



User Guide

Cyclo G6[®] Laser with Sweep Management Software for MicroPulse[®] Transscleral Laser Therapy

Provides information on procedure-specific screens,
audible tones, and summary of patient treatment parameters



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1. Introduction

1.1 Purpose of the User Guide

This User Guide is intended to provide information specific to the Cyclo G6® Sweep Management Software Upgrade for MicroPulse® Transscleral Laser Therapy (TLT) delivered with the MicroPulse P3® Delivery Device (also referred to as “MicroPulse P3 Probe”).

This User Guide will describe and explain the operation of the graphical user interface screens and treatment parameter fields specific to the software upgrade. The User Guide will not provide information that is common to both the standard software and the software upgrade. For complete instructions for use, refer to the Cyclo G6 Laser System Operator Manual and MicroPulse P3 Delivery Device Instructions for Use (IFU).

NOTE: This User Guide is intended to be used in conjunction with the Cyclo G6 Laser System Operator Manual and the MicroPulse P3 Delivery Device IFU.

1.2 Intended Use and Indications for Use

This software upgrade is intended to facilitate console and probe use when performing MicroPulse TLT by providing procedure-specific screens, audible tones, and a summary of patient treatment parameters.

Please refer to the Cyclo G6 Laser System Operator Manual and the MicroPulse P3 Delivery Device IFU for complete description of Intended Use and Indications for Use.

1.3 Contents of the Sweep Management Software Upgrade

This software upgrade includes Set-up Screens, a Treat Screen, and a Post-Treatment Screen that are specific to the MicroPulse TLT procedure. These separate procedure-specific screens allow the user to navigate the loading and programming of parameters during setup, monitor delivery during treatment, and then view a summary of treatment information used for the patient.

Additionally, the software upgrade provides audible tones to help the physician match the desired sweep speed velocity while sweeping the MicroPulse P3 Probe over a given segment (i.e., quadrant or hemisphere).

2. Overview of Procedure-Specific Screens

The Cyclo G6 Sweep Management Software upgrade for MicroPulse TLT differs from the standard software provided with the Cyclo G6 laser system, in that the upgrade provides procedure-specific Set-Up Screens, a Treatment Screen, and a Post-Treatment Screen, in addition to audible tones.

The following sections only describe screens and fields specific to the software upgrade. This user guide does not describe screens or fields that are common to both the software upgrade and the standard software. Please refer to the Cyclo G6 Laser System Operator Manual and the MicroPulse P3 Delivery Device IFU for information on the general operation and maintenance of the Cyclo G6 laser console and MicroPulse P3 Probe, including a description of the screens that are common to both the software upgrade and the standard software.

2.1 Set-up Screens

2.1.1 Standby Screen & Treatment Parameter Fields

The Standby Screen is used to enter the treatment parameters for MicroPulse TLT.

The screen includes two user programmable fields: "Duration/Sweep" (i.e., sweep velocity) and "Sweep/Segment" (i.e., number of sweeps per segment), and a treatment summary ("Tx Summary") icon that are not included in the standard software.

The two user programmable fields are "Duration/Sweep" (i.e., sweep velocity) and "Sweep/Segment" (i.e., number of sweeps per segment). These are two MicroPulse TLT treatment variables that have been underreported in the literature. Documenting these treatment variables will help users analyze their MicroPulse TLT treatment outcomes, and adjust parameters as needed to achieve the desired clinical outcome for each patient.

When the Tx Summary icon is pressed, the Treatment Summary Screen will appear. The Treatment Summary Screen offers the user the opportunity to document treatment information in the patient's record. No personal or identifying patient information is saved to the software.

See Table 1: Overview of Sweep Management Software Upgrade Screens

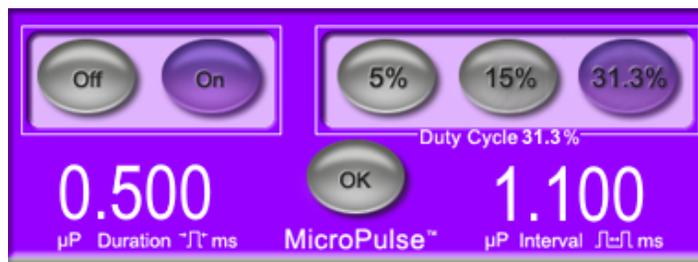
2.1.2 MicroPulse-Related Programmable Screens

The MicroPulse Duty Cycle Settings and the MicroPulse Preset Screen in the software upgrade differ from the standard software provided with the Cyclo G6 laser, as shown below.

