

# *Mosaic*

## Operator's Manual



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# 1 Foreword

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## 1.1 Intended Use of Manual

This manual is designed to serve the operators of the Avedro, Inc. Mosaic System. All operating instructions, product illustrations, screen graphics, troubleshooting/error messages, and other relevant information are contained in this manual. It is the operator's responsibility to ensure that all safety instructions in this manual are strictly followed.

## 1.2 Intended Use / Indications for Use

The Mosaic System delivers a uniform, metered dose of UV light to a targeted treatment area for the intended use of illuminating the cornea during corneal cross-linking procedures

## 1.3 Essential Requirements

The Mosaic System must maintain the programmed intensity and spatial characteristics of the emitted UV light while in treatment mode.

## 1.4 Design Change Disclaimer

- Due to design changes and product improvements, information in this manual is subject to change without notice. Avedro, Inc. (hereafter called "Avedro") reserves the right to change product design at any time without notice, which may subsequently affect the contents of this manual.
- Avedro assumes no responsibility for any errors that may appear in this manual. Avedro will make every reasonable effort to ensure that this manual is up to date and corresponds with the shipped Mosaic System.
- The computer display screens depicted in this manual are representative only. Depending on the software version of the system, minor differences may appear between the actual computer displays and those shown in this manual.
- All patient data appearing in this document, including the sample screen graphics, are fictitious and representative only. No patient's confidentiality has been violated, with or without permission.

## 1.5 Reproduction Disclaimer

Neither this manual nor any part of it may be reproduced, photocopied, or electronically transmitted in any way without the advanced written permission of Avedro.

## 1.6 User Operation Assistance Statement

Should you experience any difficulty in running your Mosaic System, please contact your local Avedro authorized representative.

## 1.7 Contraindications, Warnings and Cautions

### 1.7.1 Contraindications

This section describes situations in which the device should not be used because the risk of use clearly outweighs any possible benefit. Conditions that may contraindicate the use of the device include:

- Corneal thickness, with epithelium of less than < 375 microns.
- Corneal melting disorders
- Aphakic patients
- Pseudophakic patients without UV blocking lens implanted
- Pregnant and nursing women

### 1.7.2 Warnings

Physicians should evaluate the potential benefits in patients with the following conditions:

- Herpes simplex, herpes zoster keratitis, recurrent corneal erosion, corneal dystrophy
- Epithelial healing disorders

### 1.7.3 Electrical Safety Warnings

For Equipment Classifications please refer to chapter 7: Equipment Classifications



**WARNING:** Any repair or service must be carried out by Avedro trained personnel only.

**WARNING:** Do NOT modify this equipment without authorization of the manufacturer.



**WARNING:** To avoid the risk of shock this equipment must only be connected to a supply mains with protective earth.

To separate system connection to mains, grasp the power cord plug and pull it from outlet to disconnect.

The system is designed for continuous operation using the external connector.



**WARNING:** This equipment is operated with hazardous voltages that can shock, burn, or cause death. To reduce the possibility of electrical shock and inadvertent UV exposure do not remove any fixed panels.



**WARNING:** Remove the wall plug and turn off the power switch before servicing or cleaning (disinfecting) the equipment.



Never pull cords to remove the power cord from the outlet. Grasp the power cord plug and pull it from the outlet to disconnect.



**WARNING:** Do not operate the equipment with a damaged power cord.



**WARNING:** Position the power cord so that it cannot be tripped over, walked on, rolled over, crimped, bent, pinched, or accidentally pulled from the wall outlet.



**WARNING:** To remove power completely from the system, unplug power cord from mains outlet. Always keep power cord area free to effectively unplug cord and remove power from system.



**WARNING:** Do not use the instrument near water and be careful not to spill liquids on any part of it.



**WARNING:** Do not operate the Mosaic System in the presence of flammable mixtures or anesthetics.



**WARNING:** Never look directly into the UV light beam. Never direct the beam towards a person except for therapeutic purposes.



**WARNING:** Ignoring local regulations on use of electro-optical medical devices may cause malfunction due to electromagnetic interference.

## 1.8 Patient Safety

- The treatment should take place in a quiet and relaxed atmosphere in order not to distract the attention of the patient. The patient should lie on a table or patient's chair. The patient's head should rest comfortably in a headrest. It is imperative that the table or patient's chair or the system not be moved during the treatment procedure.



**CAUTION:** The Mosaic System is a medical device. It may be operated, therefore, only in health care facilities or medical areas under the supervision of medically trained personnel.

## 1.9 Additional Safety Considerations

- UV irradiance of the Mosaic System is calibrated by the manufacturer and must be checked annually. Any modification of the system's external light beam by means of optical elements is strictly prohibited.
- Plastic instrumentation such as speculums or eye shields may be damaged when impacted by the UV beam, possibly resulting in product degradation. Therefore, only Avedro recommended accessories or stainless steel surgical instruments should be used.
- Smooth metallic surfaces can reflect despite the effort to blank them. Therefore, only laser grade instruments should be used.

## 1.10 FCC Compliance Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an electrical outlet on a circuit different from that to which the receiver is connected.
- Consult Avedro Customer Service for help.

Properly shielded and grounded cables and connectors must be used in order to meet FCC emission limits. Proper cables and connectors are available from Avedro. Avedro is not responsible for any radio or television interference caused by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the user's authority to operate the equipment.

# 2 Introduction

---

## 2.1 System Overview

The Mosaic System is an electronic medical device which delivers ultraviolet light (365 nm wavelength) in a programmable pattern onto the cornea after a solution of ophthalmic riboflavin solution has been applied. UV flux and irradiation time (i.e., fluence) at the cornea are controlled by an onboard computer system.

The Mosaic is a portable system with an articulating arm to allow movement of the system for alignment of the UV Beam to the patient's cornea. The Optics Head houses the UV irradiation mechanism. The height of the Optics Head can be adjusted through a lift in the body of the system. The LED is preset by the manufacturer to emit UV radiation at a wavelength of 365 nm at an intensity of 10 mW/cm<sup>2</sup> to 100 mW/cm<sup>2</sup> ( $\pm 10\%$ ).

The treatment parameters (Riboflavin Induction Period, Total UV Energy, UV treatment patterns, UV Power and UV Pulse Cycle Times) are selected through the user interface touch screen computer.

The Mosaic System is used in conjunction with an ophthalmic riboflavin solution and a Treatment Activation card.

### 2.1.1 Major Components

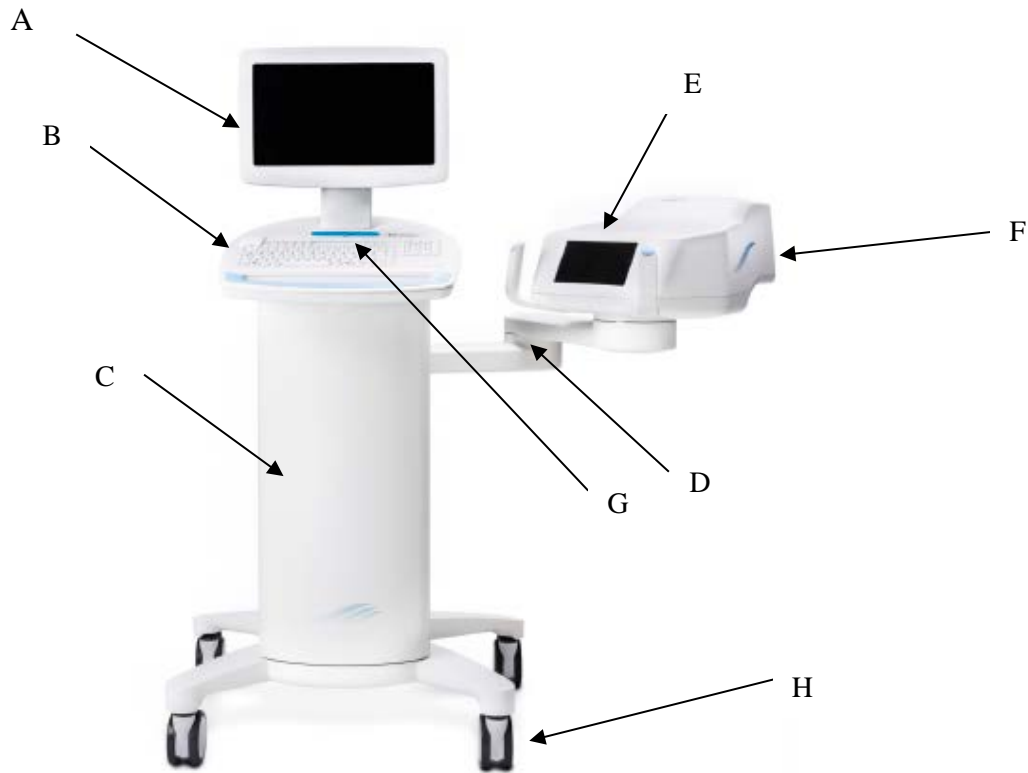
The major components of the Mosaic System include the following:

- **Articulating arm with optics head with UV source and heads up display**
- **Mosaic main console with user interface**
- **Mosaic accelerated cross-linking treatment kit** (disposable supplied separately)
- **USB port**
- **USB flash drive**

### 2.1.2 Disposables

The following disposables (supplied separately) are required for performing treatments with the Mosaic System:

- Riboflavin ophthalmic solutions
- Treatment Activation card



**Figure 2-1. Overview Illustration of System with Callouts**

- A Main Console with USB flash drive and treatment activation slot
- B System Keyboard
- C System Body with lift system
- D Articulating Arm
- E Heads Up Display
- F Optical Head
- G Stand by Switch
- H Wheels

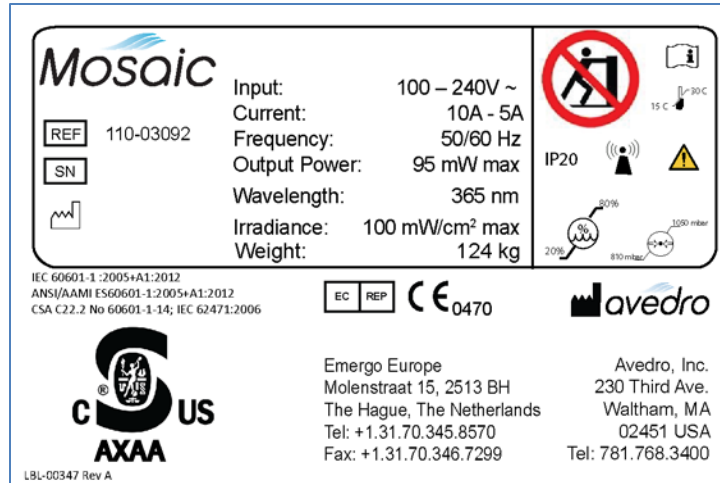


Figure 2-2. Mosaic Label



Figure 2-3. UV emitting Label

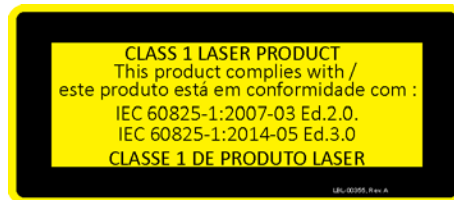


Figure 2-4 Laser Classification Label



Figure 2-5 Do Not Sit or Step on Label

### 2.1.3 Frequently Used Functions

<b>FUNCTION</b>	<b>MODE</b>	<b>SECTION</b>
Turn System On	Press Stand By switch under the keyboard in the front of the Mosaic console	3.3
Go on Stand By	Select "Power Off" on main console display	4.13
Treatment Design	Select "Design OD" / "Design OS". This initiates a new treatment design.	4.2
Scan Treatment Activation Card	Insert Treatment Activation card into slot on the left side of main console	3.4
Begin UV Treatment	Select "Begin UV Treatment". This starts the eye tracking capability of the system.	4.11
Pause	Select "Pause" to interrupt treatment at any time.	4.11









## 2.2 System Operation



Unpacking and installation of the Mosaic system should **ONLY** be carried out by trained Avedro personnel.

### 2.2.1 Touchpad/Keyboard Use

The table below identifies and describes important touchpad keys and icons unique to Mosaic System operation.

Touchpad Key	Icon	Description/Function
Power Off button (Initial screen)		Turns OFF electric power to the personal computer and goes on Stand By Mode
Start New Treatment button (Initial screen)		Directs the system to repeat the entire clinical treatment protocol so the physician can treat another patient.
UP arrow (various Clinical Protocol screens)		Increases the value of the current field.
DOWN arrow (various Clinical Protocol screens)		Decreases the value of the current field.
X button (various Device Settings screens)		Cancel all the entries on a particular screen and returns to the previous screen.
Checkmark button (various Clinical Protocol screens and Device Settings screen)		Directs the system to accept the current screen entries and to proceed to the next step.
Cancel Session button (various Clinical Protocol screens)		Cancel a treatment session for a particular patient. A prompt is then displayed to confirm your decision.
Return button (various Device Settings screen)		Returns to the Device Settings menu.



