary, lightly shake to unfold the Screen Cover.
   4.4. Slip the Screen Cover over the Console so that the narrow strip is behind the Console screen and the longer strip covers the screen.

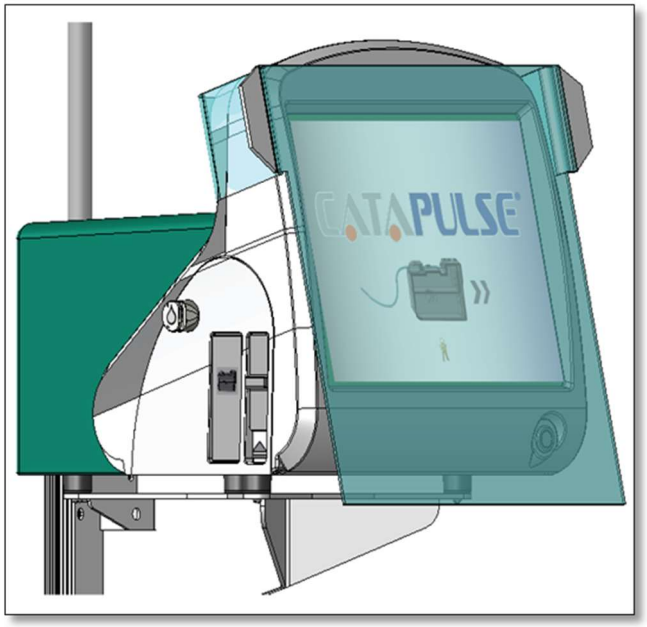


Figure 21: Installation of Screen Cover

5. Install the Irrigation Set.
   5.1. Carefully position the Irrigation Line so that each hand is holding an end of the six inch clear pinch tubing.
   5.2. Place the pinch tubing section in the pinch valve located above and behind the Cassette Receiver. This can be done by holding the six inch soft section of the Irrigation Set tubing and pulling it into the Console Pinch Valve until it is against the inner wall of the Pinch Valve.

   NOTE: Make sure that the spiker is connected to the end that will be positioned out of the top of the pinch valve and the handpiece is connected to the end that will be positioned out of the bottom of the pinch valve.

5.3. The circulating nurse can now spike a new irrigation bag/bottle with the irrigation line spiker.

5.4. Hang the irrigation bag/bottle on the IV Pole. Only a 250mL or 500mL irrigation bag/bottle should be used

WARNING: Do not manually modify or force the CataPulse Cart pole height because this could cause incorrect indication of bottle height and patient injury.

5.5 Repeat steps 5.1 - 5.4 for each new patient or eye.

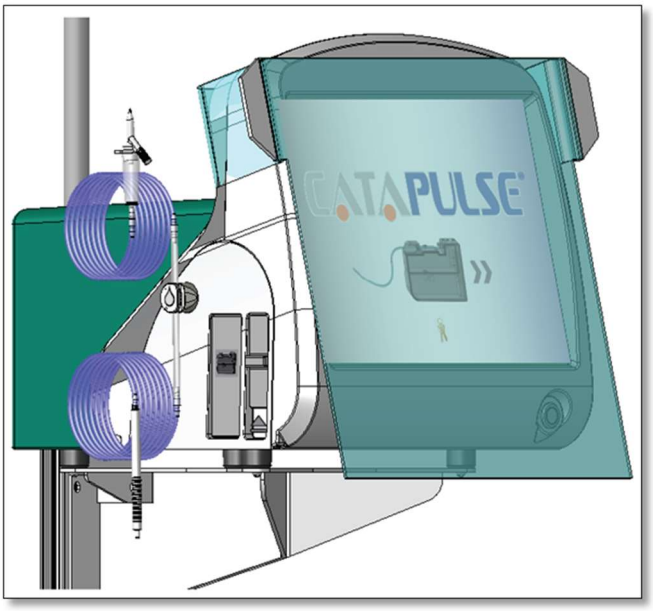


Figure 22: Installation of the Irrigation Line

BOTTLE HEIGHT MEASUREMENT

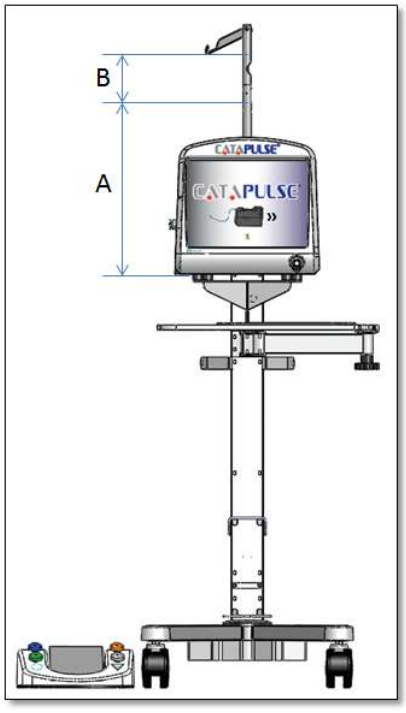


Figure 23: Bottle Height Measurement

Dimension B is the height of the Irrigation Bottle, and is assumed to be 20 cm. Dimension A is the height of the Irrigation Bottle above the patients eye level.