2.1.2.1 Duty Cycle Settings

| | Standard Software | Software Upgrade |
|--------------------|-------------------|------------------|
| Default Selections | 5%, 10%, 15% | 5%, 15%, 31.3% |

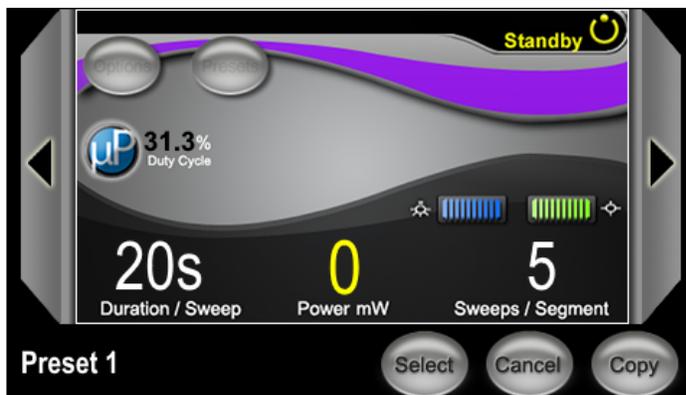
NOTE: There is no change to the manual adjustment of duty cycles, and there is no change to the range of MicroPulse durations and intervals.



MicroPulse Duty Cycle Settings
as shown in the Software Upgrade

2.1.2.2 Preset Screen

| | Standard Software | Software Upgrade |
|---------------------|-------------------|----------------------------------|
| Programmable Fields | Total Duration | Duration/Sweep Sweeps/Segment |



MicroPulse Preset Screen
as shown in the Software Upgrade

2.2 Treat Screen

The Treat Screen is displayed when the user presses the Standby/Treat button to enter Treat Mode. There are no programmable fields on the Treat Screen.

The Treat Screen allows the user to track the progress of a treatment segment (i.e., quadrant or hemisphere). The following information is displayed:

1. Total Sweeps per Segment
2. Current Sweep
3. Sweep Duration Remaining
4. Total Segment Duration
5. Total Seconds Remaining
6. Power

Once a treatment segment is completed, the **"Next Segment" button** automatically replaces the stopwatch. The field caption next to the button, reads "Segment Completed." To deliver treatment to the next segment (i.e., quadrant or hemisphere), press the "Next Segment" button to reset the "Sweep Duration Remaining" the "Current Sweep," and the "Total Seconds Remaining" fields to their starting values.

See Table 1: Overview of Software Upgrade Screens, Treat Screen

2.3 Post-Treatment Screen ("Treatment Summary" Screen)

The Treatment Summary Screen is accessible by selecting the "Tx Summary" icon on the Standby Screen. There are no programmable fields on the Treatment Summary Screen.

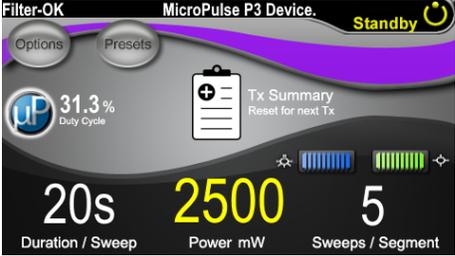
The Treatment Summary Screen allows the user to view a summary of treatment information used for the patient, including:

1. Total Segments
2. Total Duration
3. Total Sweeps
4. Procedure Duration/Sweep, Power, and Sweeps/Segment

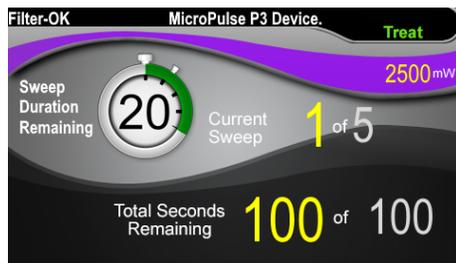
Cumulative values should be reset between treatments. Resets can be performed either before or after each MicroPulse TLT treatment.