**CAUTION:** Only qualified and experienced personnel shall operate the Mosaic System.

## 2.3 UV Energy (Dose)

- The UV Energy (Dose) is the product of the UV Power (Intensity) and the UV Irradiation Time. The UV Energy, UV Power and pulsing times are adjustable and the calculated total treatment time is displayed.
- The system tracks UV Energy, UV Power, UV Irradiation Time and Total Treatment Time during the treatment.
  - Treatment Parameters:

Induction Period:	1 second – 30 minutes
UV Energy:	0 – 15 J/cm <sup>2</sup>
UV Power:	10 – 100 mW/cm <sup>2</sup> (± 10%)

**Please reference Riboflavin Instructions for Use (IFU) for formulation information.**



# 3 System Set Up

---



**CAUTION:** Only qualified and experienced personnel initially trained by Avedro shall operate the Mosaic System.

## 3.1 Important Steps before Turning on the System

- The user is responsible for assuring that the Mosaic System is functioning properly, is within normal operating ranges for temperature and humidity, and is in good-working condition before starting a treatment.
- To ensure the system is functioning properly, consider the following mandatory points:
  - Inspect the device, accessories, and connecting cables for visible damage.



**Carefully inspect the power cord for any possible damage prior to powering up the system.**

- Take into consideration all local regulations for use of portable electro-optical medical devices to minimize any risk of electromagnetic interferences.

## 3.2 Preparing the System

- Position the Mosaic System adjacent to the treatment table or chair. Lock the casters to secure the device's position.
- Ensure that the power plug is readily accessible to the user and can be easily unplugged by grasping the power cord plug and pulling on it.

## 3.3 Powering Up

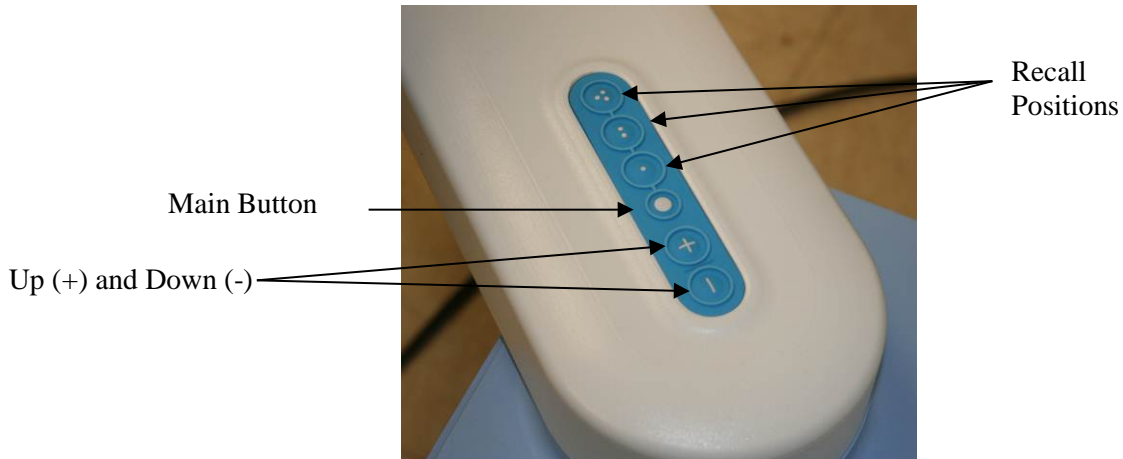
- Turn ON the single stand by switch under the keyboard in the front of the Mosaic console. This switch turns on all the system components and loads the Mosaic software.

## 3.4 Setting Optics Head Height




- Continuously press the up/down (+ / -) button and the main button (○) **simultaneously** to raise or lower the optics head to the approximate desired height above the treatment table or chair.

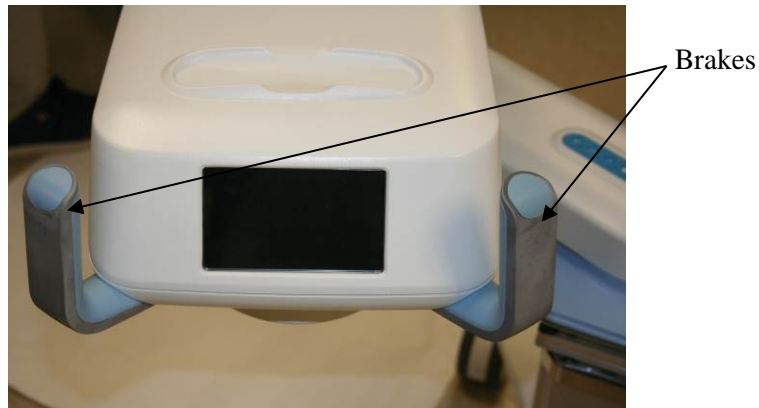


**The lift only functions when BOTH buttons are pressed and is disabled during treatment. If the lift keeps moving when the buttons are released, press the Stand By button and contact your distributor or Customer Service immediately.**



**Figure 3-1 Lift Buttons**

- There are three memory recall positions. Factory default for (1) , (2)  and (3)  is set to lower height, mid height and upper height positions respectively. The user can store a user- specific height in the memory for future use.
- In order to save a desired height to memory, press the memory button once, wait for it to flash and then press on (1), (2) or (3) for the desired recall position. The new user- specified height will now be stored in this designated recall position.
- To move the head to one of the stored memory positions, press on the (1), (2) or (3) and the main button **simultaneously**.
- Steer the optics head and align to desired position by continuously pressing on either brake button (left or right) to disengage the brakes of the articulating arm. Once the brake buttons are let go, the head locks into place.



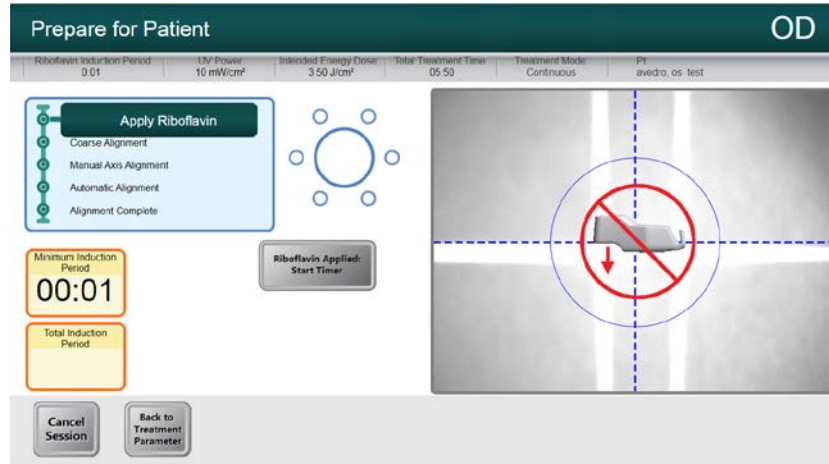
**Figure 3-2 Optics Head**



**Brake release is disabled during treatment. In case of emergency, the optics head can be steered away from patient by grabbing the handles and moving the head away.**

## 3.5 Proximity Warning

- Moving the lift of the optical head too far down may trigger a proximity sensor. This is a safety feature for the optical head not to get too close to the patient's head.
- If the proximity sensor is triggered, the lift will stop responding and a warning will flash on the screen.



**Figure 3-3 Proximity Warning: move lift up**

- Move the lift back up to clear the proximity warning or ensure that no object is obstructing the optical head underneath the UV window.

## 3.6 Startup Screen

- Once the single stand by switch above the keyboard is turned on, the Mosaic System begins a power-up sequence, loading the operating system and all configuration and reference files.
- The Mosaic software launches itself and the startup screen in **Figure 3-4** is displayed.
- To begin patient treatment, press **Start**.



Figure 3-4. Startup Screen

**NOTE:** If there is a Start-up error, please note any error messages and contact your distributor or Customer Service immediately.

**NOTE:** Screen shots are for demonstration purposes only and may have slight modifications.

# 4 Treatment Procedure

---

## 4.1 Patient Central

- ▶ Patient central is the main page where patient information can be imported or new patient files can be created. No information is stored on the system, but is instead saved on the USB flash drive. Patient topographies can be imported via the patient central from the USB flash drive for guided treatment patterns.



**A USB flash drive should be inserted in the USB slot () to proceed to a treatment plan.**

### 4.1.1 Entering New Patient

- Enter a new patient's data by clicking on "New Patient" and filling in the fields with the patient's information.
  - Note: Patient's "First Name" and "Last Name" and Patient "ID" are required fields. "Sex" and "D.O.B" will remain as default if not edited.

### 4.1.2 Importing Patient Topographies

- ▶ Patient topographies are exported onto the main root menu of a USB flash drive then used with the Mosaic system.
- After inserting the USB flash drive, click on "Import / Refresh Patient List" to refresh the page and list all patients on the USB drive.
- Patient data exported from a commercial topographer can be distinguished under the "Source" column.

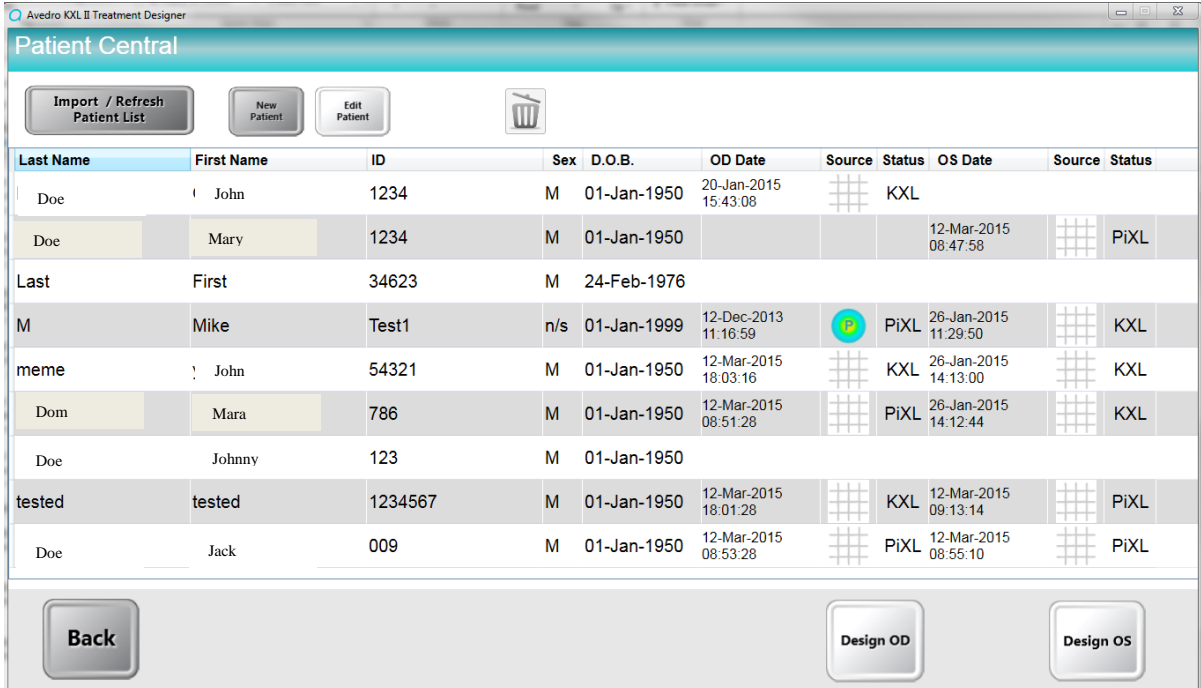


Figure 4-1. Import/Enter Patient Data Screen

## 4.2 Creating Treatment map

- Select the patient to be treated.
- Select “Design OD” or “Design OS” to create right or left eye treatments respectively. This takes the user to the Treatment Design Window.