NOTE: If dimension B is longer than 20 cm use the following formula to get the height: Irrigation Bottle Height = Displayed height – (Dimension B-20 cm)

If dimension B is shorter than 20 cm use the following formula to get the height: Irrigation Bottle Height = Displayed Height + (20 cm + Dimension B).

WARNING: If the CataPulse® Cart is not in use, the patient eye level must be at or below the bottom of the Console. Contact a MED-LOGICS Surgical Specialist if any further information is needed.

FUNCTIONALITY TEST

Irrigation Flow Test:

1) The BSS bottle/bag should be attached to the Irrigation Set with the Irrigation Set properly and securely placed in the Irrigation Pinch Valve.
2) A sterile Irrigation Cannula can now be attached to the plastic Irrigation Handpiece.
3) Place a Cassette in the Cassette Receiver.
4) Set the hold switch in the 'ON' position (Irrigation Section of the Screen) and verify that irrigation fluid flows out the tip of the cannula and that there are no leaks in the fluid path from the BSS bag/bottle to the tip of the irrigation cannula.
   NOTE: Sterile BSS solution for this test can be drained into the sterile disposable tray for the Lens Removal and Anterior Vitrectomy test.
   a. If BSS does not flow out of the cannula or flows at a reduced rate, check for obstructions in the irrigation line.
   b. If a leak is found in the irrigation line at one of the connections and cannot be corrected by pressing those connections together, discard the irrigation line and install another irrigation line.

Lens Removal Handpiece Test:

1. Insert the Lens Removal Cassette and verify that the correct operating screen is displayed.
2. Activate that the irrigation switch to the 'ON' position.
3. Place the cannula or cutter tip in the sterile BSS that was drained in the tray, or other containment vessel.
   NOTE: Securely attach the intended cannula for operation. The CataPulse Lens Removal Handpiece does not need to be primed before testing or before use.
4. Press the pedal on the Footswitch and verify that fluid is being aspirated through the blue tube and is draining into the top chamber of the Cassette. Verify that the pulsation of the applied vacuum can be heard and felt in the handpiece. The Lens Removal Handpiece pulsation will only occur if the actual vacuum is elevated above the preset Pulse Activation value set by the user or default 125 mmHg.
   a. If the fluid is not aspirated or an obstruction in the fluid path is observed, discard the disposable set and install another.
   b. If a leak is found in the disposable set at one of the connections or the containment vessel, and cannot be corrected by pressing those connections together, discard the disposable set and install another.
5. If the Lens Removal Handpiece is working properly the surgeon can continue with the procedure.

OPERATION

Prior to beginning operation, the user should have completed the following steps:

- Connected the Footswitch and Cart to the CataPulse® Console.
- Turned ON the CataPulse® Console.
- Placed the sterile cover on the Mayo tray.
- Placed the Screen Cover on the CataPulse® Console Screen.
- Connected the Irrigation line to the CataPulse® Console Pinch Valve.
- Logged into their user profile (optional).
- Test for;
    - Irrigation flow through the Irrigation Cannula.
    - Disposable aspiration at the tip of the Lens Removal Handpiece.
    - Mechanical function of the pulse, which can be felt or heard at the tip of the Handpiece.

WARNING: When using the CataPulse Cart automated IV pole or a manual cart with IV pole to provide gravity feed irrigation it is important that the bottom of the Console always remain above the patient's eye level.

WARNING: The operator of the equipment should be aware of and ensure sufficient volume of irrigation solution for and during the procedure.

WARNING: The operator of the equipment shall ensure that the maximum capacity of the Cassette is not exceeded as this could cause a hazardous situation to the patient and could also damage the internal components of the Console. There is a Fault that will show if the fluid level reaches an unsafe level. See the section on Troubleshooting in the back of this manual for more information on the Fault.

WARNING: The CataPulse System should not run continuously at 650mmHg for more than fifteen minutes at a time. There should be at least a thirty second cool-down period. NOTE: The Disposable Cassette, at 650mmHg fills within three minutes.

LENS REMOVAL

The surgeon will create 2 incisions for a bimanual surgical approach. One incision is for the Lens Removal Aspiration Cannula and the second incision is for the Irrigation Cannula. Both the standard Lens Removal Cannula and the standard Irrigation Cannula have a diameter that is approximately 1.0mm. The size of the incisions can be as small as 1.4 mm. A small incision will help prevent wound leakage. However, the incision size is dependent on surgeon preference. Since the incisions can be the same size, the surgeon can alternate the cannulas between the two incisions.