The Treatment Summary Screen provides MicroPulse TLT treatment data that the user may record in the patient's file. Alternatively, the user may take a picture of the Treatment Summary screen, to place in the patient's file. No personal or identifying patient information is saved to the software.

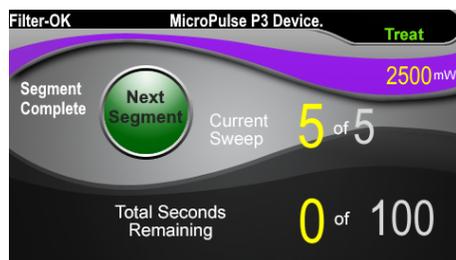
Table 1: Overview of Sweep Management Software Upgrade Screens

| Software Upgrade Screens | Description |
|--|--|
| <p>Standby Screen</p>  <p>The screenshot shows the Standby Screen interface. At the top, it says 'Filter-OK' and 'MicroPulse P3 Device.' with a 'Standby' indicator. There are 'Options' and 'Presets' buttons. A 'Tx Summary' icon is present with the text 'Reset for next Tx'. The duty cycle is shown as 31.3%. The main parameters are displayed in large numbers: 20s (Duration / Sweep), 2500 (Power mW), and 5 (Sweeps / Segment). There are also small bar graphs for aiming beam settings.</p> | <p>The Standby Screen is used to enter the following treatment parameters* for MicroPulse TLT:</p> <ul style="list-style-type: none"> • Duration/Sweep • Power • Sweeps/Segment <p>The Standby Screen gives access to the Options menu, Presets menu, MicroPulse duty cycle settings, aiming beam settings, and Treatment Summary Screen.</p> <p>* The MicroPulse duty cycle defaults at 31.3% when a MicroPulse P3 Probe is connected to the Cyclo G6 laser.</p> |

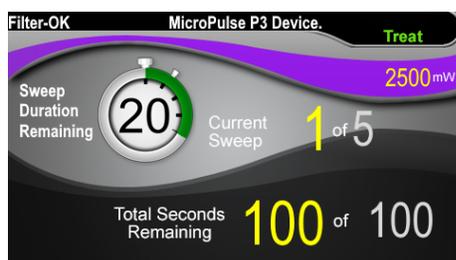
Treat Screen



The Next Segment button appears over the stopwatch when a user completes treatment of a segment.



To treat the next segment, press the Next Segment button to reset the Sweep Duration Remaining stopwatch, the Current Sweep and the Total Seconds Remaining fields to their starting values. The stopwatch reappears.



The Treat Screen displays the following fields:

- Power
 - Its value is automatically transferred from the “Power” field on the Standby Screen.
- Sweep Duration Remaining (Stopwatch)
 - Its value is automatically transferred from the “Duration/Sweep” field on the Standby Screen.
 - The Sweep Duration Remaining field tracks the progress of a single sweep and automatically resets after each sweep.
- Total Sweeps per Segment
 - Its value is automatically transferred from the “Sweeps/Segment” field on the Standby Screen.
- Current Sweep
 - The current sweep automatically advances after each completed sweep.
- Total Segment Duration
 - Its value is automatically calculated as the product of the Duration/Sweep and Sweeps/Segment fields.
- Total Seconds Remaining
 - Automatically counts down the total seconds remaining for the segment.

The **Next Segment button** appears over the Sweep Duration Remaining stopwatch when a user completes treatment of a segment.

To treat the next segment, press the “Next Segment” button to reset the “Sweep Duration Remaining,” the “Current Sweep,” and the “Total Seconds Remaining” fields to their starting values.

Treatment Summary Screen



The Treatment Summary Screen displays a summary of the MicroPulse TLT treatment delivered, including:

- Total Segments
- Total Duration in seconds
- Total Number of Sweeps
- Duration per Sweep
- Treatment Power
- Number of Sweeps per Segment

The Total Segments, Total Duration, and Total Number of Sweeps are cumulative until the Reset and Close button is selected. Prior to a new MicroPulse TLT treatment, view the Treatment Summary Screen to confirm that these values have been reset to zero.