## 4.3 Screen Layout – Treatment Design Window

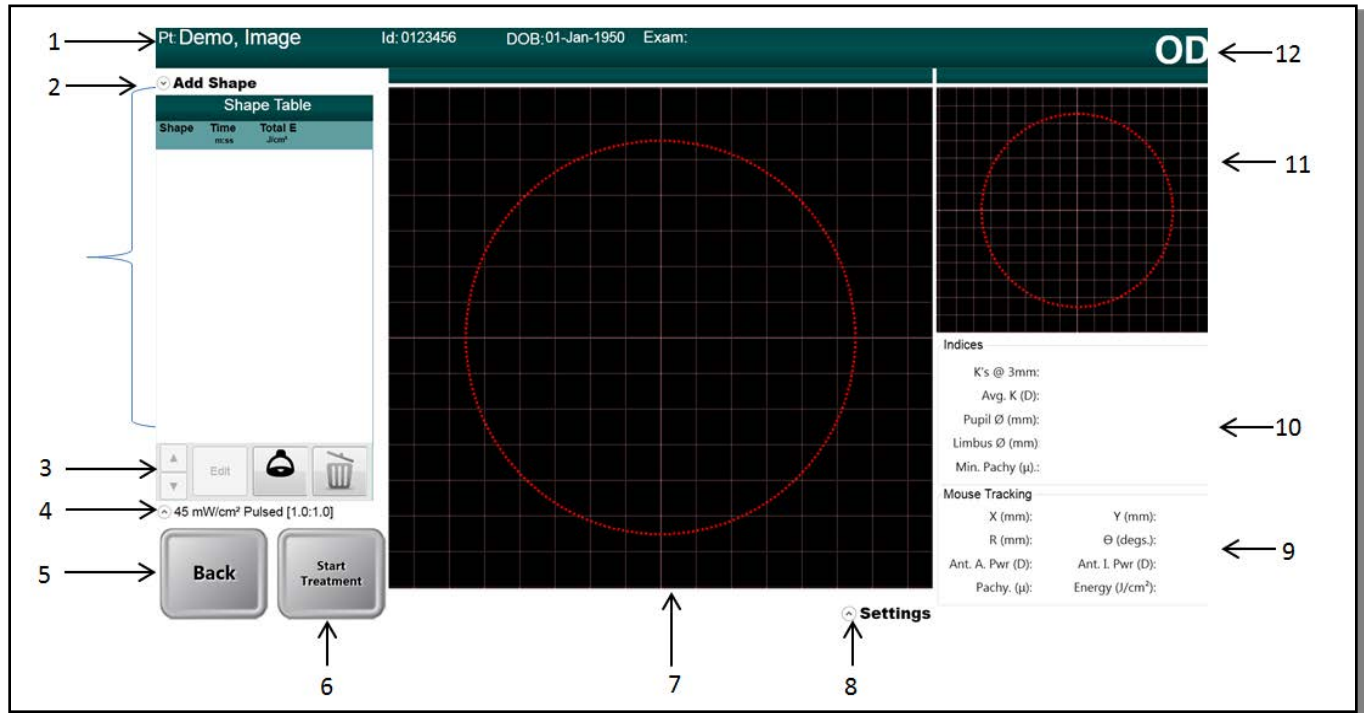


Figure 4-2 Main Screen Layout

- |   |   |    |                                |
|---|---|----|--------------------------------|
| 1 | Patient Information   | 7  | Design window with map overlay |
| 2 | Treatment/Shape Selection                                     | 8  | Map Settings                   |
| 3 | Treatment change, edit or delete                              | 9  | X/Y Coordinate tracking        |
| 4 | Irradiance power Selection –<br>Continuous/Pulse UV selection | 10 | Indices                        |
| 5 | Back to Patient Central                                       | 11 | Secondary Map                  |
| 6 | Start New Treatment   | 12 | Left/Right Eye                 |

## 4.4 Create Treatment Map

Select “Add Shape” (2) to select the type of treatment per clinical requirements. KXL treatments are limited to one 9 mm circle. PiXL treatments can have up to five shapes that can be juxtaposed or overlaid together.

### 4.4.1 KXL treatment (KXL treatment Activation Card Required)

- Select the KXL treatment.
- Click or touch on the Main Design Window to place a 9 mm circle.

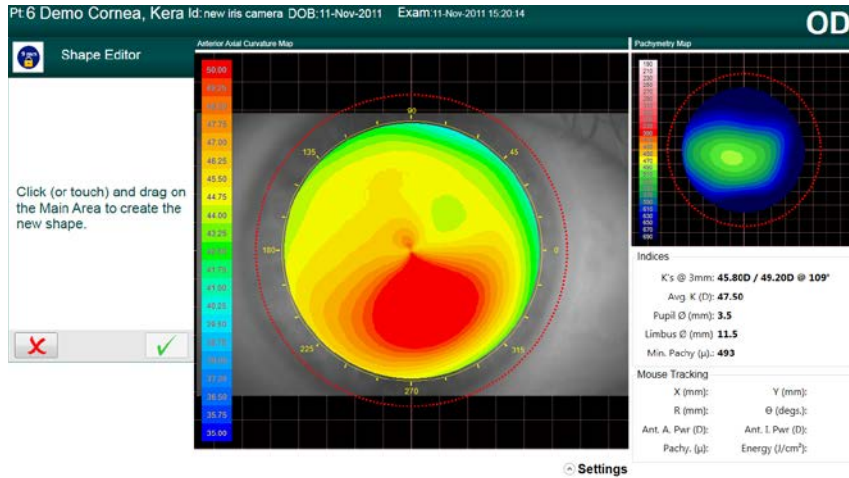


Figure 4-3 Click/Drag to set KXL treatment

- The circle can then be centered on the limbus, pupil or vertex (if available). If no selection is made, the circle automatically centers around the vertex (for topography imports) or centers around the grid (for no topography imports).
- Adjust the energy dosage. Treatments energy and irradiance limits are controlled by the KXL Treatment Activation Card. Tracking feature is not available during a KXL treatment.

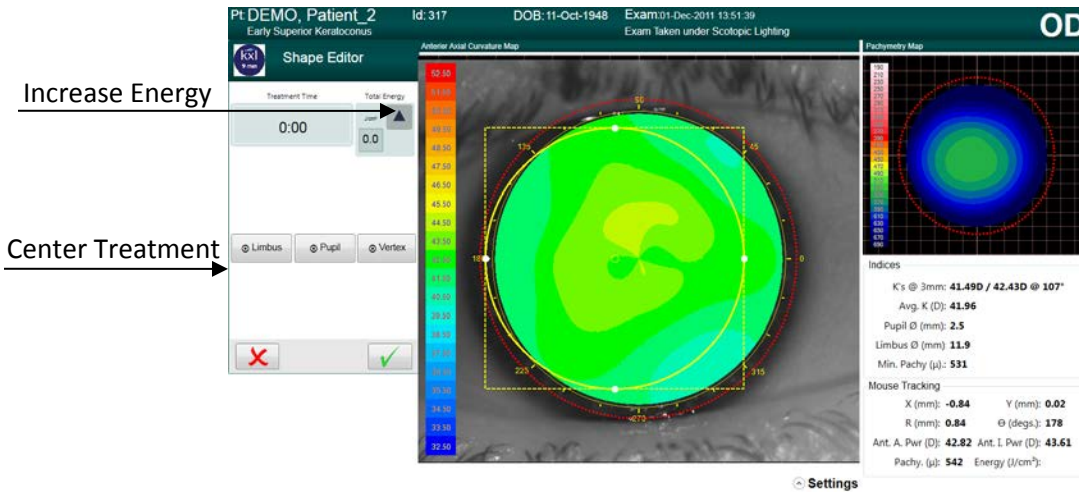


Figure 4-4 Adjust Energy for KXL treatment

#### 4.4.2 PiXL treatment (PiXL treatment Activation Card Required)

- Select the PiXL treatment from the “Add Shape” menu.
- Select a PiXL treatment shape from the drop down list:
  - circular shapes of user-defined diameter (7 mm, 9 mm and 11 mm circles are pre-set);
  - ellipses of user-defined diameter and axis;
  - single arcuate sector of user-defined size, thickness and angle;



- symmetrical double arcuate sectors of user-defined size, thickness and angle;
- annular surface with user-defined diameters;
- or, any free-hand user-defined drawn surface.

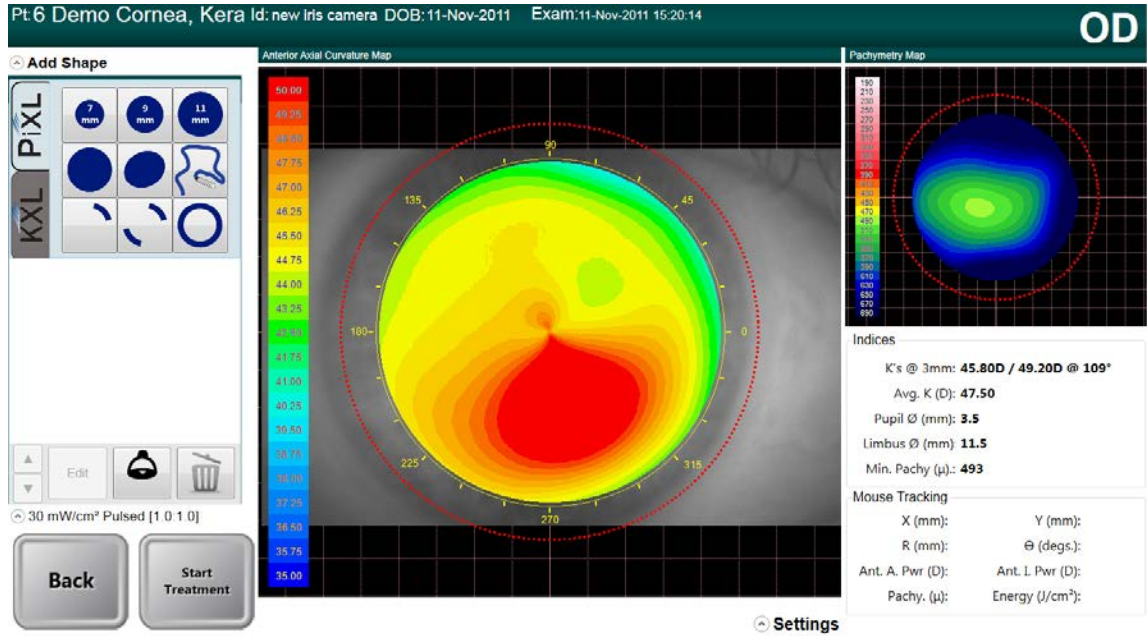


Figure 4-5 Treatment Shape Selection

- Select the Up/Down Arrow (1) in Figure 4-6 to adjust the energy required for the specific treatment shape. Treatment time automatically adjusts itself based on energy dose selected.

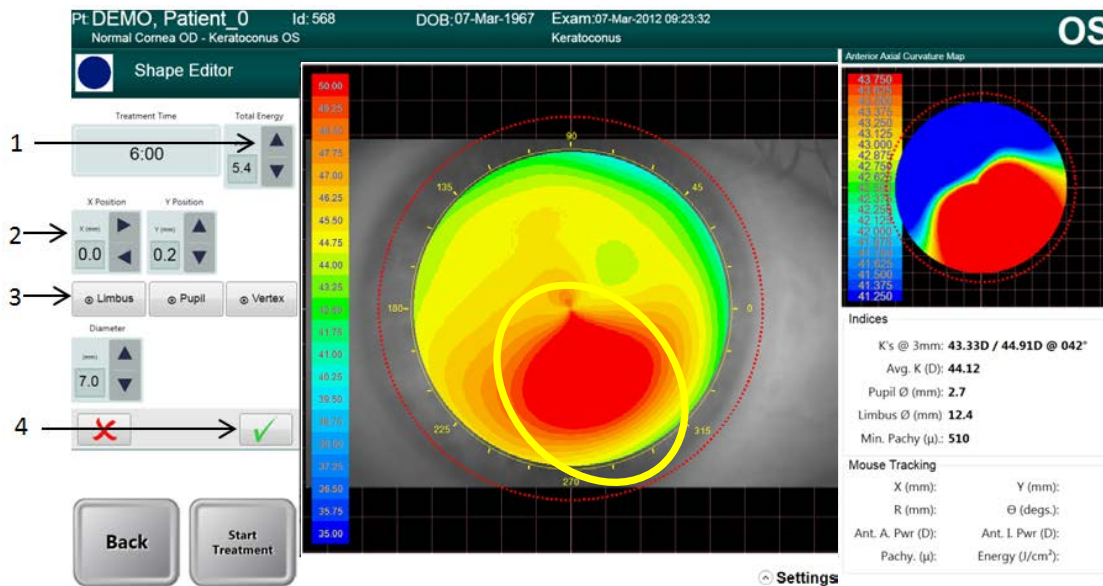


Figure 4-6 Selecting Energy Dose and Centering Pattern

- Use the X Position and Y Position (2) to adjust the location or center around the Limbus, Pupil or Vertex (3) by selecting one of the three buttons.
- Press green checkbox (4) to continue.
- Up to four additional shapes can be added (total of 5) and each shape can be assigned with its own total energy selection.
  - Press green checkbox to continue for each shape selected.

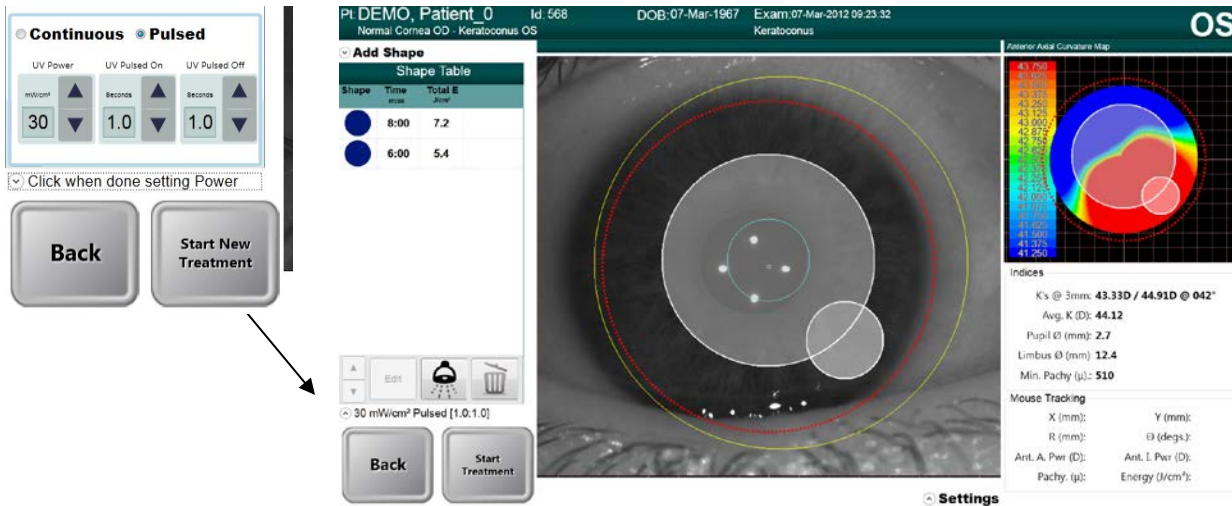


Figure 4-7. Power and Pulse Selection

#### 4.4.3 Power (Irradiance) setting

- Power setting can be modified by clicking on the drop down menu beside the power (irradiance) value (see figure 4-7).
- Pulsed or Continuous UV can be similarly selected. When Pulsed UV is selected, the time on and off for Pulsed can be adjusted using the up/down arrows. Pulsing times range from 0.1 s – 4.0 s in 0.1 s increments.
- Once energy, power and all other parameters have been entered, select “Start Treatment” to proceed with the treatment.

