

# Pacifier Activated Lullaby<sup>®</sup> P.A.L.<sup>®</sup>

## Instructions for Use



IFU English  
500055 Rev F  
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## User Responsibility

The P.A.L. device will perform in conformity with the description contained in the instructions for use (IFU), service manual, and accompanying labels and/or guides, when assembled, operated, maintained, and repaired in accordance with the instructions provided. This product must be checked periodically. A defective product should not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately. Should such repair or replacement become necessary, NeoLight recommends making a service request by contacting Customer Service. This product or any of its parts should not be repaired other than in accordance with written instructions provided by NeoLight and by NeoLight trained personnel. The product must not be altered without NeoLight's prior written approval. NeoLight is not responsible for any damages or consequences resulting from unauthorized attempts to open, modify, or repair the device. This unauthorized service of the product also voids the warranty.

The user of this product shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than NeoLight. The user is also responsible for ensuring the manual version they reference is the most up-to-date and that the instructions and requirements are followed.

The P.A.L. Sensor has been designed for use with the Soothie Pacifiers manufactured by Philips. Use with any other pacifiers will be ineffective and may result in the P.A.L. device not functioning properly.



**CAUTION:**

U.S. Federal law restricts this device to sale by or on the order of a licensed medical practitioner

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## Chapter 1: About this Manual

### 1.1 Indications for Use

The P.A.L. device encourages and reinforces effective non-nutritive sucking of premature infants. This is accomplished by giving positive feedback to the infant in the form of recorded sound including but not limited to mother voice and music as auditory input in direct response to effective sucking.

### 1.2 Intended Users

The P.A.L. device should only be operated by health care providers or others designated by health care providers who are trained in its operation and familiar with the risks of this type of device.

### 1.3 Product Description

The P.A.L. device is based on the research of Jayne Standley, PhD., of Florida State University, and has been shown to assist in accelerating an infant's ability to suck effectively. The P.A.L. device is based on the hypothesis that premature infants may be able to improve sucking ability (intuitive in most full-term infants) when effective sucking is rewarded with music or mother's voice. The P.A.L. device was developed to encourage and reinforce effective non-nutritive sucking of premature infants. This is accomplished by giving positive feedback to the infant in the form of music or mother's voice as auditory input in direct response to effective sucking.













The P.A.L. device has a P.A.L. player, P.A.L. Sensor and a power supply. The P.A.L. Sensor senses the strength and duration of an infant's sucking on an attached pacifier and responds with music or a recorded sound (i.e., mother's voice) contingent to the infant's sucking. The P.A.L. Sensor consists of a wired transmitter with a built-in pressure transducer that connects to the pacifier and a receiver. The receiver decodes the signal and plays music or a recorded sound for a predetermined length of time via the P.A.L. player to the infant contingent on his/her sucking on the pacifier transmitter. This action occurs when the sucking strength and duration exceed the preset threshold. The user can control the sensitivity of the transducer.







The P.A.L. device has been designed to fit within an incubator or bassinet. The P.A.L. Device must be placed at the patients' midline at approximately 6 inches from the ears so that sound source is equidistant from the infant's ears. The P.A.L. Device delivers music binaurally (equally to both ears). The infant will not be able to maintain the pacifier in their mouth by themselves for any extended length of time, so the caregiver must hold the P.A.L. Sensor in the infant's mouth during the P.A.L. session. The P.A.L. Sensor will monitor usage time and disable after 90 minutes have elapsed. A P.A.L. session may be administered for 15 minutes once or twice daily until the infant is able to suck effectively.

## Chapter 2: Safety Information

### 2.1 Symbols

The following symbols are used in this IFU, on the device packaging, on the device, and accessory labeling.

Symbol	Description
	Reference Number; Part Number
	Catalog Identification
	Lot Number
	Serial Number
	Manufacturing Date
	Legal Manufacturer Name
	Follow Instructions for Use
	Prescription-only (USA)
	The product contains electrical equipment. Therefore, users should not discard this product along with other household waste
	Equipment not suitable for use in the presence of a flammable anesthetic mixture
	Type B.F. Applied parts
	Symbol placed next to <b>CAUTION</b> or <b><u>WARNING</u></b> to alert the users to important statements
<b>IPOX</b>	Do not expose to dust or moisture













	Keep the device away from sunlight
	Keep the device dry
	P.A.L. Sensors are single patient use only
	Hazard of severe electric shock or burn
	Non-Sterile
	Class II Equipment
<b><u>WARNING</u></b>	A <b><u>WARNING</u></b> statement is used when the possibility of injury exists
<b>CAUTION</b>	A <b>CAUTION</b> statement is used when the possibility of damage to the equipment exists
<b>IMPORTANT!</b>	Instruction provided to help ensure correct clinical results and provide quality assurance to the use of the P.A.L. device
<b>NOTE</b>	Background information provided to clarify a particular step or procedure. Information in this category is not considered precautionary



## 2.2 Warnings and Cautions

Before using the P.A.L. Device read through this entire manual. As with all clinical equipment, attempting to use this device without a thorough understanding of its operation and intent may render it ineffective or injurious to the patient. This device should only be operated by personnel familiar with the risks and benefits of this type of device. Additional precautions are listed in the text of this manual. If the P.A.L. Device or any of its accessories fail or are damaged, they should be repaired or replaced by the manufacturer or its authorized service representative. Any unauthorized repair or tampering will void applicable warranties. Do not use any accessories not supplied by the manufacturer. Always make sure the P.A.L. Device is disconnected and turned off prior to making any repairs or performing any maintenance procedures.