In the case of a harder crystalline lens, Grade 4 (LOCS II) or more, it is recommended to fracture the lens through the use of a femtosecond cataract laser to reduce operation time.

The CataPulse® Lens Removal System is an occlusion based design that allows the surgeon to reduce the amount of fluid through the eye.

After the cataract is removed, the Lens Removal Cannula is removed from the eye and detached from the Lens Removal Handpiece. A Side Port Cortex Removal Cannula is then placed on the distal tip of the Lens Removal Handpiece. The surgeon can then remove the residual cortex.

NOTE: The Lens Removal Screen is utilized for the removal of both the crystalline lens and the cortex.

NOTE: The CataPulse® is intended to be used on a crystalline lens (cataract) that is grade 3 (LOCS II) or less, unless a femtosecond laser is used to break up the grade 4 cataract.

In the event the Console alerts the user the Cassette has reach capacity, simply eject the Cassette and insert a new Cassette. Remove the Cannula from the old Lens Removal Handpiece and place it onto the new Lens Removal Handpiece and continue with the operation.

ANTERIOR VITRECTOMY

In the case where the posterior bag is compromised and vitreous enters the anterior chamber, immediately stop vacuum application and remove the Lens Removal Cassette from the Console.

WARNING: Further aspiration with the Lens Removal Handpiece can harm the patient.

NOTE: During the switch from Lens Removal Handpiece Cassette and Anterior Vitrectomy Handpiece Cassette the user should remove all instruments from the patient's eye. The irrigation line should remain attached to the Console as it will be necessary for Anterior Vitrectomy removal.

NOTE: The Console is automatically switched to the Anterior Vitrectomy mode when the Anterior Vitrectomy Handpiece Cassette has been inserted.

Anterior Vitrectomy Handpiece Test:

1. Eject the Lens Removal Handpiece Cassette and place it along with the Handpiece in a sterile area in case the surgeon needs to use after removing the vitreous.
2. Open an Anterior Vitrectomy Handpiece Set and insert the Cassette into the Console. Verify that the correct operating screen is displayed.
3. Activate the irrigation switch to the "ON" position.
4. Place the Vitrectomy Handpiece Cannula into Balanced Salt Solution (BSS) or Sterile Distilled Water before testing. You can use the plastic handpiece tray or other containment vessel to hold the fluid in order to perform the test.
   CAUTION: Do not test or operate the Vitrectomy Handpiece unless cannula tip is immersed in fluid or is in use. Operating the Vitrectomy Handpiece without fluid can damage it.
   NOTE: The Vitrectomy Handpiece does not need to be primed before testing or before use.

5. With the Vitrectomy Handpiece Cannula immersed in fluid, press the pedal on the Footswitch and observe the guillotine cutter actuate properly and that fluid is being aspirated through the blue tube and draining into the top chamber of the Cassette.
    a. If the fluid is not aspirated, there is a leak, or an obstruction in the fluid path is observed, discard the disposable set and install another set.
6. If the Vitrectomy Handpiece is working properly the surgeon can continue with the removal of vitreous from the anterior chamber.

POST SURGERY

After the procedure it is important to follow the instruction listed below.

1. Remove irrigation (bottle or bag) from Cart pole hanger and set aside. Remove spiker from irrigation bottle and place irrigation tubing set on the medical tray along with the Lens Removal Handpiece. Flip the pole hanger back over and into its storage position.
2. Remove clear screen cover from Console and place on medical tray.
3. Eject the Lens Removal Handpiece Cassette from the Console and discard it and any "single-use" items (ex: Irrigation Tubing Set, Anterior Vitrectomy Cassette, Console Screen Cover, Disposable Cannulas and/or any "single-use" instruments) placing them into a designated bio-hazard container or sharps bin and disposing the container and bin according to facility or local requirements.

End of Day

4. Press and hold the Standby Power Button for 2 seconds or until it starts blinking. The Console will begin to shut down and the Cart pole will return to its storage position. **WARNING:** When the Cart pole is moving keep clear to prevent skin, hair, and/or clothing from being trapped in the poles pathway.
5. Return Footswitch to the storage position located at the base of the Cart. Inspect Footswitch and cord and if required clean or dry outer surface.
6. Once the Console screen is dark the Main power inlet on the back of the Console can be switched to the OFF position and the power cord can be removed from the wall outlet and the back of the Console.

