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# Avedro, Inc. Mosaic<sup>®</sup> System

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## 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 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 UVA 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 UVA 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
- Children

### 1.7.2 Warnings and Cautions



In this manual, “Warning” is defined as: a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device. 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



In this manual, “Caution” is defined as: a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property. The caution statement includes the precaution that should be taken to avoid the hazard.



### 1.7.3 Electrical Safety Warnings

- This equipment 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 can affect medical electrical equipment such as the Mosaic System.

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. Ensure that all service to the System, beyond what is described in this manual, is performed only by qualified Avedro service personnel.



WARNING: Power down System and remove the wall plug 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.

The equipment must be positioned so that it is not difficult to remove the power cord from the outlet.



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: 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.



WARNING: Use of not included accessories results in non-compliance of the device.



WARNING: System may be interfered with by other equipment even if that equipment complies with CISPR Emissions requirements. See Table 5-1.



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Avedro Mosaic System (110-03029), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING: System shall not be serviced or maintained while in use with a Patient.



WARNING: MR Unsafe - Keep away from magnetic resonance imaging equipment.



WARNING: Do not use a damaged or malfunctioning device. Use of such devices may harm the user and/or patient.

#### 1.7.4 Radiation Safety Warnings



WARNING: Use only laser grade instruments in order to prevent reflected UV radiation from smooth metallic surfaces.



WARNING: UV emitted from this product. Avoid eye and skin exposure to unshielded products. Never direct the beam towards a person except for therapeutic purposes.

## 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 and 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. 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 this 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

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### 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 has been applied. Irradiating the riboflavin creates singlet oxygen, which forms intermolecular bonds in corneal collagen, stiffening the cornea through cross-linking. 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 touchscreen.

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

**NOTE:** The depictions of the Mosaic System and user interface screenshots included in this manual are for demonstration purposes only. Actual product may vary due to product enhancements.

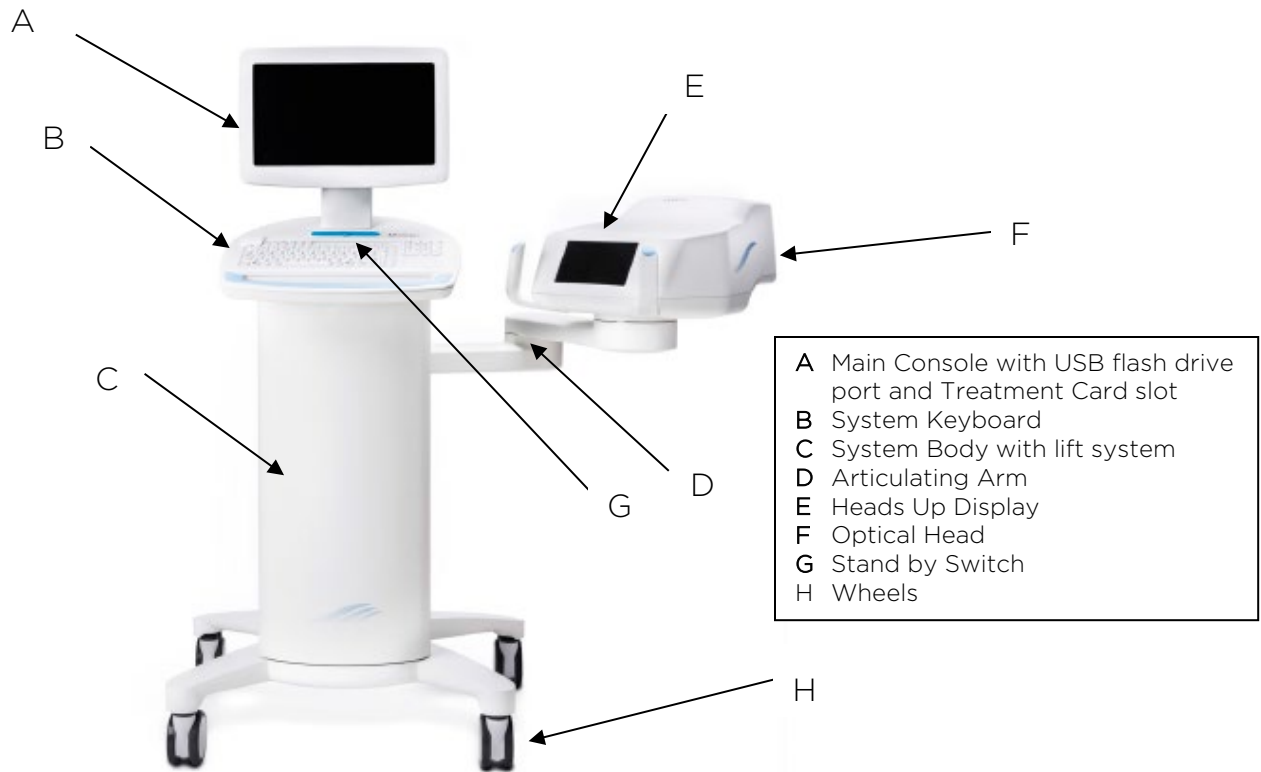
## 2.1.1 Major Components

The major components of the Mosaic System include the following:

- Articulating arm with optics head with UV source and heads up display
- Mosaic console with user interface
- Mosaic Accelerated Crosslinking Treatment Kit (disposable supplied separately)
- USB flash drive port
- System Part Number: 110-03092



*Figure 2-1. Overview Illustration of Mosaic System*



*Figure 2-2. System Overview with Callouts*

## 2.1.2 Disposables

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

- Riboflavin ophthalmic solutions
- Treatment Activation card
- Boost Goggles (optional)



### 2.1.3 Mosaic System Labels

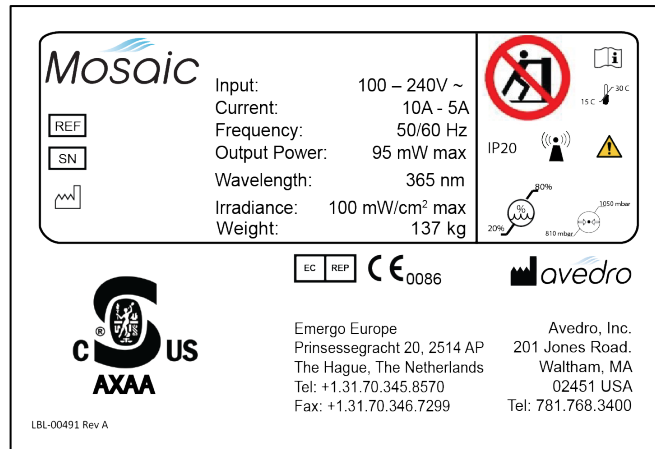


Figure 2-3. Mosaic Label

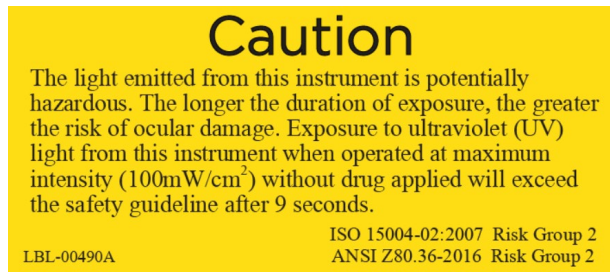


Figure 2-4. UV Safety Label



Figure 2-5. Laser Classification Label



Figure 2-6. Do Not Sit/Step On Label

## 2.1.4 Frequently Used Functions










The table below identifies the System functions that are most frequently used and where to find these functions described in this Manual.

Function	Mode	Manual Section
Turn System On	Press Stand By switch under the keyboard in the front of the Mosaic console	4.3
Treatment Design	Select "Design OD"/ "Design OS". This initiates a new treatment design.	5.2
Scan Treatment Activation Card	Insert Treatment Activation card into slot on the left side of main console	5.3
Begin UV Treatment	Select "Begin UV Treatment". This becomes available at the end of the patient preparation step.	5.10
Pause	Select "Pause" to interrupt treatment at any time.	5.10
Go on Stand By	Select "Power Off" on main console display	5.13

# 3 System Operation

## 3.1 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 console and goes on Stand By Mode.
Start button (initial screen)		Directs the System from the Startup Screen to Patient Central.
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)		Cancels 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.
Pause button (Treatment screen)		Halts the delivery of UV light until the physician decides to realign the eye, resume, or cancel the treatment session.
Cancel Session button (various Clinical Protocol screens)		Cancels 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.

### 3.2 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.

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# 4 System Set Up

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## 4.1 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.

## 4.2 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.

## 4.3 Powering Up

- Turn ON the 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.

## 4.4 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 4-1 is displayed.
- To begin patient treatment, press Start.



*Figure 4-1. Startup Screen*

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

## 4.5 Setting Optics Head Height

- Continuously press the up /down (+ / -) button, shown below in Figure 4-2, to raise or lower the optics head to the approximate desired height above the treatment table or chair.



The lift 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 4-2. Lift Buttons*

- The small LED between the up (+) and down (-) buttons will flash when the lift reaches its maximum or minimum height.
- The small LED will also flash very rapidly if the proximity sensor is triggered (see Section 3.5)
- 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. See Figure 4-3 below. Once the brake buttons are let go, the head locks into place.



*Figure 4-3. 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.

## 4.6 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 as shown below in Figure 4-4.

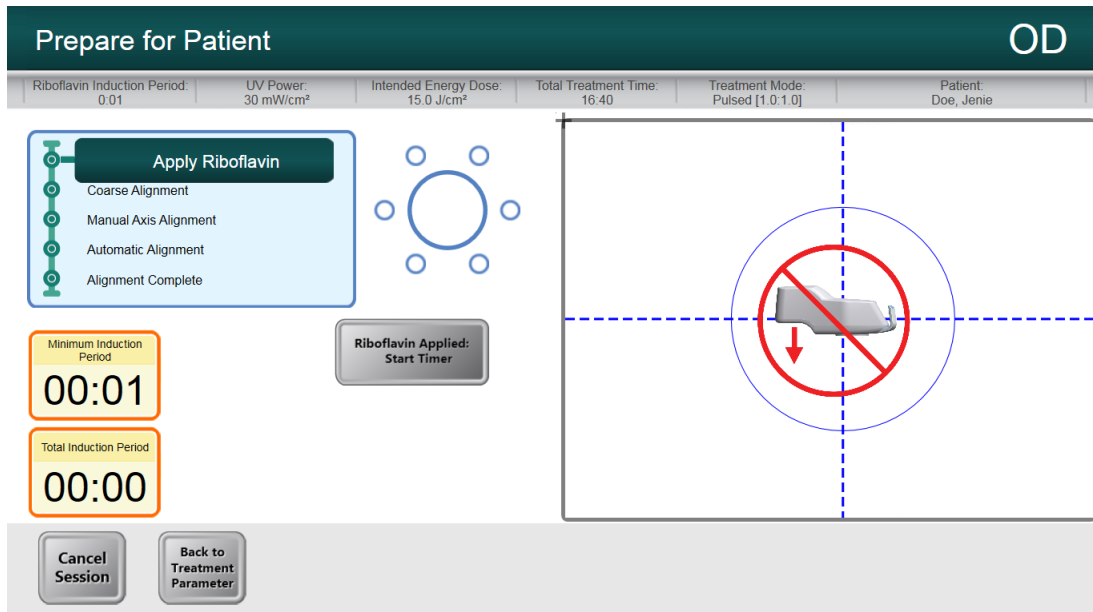


Figure 4-4. Proximity Warning: Move lift up

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



# 5 Treatment Procedure

## 5.1 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 Patient Central from the USB flash drive for guided treatment patterns.


The screenshot shows the 'Patient Central' interface. At the top, there are buttons for 'Import / Refresh Patient List', 'New Patient', and a trash icon. Below is a table with the following data:

Last Name	First Name	ID	Sex	DOB	OD Date	Source	Type	OS Date	Source	Type
0_Patient	Anonymous	Eye_Image_Test	n/s	01 Jan, 1973				05 May, 2017 09:42:41		
0_Patient	Anonymous	Image_Orientation	n/s	01 Jan, 1973	05 May, 2017 09:43:59			05 May, 2017 09:42:41		PiXL
0_Patient	Anonymous	Map_Center_Test	n/s	01 Jan, 1973				05 May, 2017 09:42:41		
B	Max	101	n/s	01 Jan, 1990				05 May, 2017 09:07:17		PiXL
Charles	Grover	G808477(6)	n/s	07 Nov, 1970	21 Mar, 2017 10:25:39		PiXL			
Deschamps	Marie-France	V&V 8	F	26 Feb, 1986	11 Oct, 2018 12:37:46		PiXL	20 Apr, 2018 15:52:20		KXL
Doe	Jenie	V&V 7	F	31 Dec, 2007	20 Apr, 2018 15:52:20		PiXL			
Dupont	Pierre	V&V 5	M	02 Sep, 1942				11 Oct, 2018 23:30:38		PiXL
Echo-Delta	Tango	V&V 9	M	19 Feb, 1994	01 Nov, 2018 15:51:02		PiXL	05 Nov, 2018 17:12:50		PiXL
Fernandez	Maria	V&V 4	F	09 Feb, 1980				20 Apr, 2018 15:52:20		KXL

At the bottom of the screen, there are buttons for 'Back', 'Design OD', and 'Design OS'.