#### 4.4.4 Multiple Treatment Order

- The shape layer order plays an important role. The first shape has higher priority than the next shape in setting the DMD.
  - ▶ Altering the shape order changes the end treatment: the top shape layer has higher priority and the DMD setting will be prioritized according to that higher priority shape. The figure below shows an example of how changing the order of two shapes changes the end treatment to the patient.
  - ▶ In the first treatment summary (Fig 4-8), the higher energy smaller circle has higher priority; therefore, even when the 7 mm circle treatment is complete after 6 minutes, the DMD keeps the smaller circle ‘on’.

- ▶ In the second treatment summary, the 7 mm circle treatment has higher priority. Therefore, when the 6 minute treatment is up, the DMD mirrors in that area shut off since the treatment is up and the resultant treatment resembles the smaller circle with an area cut off.

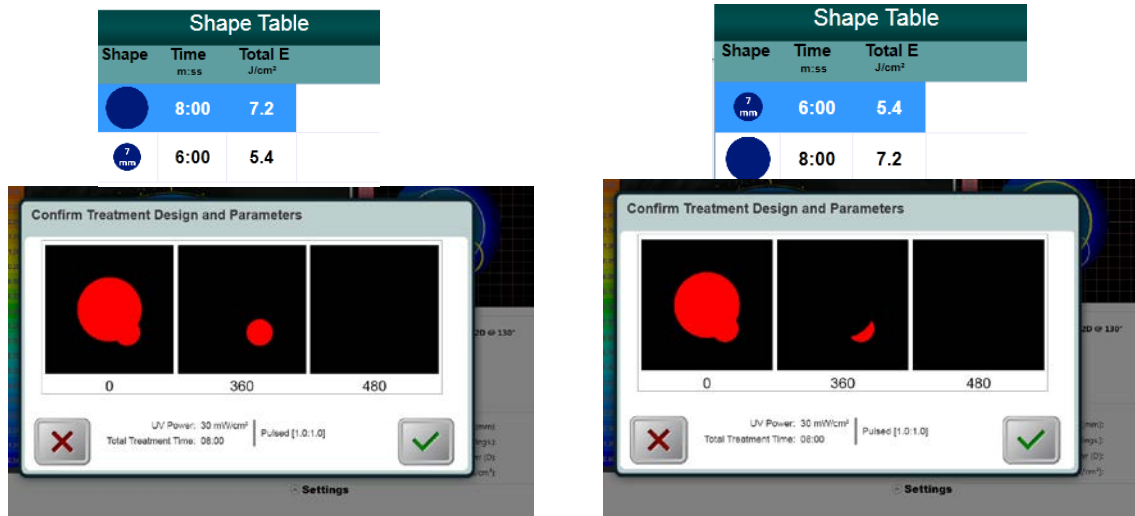


Figure 4-8. Resulting Treatment Pattern

## 4.5 Treatment Activation Card

**NOTE:** Screen shots are for demonstration purposes only and may have slight modifications.

### 4.5.1 Multi-use disposables

- When “Start Treatment” is selected, if no Treatment Activation card has yet been inserted, an error message will show up to remind the user to insert the RFID card now into the slot on the left side of the main console before proceeding. Once a multi-use activation card has been scanned, the display will show the number of treatments remaining on the card.

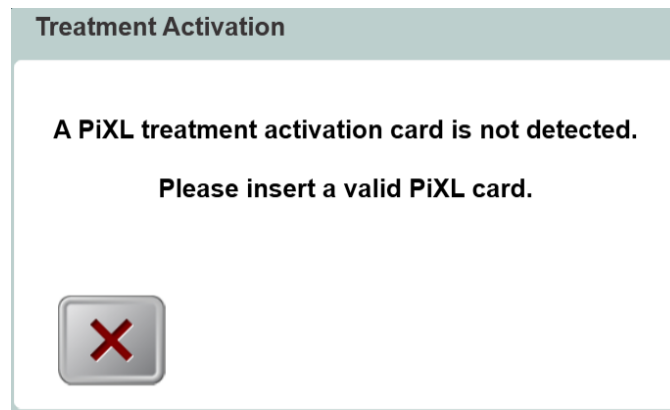


Figure 4-9. Activation Card not detected

- Prior to the final treatment, a message will be displayed to warn the user of only one treatment remaining.

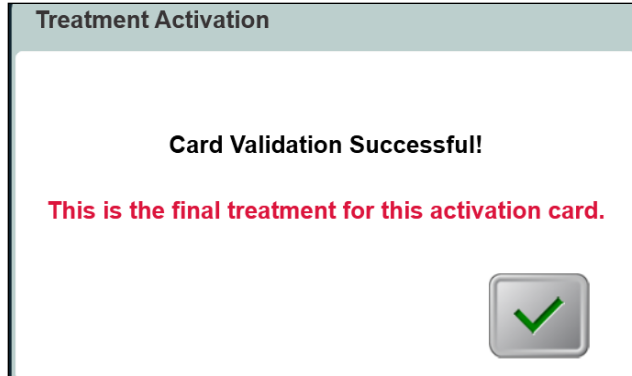


Figure 4-10. Final Treatment

## 4.5.2 Treatment Activation Card Limit

- Once card has been read, a window will appear (“Confirm Treatment Design & Parameters”) showing the summary of the treatment parameters similar to Fig 4-8.
- If the user has selected a parameter that is outside the allowable value(s) controlled by the Treatment Activation card (UV power, energy, treatment time, etc.), the user will not be allowed to proceed with the treatment. The user will have to go back and edit the parameters that are accepted with the Treatment Activation Card.

## 4.6 Set Riboflavin Induction Period

- Specify the desired Riboflavin Induction Period (1 sec – 30 min).
- When finished entering parameters, select the Checkmark button.

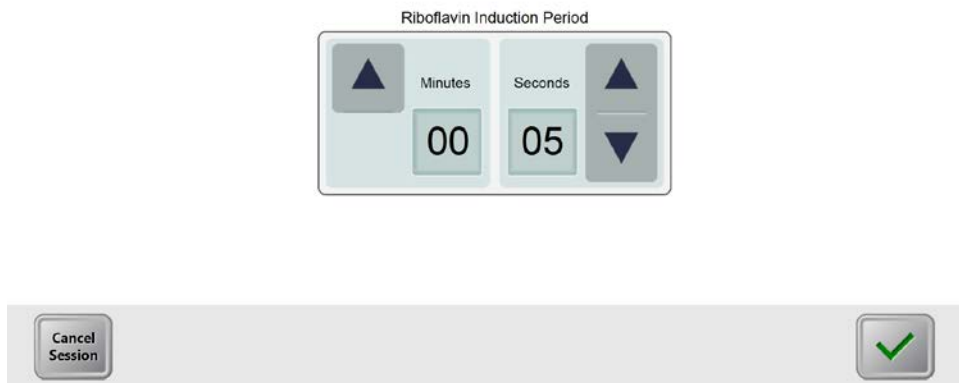


Figure 4-11. Induction Period Screen

**NOTE:** Default treatment parameters will auto-populate user selectable fields but are adjustable.

## 4.7 Preparing the Patient

- Ensure that the patient is lying flat on a patient table or chair. His or her head should rest in a head rest.
- Adjust the table or chair and head rest so that the patient can rest comfortably for the duration of the treatment without head movement.
- When needed, mark the visual axis on the cornea using a corneal Gentian Violet marker.
- Apply a lid speculum and optional drapes using standard clinical technique.



**CAUTION: Riboflavin (vitamin B2) is not a part of the Mosaic System described in this manual. For details of component use, please refer to the component's Instructions for Use.**

## 4.8 Apply Riboflavin

- Apply Riboflavin to the area of treatment in accordance with the Riboflavin Instructions for Use (IFU).
- Once the Riboflavin is applied to the eye, start the induction by selecting “Riboflavin Applied: Start Timer”.

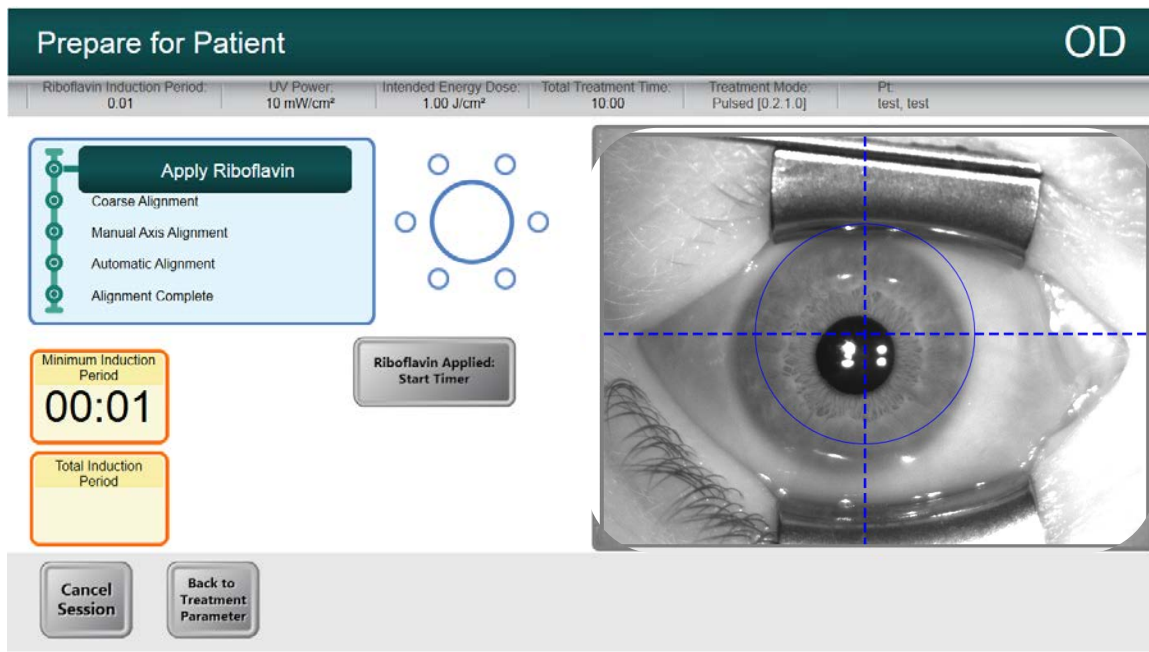


Figure 4-12. Apply Riboflavin & Start Timer Screen

## 4.9 Coarse Alignment with Laser Crosshairs

- Pressing the buttons on the handles of the articulating arm to disengage the brakes, steer the optics head over the patient's head.

- Align the optics head such that the laser crosshairs are closely aligned/overlapped on each other. The height of the optics head may require to be adjusted by using the lift system to align the laser crosshairs.
- Align the crosshairs on the Heads Up Display to the center of the pupil of the eye to be treated. Release the buttons to engage the brakes once closely aligned.
- Alignment should aim to position the center of the pupil to the center of the crosshair and the blue circle. The blue circle refers to the center of the DMD and the pupil should be aligned to this center for more optimum pupil tracking.

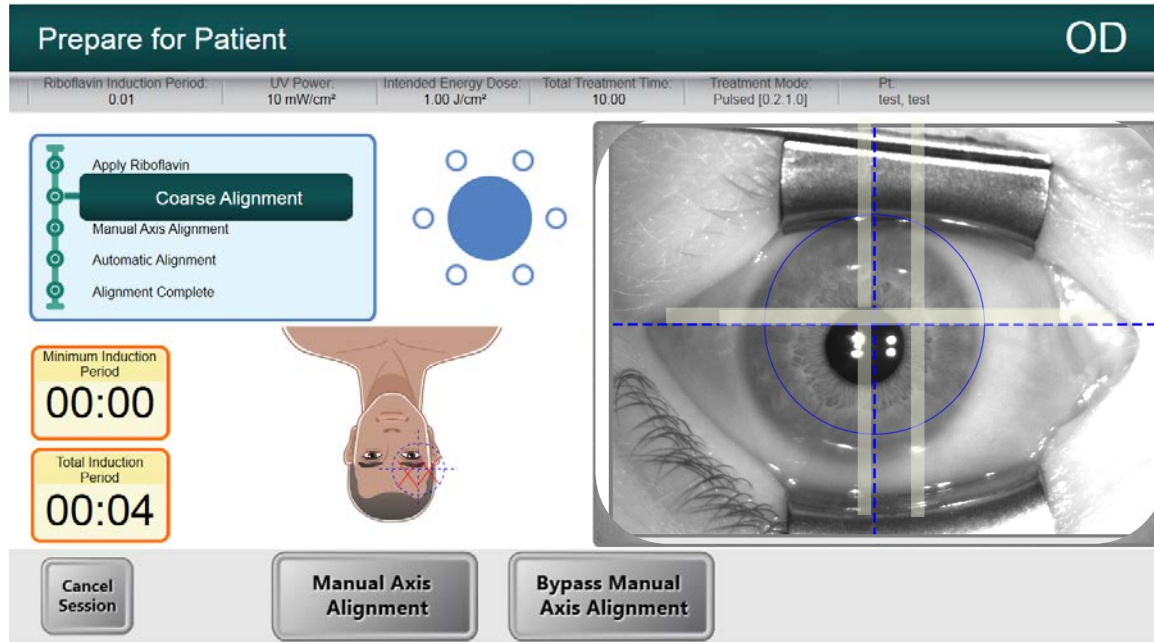


Figure 4-13 Coarse Alignment with lasers

### 4.10 Visual Axis Marker Alignment Mode (No topography import)

- ▶ **Visual Axis Marker Alignment Mode should be used on patients who have had their corneal axis marked along the horizontal meridian with a Corneal Gentian Violet marker previously. If the corneal axis has not been previously marked and if no axis registration is desired, user can bypass the manual axis alignment.**
- Once coarse alignment is over, select the Visual Axis Marker alignment mode to illuminate the cornea rendering the axis markers on the cornea clearly visible.
- Pressing the buttons on the handles of the articulating arm to disengage the brakes, rotate the optics head such that the visual axis markers are aligned with the horizontal blue line on the Heads Up Display.
- Alignment should continue aiming to position the center of the pupil to the center of the cross-hair and the blue circle.