OPERATIONAL USER ADJUSTABLE PARAMETERS

Operation	Minimum Value Setting	Maximum Value Setting	Adjustable Increments	Operational Availability	Default Value	Accessible Screens for Adjustment
Vacuum (Accuracy +/- 3 mmHg)	50 mmHg	650 mmHg	5 mmHg or 20 mmHg if screen button held for 3 seconds	Lens Removal Module	400 mmHg	• Lens Removal Screen • Settings Screen
				Cortical Removal Module	250 mmHg	
				Capsule Polish Module	50 mmHg	
				Vitrectomy	250 mmHg	• Vitrectomy Screen • Settings Screen
Vacuum Pulse Rate (Accuracy +/- 20%)	450 Pulses Per Minute	800 Pulses Per Minute	25 Pulses Per Minute	Lens Removal Module	600 Pulses Per Minute	• Lens Removal Screen • Settings Screen
				Cortical Removal Module	600 Pulses Per Minute	
				Capsule Polish Module	600 Pulses Per Minute	
Pulse Activation	100 mmHg	650 mmHg	5 mmHg or 20 mmHg if button held for 3 seconds	Lens Removal Module	125 mmHg	• Lens Removal Screen • Settings Screen
				Cortical Removal Module	650 mmHg	
				Capsule Polish Module	650 mmHg	
Duty Cycle	40%	60%	5%	Lens Removal Module	50%	• Lens Removal Screen • Settings Screen
				Cortical Removal Module	50%	
				Capsule Polish Module	50%	
Cut Rate (Accuracy +/- 20%)	50 Cuts Per Minute	2500 Cuts Per Minute	10 Cuts Per Minute	Vitrectomy	600 Cuts Per Minute	• Vitrectomy Screen • Settings Screen
Bottle Height / Irrigation (Accuracy +/- 1%)	32cm	102 cm	1 cm	Lens Removal Module	62 cm	• Lens Removal Screen • Settings Screen
				Cortical Removal Module	62 cm	
				Capsule Polish Module	62 cm	
				Vitrectomy Removal	62 cm	• Vitrectomy Removal Screen
Volume	muted	loudest	Adjustable in 20% increments	All	0	• Lens & Vitrectomy Screens • Setting Screen
Brightness	1	5	1	All	5	• Settings Screen

Table 15: Operational User Adjustable Parameters

TROUBLESHOOTING

FAULT WINDOWS

A 100 level fault is a correctable fault. This window will appear as a radiated Yellow transparent background over the operation window currently being used and will identify the Fault by a 3 digit number (See Figure 23). The Fault text will be displayed in the language selected in the user profile. The Fault can be cleared by addressing and correcting the fault or by touching the screen, depending on the nature of the Fault. See Table 16.

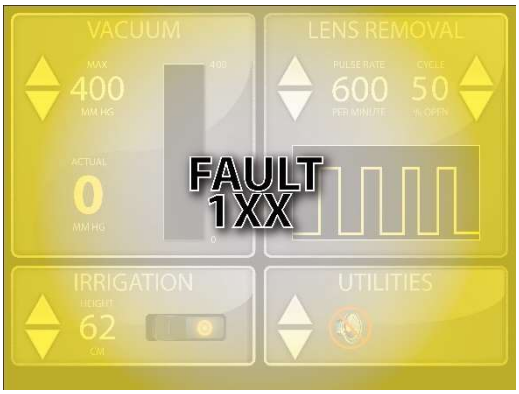


Figure 24: 100 level Fault Screen

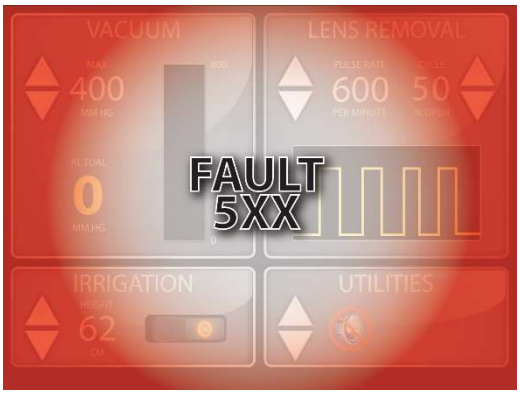


Figure 25: 500 level Fault Screen

100 LEVEL FAULT CODES AND DESCRIPTIONS

Fault Code	Description	How To Clear The Fault
Fault 101	Footswitch is not connected	Attach the Footswitch connector into the back of the Console and touch screen to clear fault.
Fault 102	Cassette door was opened and does not detect a Cassette for 5 sec. or if the eject switch is activated and the Cassette door fails to close for 5 sec. after the removal of the Cassette	If installing a Cassette: Make sure Cassette is fully installed. Touch screen to clear fault. If removing Cassette: Remove Cassette and make sure the door closed completely. Touch screen to clear fault.
Fault 103	Cassette Full – Top tank fluid level sensor is activated.	If bottom tank is empty: Once user releases the Vacuum Footswitch, fluid will begin to drain to the bottom tank until the bottom tank fluid level sensor is activated. If bottom tank is full: Stop all Vacuum application to the Cassette. User must remove the Cassette and install an empty Cassette to proceed. If user clears the 103 Fault from screen and both sensors are still indicating a full cassette then a 506 Fault code will be generated and the user will need to replace cassette and cycle the device to clear 506 Fault.
Fault 104	IV Pole – If IV Pole height is changed on the screen and there is no height change from the IV Pole.	The IV Pole maybe jammed or overloaded with weight. Inspect the pole to be sure it is not jammed and cycle the power to the console.