No personal or identifying patient information is saved to the software.

3. Audible Tones

To help the physician match the desired sweep speed velocity while sweeping the MicroPulse P3 Probe back and forth over a given segment (i.e., quadrant or hemisphere), a single tone is automatically played at the halfway point of a sweep, and a double tone of the same sound is played at the start of the next sweep.

The volume of the tone can be adjusted in the Options menu, accessible from the Standby Screen.

4. Operation

The following operation descriptions are specific to the software upgrade. Please refer to the Cyclo G6 Laser System Operator Manual and the MicroPulse P3 Delivery Device IFU for a complete description of Intended Use and Indications for Use.

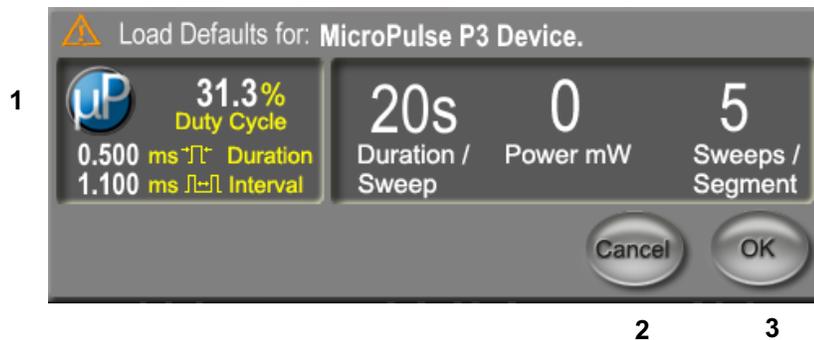
4.1 Setting Parameters

4.1.1 Load Default Parameter Options

After setting up the Cyclo G6 laser, turning on the laser, and connecting the MicroPulse P3 Probe, a Load Defaults pop-up window appears with the options to load or to cancel default treatment values.

The Load Defaults pop-up window in the software upgrade replaces the Total Duration field in the standard software with the Duration/Sweep and the Sweeps/Segment fields.

The product of the Duration/Sweep and Sweeps/Segment fields automatically calculates the total duration per segment. The total duration per segment is displayed in the Treat Screen.



Load Defaults for MicroPulse P3 Device Pop-up Window

| | | |
|---|-------------------|--|
| 1 | Parameter Display | Default parameters, excluding Power, for the connected device. |
| 2 | Cancel | Press to cancel changes and return to the Standby Screen to retain prior parameters. |
| 3 | OK | Press to load the default parameters and go to the Standby Screen. |

After pressing either “Cancel” or “OK,” a pop-up screen will appear for the user to acknowledge eye safety requirements as shown below. Select “OK” to acknowledge eye safety requirements and go to the Standby Screen.