- Once aligned, release the brakes and select the Auto Alignment Mode.

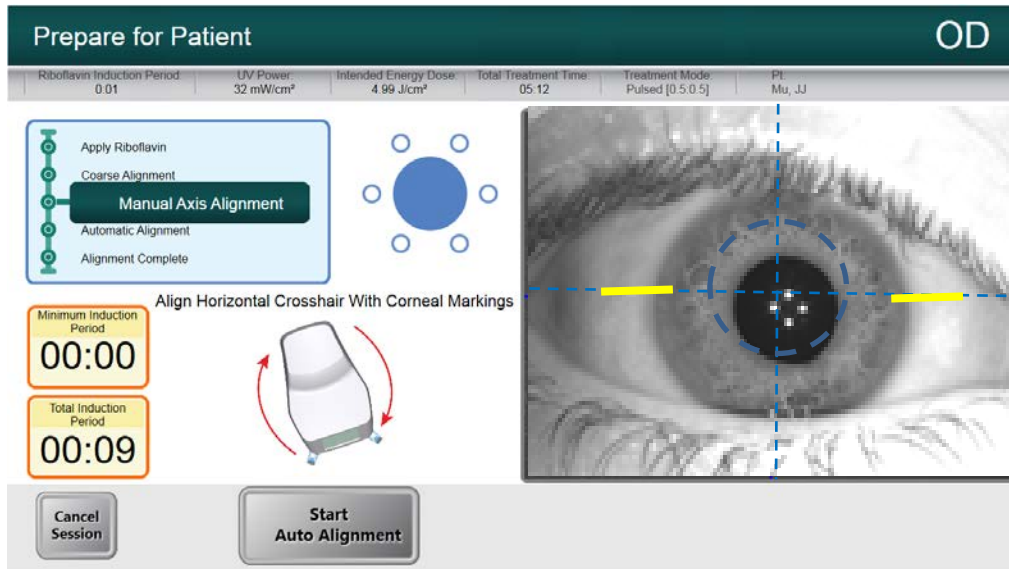
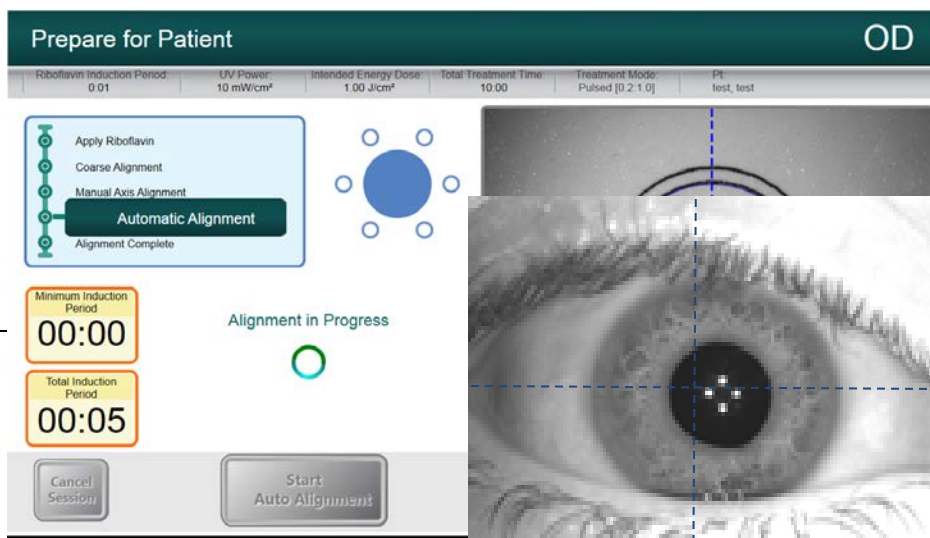


Figure 4-14 Manual Axis Alignment Mode

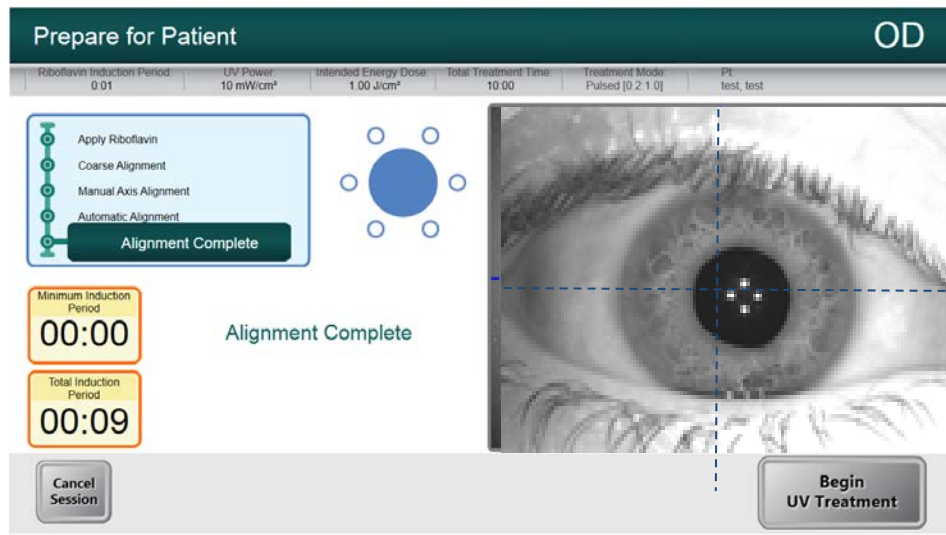
## 4.11 Auto-Alignment

- “Start Auto-Alignment” is selected to engage the auto alignment process. The alignment process is a three step process. The system:
  - auto-aligns in X-Y axes for pupil tracking;
  - auto-aligns in the Z axis for best focus;
  - performs iris registration (when available)
- Iris registration uses the iris image from the imported topographer (when available) and performs an iris registration to compensate for cyclo-torsion. For cases where a topography is not available, the visual axis marker mode is available to allow the user to manually adjust for cyclo-torsion when a patient’s cornea is previously marked with a corneal gentian violet marker.



**Figure 4-15 Start Auto Alignment**

- After the alignment sequence is performed, the user is alerted that alignment is complete.



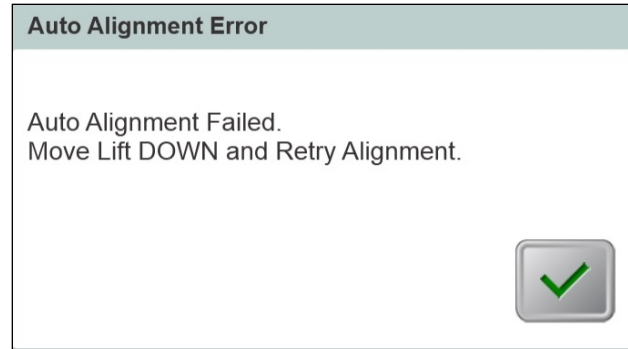
**Figure 4-16 Alignment Complete**

- Once alignment is completed, and riboflavin induction is over, the “Begin UV Treatment” button appears and user can select to start treatment.

#### 4.11.1 Unsuccessful Auto-Alignment

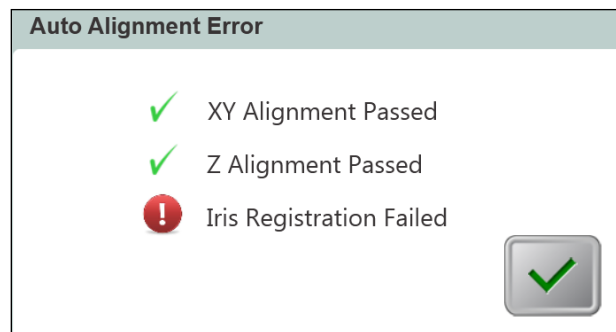
- Auto-alignment may fail during any of the three processes for various reasons including the head being out of range, or poor image contrast. If so, an error message will pop up to notify the user.
- Some causes for z-alignment failure may be due to the internal z-motors running out of range. In such a case, the error message will instruct the user to move the lift up or down before re-alignment. The user should use the lift to move the head further up or down until the image of the eye looks more focused. This will facilitate the auto focus algorithm when the user re-starts the auto-alignment process.



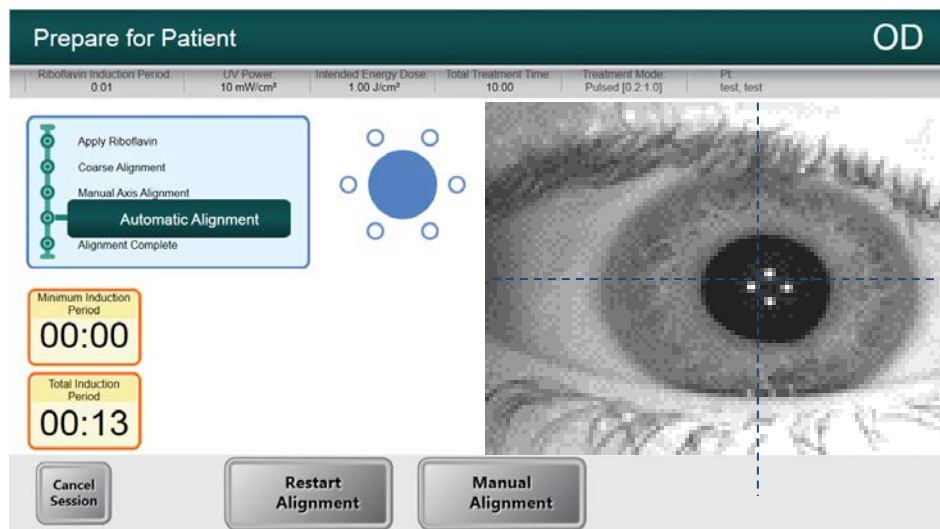


**Figure 4-17 Z-Alignment Error**

- If the iris registration fails, the user is notified of the failure and the user has the option to re-start the auto-alignment or forego auto-alignment and proceed with manual alignment.



**Figure 4-18 Iris Registration Error**



**Figure 4-19 Re-start Auto Alignment or Manual Alignment Option**

- Skipping auto alignment to do manual alignment will provide the user of motor controls to manually align in X-Y and Z direction.



**WARNING:** In case of manual alignment for asymmetrical treatment shapes, the user should manually perform rotational alignment in order to accurately apply the treatment.

- Within Manual Alignment Mode, the user can toggle between Manual Axis Alignment mode for aligning the axis to corneal markings on the patient’s cornea, or the Alignment lasers for manual alignment in X-Y and Z direction.

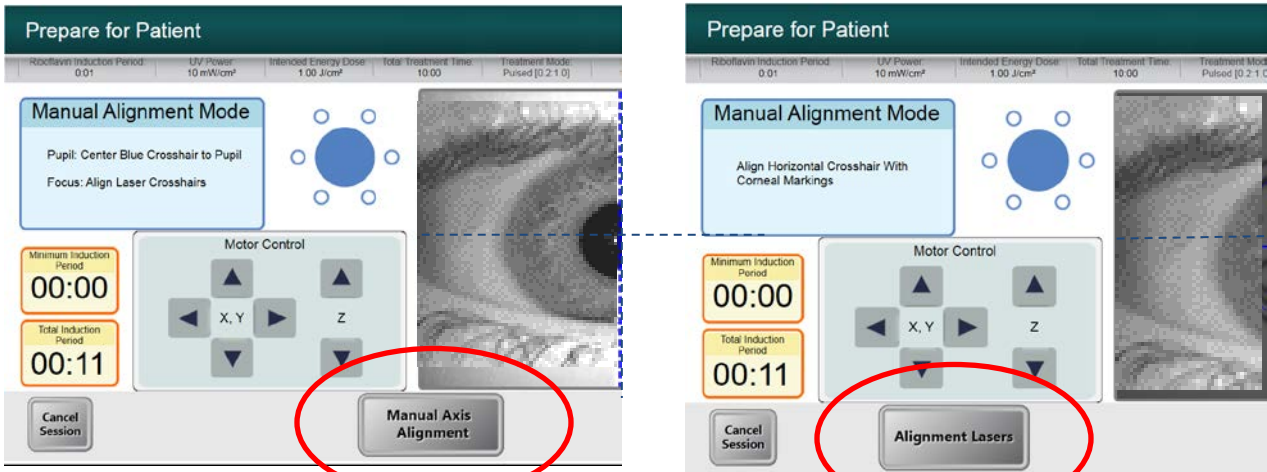


Figure 4-20 Toggling between Manual Axis Alignment & Alignment lasers

## 4.12 Begin UV Treatment

- The user is notified by an audible sound once induction and alignment is complete. Select “Begin UV Treatment” to start UV irradiation. Once UV is on, the software will track the eye and the UV pattern will follow the eye, irradiating the same specific region of the cornea.