Table 16: 100 Level Fault Codes and Descriptions

500 LEVEL FAULT WINDOW

A 500 Level fault is not recoverable. This window will appear as a radiated Red transparent background over the operation window currently being used and will identify the Fault by a 3 digit number (See Figure 25). The Fault text will be displayed in the language selected in the user profile. The Fault cannot be cleared by the user as it indicates a larger problem with the device. When this fault is displayed, the device must be sent in to be MED-LOGICS for service.

TROUBLE SHOOTING FUNCTIONAL SCENARIOS

Although it is impossible to predict every potential issue, MED-LOGICS has included the following list of possible scenarios and proposed solutions. If there are issues being experienced that are not addressed below, contact MED-LOGICS for technical support.

PROBLEM CONDITIONS AND MITIGATIONS		
Symptom	**Probable Cause**	**Corrective Action**
Anterior Chamber of the eye is not stable.	BSS bottle is too low.	Elevate the level of BSS bottle.
	Drip Chamber in the irrigation line is not adequately filled with fluid.	Squeeze drip chamber until it is 2/3 to 3/4 full.
	Clogged irrigation cannula or line.	Flush and clean cannula.
	Kinked or damaged tubing.	Check tubing and/or replace.
Insufficient Aspiration.	Interference under the Footswitch	Check for foreign objects under the Footswitch.
	Full Cassette.	Release Footswitch to allow Cassette to drain. If Cassette is completely full, replace the Cassette.
Irrigation does not stop.	Irrigation Line is not properly installed in the Irrigation Pinch Valve.	Reinstall the Irrigation Line in the Irrigation Pinch Valve.
Bubbles in irrigation line.	Air leak in Irrigation Line.	Replace Irrigation Line.
Anterior Vitrectomy cutter does not function.	Cutting port not closing fully when inner cutter moves.	Reduce cutting speed until port closes completely or replace Vitrectomy Cutter Set.
Poorly functioning Vitrectomy Cutter.	Kinked, damaged or loose actuation tubing.	Check for damaged or kinked tubing. Replace cutter if visual inspection reveals damaged components.
	Footswitch connector not properly inserted into Console connector.	Disconnect and reconnect Footswitch cable connector to Console
Footswitch does not respond properly.	Debris under rear section of pedal.	Clean and remove debris.
	Console malfunction.	Disconnect and reconnect Footswitch cable connector into Console connector.
	Faulty Footswitch.	Footswitch requires repair.
Vacuum or Pressure Pump runs constantly	Console malfunction	Console requires repair

Table 17: Problem Conditions and Mitigations

EMC STATEMENT

Important information regarding Electromagnetic Compatibility (EMC)

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) with the aim to prevent unsafe product situations, the IEC 60601-1-2 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.

The CataPulse conforms to this IEC60601-1-2:2001 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

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

Below is further guidance regarding the EMC environment in which the device should be used.

Guidance and manufacturer's declaration – electromagnetic emissions

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

<table>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RE emissions CISPR 11</td><td>Group 1</td><td>The CataPulse 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.</td></tr>
<tr><td></td><td>Class A</td><td rowspan="3">The CataPulse is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating or shielding the location.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV 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 IED 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) 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 input lines 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 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s		Mains power quality should be that of a typical commercial or hospital environment. If the user of the CataPulse requires continued operation during power mains interruptions, it is recommended that the CataPulse be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHzs to 80MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the CataPulse, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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,[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: 

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: 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. 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 CataPulse is used exceeds the applicable RF compliance level above, the CataPulse should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CataPulse.

[b] 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 CataPulse.

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

Rated maximum output power of the transmitter In watts(W)	**Separation distance according to frequency of transmitter in meters** (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

MAINTENANCE

The CataPulse® Lens Removal System includes a Console, Footswitch and Cart. It is suggested that these three units receive yearly service or maintenance. The other components are sterile and/or single use, therefore do not require maintenance.

WARNING: There is a risk of electrical shock if the internal components of the Console, Footswitch, or Cart become exposed to, or immersed in fluid. Do not operate if Console is wet or exposed to fluids. Call MED-LOGICS at 949-582-2676 or 800-651-2962 for repair.

FUSE REPLACEMENT

If the power cord is connected and the Console power switch is turned "ON" but the front panel standby button does not illuminate blue, the fuses may need to be replaced. In order to replace the fuses at the back of the Console follow these steps carefully:

1. Turn “OFF” the back power switch on the Console.
2. Unplug the power cord from the Console.
   WARNING: If power supply is not removed from the Console there will be a risk of electrical shock.
3. Remove the inlet cover by prying it open with a small flathead screwdriver or similar tool.
4. Pull out the fuse carrier while pushing the outer edge with a screw driver or similar tool.
5. Replace both fuses with fuses of the following specifications:
   2A/250V .25” X 1.25” (5 mm X 20 mm) Time Delay Fuse
6. Re-insert the fuse carrier in the reverse order of step 4.
7. Verify the fuse function by following the procedures below:
   A. Plug the power cord into the Console inlet and the wall outlet.
   B. Turn ON the power switch on the Console and verify that the POWER indicator on the Console front panel illuminates with a flashing blue light.
   NOTE: If the fuses fail again, turn off the power on the back of the unit and unplug from wall. Contact the authorized MED-LOGICS distributor/representative or contact MED-LOGICS directly.
8. Attach the inlet cover in the reverse order of step 3.