Figure 5-1. Import/Enter Patient Data Screen



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

### 5.1.1 Entering a 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.

## 5.1.2 Importing Patient Topographies

Patient topographies exported onto a USB flash drive may be used with the Mosaic System.

- Insert the USB flash drive into the Mosaic USB port.
- Click on “Import/Refresh Patient List” to refresh the page and list all patients on the USB drive.
- Patient data imported from a commercial topographer can be distinguished under the “Source” column.

## 5.2 Designing a Patient Treatment

- Starting from Patient Central, select the patient to be treated.
- Select “Design OD” or “Design OS” to create right or left eye treatments respectively.
- Perform pupil center verification if applicable (only for patients with topography imports).

### 5.2.1 Verifying Pupil Location

When patient topographies are imported and prior to creating treatment maps, users will be prompted to verify the location of the pupil center as shown in Figure 5-2. This is to ensure an accurate treatment location is used for treatment.

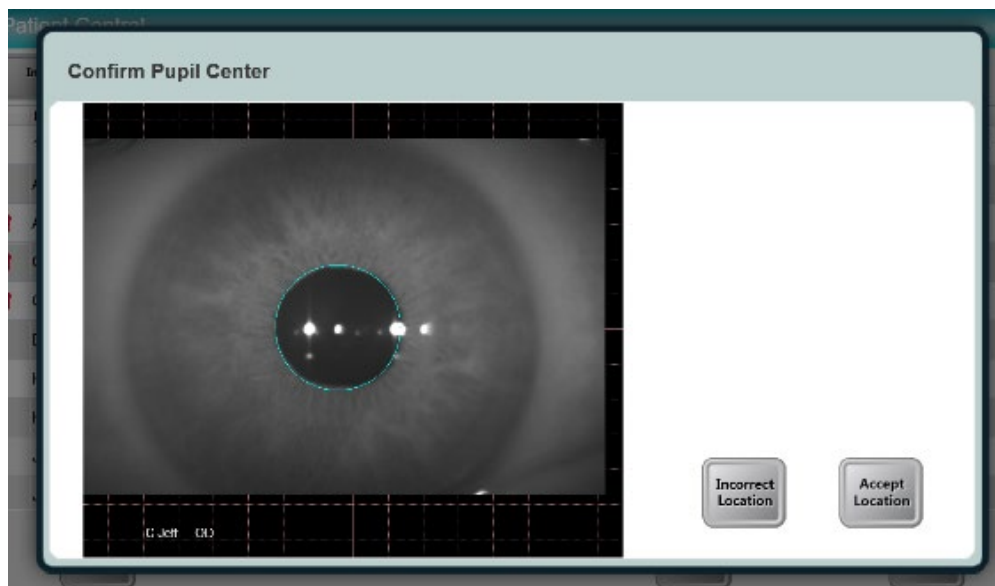


Figure 5-2. Verifying Pupil Location

- If the location is confirmed, the user can proceed to the Treatment Designer depicted in Section 5.3.
  - The user must confirm the pupil location for each patient record.
  - If the pupil location needs to be reconfirmed, the user can manually access the Settings Menu (see Section 5.2.7) and select the “eye” icon to reconfirm.
- If the location is not confirmed, the user will be prompted to create a new patient record for the patient with a grid-base that can be utilized for treatment map creation.
  - The patient name will be the same, but a new patient ID will be automatically generated.

### 5.2.2 Overview of the Treatment Designer

The various areas of the Treatment Designer are depicted in Figure 5-3.

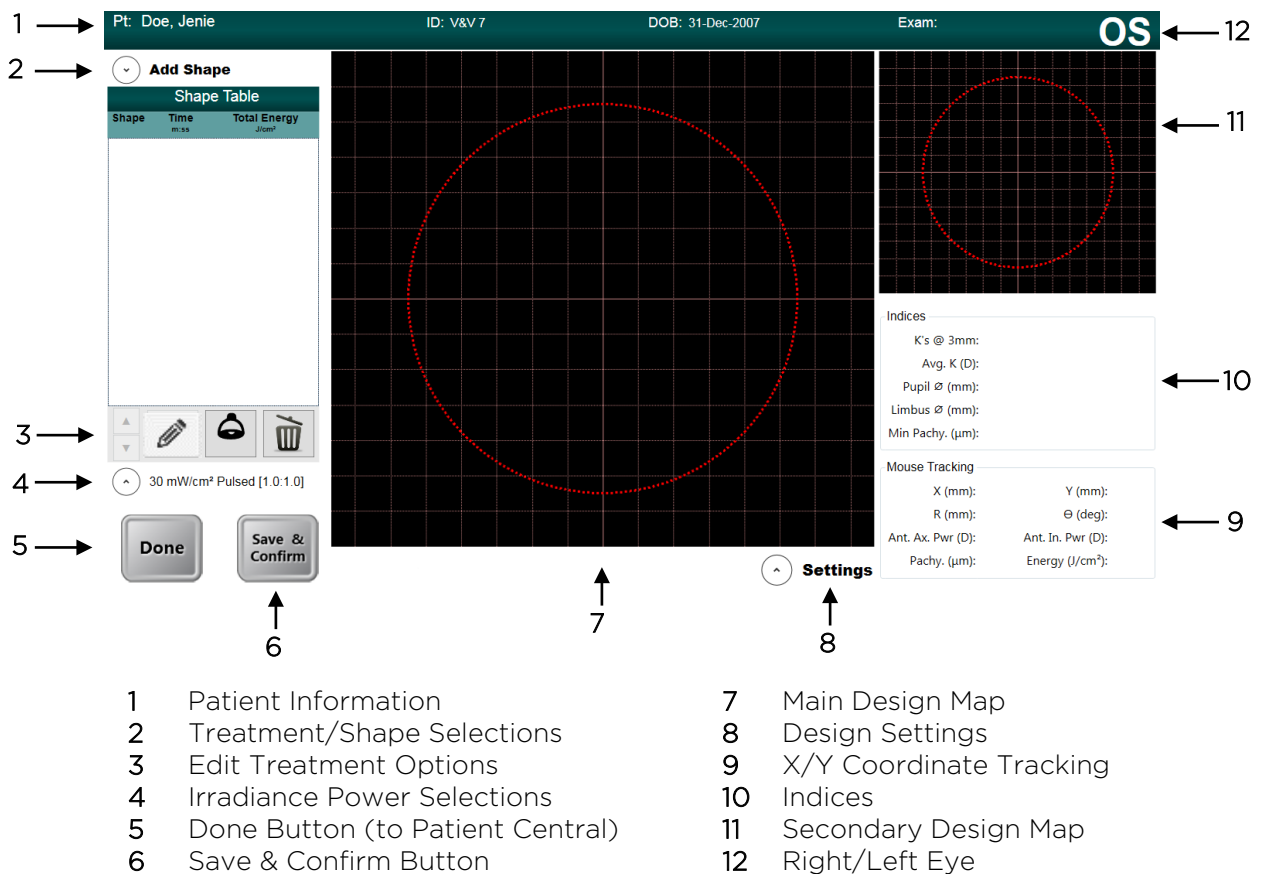


Figure 5-3. Treatment Designer Layout

### 5.2.3 Treatment Type Options

Select “Add Shape” 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.

### 5.2.4 Designing a KXL Treatment

NOTE: Requires KXL Treatment Activation Card

- Open the “Add Shapes” menu and select the “KXL” tab.
- Select the KXL 9 mm circle to add it to the treatment design.

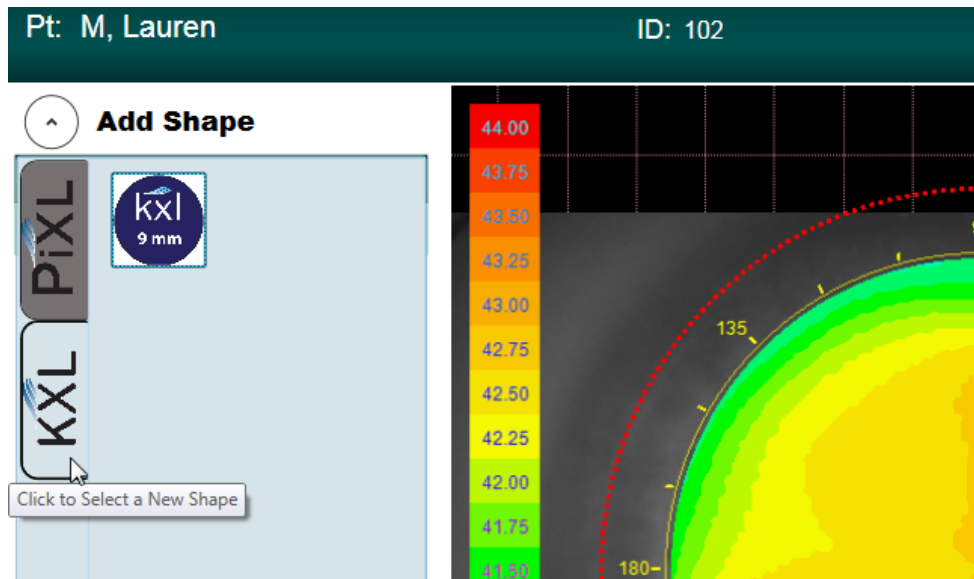


Figure 5-4. Create KXL Treatment Design

- The circle can then be centered on the limbus, pupil or vertex (if available) as shown in Figure 5-5. 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 as shown in Figure 5-5. Treatment energy and irradiance limits are controlled by the KXL Treatment Activation Card.

NOTE: Eye Tracking is available during a KXL Treatment on the Mosaic.



Figure 5-5. Adjust Energy for KXL Treatment

### 5.2.5 Designing a PiXL or CuRV Treatment

NOTE: Requires PiXL Treatment Activation Card

- Open the “Add Shape” menu and select the “PiXL” tab.
- Select a PiXL treatment shape from the drop-down list as depicted in Figure 5-6:
  - 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
  - Any free-hand user-defined drawn surface

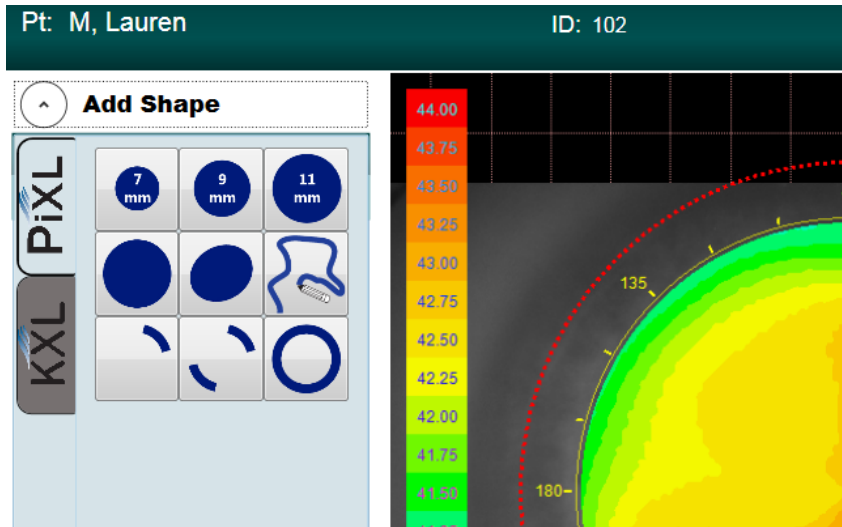


Figure 5-6. Treatment Shape Selection

- As shown in Figure 5-7, select the up/down arrow (1) to adjust the energy required for the specific treatment shape. Treatment time automatically adjusts itself based on energy dose selected.
- 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.