**WARNING:** Start treatment only after the photosensitizer is applied.

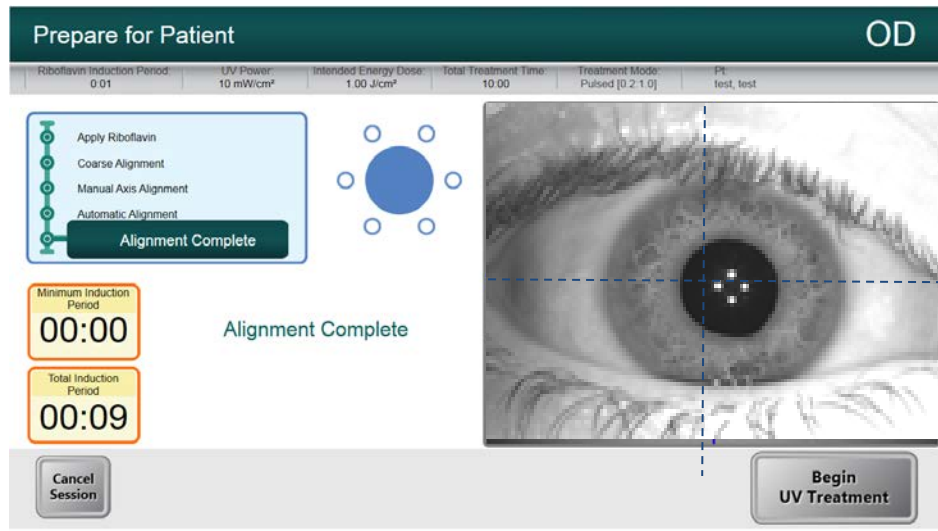


Figure 4-21 Begin UV Treatment

- A Treatment in Progress bar shows the progress of the UV treatment and Treatment Time Remaining, Total Energy Delivered and Total Induction Period are displayed.

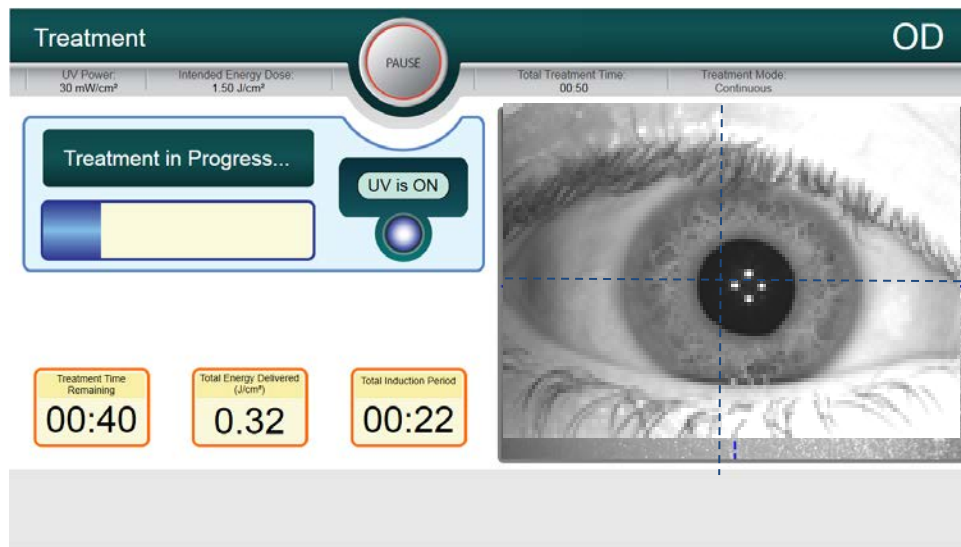
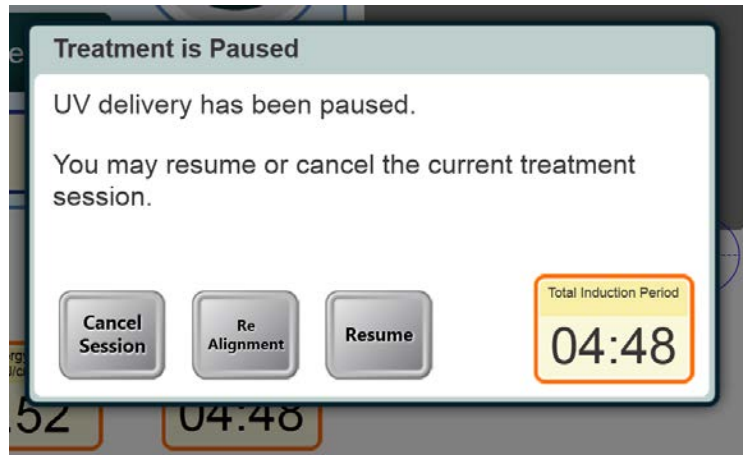


Figure 4-22 Treatment in Progress

- UV treatment can be paused or interrupted at any time by selecting the "Pause button". This turns the UV irradiation off.

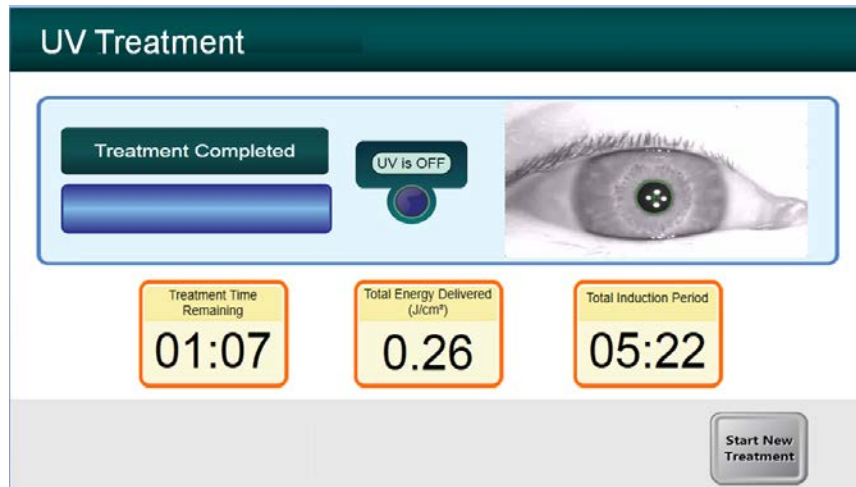


**Figure 4-23 Pausing UV Treatment**

- Prior to resuming UV treatment, ensure that the alignment is correct. The user can choose to re-align or proceed without re-aligning and select “Resume” to start the UV irradiation again.

### 4.13 Treatment Complete

- At the completion of a treatment the Total Treatment Parameters will be displayed and the screen will show Treatment complete.



**Figure 4-24. Treatment Complete Screen**

- To exit treatment and / or start a new treatment select “Start New Treatment”.
- If treatments are complete Power OFF the system using the “Power Off” button on the Main Screen and unplug the system.
- Carefully remove the device from the patient area.
- Remove speculum and provide post-op treatment according to appropriate clinical protocol.

## 4.14 Settings

- The settings button allows the user to save a report of the treatment parameters to the USB stick.



Figure 4-25 Settings to save report

- Select the “PDF” button. This saves a report to the USB drive.

## 4.15 Powering Down the System

- Press the “Power Off” on the touch screen monitor to go on Stand By Mode.
- Unplug the system to power down.

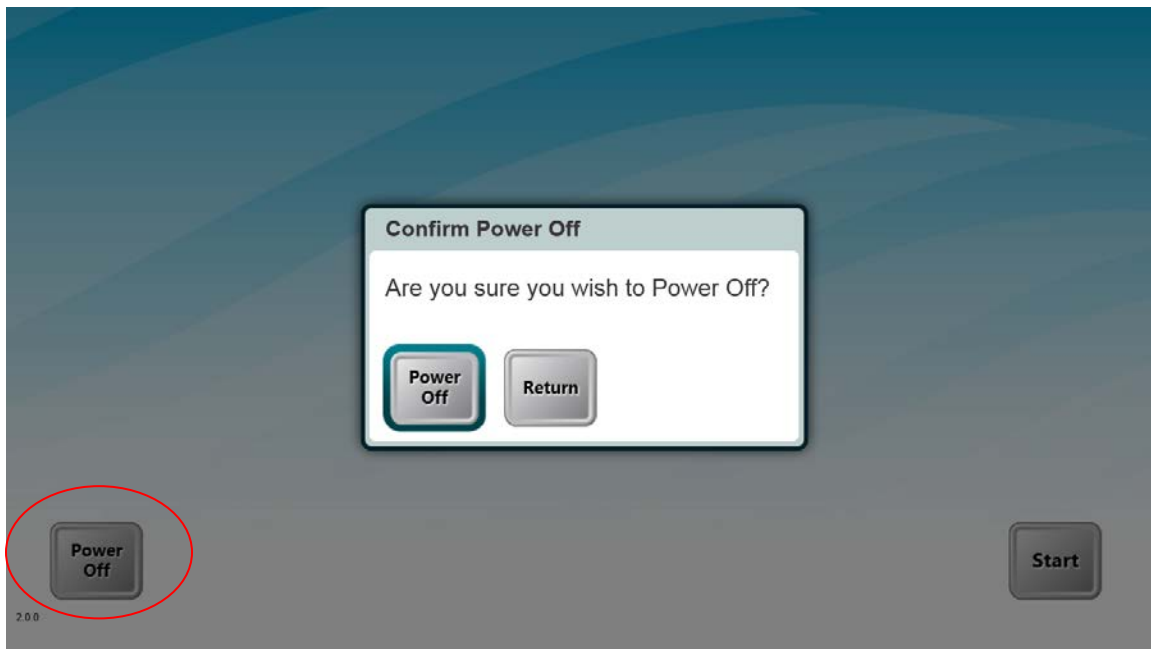


Figure 4-26. Power Down System



# 5 Device Settings

---

## 5.1 Using the Device Settings Menu

- With the Initialization screen (New Patient Start) displayed, press and hold the Mosaic on the touch screen.

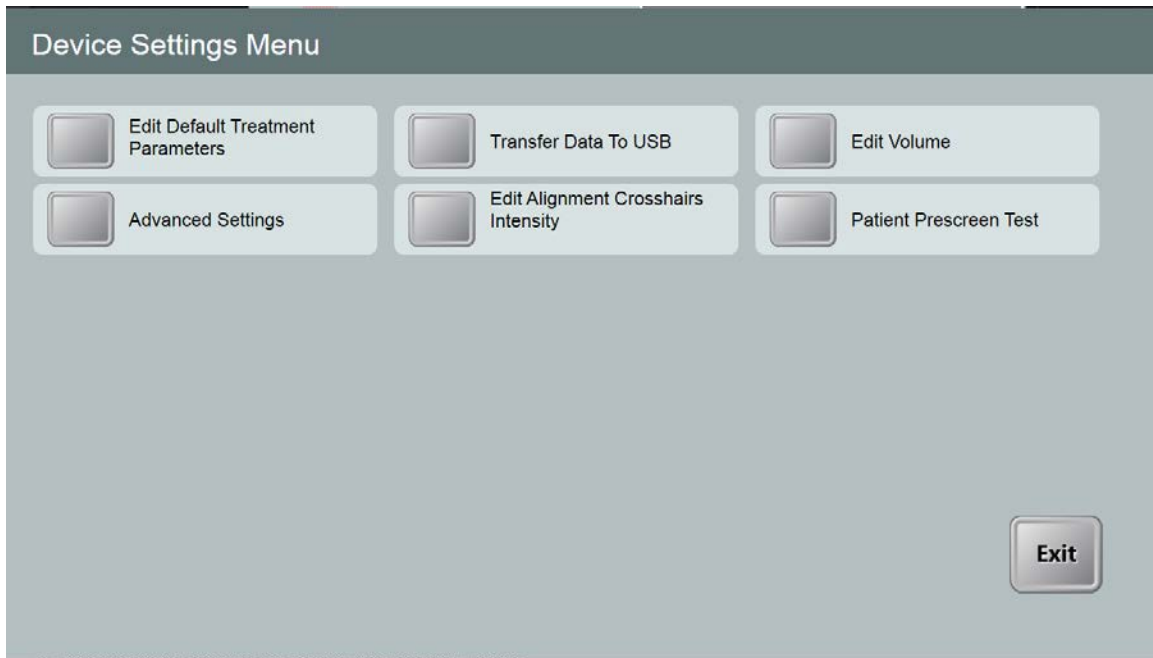


Figure 5-1. Device Settings Menu

### 5.1.1 Advanced Settings

- Advanced Settings are only available to Avedro and Service personnel with a Mosaic Advanced Settings access card. If selected the user will be prompted to scan an access card.