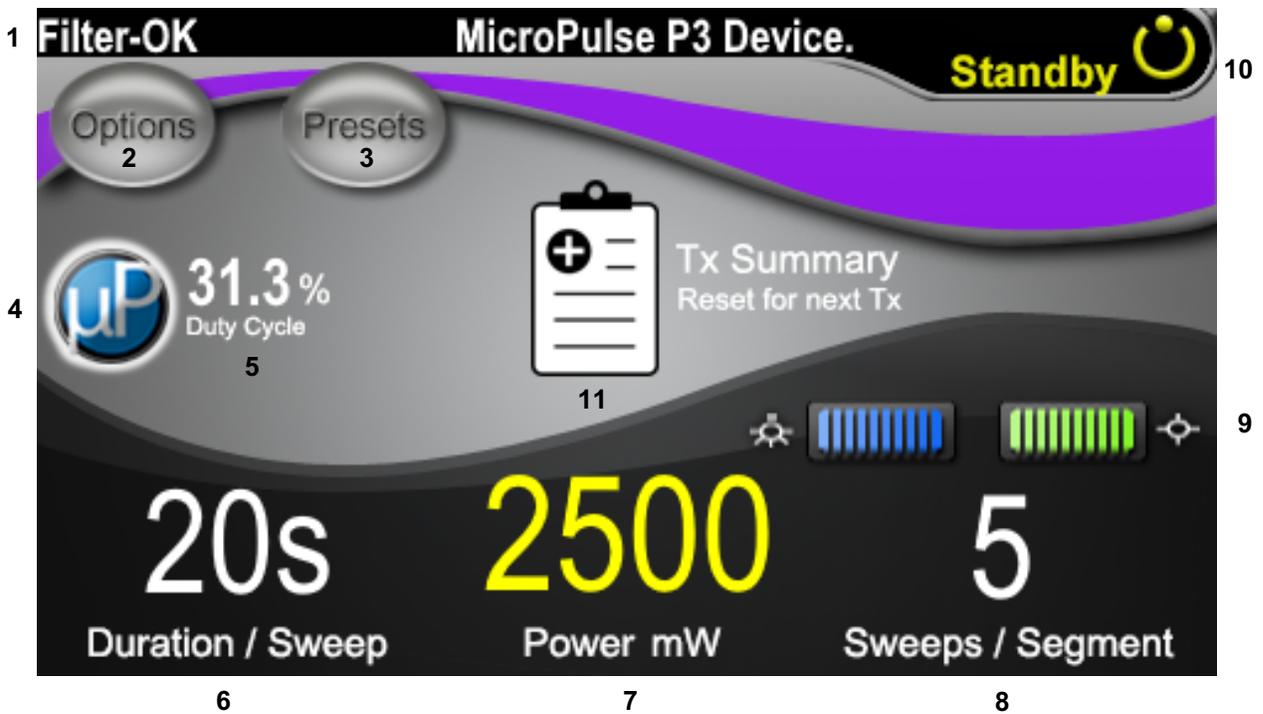
Eye Safety Requirements Pop-up Window

4.1.2 Press the “Tx Summary” icon to reset treatment summary values to zero

Select the “Tx Summary” icon in the Standby Screen to access the Treatment Summary Screen. In the Treatment Summary Screen, select the “Reset and Close” button. It will reset the total segment, total sweeps, and total duration values to zero.

4.1.3 Review/Modify Treatment Parameters

In the Standby Screen, review your desired treatment parameters for MicroPulse Duty Cycle, Duration/Sweep, Power, and Sweeps/Segment fields, and modify as needed. To modify parameters, either adjust the values manually or select a Preset to load user-programmed treatment parameters.



Standby Screen

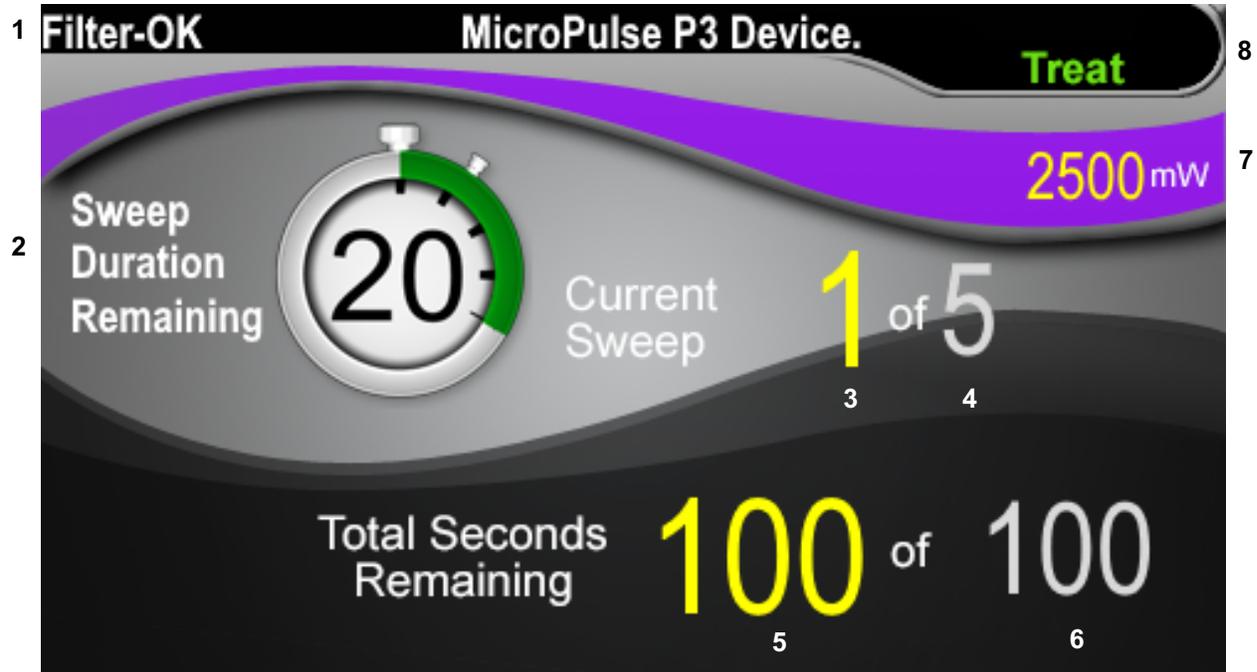
| | |
|---|--|
| 1 | Displays eye safety filter status and the connected delivery device. |
| 2 | Press to go to the Options Screen. |
| 3 | Press to go to the Presets Screen. |
| 4 | Press to adjust MicroPulse settings. |
| 5 | Displays the selected MicroPulse duty cycle. |