CARE AND CLEANING

The following recommendation for the proper care of the CataPulse Console, Cart, Footswitch, and components should be followed and any questions should be communicated to a MED-LOGICS Surgical Specialist.

- The Console, Footswitch, and Cart are designed to be wiped clean before every use using a lightly damp lint-free cloth of Isopropyl Alcohol, gently wiping down all external surfaces.
  WARNING: Make sure the device is not powered ON and that the power cord is not plugged into the Console or wall outlet.
- The Console touch screen may be cleaned using a soft, non-abrasive cloth towel and a mild window cleaner. Apply the cleaner to the towel rather than the touch screen.
- Periodically check the Console cover and chassis for cracks or damage.
- Damaged hardware must be replaced to ensure safe operations.

Annual service and inspection of the CataPulse Console, Cart, and Footswitch must be performed by a qualified Surgical Specialist from MED-LOGICS.

WARRANTY

MED-LOGICS guarantees that the CataPulse® will conform to the manufacturer's current version for the specifications and that all material respects and/or workmanship shall be free from defects for a period of 12 months from ship date it leaves MED-LOGICS.

The exclusive remedy for any breach of the Warranty shall be at MED-LOGICS's discretion. The repair or replacement of the non-conforming equipment or parts shall be returned to MED-LOGICS. A Return Goods Authorization (RGA) number can be obtained by calling MED-LOGICS Customer Service at 949-582-3891 or 800-651-2962. The RGA must accompany equipment returned for any reason. Please print the RGA number on the outside of the shipping box.

MED-LOGICS shall pay only for shipping expenses for equipment repaired under Warranty. For equipment returned for repair, which is not under warranty, the standard repair and shipping charges of MED-LOGICS then in effect shall apply.

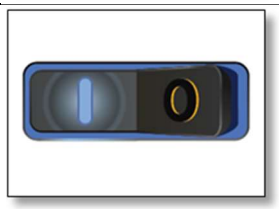
This Warranty does not apply to normal wear and tear or to defects, malfunctions or failures that result from the abuse, neglect, improper installation or maintenance, alteration, modification, accident, or misuse of the equipment.

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICLUAR PURPOSE. NO WARRANTY IS GIVEN THAT THE EQUIPMENT IS DELIVERED FREE OF THE RIGHTFUL CLAIM OF ANY THIRD PARTY FOR PATENT INFRINGEMENT AND THE LIKE.

The Warranty set forth above may not be extended, enlarged, or otherwise modified by any MED-LOGICS agent or employee. MED-LOGICS does not assume any liability or make any warranty except as stated above.

SCREEN SYMBOL DEFINITIONS

Icon	Title	Description
	Unlock Profile (The Key Icon)	Located on the Home Screens and indicates the desire of the user to select a user profile. Touching this Icon will transport the user to the User Identification Screen where they can select a user profile or generate a user profile.
	Insert A Disposable Cassette	Located on the Home Screen and indicates the user's next step needs to be the insertion of the Lens Removal Cassette.
	Apply Profile (The Green Check Mark Icon)	Located on the User Identification Screens and indicates the selection of a user profile.
	Settings (The View Profile Settings Icon)	Located on the User Identification Screens and transports the user to the Settings Screen of that user's profile. Located on the operating screens (Lens Removal and Anterior Vitrectomy) and transports the user to the Settings Screen of that user's profile.
	Close window (The Red X Icon)	Located in the upper right corner of the User Identification Window and transports the user back to the Home Screen from which they entered. Located in the upper right corner of the Settings Screen and Transports the user back to either the User Identification Window or the Operating Screen depending from where they entered.
	Add Profile (The Add Profile Icon)	Located at the bottom of the User Identificaiton Window, selection of this Icon transports the user to a blank Setting Screen from which they can generate a User Profile. This Icon is only functional if there are fewer than 5 profiles.
	Increase Arrow	Located on the Settings Screen and the operating screens (Lens Removal and Anterior Vitrectomy), this arrow allows the user to increase the desired parameter.
	Decrease Arrow	Located on the Settings Screen and the operating screens (Lens Removal and Anterior Vitrectomy), this arrow allows the user to decrease the desired parameter.
	Language Selection (The Globe Icon)	Located in the upper center of the Settings Window, to the right of the Language text. Selection of this Icon transports the user to the language Screen to select a language.