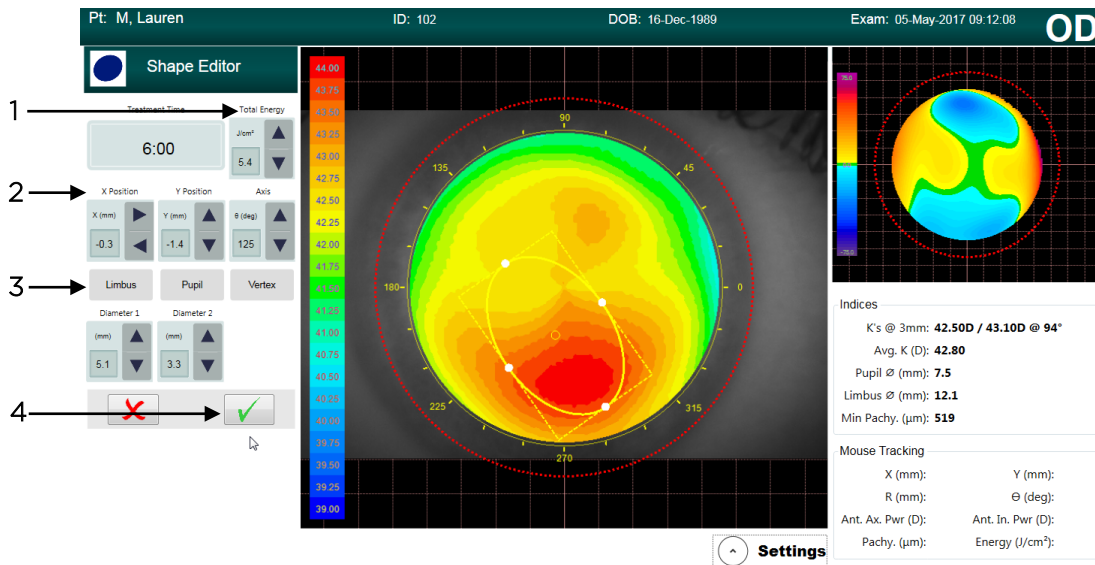


Figure 5-7. Selecting Energy Dose and Centering Shape

- 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.

### 5.2.6 Multi-Shape Treatments

The order of shapes included in a multi-shape treatment design plays an important role. The first shape has higher priority and the DMD setting will be prioritized according to that higher priority shape. Figure 5-8 depicts an example of how changing the order of two shapes results in different patient treatments.

- In the treatment summary on the left, 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 on the right, 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.

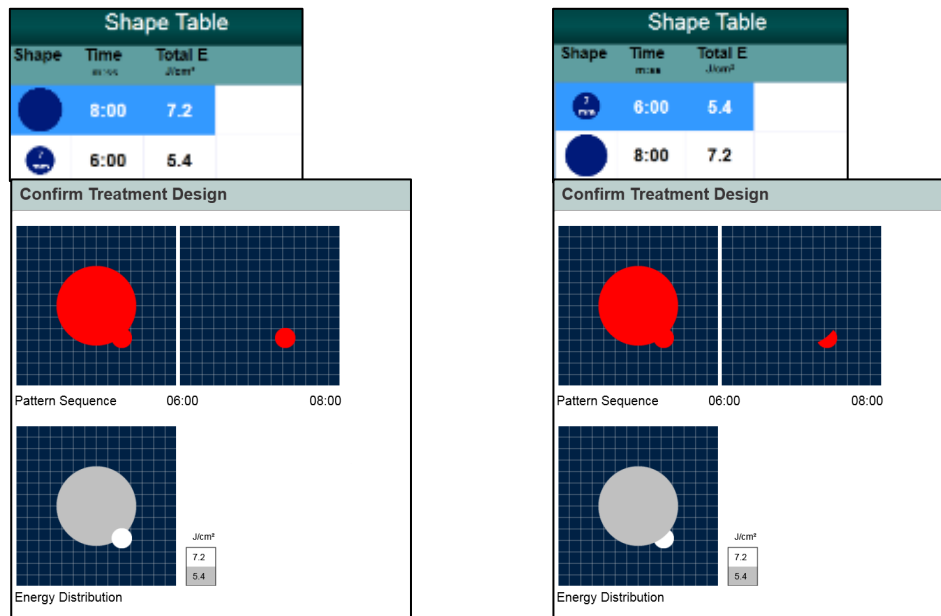


Figure 5-8. Resulting Treatment Pattern

### 5.2.7 Settings

The Settings menu, shown in Figure 5-9, allows the user to:

- Save and send a PDF report to the USB flash drive
- Change treatment map views
- Reconfirm pupil location (only for patients with topography imports)
- Access the Help Section

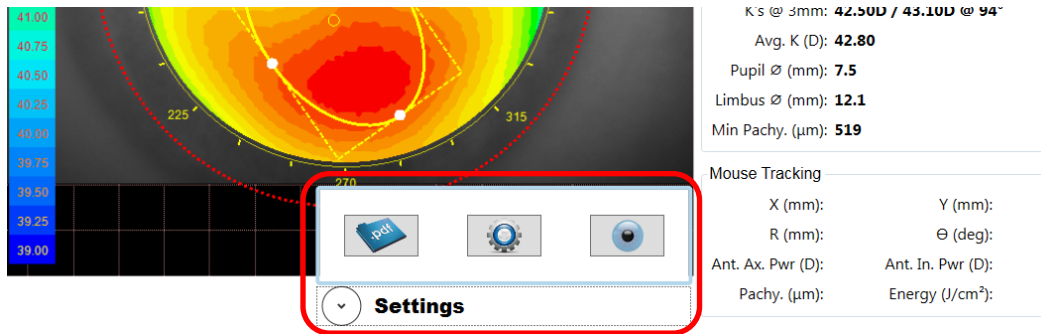


Figure 5-9. Settings Menu

The Map Options settings menu, shown in Figure 5-10, allows the user to choose the treatment map options (when applicable) to use on both the Main Design Map (Main View) and the Secondary Map (Auxiliary View).

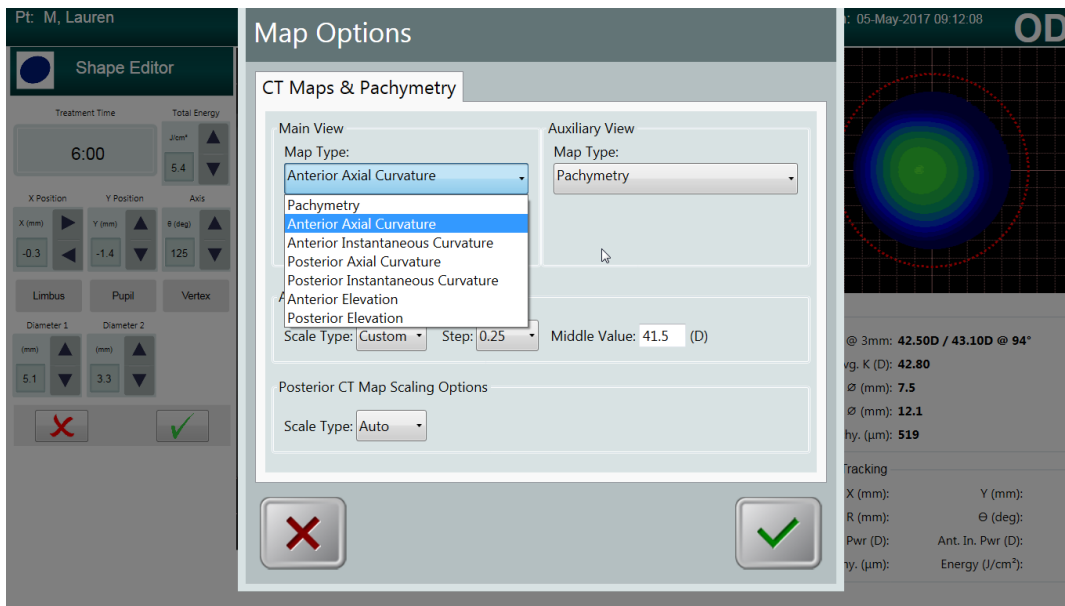


Figure 5-10. Settings for Map Options

Map options include but are not limited to:

- Pachymetry
- Anterior axial curvature
- Posterior axial curvature
- Front and back elevation maps



## 5.2.8 Adjusting Power (Irradiance) and UV Mode

- Power and UV mode (pulsed or continuous) settings can be modified by clicking on the drop-down menu beside the power (irradiance) value (see Figure 5-11).

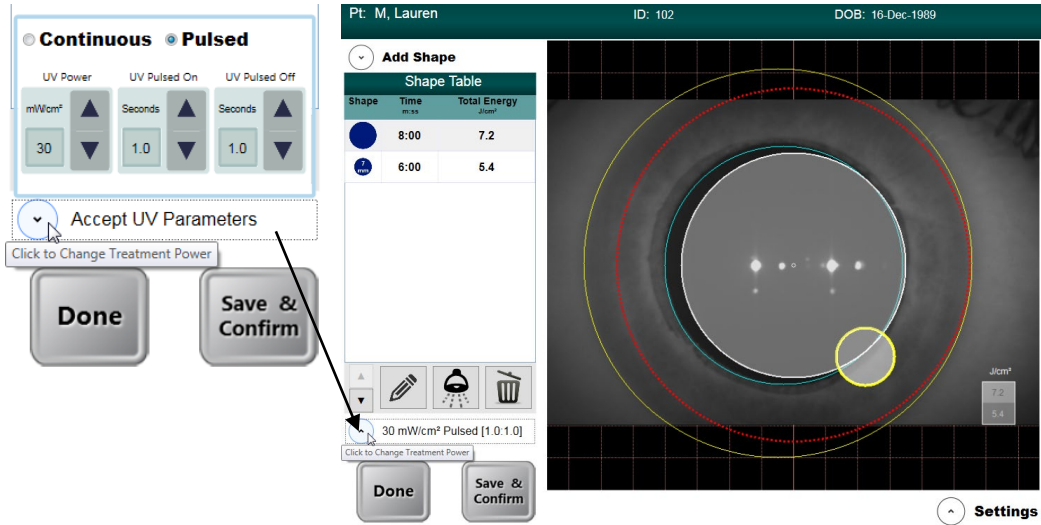


Figure 5-11. Power and Pulse Settings

- When Pulsed UV is selected, the time on and off for Pulsed can be adjusted using the up/down arrows. Pulsing times range from 0.2 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.

## 5.2.9 Confirm Treatment Design

- As the user enters the treatment parameters, the user can confirm the treatment design by selecting the “Save & Confirm” button. This can be done at any time during the treatment design to help optimize treatment accuracy.
- As depicted in Figure 5-12, the Confirm Treatment Design window shows a timeline of the various shapes that the UV beam will make during the course of the treatment.
- For viewing multiple shapes, the user can move the slider left and right.
- The lower square shows the energy dosage distribution for each shape; darker shapes have lower energy while brighter shapes have higher energy.
- Once the treatment design is confirmed, the user selects the green checkmark to proceed with scanning the activation card.

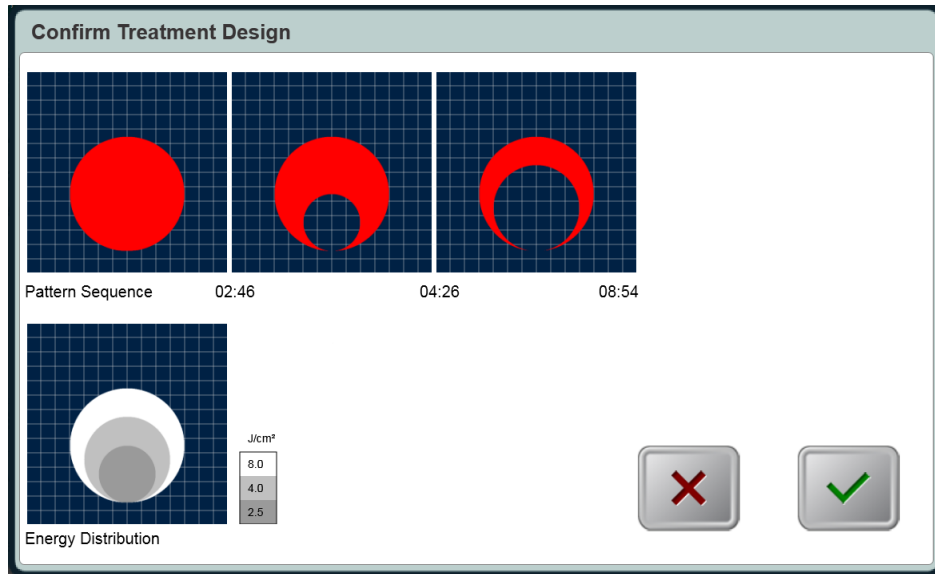


Figure 5-12. Confirm Treatment Design Window

### 5.3 Treatment Activation Card

- After treatment design is confirmed, a treatment activation card must be inserted to proceed with the patient treatment.
- If no card has yet been inserted, an error message will appear as shown in Figure 5-13.