| | |
|----|---|
| 6 | <p>Duration/Sweep field</p> <p>Values range from 5 seconds to 40 seconds in 5-second increments.</p> <p>Use the left control knob to enter the duration (velocity) per sweep in the “Duration/Sweep” field. The value will be transferred to the “Sweep Duration Remaining” field (stopwatch countdown timer) in the Treat screen.</p> |
| 7 | <p>Power field</p> <p>Values range from 50 mW to 3,000 mW in 10-mW increments.</p> <p>Use the center control knob to enter the laser power setting (mW). The value will be transferred to the “Power” field in the Treat Screen.</p> |
| 8 | <p>Sweep/Segment field</p> <p>Values range from 1 sweep to 10 sweeps in 1-sweep increments.</p> <p>Use the right control knob to enter the number of sweeps per segment in the “Sweeps/Segment” field. The value will be transferred to the “Total Sweeps per Segment” field in the Treat Screen.</p> |
| 9 | <p>Displays the selected Illumination and Aiming Beam settings.</p> |
| 10 | <p>Displays the current laser mode:</p> <ul style="list-style-type: none"> Ready: The laser is ready and will fire when you press the footswitch. Standby: The laser is disengaged. Treat: The laser is firing (the footswitch has been pressed). |
| 11 | <p>Press to open the Treatment Summary Screen.</p> |

4.2 Delivering Treatment

Note: Before delivering treatment, please refer to the Cyclo G6 Laser System Operator Manual and the MicroPulse P3 Delivery Device IFU for delivery instructions, including safety, warnings, and cautions.