	Save Profile (The Floppy Disc Icon)	Located in the upper right corner of the Setting Screen, selection of this Icon allows the user to save a profile or changes to a profile and transports the user back to the screen from which they entered.
	Delete Profile (The Delete Profile Icon)	Located in the upper right corner of the Settings Screen, selection of this Icon allows the user to delete a profile and transports the user to the Delete Profile Window. The user can then be transported back to the screen from which they entered.
	Refresh	Located at the bottom of the Logged In Home Screen, selection of this Icon will log out the user from the current profile and transport the user to the default Home Screen.
	The Irrigation Switch (OFF)	The irrigation switch is located on the operating screens (Lens Removal and Anterior Vitrectomy). This switch controls the flow of Irrigation solution to the eye. When the switch is in the 'OFF' position, irrigation flow to the eye is stopped.
	The Irrigation Switch (ON)	The irrigation switch is located on the operating screens (Lens Removal and Anterior Vitrectomy). This switch controls the flow of Irrigation solution to the eye. When the switch is in the 'ON' position, irrigation flow to the eye is allowed.
	Icon for Lens Removal Operational Module (Active)	The Lens Removal operational module is located on the setting and lens removal operating screen. When activated, this button loads the settings that have been pre-selected by the operator for this module. Changes to the module presets can be saved in the settings screen, or by holding the icon for 3 or more seconds.
	Icon for Lens Removal Operational Module (In-active)	The Lens Removal operational module is located on the setting and lens removal operating screen. When inactive, the icon will remain greyed out.
	Icon for Cortical Removal Operational Module (Active)	The Cortical Removal operational module is located on the setting and lens removal operating screen. When activated, this button loads the settings that have been pre-selected by the operator for this module. Changes to the module presets can be saved in the settings screen or by holding the icon for 3 or more seconds..
	Icon for Cortical Removal Operational Module (In-active)	The Cortical Removal operational module is located on the setting and lens removal operating screen. When inactive, the icon will remain greyed out.

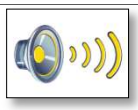
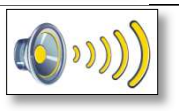
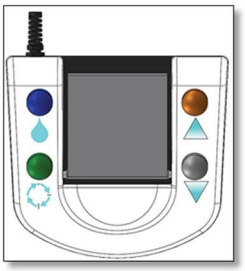
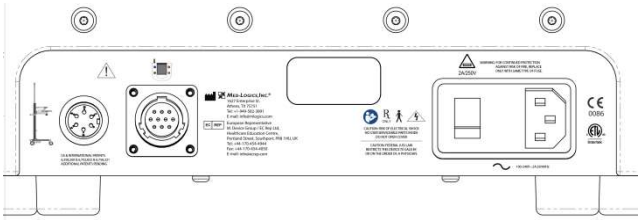
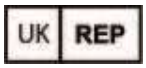
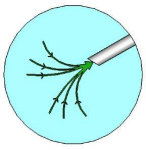
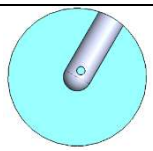
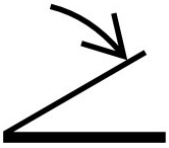
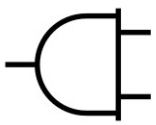
	Icon for Capsule Polisher Operational Module (Active)	The Capsule Polisher operational module is located on the setting and lens removal operating screen. When activated, this button loads the settings that have been pre-selected by the operator for this module. Changes to the module presets can be saved in the settings screen or by holding the icon for 3 or more seconds..	
	Icon for Capsule Polisher Operational Module (In-active)	The Capsule Polisher operational module is located on the setting and lens removal operating screen. When inactive, the icon will remain greyed out.	
	The Volume Icon (The Volume Level Icon represents the current volume level and is located on the operating screens (Lens Removal and Anterior Vitrectomy). The Volume Icon (The Volume Level Icon represents the current volume level and is located on the operating screens (Lens Removal and Anterior Vitrectomy).		This is a speaker with a Red circle and diagonal line to represent no volume.
			This is a speaker with 1 curve emanating from it representing a volume level of 1.
			This is a speaker with 2 curves emanating from it representing a volume level of 2.
			This is a speaker with 3 curves emanating from it representing a volume level of 3.
			This is a speaker with 4 curves emanating from it representing a volume level of 4.
			This is a speaker with 5 curves emanating from it representing a volume level of 5.

Table 18: Screen Symbol Identification and Definitions

EQUIPMENT & PACKAGING SYMBOL DEFINITIONS

		
REF	Catalog or Re-Order Number	This symbol can be found on all items that have a part number.
	Risk of Electric Shock	Located on the back panel of the Console and Cart.
	Mandatory To Consult Operators Manual Before Using the Product	This symbol can be found on any product or device (labeling or packaging) that are used with this device.
	Reference the Operators Manual Before Using	The symbol can be found on all items that are used with the CataPulse® that require some knowledge before using.
	Location of Connection for Equalization	This symbol can be found on the Console.
	Fuse Rating	Located on the back panel of the Console.
O	"OFF" Position	Located on the back Console Power Switch.
I	"ON" Position	Located on the back Console Power Switch.