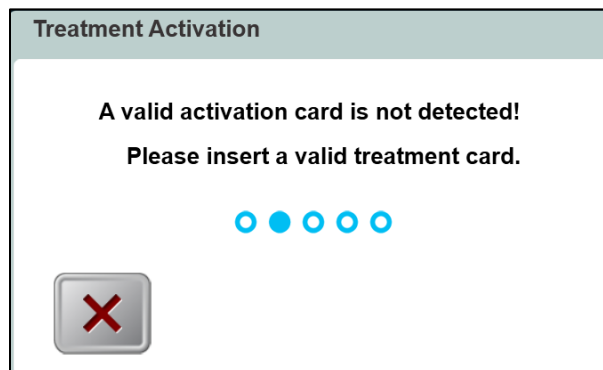


Figure 5-13. Activation Card Not Detected

- Insert the card into the slot on the left side of the main console.
- Selected treatment parameters must be within the allowable values controlled by the treatment activation card (UV power, energy, treatment time, etc.).
  - For example, if the treatment design uses PiXL shapes, a PiXL treatment activation card must be used.
  - The user may edit the treatment design parameters to meet the treatment activation card requirements.

### 5.3.1 Multi-use Treatment Activation Cards

- When a multi-use activation card has been scanned, the display will show the number of treatments remaining on the card.
- Prior to using the final treatment on a multi-use activation card, a message, as shown in Figure 5-14, will appear to inform the user that this is the final treatment.

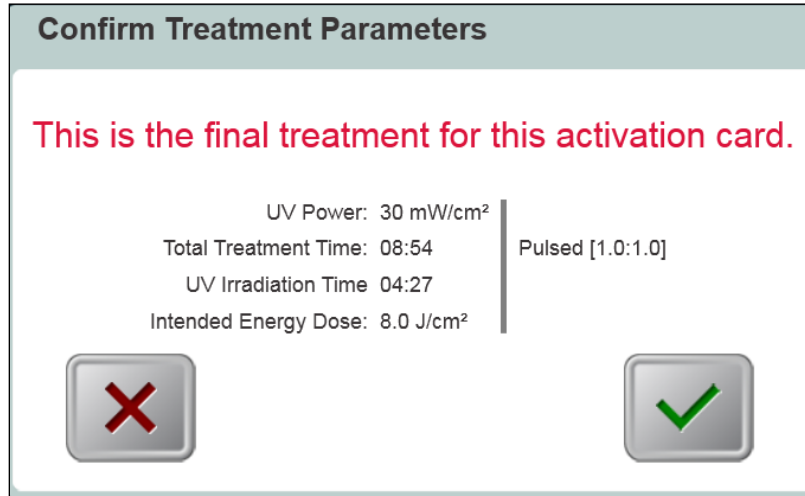


Figure 5-14. Final Treatment

### 5.4 Set the Riboflavin Induction Time

To set the riboflavin induction time, the user has two options as shown in Figure 5-15:

- Use the Mosaic Induction Timer
- Use the External Induction Timer

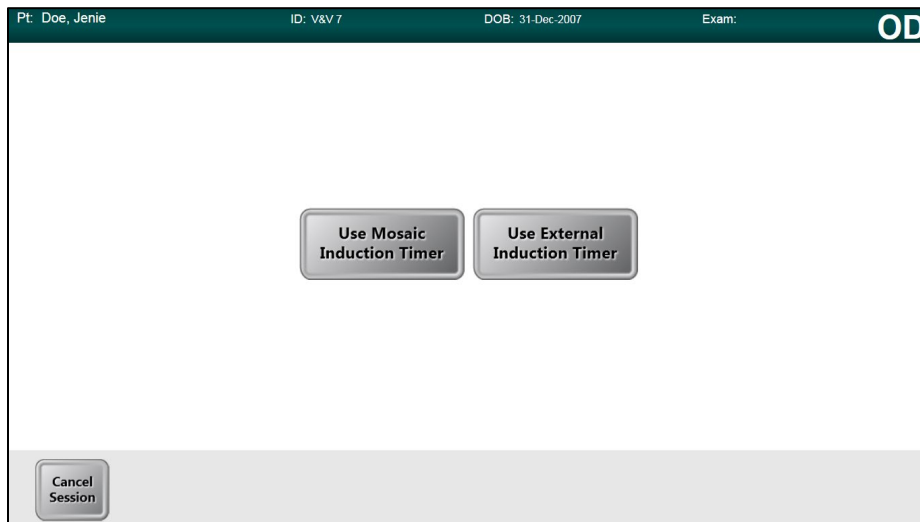


Figure 5-15. Induction Timer Options

## 5.4.1 Mosaic Induction Timer

The Mosaic Induction Timer is a system-based timer that may be used for either a single or a two-part induction process. See Figure 5-16.

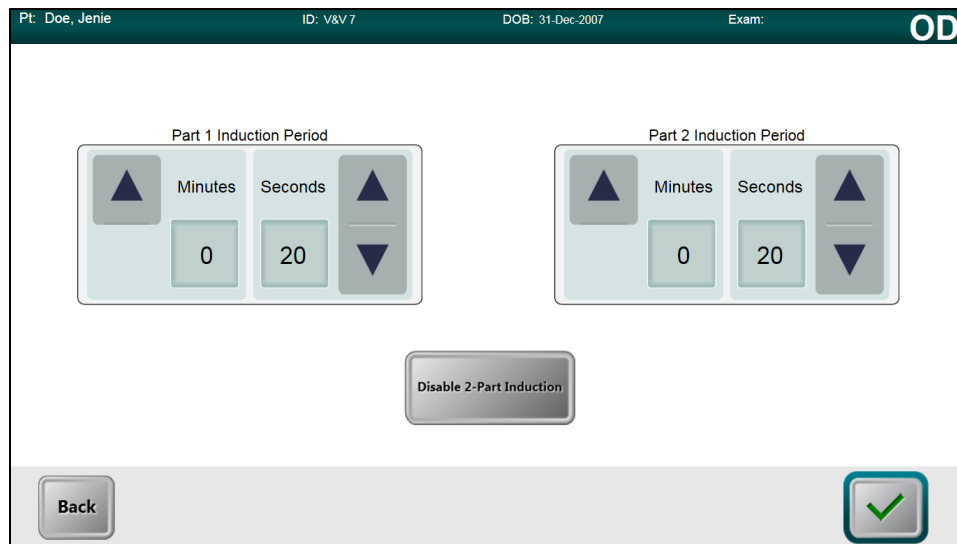


Figure 5-16. Two-Part Induction Timer

- User specifies the desired riboflavin induction period (1 sec – 30 mins) by clicking on the up/down arrows.
- When finished entering parameters, select the green checkmark button.

## 5.4.2 External Induction Timer

When the user selects the Use External Induction Timer button, it is assumed that the user has an external timer and will by-pass both the setting and the use of the Mosaic Induction Timer.

## 5.5 Prepare the Patient

- Ensure that the patient is lying flat or reclined on a patient table or chair. His or her head should rest on 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.
- *Optional* - 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.

## 5.6 Apply Riboflavin

- Apply Riboflavin to the area of treatment in accordance with the Riboflavin Instructions for Use (IFU).



**CAUTION:** Riboflavin is not a part of the Mosaic System described in this manual. For details, please refer to the Riboflavin Instructions for Use.

- Once the Riboflavin is applied to the eye, start timing the induction.
  - If using the Mosaic Induction Timer: Select “Riboflavin Applied: Start Timer,” as shown in Figure 5-17.
  - If using an External Induction Timer: Start external timer and monitor induction time.

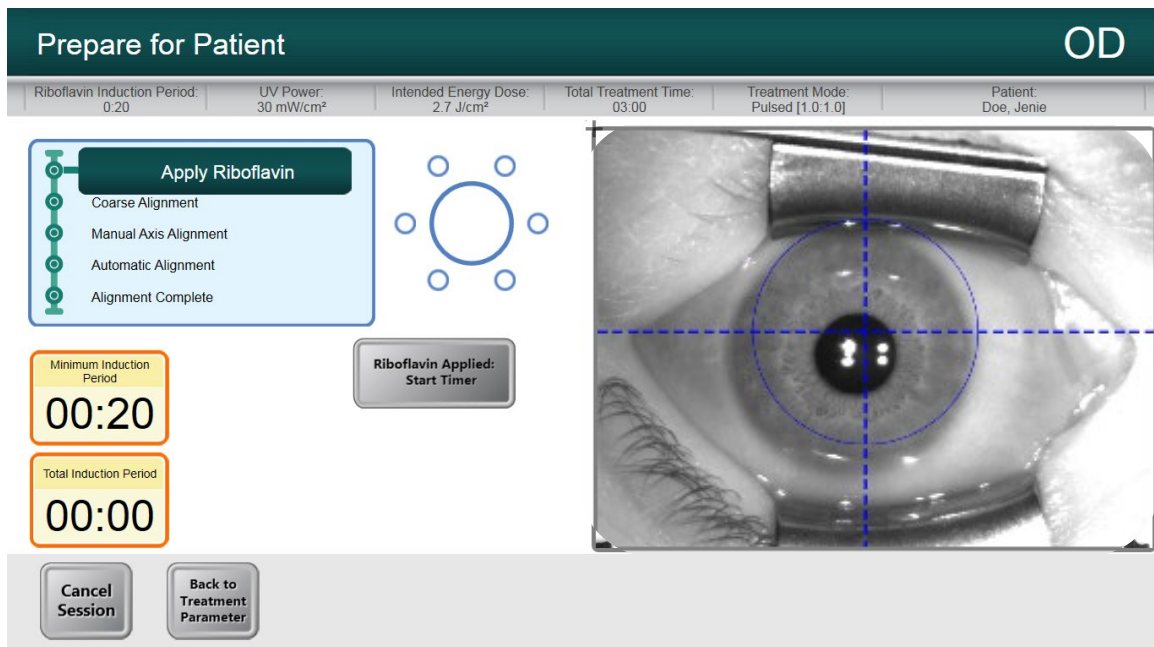


Figure 5-17. Apply Riboflavin & Start Timer Screen

## 5.7 Coarse Alignment of Laser Crosshairs

The goal of the Coarse Alignment process is center the red crosshairs and the blue circle over the treatment eye pupil, as shown in Figure 5-18. The blue circle refers to the center of the DMD and the pupil should be aligned to this center for optimal pupil tracking during treatment.

- Press the buttons on the handles of the articulating arm to disengage the brakes.
- Steer the optics head over the patient's head and treatment eye.
- Align the optics head such that the laser crosshairs are closely aligned/overlapped on each other.
  - The height of the optics head may require adjustment by using the lift system described in Section 4.5 to align the laser crosshairs.
- Align the crosshairs on the Heads Up Display to the center of the treatment eye pupil.
- Release the buttons to engage the brakes once closely aligned.

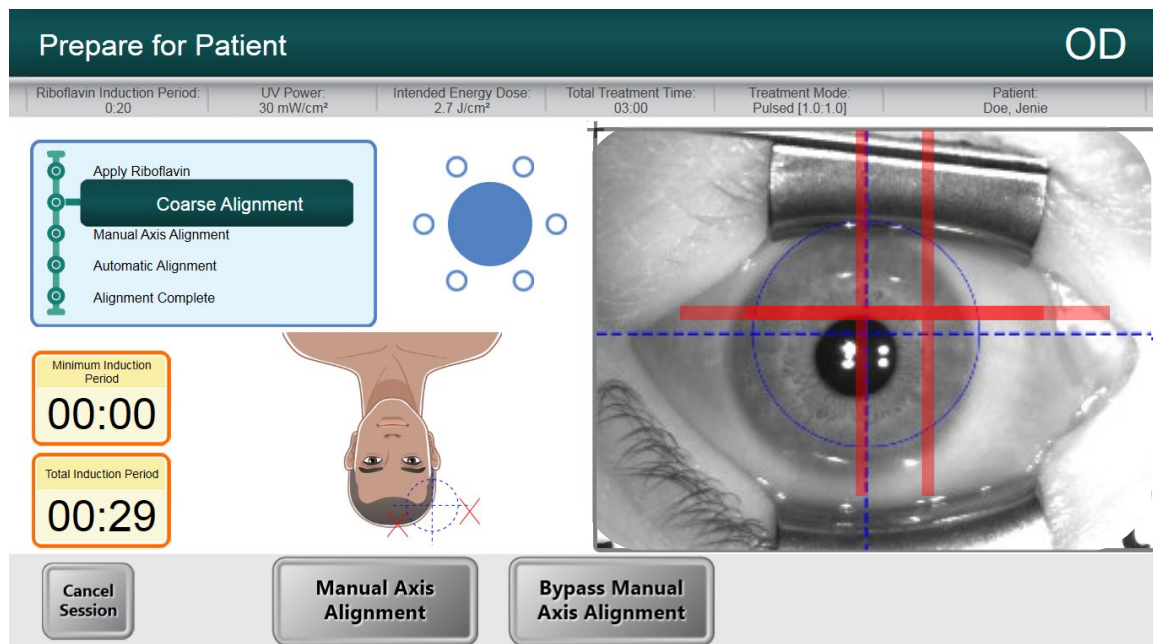


Figure 5-18. Coarse Alignment with Lasers

## 5.8 Manual Axis Alignment Mode

NOTE: Manual Axis Alignment Mode should only be selected for patients who have had their corneal axis marked along the horizontal meridian with a Corneal Gentian Violet marker. If the corneal axis has not been previously marked and if no axis registration is desired, user should select “Bypass Manual Axis Alignment.”