### 5.1.2 Transfer Data to USB

- Select "Transfer Data to USB" on the Device Settings menu.

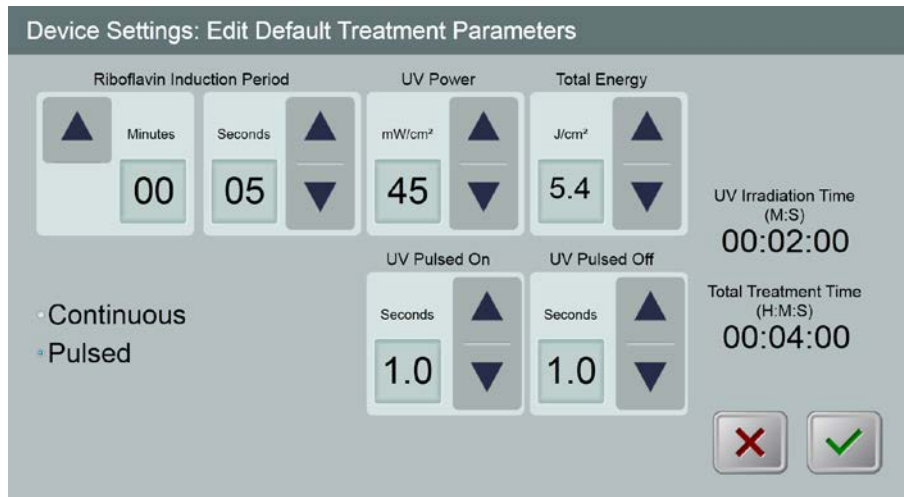


**Figure 5-2. Device Settings Transfer to USB**

- Insert a USB device to a USB port and then select “Copy treatment data to USB”. The system begins transferring the treatment data and shows a progress bar of the transfer process as shown in the screen below.
- Once complete, select “Return”. The system will return you to the Device Settings menu.

### 5.1.3 Editing Default Treatment Parameters Screen

- The Edit Default Treatment Parameters option allows a user to set the default treatment parameters that are displayed on entry to the Set Induction Time, Set UV Parameters screens, Total Energy or Pulse and Continuous.



**Figure 5-3. Edit Default Treatment Parameters (Continuous & Pulsed)**

- When finished entering treatment parameters, select the green Checkmark.



### 5.1.4 Patient Prescreen Test

The patient prescreen test allows the user to prescreen a patient with an intra-ocular lens (IOL) to ensure that the IOL will not interfere with the auto alignment and eye tracking system during a future PiXL treatment. Prescreening should be performed with a lid speculum in place and room lighting configured as it would be during a PiXL treatment. Note that no UV light is delivered during the prescreen. Only diagnostic NIR and pulsed yellow light are used for this process.

- Select Patient Prescreen Test. User will be prompted to insert a USB drive (with at least 6 GB of available space) in the device.

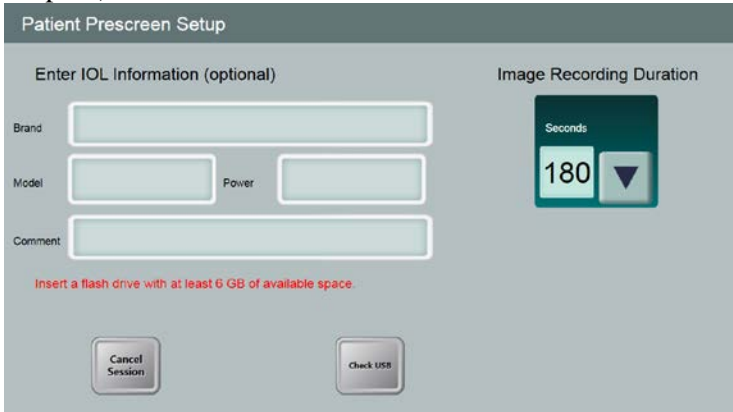


Figure 5-4 Insert flash drive

- The user will then be prompted to enter information regarding the IOL brand, model and power. This information is optional and is not required to proceed with the screening.

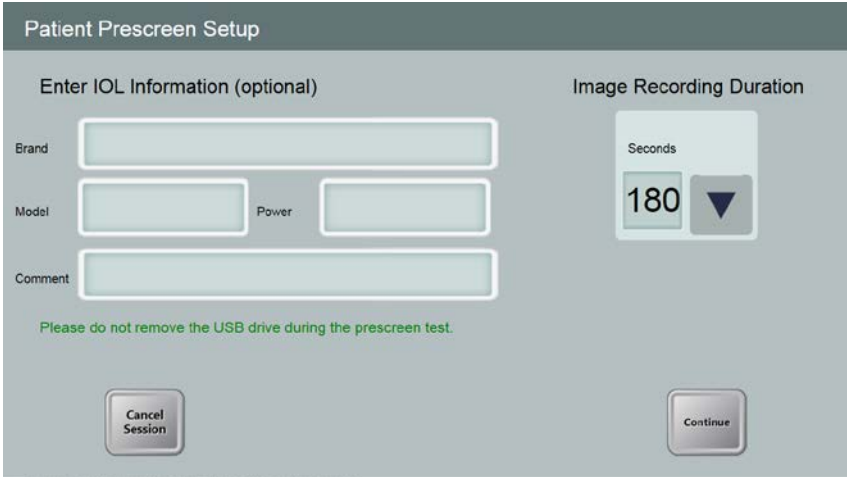
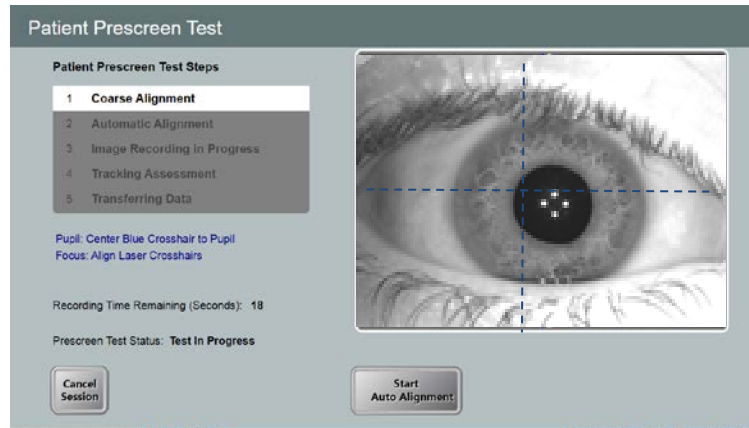


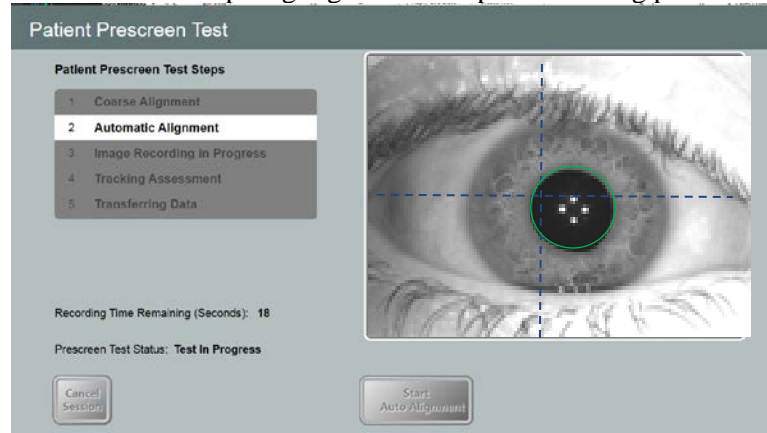
Figure 5-5 Enter IOL Information

- Image Recording Duration allows the user to modify the video recording length (varies from 90s to 180s with default at 90s).
- Once the information is entered and the image recording duration is specified, the user can select Continue to proceed with the screening.



**Figure 5-6 Alignment Step**

- In the Patient Prescreen Test, the user is prompted to perform the coarse alignment procedure (similar to section 4.9).
- Once coarse alignment is performed, select “Start Auto Alignment” to start the auto-alignment.
- The device starts auto-alignment as well as image recording.
- The Patient Prescreen Test Steps highlights each step as it is being performed.



**Figure 5-7 Screening Step Process**

- The user should observe the screen throughout the recording period to confirm that the green circle is correctly tracking the pupil during the auto-alignment and image recording steps.

### **Failure Modes**

- If auto-alignment fails, the user has two more attempts to repeat the auto-alignment. Confirm that the patient is properly positioned prior to repeating auto-alignment.
- If all three auto-alignment attempts fail, the prescreen has failed and the user should not proceed with the PiXL treatment.

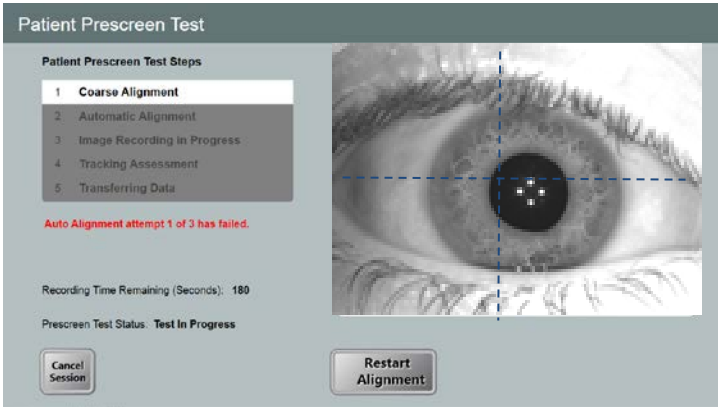


Figure 5-8 First attempt fail

- If auto-alignment succeeds but eye tracking failures are detected by the system during the image recording period, the prescreen has failed and the user should not proceed with the PiXL treatment.

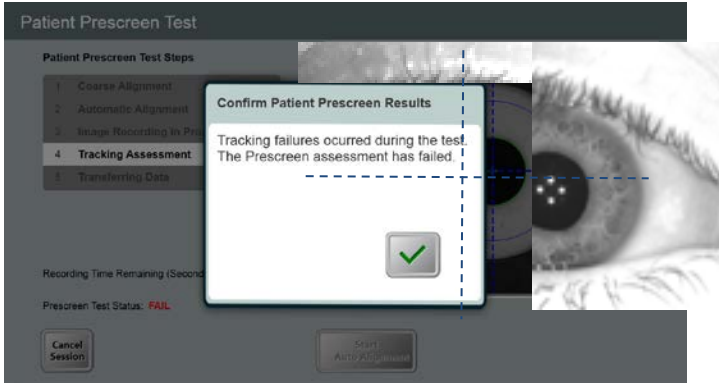
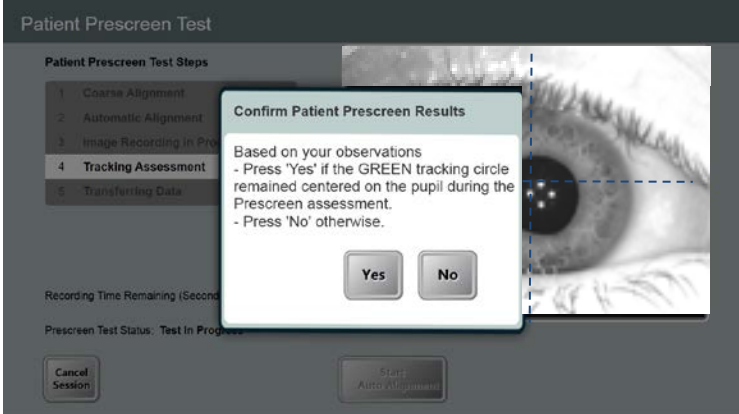


Figure 5-9 Failed prescreen assessment due to eye tracking errors

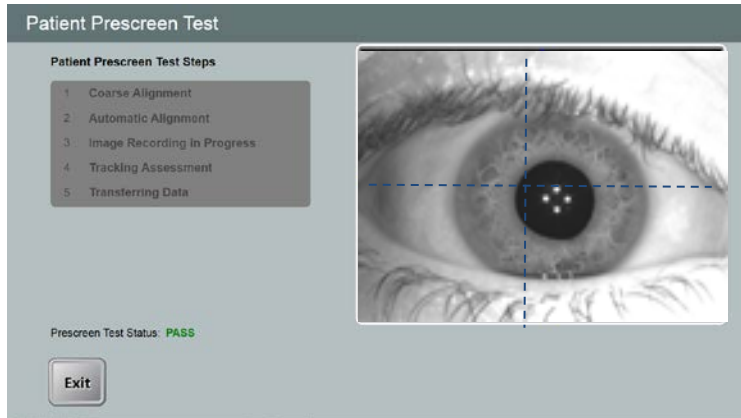
**Pass Mode**

If auto-alignment passes and no eye tracking failures are detected by the system, the user is then required to confirm that the green circle correctly tracked the pupil throughout the recording period.



**Figure 5-10 Confirm Patient Prescreen Results**

- Following a positive confirmation, the prescreen test will indicate that the test has passed and data will be transferred to the USB drive. Do not remove the USB drive during this step.