	Classified as a Type B System	Located on the back panel of the Console.
	Identifies Manufacturer Information	This symbol can be found on all items that have a part number.
	Identifies the Footswitch Electrical Connection	Located on the back panel of the Console.
	Identifies the Cart Electrical Connection	Located on the back panel of the Console.
	Irrigation Pinch Valve Button	This symbol can be found on the Footswitch just below the blue button allowing opening and closing of the Irrigation Line Pinch Valve.
	U.S. Law Restricts The Sale By, Or On The Record Of, A Physician	This symbol can be found on any product or device (labeling or packaging) that are used with this device and able for sale the United States.
	European Authorized Representative Information	This symbol can be found on any product or device (labeling or packaging) that are used with this device and able for sale in European Markets.
	United Kingdom Authorized Representative Information	This symbol can be found on any product or device (labeling or packaging) that are used with this device and able for sale in United Kingdom Markets.
	European Notified Body Identification Number	This symbol can be found on any product or device (labeling or packaging) that are used with this device and able for sale in European Markets. The product meets the essential requirements of the Medical Device Directive (93/42/EEC).
	Identification Label for Lens Removal Cannulas	This symbol can be found on the box, pouch, and plastic tray of CataPulse lens removal cannulas. This symbol identifies the cannula as a lens removal cannula.
	Identification Label for Irrigation Cannulas	This symbol can be found on the box, pouch, and plastic tray of CataPulse irrigation cannulas. This symbol identifies the cannula as an irrigation cannula.

	Identification Label for Cortical Removal Cannulas	This symbol can be found on the box, pouch, and plastic tray of CataPulse cortical removal cannulas. This symbol identifies the cannula as a cortical removal cannula.
	Single-Use	This symbol can be found on any product (labeling or packaging) that is not to be reused or to be sterilized again.
	Manufactured Date and Country	This symbol can be found on any product or device (labeling or packaging) that has been assembled and tested.
	Manufacturers Expiration Date	This symbol can be found on any product (labeling or packaging) that has been sterilized.
	Lot Code	This symbol can be found on any product or device (labeling or packaging) that has been assembled and tested.
	Sterilized Using Ethylene Oxide	This symbol can be found on any product (labeling or packaging) that has been sterilized using ethylene oxide.
	Footswitch	This symbol can be found adjacent to a footswitch's connection point.
	Eject	This symbol can be found on a device's ejection point.
	Medical Device	This symbol can be found on all medical devices.
	Unique Device Identifier	This symbol can be found on any device with a UDI number
	Power Plug	This symbol can be found on a device's power connection point.

	Pressure Measurement	This symbol can be found on any device that measures pressure.
	Occular Irrigation	This symbol can be found on any device that performs ocular irrigation.
	Fragmentation	This symbol can be found on any device that performs fragmentation.
	Vitrectomy	This symbol can be found on any devie that perfoms vitrectomy.

Table 19: Equipment & Packaging Symbol Identification and Definitions

WARNINGS

A qualified technician should perform a visual inspection of the following components every twelve months:

- Power Cord
- Fuses
- Electrical connections for the Footswitch
- Electrical connections for the Cart

If, during such an inspection, a deficiency is discovered, do not use the system and call MED-LOGICS Technical Services.

A qualified technician should check ground continuity for leakage current every twelve months to ensure they are within the applicable standards. Values must be recorded and if they are above the applicable standards or 50% above initial measurement, do not use the system and call MED-LOGICS Technical Service.

Modification of the equipment is NOT allowed without prior authorization from the MED-LOGICS. Do not remove the Console cover for any reason. If the CataPulse® is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the device.

Good clinical practice dictates testing for adequate irrigation, aspiration flow, and good operation as applicable for each handpiece prior to entering the eye.

Keep clear of the IV pole when it is in motion to prevent injury or damage.

Use of accessories and cables, other than those provided by MED-LOGICS, may result in increased emissions or decreased performance of the system. Portable and mobile RF communications equipment can affect the performance of this medical electrical equipment.

When the Console is used on the standard CataPulse® cart, make certain the wheels are unlocked prior to pushing or moving the cart.

Route the Footswitch cable, power cord, and any other cables connected to the CataPulse® to avoid tripping.

Use of non-MED-LOGICS surgical reusable or disposable handpieces or cannulas that do not meet MED-LOGICS surgical specifications may result in a fluidic imbalance or malfunction. This, in turn may cause patient complications.

REFERENCES

American Optometric Association: (2004) Optometric Clinical Practice Guideline on Care of the Adult Patient with Cataract. (http://www.aoa.org/documents/optometrists/CPG-8.pdf)