- Select “Manual Axis Alignment” to illuminate the cornea rendering the axis markers on the cornea clearly visible, as shown in Figure 5-19.

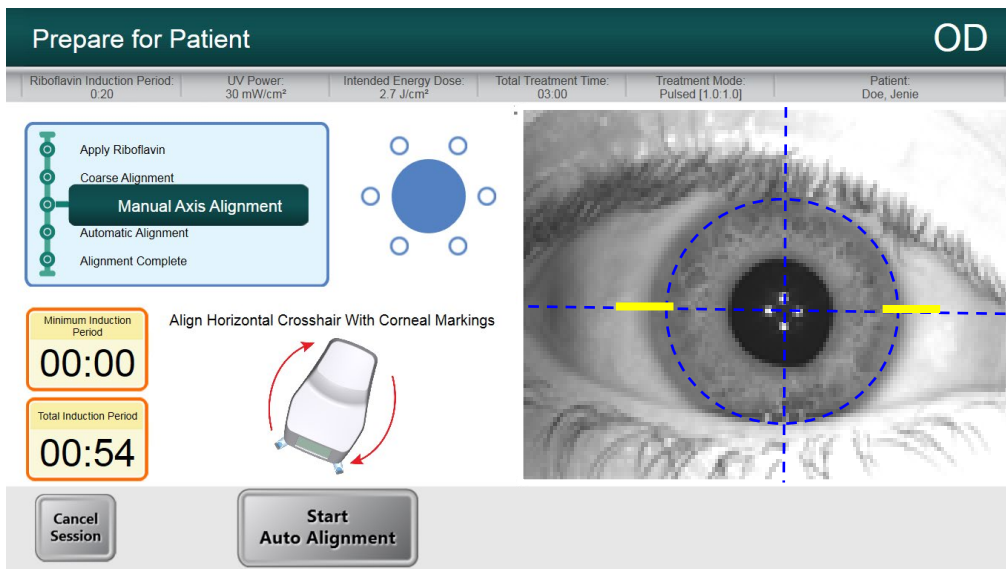


Figure 5-19. Manual Axis Alignment Mode

- Press 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 crosshairs and the blue circle.
- Once aligned, release the brakes.

## 5.9 Auto Alignment

Select “Start Auto Alignment.” Auto alignment is a three-step process as follows:

- Auto-aligns in X-Y axes for pupil tracking;
- Auto-aligns in the Z axis for best focus;

- Compensates for cyclo-torsion
  - Performs iris registration from the imported topographer (when available)
  - For cases where a topography is not available, the Manual Axis Alignment allows the user to manually adjust for cyclo-torsion.

Figure 5-20 displays the onscreen auto alignment process and Figure 5-21 shows the onscreen user alert when auto alignment successfully completes.

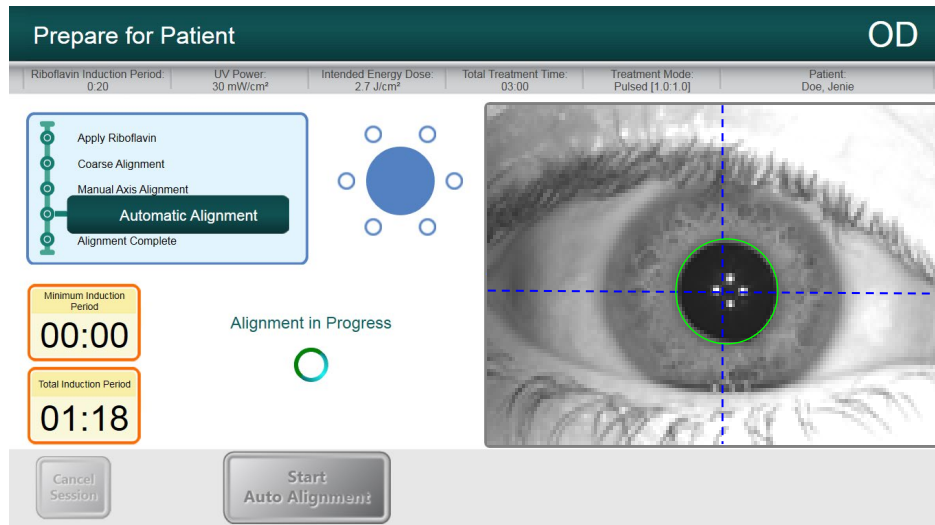


Figure 5-20. Alignment in Progress

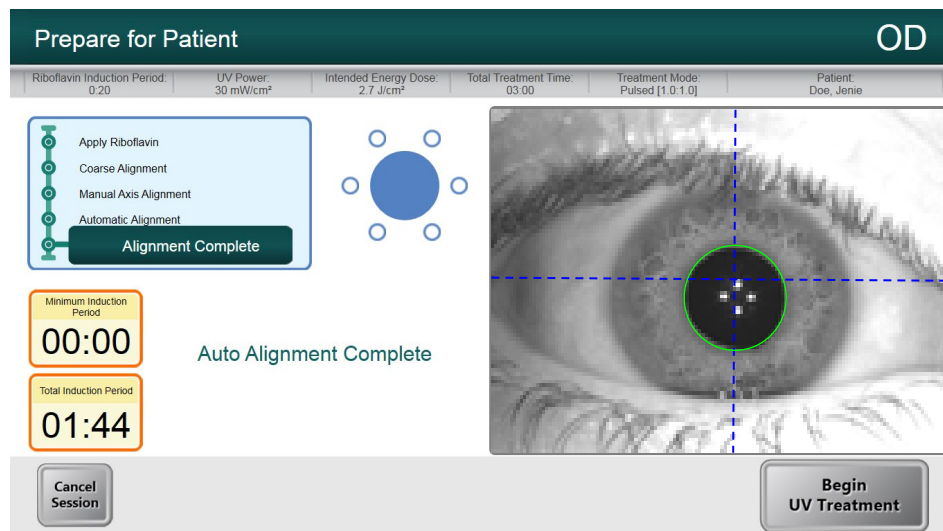


Figure 5-21. Alignment Complete

- When both auto alignment and riboflavin induction are complete, the “Begin UV Treatment” button appears.



### 5.9.1 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 appear as shown in Figure 5-22 to notify the user.

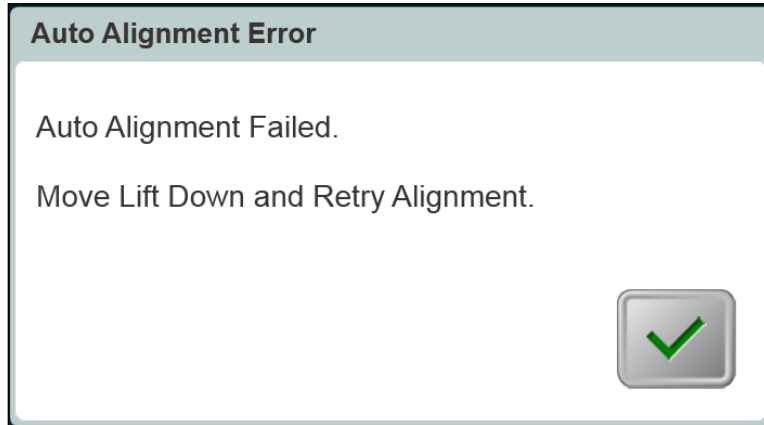


Figure 5-22. Z-Alignment Error

- The error message may instruct the user to move the lift up or down before retrying alignment.
  - The user should use the lift to move the optics head up or down until the image of the eye looks more focused. This will facilitate the auto focus algorithm when the user restarts the auto alignment process.
- In the case of iris registration failure, as shown in Figure 5-23, the user is notified of the failure and has the option to restart the auto alignment or forego auto alignment and proceed with manual alignment, as shown in Figure 5-24.

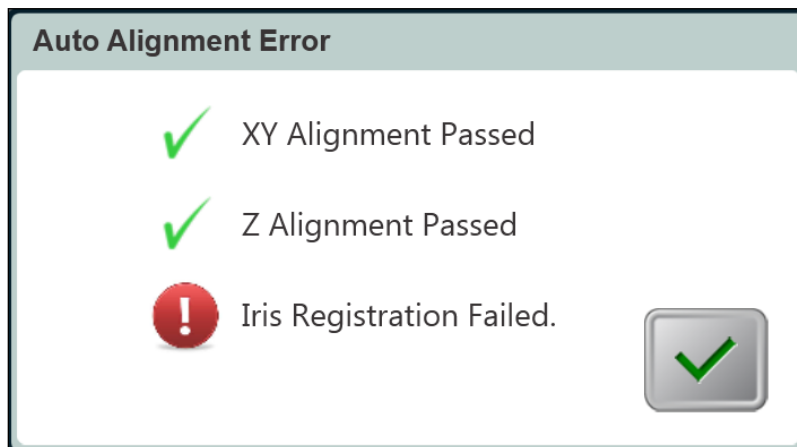


Figure 5-23. Iris Registration Failure

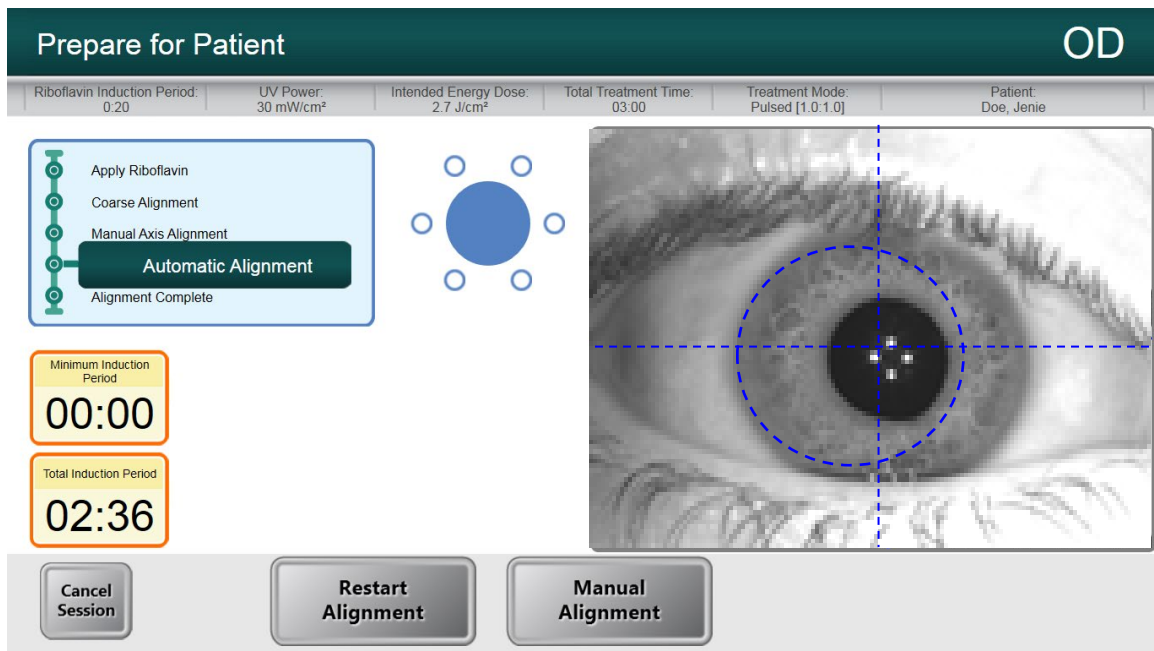


Figure 5-24. Restart Auto Alignment or Manual Alignment Option

- Selecting manual alignment provides use 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 for aligning the axis to corneal markings on the patient's cornea, and Alignment Lasers for manual alignment in X-Y and Z direction. See Figure 5-25.