1. Press the Treat/Standby button to go to the Treat Screen.



Treat Screen

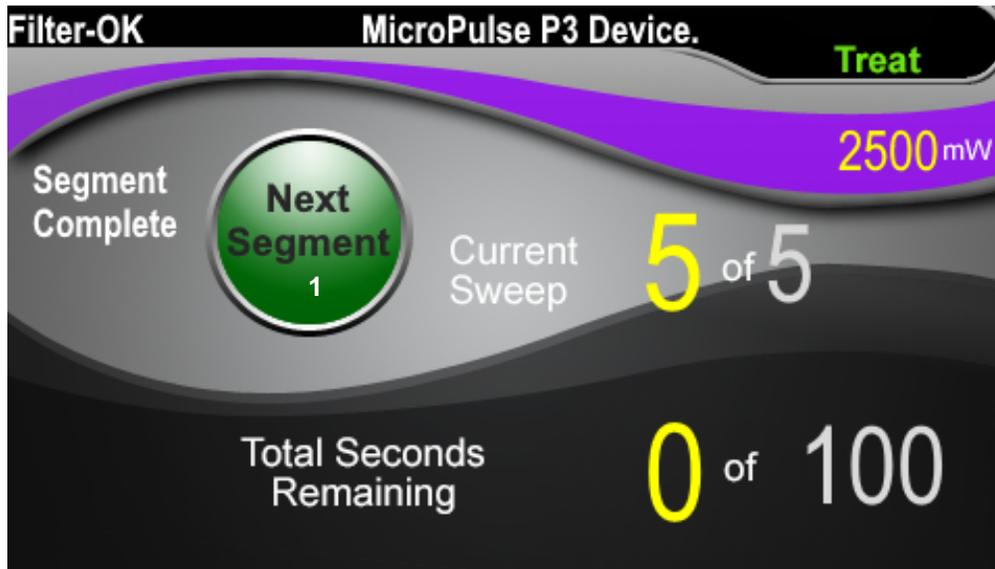
| | |
|---|--|
| 1 | Displays eye safety filter status and the connected delivery device. |
| 2 | The Sweep Duration Remaining stopwatch tracks the progress of a single sweep and automatically resets after each sweep. The starting value is transferred from the value entered in the “Duration/Sweep” field in the Standby Screen. At the completion of a treatment segment, the Next Segment button will appear over the stopwatch. Press the Next Segment button to reset the “Sweep Duration Remaining” the “Current Sweep” and the “Total Seconds Remaining” fields to their starting values. |
| 3 | Displays the current sweep being performed. |
| 4 | Displays the “Total Sweeps per Segment” programmed in the Sweeps/Segment field in the Standby Screen. |
| 5 | Displays the number of seconds remaining in the segment. |

| | |
|---|--|
| 6 | Displays the “Total Segment Duration” calculated as the product of the Duration/Sweep and Sweeps/Segment fields programmed in the Standby Screen. |
| 7 | Displays the selected laser power setting (mW) programmed in the Standby Screen. |
| 8 | Displays the current laser mode: Ready: The laser is ready and will fire when you press the footswitch. Standby: The laser is disengaged. Treat: The laser is firing (the footswitch has been pressed). |
| | |

2. Press the footswitch to activate the laser according to the instructions in the Cyclo G6 Laser System Operator Manual. If you need to interrupt the treatment, release the footswitch.

4.2.1 Advance to Next Segment

1. When a user completes treatment of a segment (i.e., quadrant or hemisphere), the stopwatch changes into a "Next Segment" button.
2. To treat the next segment, press the Next Segment button to reset the "Sweep Duration Remaining," the "Current Sweep," and the "Total Seconds Remaining" fields to their starting values.
3. When all the desired segments have been treated, select the Treat/Standby button to return to the Standby Screen.



Next Segment Button

| | |
|---|---|
| 1 | Press the Next Segment button to reset the "Sweep Duration Remaining", the "Current Sweep," and the "Total Seconds Remaining" fields to their starting values prior to treating the next segment. |
|---|---|