**Figure 5-11 Prescreen test Pass**

- If the patient passes the test, this patient can then be treated with PiXL treatment.

# 6 Maintenance / Service

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By definition, “maintenance” refers to those non-technical procedures an everyday operator should perform to keep the system working properly. The word “service,” by contrast, refers to tasks that are intended to be performed only by a qualified service representative.

## 6.1 Installation Policy

- For each new Mosaic System customer, your Avedro-authorized distributor provides a full initial installation and start-up of the system by trained personnel. Following initial installation and once the system is operating properly, the Avedro representative may also provide basic training to a designated operator about the operation of the Mosaic System.
- Consequently, this manual does not include any specific instructions relating to installation or set-up of the system. Per your service agreement, any further hardware adjustment, other than what is specified for normal operation, should be performed by, or with the guidance of, an Avedro-authorized distributor.

## 6.2 Customer Maintenance

- In general, there is no customer maintenance required for The Mosaic System. All technical maintenance or service will be performed by a qualified service representative while under service contract. If you have trouble with your system, refer to the troubleshooting section below or call your local Avedro Representative.

## 6.3 Warranty Information

- A Warranty is supplied separately with the purchasing information.

## 6.4 Per Patient Disposables

- Per Patient Disposables can be ordered from Avedro or your Avedro-authorized distributor. **Use only Avedro products or Avedro-approved products with your Mosaic System.** Avedro shall not be liable for damage to or malfunction of the system, which it deems, was caused by the use of unauthorized materials.

## 6.5 Trouble Shooting

- The Mosaic System checks its status at start-up automatically. If the status is incorrect, the software prevents the operator from initiating treatments when the system is in the normal operating state.

## 6.6 Directions for Sterilization or Disinfection

- No components of the Mosaic System are designed to be sterilized by the operator. External cleaning and disinfection ONLY is recommended. For disinfection purposes, use only isopropyl alcohol spray or preparations. Use small amounts of liquid and soft fiber-free wipes.

## 6.7 Cleaning the System

- Use a soft damp cloth to clean the system.
- The exterior of the Mosaic System can be cleaned using a lint-free cloth dampened with dilute bleach, soapy water, or isopropyl alcohol.
- A 70% isopropyl alcohol or 10% chlorine bleach solution can also be used if necessary.
- DO NOT submerge the system in liquid or pour liquid onto the system.



**CAUTION:** Remove the power supply cord from the main outlet and turn off the power switch prior to any cleaning procedure.

**CAUTION:** Aggressive cleaning agents, especially those containing abrasives or aggressive solvents can damage component surfaces.

- The glass window of the beam aperture must not under any circumstances be in contact with any of the aforementioned substances.
- While cleaning the surfaces of the device, ensure that cleaning fluids do not seep inside the device, as this leakage can damage the device.

## 6.8 Cleaning the Aperture

- Check the beam aperture routinely prior to treatment.
- Use special camera lens wipes or compressed air to remove dust and particles from the glass surface of the aperture.

## 6.9 Articulating Arm Adjustment

If the articulating arm does not hold the Optical Head in a fix vertical position contact your local Avedro service representative.

## 6.10 Performing Periodic Maintenance

Interval	Specific Task
Annual	Calibration check by Avedro trained personnel.

## 6.11 Moving the System

- The Mosaic is designed as a movable system within an office environment.
- When moving the system, ensure that the articulating arm and the head are retracted close to the monitor as shown in the image below for safe motion from one place to another.



**Figure 6-1 Moving Position of the Mosaic System**

- If it ever proves necessary to transport or ship the Mosaic System, for any reason, contact your local Avedro representative. Packing and transporting the system should be performed only by Avedro trained and authorized personnel.

## 6.12 Storing the System

- Follow all the storage temperature and humidity range specifications as listed in the Specifications Chapter 9 and allow system to re-equilibrate to normal operating temperatures and humidity ranges prior to re-starting system.
- Close all panels on the system to prevent dust and moisture from entering; this is mandatory.
- Turn OFF all the components and the main power supply as well. Disconnect the power cord physically from its electrical outlet.
- Cover the touch screen LCD display and keyboard with its original cover or packaging to prevent any damage.
- Do not disassemble any part of the system as this could cause misalignment or damage.

## 6.13 Software

- Should the software become corrupt and fail to work correctly at some point, call your local Avedro service representative. Software updates will only be carried out by Avedro trained service representatives.
- Should one of the following software errors occur, call your local Avedro service representative with the error codes:

ERROR_SYSTEM_FATAL	ERROR_XYZ_FAILED_HOMING
ERROR_UART_FRAME_ERROR	ERROR_XYZ_REMOTE_COMM
ERROR_UART_HW_OVERFLOW	ERROR_DLOG_READ_FAIL
ERROR_COMM	ERROR_DLOG_WRITE_FAIL
ERROR_UVMON_PD1_H	ERROR_DLOG_ERASE_FAIL
ERROR_UVMON_PD1_L	ERROR_DLL_RX_FRAME_READ
ERROR_UVMON_I_H	ERROR_DLL_RX_FRAME_INSERT
ERROR_UVMON_I_L	ERROR_DLL_RX_POST_ACK
ERROR_UVMON_TRMT_TIME_H	ERROR_DLL_SEND_PACKET
ERROR_UVMON_TRMT_TIME_L	ERROR_COMM_POST_PACKET
ERROR_UVMON_OVERTEMP	ERROR_COMM_PUSH_FIFO
ERROR_UVMON_DAC_RB	ERROR_COMM_SENDWAIT
ERROR_UVMON_PD2_H	ERROR_APP_POST_MESSAGE
ERROR_UVMON_PD2_L	ERROR_APP_TRANSITION

## 6.14 Identifying Risks Associated with Disposing of Waste Products

- When disposing of waste products, residues and Mosaic System and accessories, follow all applicable local regulations or contact an Avedro authorized distributor.

## 6.15 Performing a Visual Check

- Check all components of the device routinely for damage or malfunction prior to each treatment.
- Do not use a damaged or malfunctioning device. Use of such devices may harm the user and/or patient.



# 7 Equipment Classification

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## According to IEC60601-1:2005+A1:2012 Medical Device Electrical Standard

- Protection against electrical shock
  - Class 1 (external electrical power source)
- Degree of protection against electric shock
  - Not classified, equipment not provided with applied part
- Degree of protection against ingress of water
  - Common Devices IP20 (No protection against ingress of water)
- Method of sterilization or disinfection
  - Disinfectable device
- Degree of protection for use in the presence of a flammable such as aesthetic mixture
  - No protection
- Use conditions
  - Continuous service

## According to FCC Part 15, IEC55011 and IEC60601-1-2

- Class B

## According to IEC62471:2006 Photobiological safety of lamps and lamp systems

- UV LED is Risk Group 2

## According to Annex II.3 of Directive 93/42/EEC

- Class IIa

## According to IEC 60825-1 Ed. 2.0 2007-03 Safety of laser products

- Alignment lasers are Class 1 Laser Product

## According to IEC 60825-1 Ed. 3.0 2014-05 Safety of laser products

- Alignment lasers are Class 1 Laser Product

## Conforms to the following standards:

- IEC 60601-1:2005+A1:2012
- ANSI/AAMI ES 606061-1:2005+A1:2012
- CSA C22.2 No 60601-1:14
- IEC 62471:2006

## EMC Requirements



The Mosaic System requires special precautions regarding electromagnetic compatibility (EMC). Installation and use should be carried out according to the EMC information provided in this manual. Portable and mobile RF communications equipment may affect the Mosaic System.

The Mosaic System has been qualified for use with the following cables and accessories. Use of cables, and accessories other than those listed may result in increased emissions or decreased immunity of the Mosaic System.

<b>Cables</b>	<b>Accessories</b>
None	USB 2.0 compliant flash drive

**Guidance and manufacturer’s declaration - electromagnetic emissions**


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

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



The Mosaic System should not be used adjacent to, or stacked on top of other equipment. If the Mosaic System must be used adjacent to or stacked on top of other equipment, verify that the Mosaic System operates in an acceptable manner in the configuration in which it will be used.

<b>Guidance and manufacturer's declaration — electromagnetic immunity</b>			
The Mosaic System is intended for use in the electromagnetic environment specified below. The customer or the user of the Mosaic System should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable 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	±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 sec	<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 sec	Mains power quality should be that of a typical commercial or hospital environment, If the user of the Mosaic System requires continued operation during power mains interruptions, it is recommended that the Mosaic System be powered from an uninterruptible power supply or a battery.
Power frequency  (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The Mosaic System is intended for use in the electromagnetic environment specified below. The customer or the user of the Mosaic System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Mosaic System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b> $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 80 MHz to 2,5 GHz  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:  
<b>NOTE 1</b> At 80 MHz and 800 MHz, the higher frequency range applies.			
<b>NOTE 2</b> 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 Mosaic System is used exceeds the applicable RF compliance level above, the Mosaic System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Mosaic System.			
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 Mosaic System**

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter 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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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










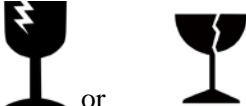
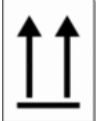
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.







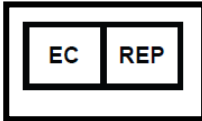






The Mosaic System contains an RFID function which transmits and receives at the 13.56 MHz frequency. This functionality may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

The Mosaic System contains the following RF transmitters:		
<b>RFID Reader</b>		
<ul style="list-style-type: none"> <li>• 13.56MHz Reader/Writer</li> <li>• Integral Antenna: Maximum 4" Read Range</li> <li>• Max output power is 200mW</li> <li>• Meets: ISO18000-3, ISO15693</li> </ul>		
<b>WiFi Adapter</b>		
<b>Frequency Modulation</b>	<b>5 GHz (802.11a/n)</b>	<b>2.4 GHz (802.11b/g/n)</b>
Frequency band	5.15 GHz - 5.85 GHz (dependent on country)	2.400 - 2.4835 GHz (dependent on country)
Modulation	BPSK, QPSK, 16 QAM, 64 QAM	CCK, DQPSK, DBPSK
Wireless Medium	5 GHz UNII: Orthogonal Frequency Division Multiplexing (OFDM)	2.4 GHz ISM: Orthogonal Frequency Division Multiplexing (OFDM)
Channels	4 to 12 (dependent on country)	Channel 1-11 (US only) Channel 1-13 (Japan, Europe)
Max Output Power	< 100mW	<100mW

# 8 Symbol Library

Text Symbol	Symbol Illustration	Definition
1. No AP symbol in presence of flammable anesthetics		Danger, Risk of Explosion. Not for use
2. AC symbol		Alternating current
3. "I" in a book		Attention: Consult ACCOMPANYING DOCUMENTS
4. Ground symbol in circle		Protected earth (ground)
5. Ingress Protection Symbol	IP20	Ingress Protection solids under 12.5 mm and no protection against water)
6. CE Mark		Conformity mark
7. Manufacturer		Name and address of the manufacturer
8. Date of Manufacture		Date manufactured
9. ! in a yellow triangle		Caution specific warning in operators manual
10. Net Weight (kgs) Gross Weight (kgs)	NW GW	Net Weight Gross Weight
11. Umbrella with raindrops		Keep Dry: Store protected from moisture (symbol is with or without rain drops)
12. Wine glass with crack on it		Contents are fragile, handle with care
13. Two up arrows		Keep arrows on carton pointing up

**Chapter 8: Symbol Library**

Text Symbol	Symbol Illustration	Definition
14. Percent sign on sea level		Humidity limits (percentages below symbol are the acceptable range for humidity)
15. Temperature limits		Temperature shipment limits
16. Reference Number		System reference number
17. Serial Number		System serial number
18. EC RP		European Authorized Representative
19. Do not Push		Do no push unless in the right moving configuration
20. Do not Sit On		Do not Sit on Optical Head
21. Do not Step On		Do not Step on Optical Head
22. Atmospheric Pressure limits		Operate within atmospheric pressure limits shown on system
23. Stand By		System in Stand By Mode
24. Signal emitted		RF transmitted through device



# 9 Specifications

Specification	Description
<b>Electrical</b>	Line voltages 100 – 240 volts AC, $\pm 10\%$ Current 10A – 5A Single Phase 50/60 Hz, $\pm 5\%$ Fuse: T 10H, 250V
<b>Energy Delivery</b>	UV Radiation 10 – 100 mW/cm <sup>2</sup> 365 nm
<b>External Interfaces</b>	USB 2.0
<b>Physical Dimensions</b>	62 x 62 x 140 cm <sup>3</sup> (Length x Width x Height)
<b>Weight</b>	NW 124 Kg GW 171 Kg
<b>Environmental Operating Conditions</b>	The system operates under the following atmospheric conditions (no condensation).
<b>Ambient temperature</b>	+15 to +30°C
<b>Relative humidity</b>	20% to 80%, non-condensing
<b>Atmospheric pressure</b>	810 to 1050 mbar
<b>Transport and Storage Conditions</b>	The instrument withstands the following transport and storage conditions without damage or performance deterioration.
<b>Ambient temperature</b>	-15 to +60 °C
<b>Relative humidity</b>	10% to 80%, non-condensing
<b>Atmospheric pressure</b>	750 to 1060 mbar



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