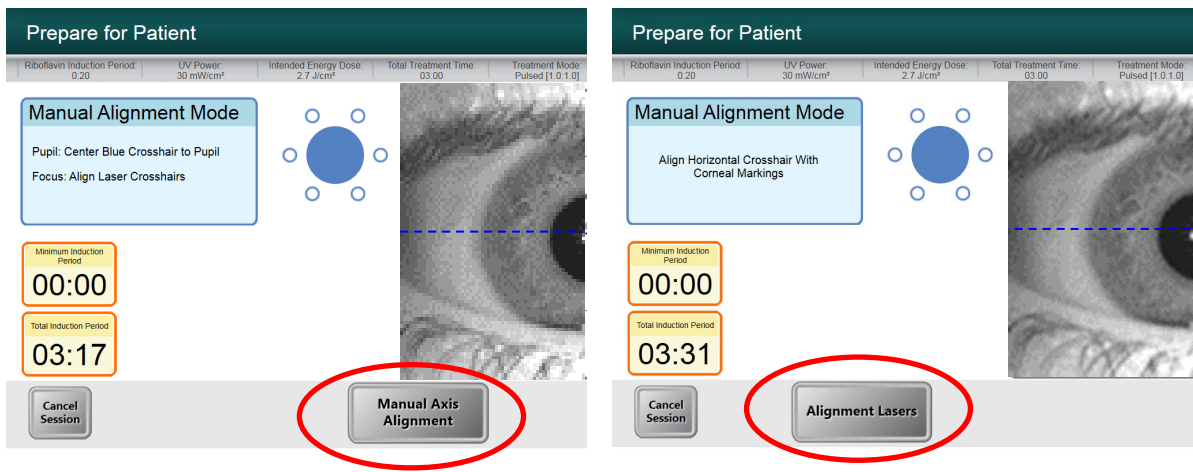


Figure 5-25. Toggling between Manual Axis Alignment & Alignment Lasers

## 5.10 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.



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

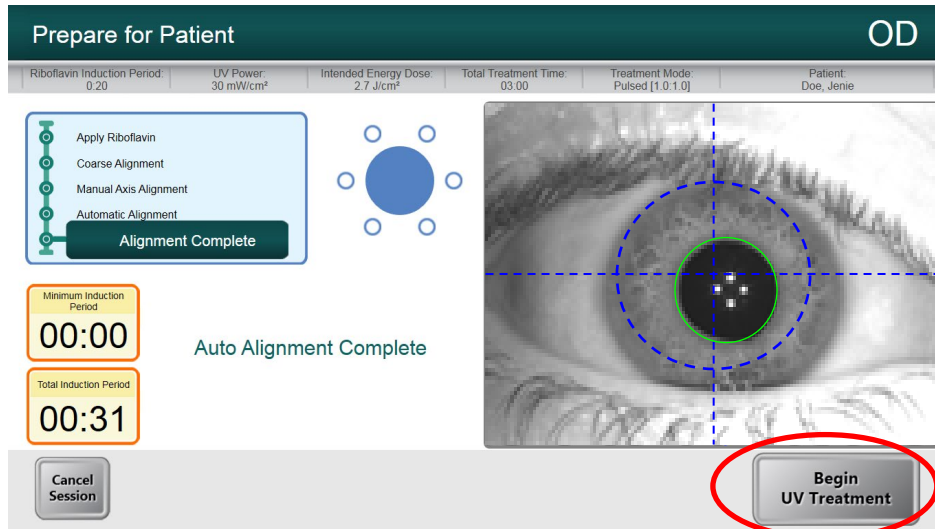


Figure 5-26. Begin UV Treatment

- 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.
- An onscreen treatment tracker shows Treatment Time Remaining, Total Energy Delivered and Total Induction Period. See Figure 5-27.

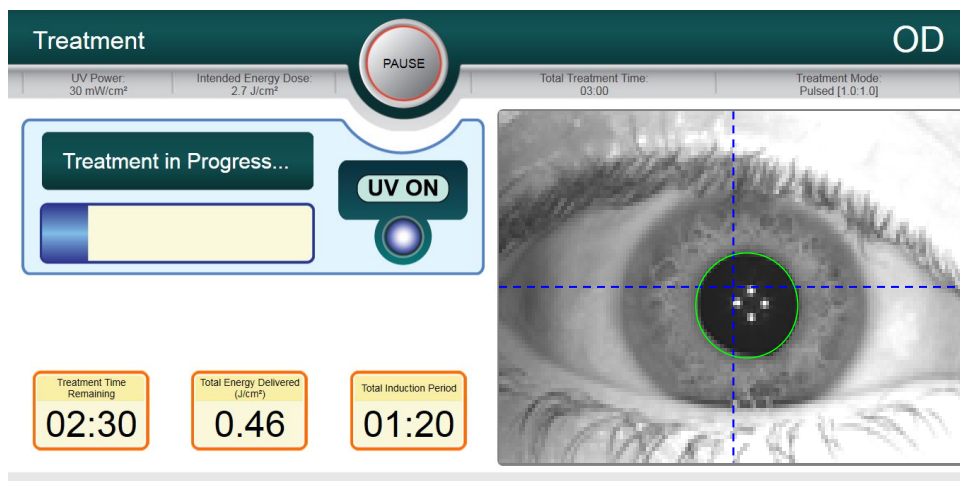


Figure 5-27. Treatment in Progress

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

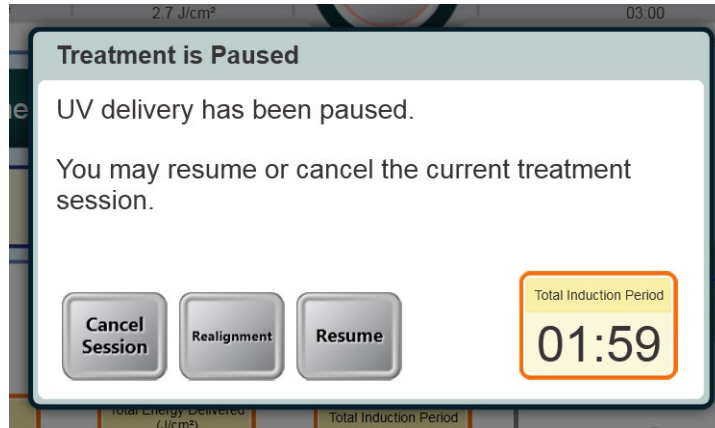


Figure 5-28. Pausing UV Treatment

- 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.

## 5.11 Treatment Complete

- At the completion of a treatment, a summary of treatment parameters will be displayed, and the screen will show “Treatment Completed”, as shown in Figure 5-29.

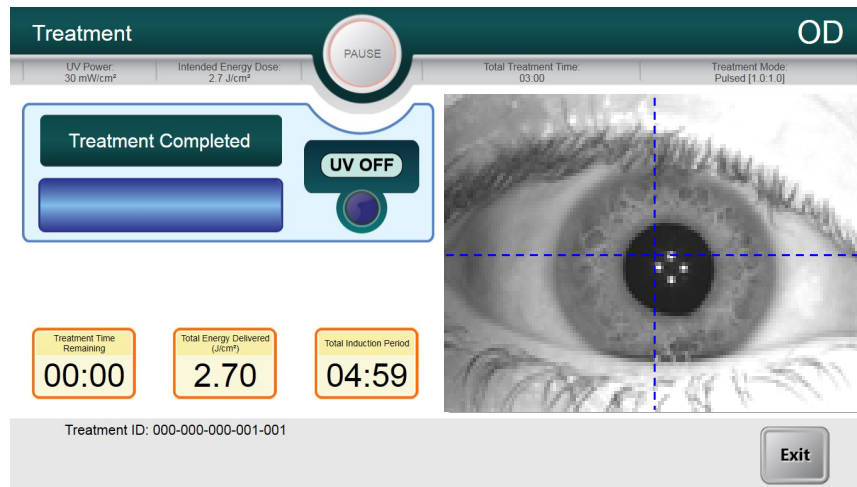


Figure 5-29. Treatment Complete Screen

- 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.

### 5.12 Treatment Incomplete

- If for some reason, the treatment is cancelled or stopped before it is complete, the patient record in Patient Central will be annotated with a red exclamation mark (!)
- In Patient Central, click on the red exclamation mark to show the actual treatment performed vs. the intended treatment, as shown in Figure 5-30.
- User can retreat patient to complete the remaining dosage. If this treatment is performed again to complete the treatment dosage, the red exclamation mark annotation will be removed.

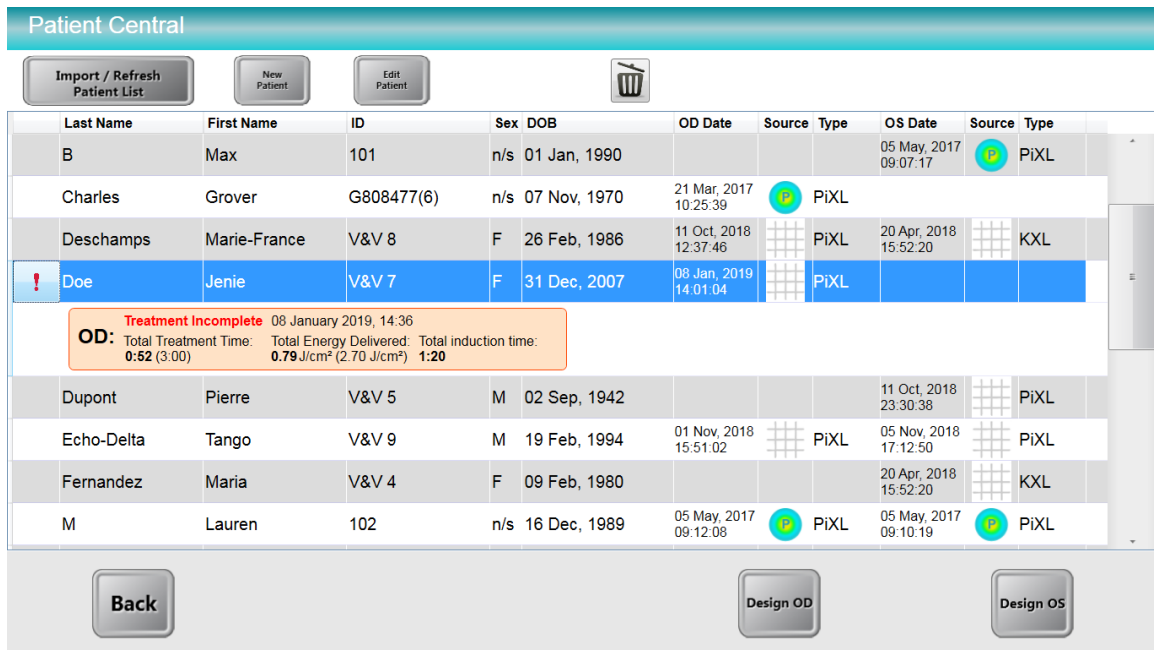


Figure 5-30. Treatment Incomplete Annotation

### 5.13 Power Down the System

- Press the “Back” button in Patient Central
- Press the “Power Off” button then press “Power Off” again, as shown in Figure 5-31 to go on Stand By Mode.
- Unplug the System to power down.