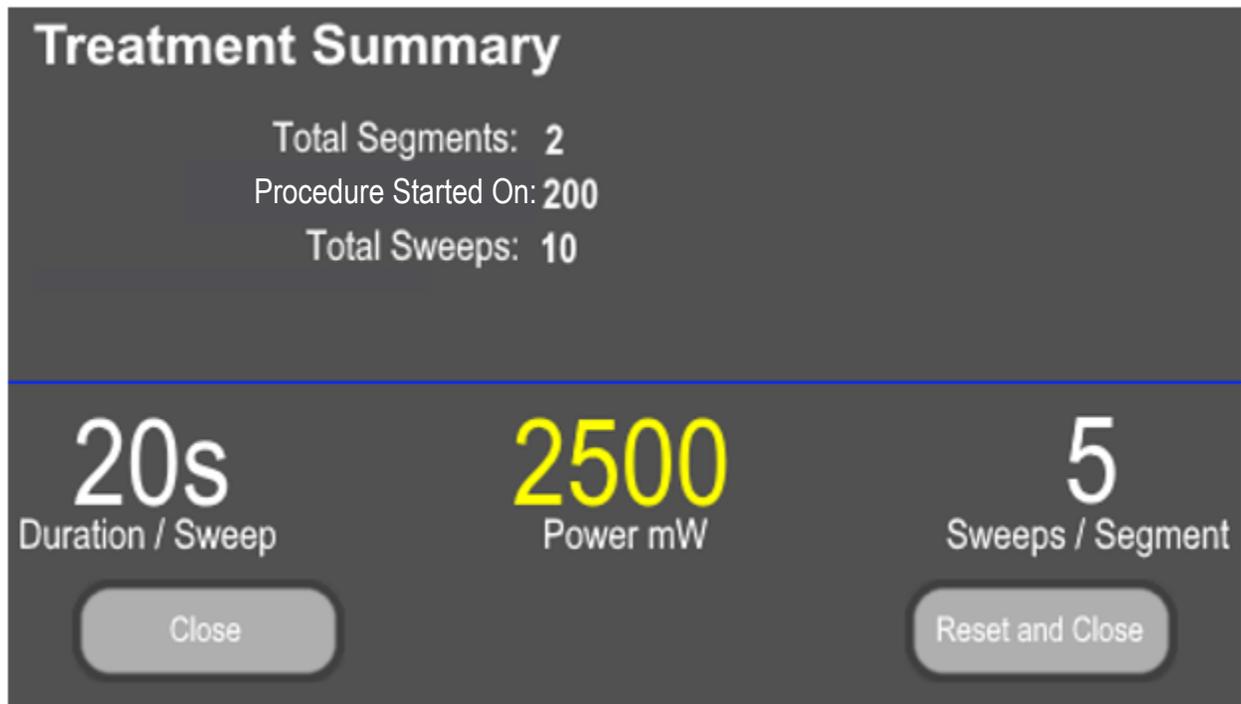
If the Next Segment button is pressed before the completion of a segment, a confirmation window will appear to confirm the reset.



| | |
|---|---|
| 1 | Press to close the window and complete the treatment segment. |
| 2 | Press to reset the timer for a new segment. |

4.3 Viewing and Documenting Patient Treatment Information

1. At the end of the MicroPulse TLT treatment
 - a. Press the "Tx Summary" icon on the Standby Screen to access the Treatment Summary Screen.
 - b. Manually document the treatment information in the patient's record, or take a photo of the Treatment Summary Screen to place in the patient's record. No personal or identifying patient information is saved to the software.
2. After documentation, select "Reset and Close" to reset the Total Segment, Total Duration and Total Sweeps values to zero in preparation for the next MicroPulse TLT treatment.



1

Treatment Summary Screen

2

| | |
|---|---|
| 1 | Press to close the screen and retain the treatment summary values. The screen closes and returns to the Standby screen. |
| 2 | Press to clear the Total Duration, Total Sweeps, and Total Segments fields. Treatment parameters are not affected. The screen closes and returns to the Standby Screen. |

5. Troubleshooting

Error Message

| Error Code | Error Message | Cause | User Action |
|------------|--|---------------------------|-------------|
| W00002 | User is aware of eye safety requirement. | Laser probe is connected. | Press OK. |

NOTE: Reference your Cyclo G6 Laser System Operator Manual for guidance on all other troubleshooting and system error messages.

6. Contact Information



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VISIBLE AND INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR SCATTERED RADIATION
CLASS 4 LASER PRODUCT
CLASS 2 LASER PRODUCT
(IEC 60825-1:2007/2014)

RAYONNEMENT LASER VISIBLE ET
INVISIBLE EXPOSITION DANGEREUSE
DE L'OEIL OU DE LA PEAU AU
RAYONNEMENT DIRECT OU DIFFUS
APPAREIL A LASER DE CLASSE 4
APPAREIL A LASER DE CLASSE 2
(CEI 60825-1:2007/2014)

$\lambda = 810 \text{ nm}$ $P_o = 3 \text{ W}$
 $\lambda = 635 \text{ nm}$ $P_o = 1 \text{ mW}$



Before delivering treatment, please refer to the “Cyclo G6 Laser System Operator Manual,” and the “MicroPulse P3 Delivery Device Instructions for Use” for delivery instructions, including safety, warnings, and cautions.

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