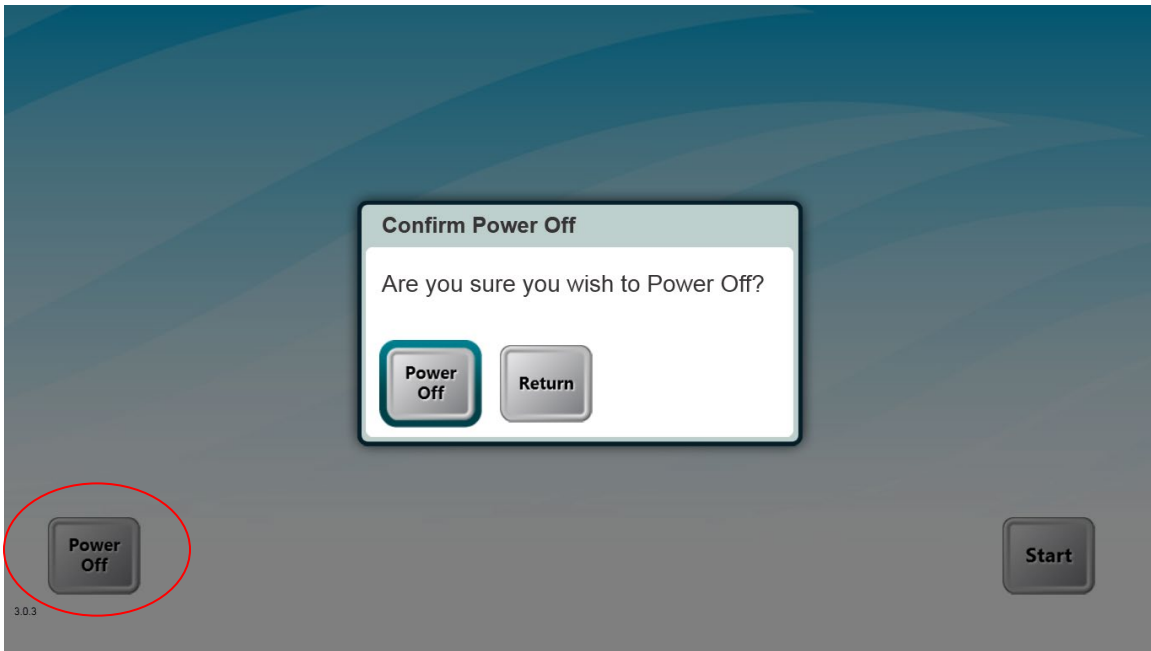
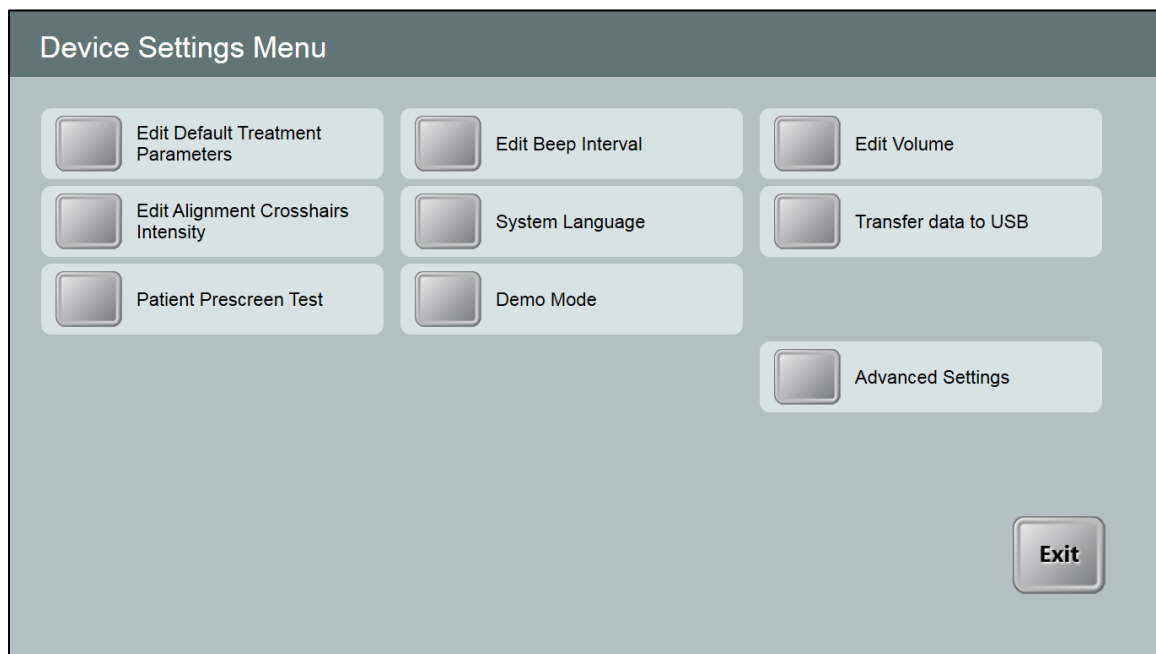


Figure 5-31. Power Down System

# 6 Device Settings

## 6.1 Using the Device Settings Menu

- To access the Device Settings Menu, press the “Back” button from Patient Central to navigate to the main initiation screen.
- Press the Mosaic logo on the touchscreen to open the Device Settings Menu as shown in Figure 6-1.



*Figure 6-1. Device Settings Menu*

### 6.1.1 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.

### 6.1.2 Transfer Data to USB

- Select “Transfer Data to USB” on the Device Settings Menu.

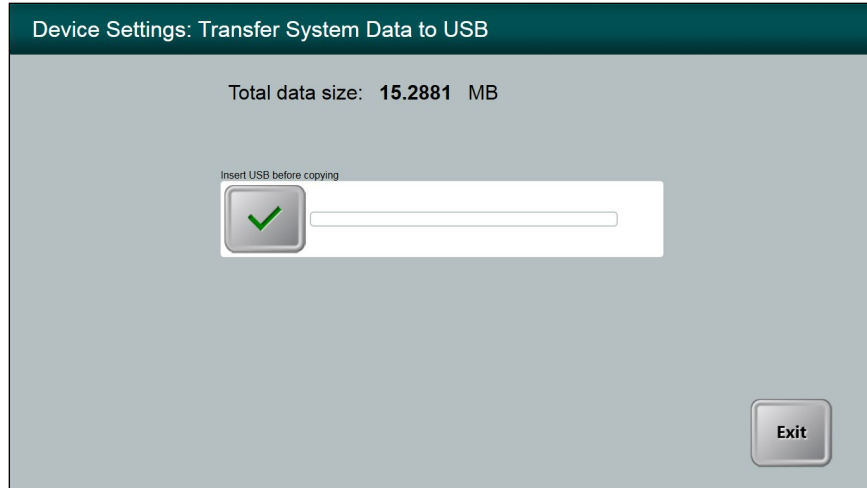


Figure 6-2. Device Settings Transfer to USB

- Insert a USB device into the USB port.
- Press the checkbox to copy treatment data to the USB. The System begins transferring the treatment data and shows a progress bar of the transfer process.
- Once complete, select “Exit”. The System will return you to the Device Settings menu.

### 6.1.3 Edit Default Treatment Parameters

- The user may elect to edit the default settings for the Induction Period, UV Power, Total Energy, and UV Mode.

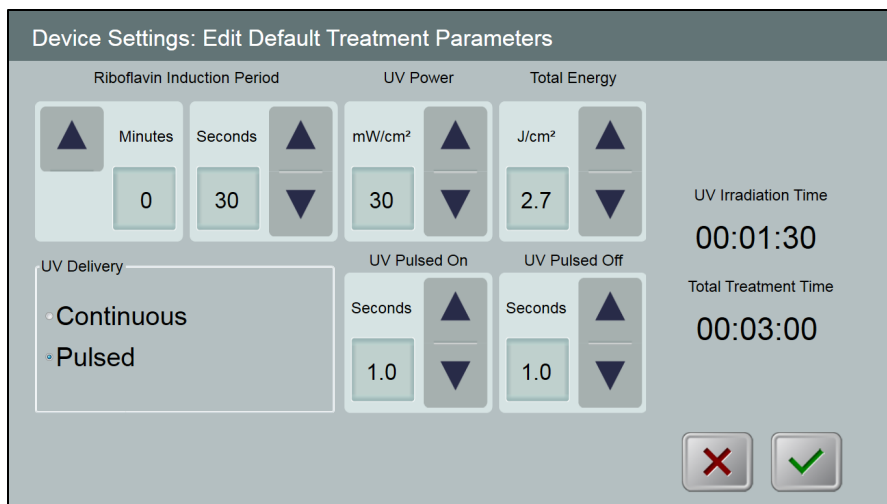


Figure 6-3. Edit Default Treatment Parameters (Continuous & Pulsed)

- When finished editing treatment parameters, select the green checkmark.



### 6.1.4 Patient Prescreen Test

The patient prescreen test allows the user to prescreen a patient with an intra-ocular lens (IOL) or a cataract to ensure that the IOL will not interfere with the auto alignment and eye tracking system during a future treatment.

Prescreening should be performed with a lid speculum in place and room lighting configured as it would be during treatment.

**NOTE:** no UV light is delivered during the prescreen. Only diagnostic NIR and pulsed yellow light are used for this process.

- Select Patient Prescreen Test.
- Insert a USB drive with at least 6 GB of available space.

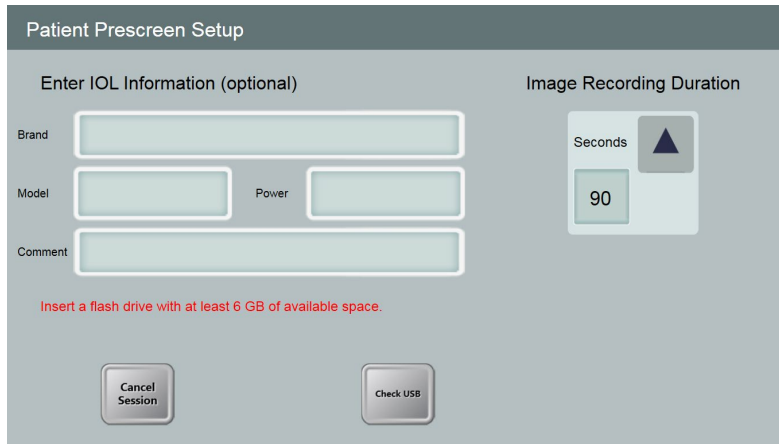


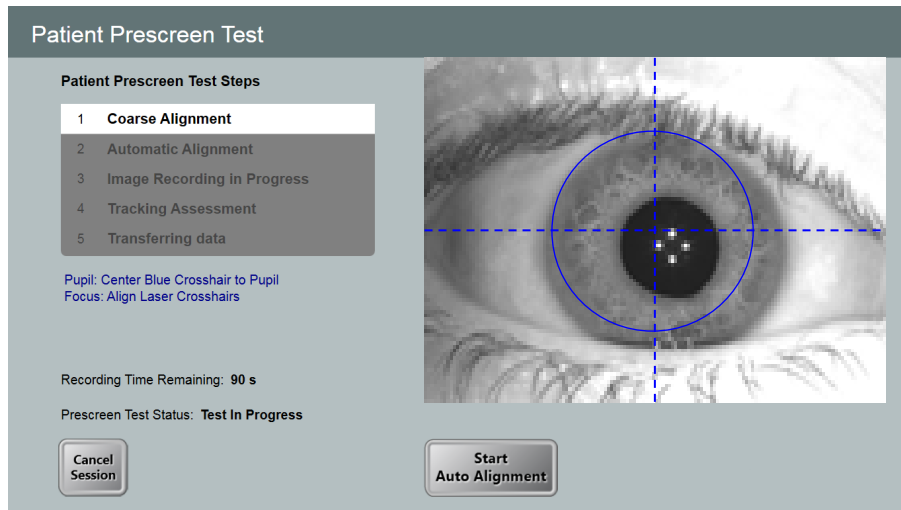
Figure 6-4. Insert flash drive

- *Optional* - Enter information regarding the IOL brand, model and power.
- Select the video Image Recording Duration (from 90 seconds to 180 seconds, with default at 90 seconds).



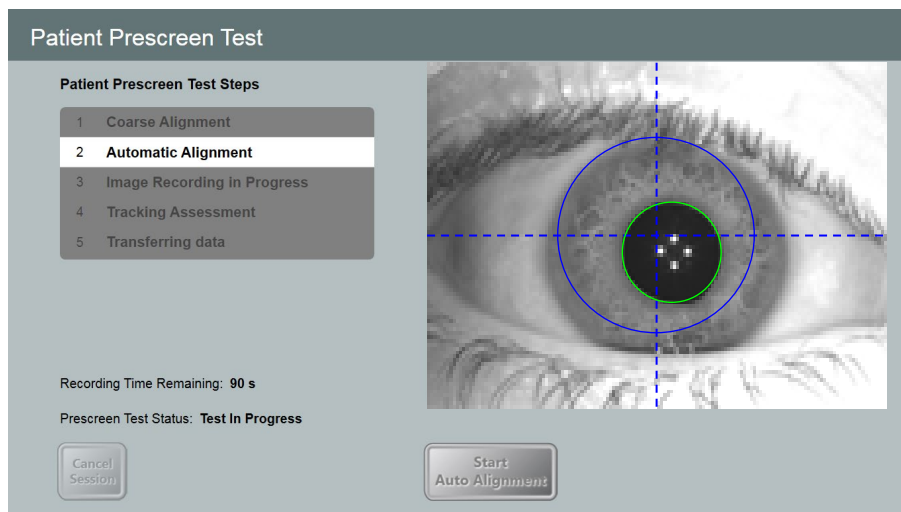
Figure 6-5. Enter IOL Information

- Select “Continue to” proceed with the screening.



*Figure 6-6. Alignment Step*

- In the Patient Prescreen Test, the user is prompted to perform the coarse alignment procedure (see Section 5.7).
- Once coarse alignment is complete, select “Start Auto Alignment” to start the auto alignment.
- The device starts auto alignment as well as image recording.
- Each step of the Patient Prescreen Test is tracked onscreen.



*Figure 6-7. Screening Step Process*

- Throughout the recording period, the user should watch the process onscreen 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 treatment.

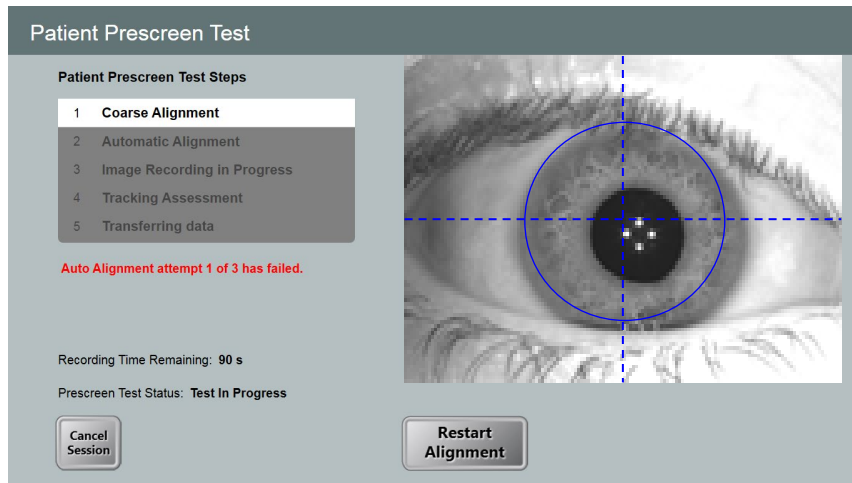


Figure 6-8. First Attempt Fail

- If auto alignment succeeds but eye tracking failures are detected by the System during the image recording period, as shown in Figure 6-9, the prescreen has failed and the user should not proceed with the treatment.

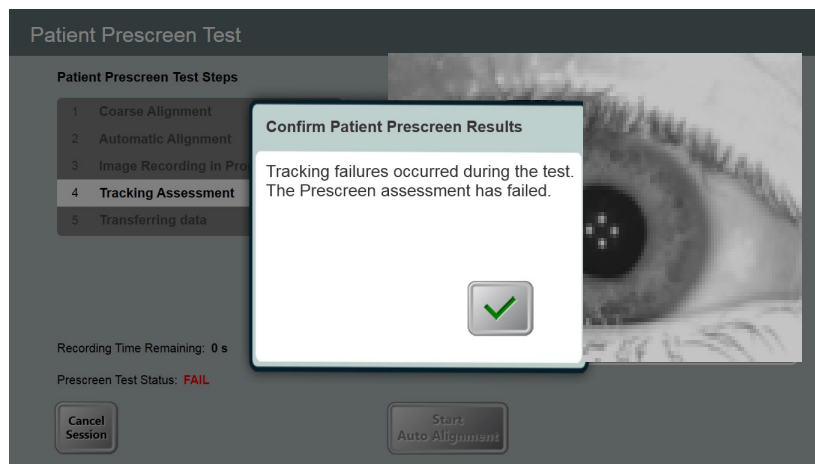


Figure 6-9. Failed Prescreen Assessment Due to Eye Tracking Errors

- Pass Mode
  - Auto alignment passes and no eye tracking failures are detected by the System
  - User is asked to confirm that the green circle correctly tracked the pupil throughout the recording period.

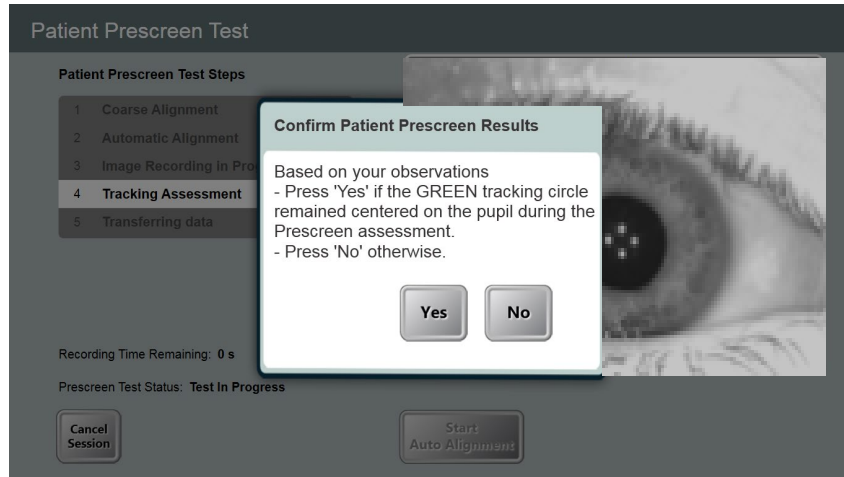


Figure 6-10. Confirm Patient Prescreen Results

- Select “Yes” to confirm.
- An onscreen “Pass” message as shown in Figure 6-11 will indicate that the test is complete and data will be transferred to the USB drive. Do not remove the USB drive during this step.

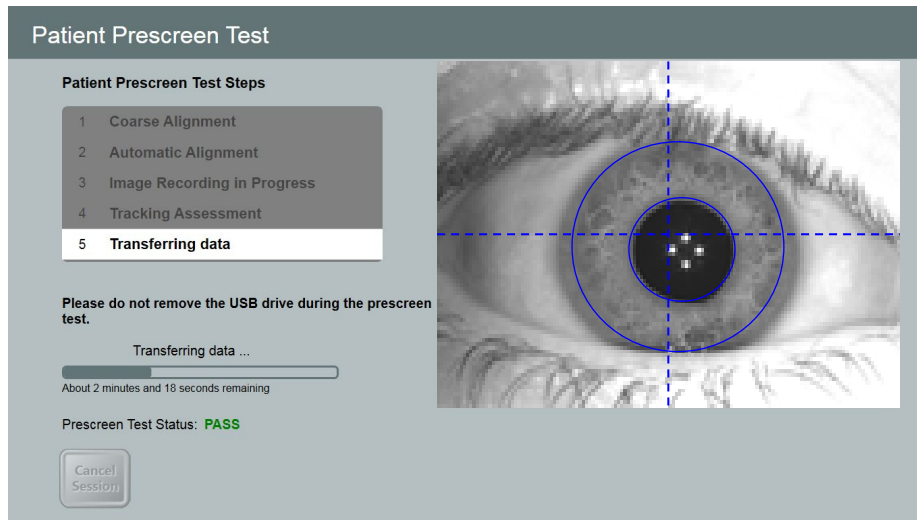


Figure 6-11. Prescreen Test Pass

- A patient who passes the prescreen test is eligible for treatment.

## 6.1.5 Demo Mode

**NOTE:** Not for use in treating patients

Demo mode allows users to train on use of the Mosaic System without requiring treatment cards and without using UV light.

- Select “Demo Mode”
- Select “Start” to use the System in Demo Mode

---

# 7 Maintenance / Service

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In this manual, “maintenance” refers to those non-technical procedures an everyday operator performs to keep the System working properly. “Service,” by contrast, refers to tasks that are intended to be performed only by a qualified service representative.

## 7.1 Installation Policy

- For each new Mosaic System customer, a trained person may provide a full initial installation and start-up of the System. Following initial installation and once the System is operating properly, the trained person may also provide basic training to a designated operator.
- 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.

## 7.2 Customer Maintenance

- In general, there is no customer maintenance required for the Mosaic System.
- All technical 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.

## 7.3 Warranty Information

- A Warranty is supplied separately with the purchasing information.

## 7.4 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.

## 7.5 Troubleshooting

- 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.

## 7.6 Directions for Disinfection

- Do NOT sterilize any components of the Mosaic System.
- 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.

## 7.7 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 soapy water.
  - 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.

## 7.8 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.

## 7.9 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 7-1. Moving Position of the Mosaic System*

- Transport or shipment of the Mosaic System should be performed only by Avedro trained and authorized personnel. Contact your local Avedro representative.

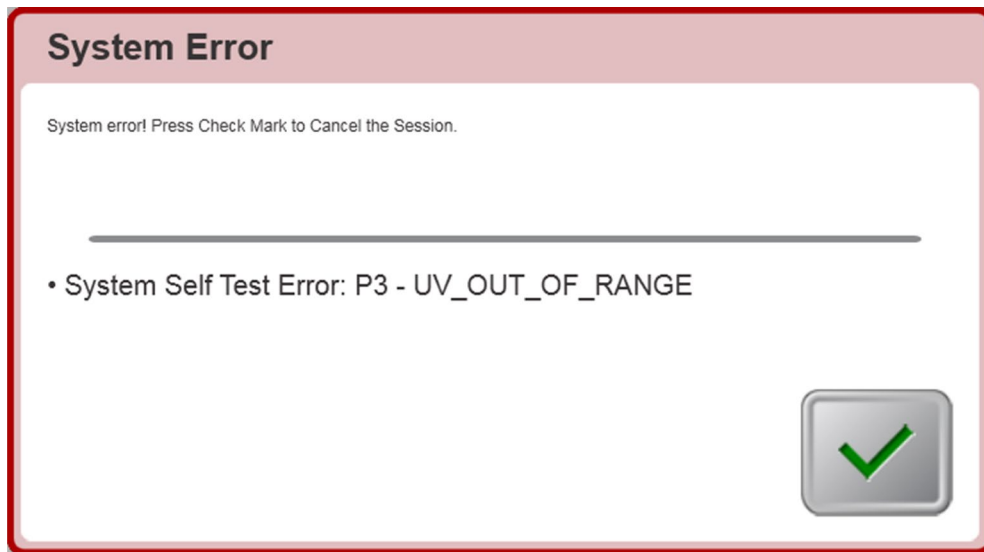


## 7.10 Storing the System

- Follow all the storage temperature and humidity range specifications as listed in Section 10, Specifications.
- 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 touchscreen 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.

## 7.11 Software

- Contact your local Avedro service representative for any suspected software corruption or failure to work correctly.
- Software updates will only be performed by Avedro-trained service representatives.
- Contact your local Avedro service representative if an error message appears as displayed below in Figure 7-1. Record and share the error code with your Avedro service representative.



*Figure 7-2. Example Error Message Box*

## 7.12 Identifying Risks Associated with Disposing of Waste Products

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

## 7.13 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.

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# 8 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
  - Disinfect-able 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 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 60601-1
- CSA C22.2 No 60601-1:14

## 8.1 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.	
Cables	Accessories
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.		
Emissions test	Compliance	Electromagnetic environment – guidance
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.  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.
RF emissions CISPR 11	Class B	
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.

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
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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	0 % UT (100 % dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100 % dip in UT) for 5 sec	0 % UT (100 % dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100 % dip in UT) 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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

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. Recommended separation distance $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 800 MHz to 2.7 GHz	3V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment (IEC 61000-4-3:2006 A1:2007 A2:2010)	15 specific frequencies. Immunity level 9-28V/m	15 specific frequencies. Immunity level 9-28V/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 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
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 2.7 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 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.












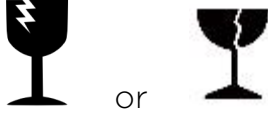
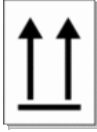
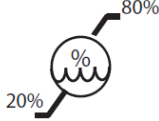



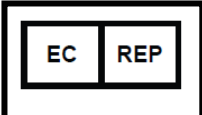



The Mosaic System contains an RFID function which transmits and receives at the 13.56 MHz frequency. This functionality may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

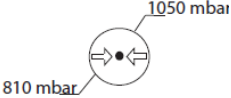


The Mosaic System contains the following RF transmitters:		
RFID Reader		
<ul style="list-style-type: none"> <li>• 13.56MHz Reader/Writer</li> <li>• Integral Antenna: Maximum 4" Read Range</li> <li>• Max output power is 200mW</li> <li>• Meets: ISO18000-3, ISO15693</li> </ul>		
WiFi Adapter		
Frequency Modulation	5 GHz (802.11a/n)	2.4 GHz (802.11b/g/n)
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



# 9 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 operator's 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)

Text Symbol	Symbol Illustration	Definition
12. Wine glass with crack on it		Contents are fragile, handle with care
13. Two up arrows		Keep arrows on carton pointing up
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

Text Symbol	Symbol Illustration	Definition
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

# 10 Specifications

Specification	Description
Electrical	Line voltages 100 – 240 volts AC, $\pm 10\%$ Current 10A – 5A Single Phase 50/60 Hz, $\pm 5\%$ Fuse: T 10H, 250V
Energy Delivery	UV Radiation 10 – 100 mW/cm <sup>2</sup> 365 nm
External Interfaces	USB 2.0
Physical Dimensions	103 x 81 x 152 cm <sup>3</sup> (Length x Width x Height)
Weight	NW 137 Kg GW 217 Kg
Environmental Operating Conditions	The System operates under the following atmospheric conditions (no condensation).
Ambient temperature	+15 to +30°C
Relative humidity	20% to 80%, non-condensing
Atmospheric pressure	810 to 1050 mbar
Transport and Storage Conditions	The System withstands the following transport and storage conditions without damage or performance deterioration.
Ambient temperature	-10 to +60 °C
Relative humidity	10% to 80%, non-condensing
Atmospheric pressure	750 to 1060 mbar

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