### Symbols And Descriptions

	<b><u>WARNING:</u></b> Failure to follow this IFU could result in injury to patient or provider
	<b><u>WARNING:</u></b> Failure to follow this IFU could result in damage to the unit
	<b><u>WARNING:</u></b> Do not remove back cover, non-user serviceable. This unit should be serviced by factory authorized personnel. Any unauthorized repair or tampering will void applicable warranties.
	<b><u>WARNING:</u></b> P.A.L. should be used only in the presence of a caregiver
	<b><u>WARNING:</u></b> Only the pacifier should come in contact with the patient.
	<b><u>CAUTION:</u></b> If using the power supply, disconnect the unit prior to wipe down
	<b><u>CAUTION:</u></b> Do not immerse in liquid
	<b><u>CAUTION</u></b> Do not place or store device where it is at risk of falling or being pulled into a tub or sink
	<b><u>CAUTION</u></b> Never force the plug into an outlet
	<b><u>CAUTION:</u></b> Never operate the P.A.L. Device if it has a damaged cord or plug
	<b><u>CAUTION:</u></b> Keep all cords away from heat sources
	<b><u>CAUTION:</u></b> Make sure that all cabling is routed away from the infant as to not impair movement

**CAUTION:**

Do not use speakers, power supplies, or any other accessory not supplied by Neolight as this could result in injury as well as void all warranties and regulatory certifications

**CAUTION:**

Dispose of batteries according to local regulations

**CAUTION:**

The P.A.L. Player should be placed at the patients' midline at approximately 6 inches from the ears so that sound source is equidistant from the infant's ears

**CAUTION:**

Infants must be monitored when using the P.A.L. Sensor

**CAUTION:**

Use of the pacifier in the P.A.L. Device should follow protocols for the use of any pacifier with the infant for whom a pacifier is appropriate

**CAUTION:**

Do not leave the P.A.L. Sensor in the crib unattended, as any unattended wire/cord in an infant's crib could cause entanglement resulting in asphyxiation or digital amputation

**CAUTION:**

Remove the P.A.L. Device from the crib when not in use

**CAUTION:**

To avoid the risk of the P.A.L. Player tipping, the caregiver should not lean his/her hand on the P.A.L. Player while it is in the crib

**CAUTION:**

No component is provided sterile, and the P.A.L. sensor is single patient use, and disposable

**CAUTION:**

If using a wall outlet connection, the P.A.L. Player should only be used with the supplied medical grade power supply. Only P.A.L. Sensor should be used. The P.A.L. Player will play MP3's from a compatible SD card or standard USB flash drive plugged into the USB port.

**CAUTION:**

Do not plug the P.A.L. Sensor into any device other than the P.A.L. Player

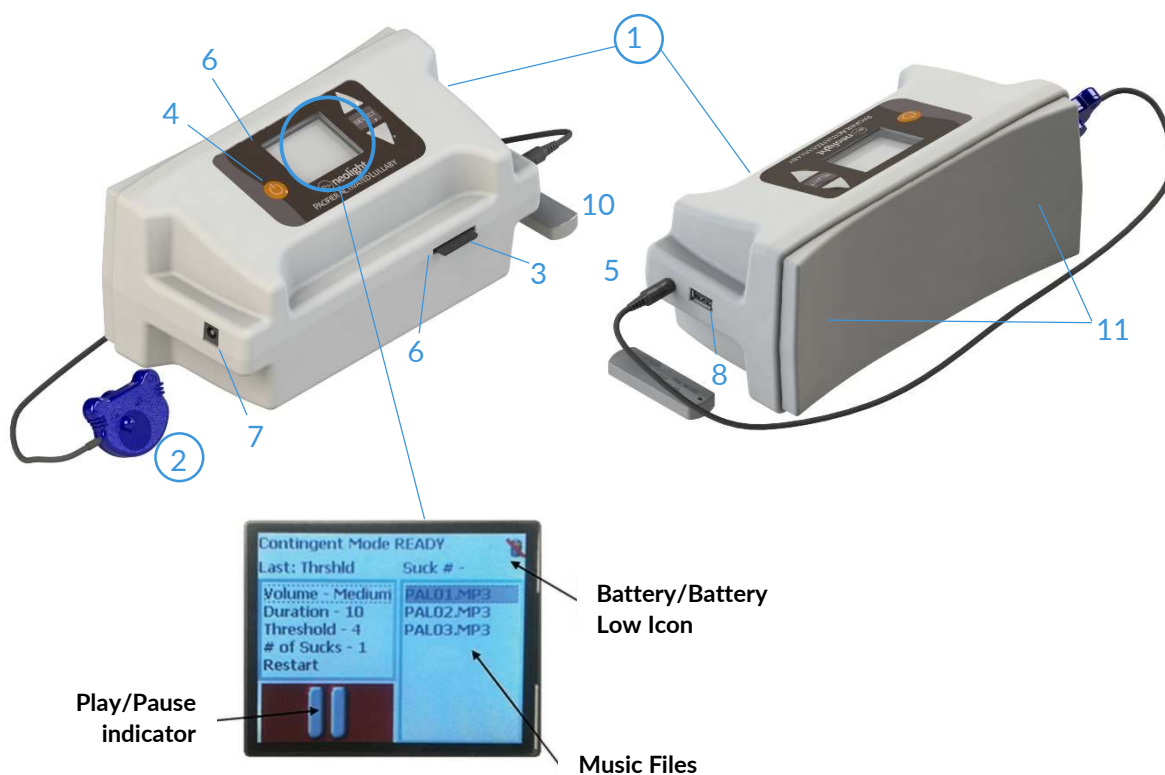
**CAUTION:**

Ensure that the P.A.L. Sensor is plugged into the P.A.L. Player before powering on the device for accurate calibration and functionality for Contingent mode use

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## Chapter 3: Components and Controls

### 3.1 System Components:



1. Player Unit	8. USB Port
2. P.A.L. Sensor	9. LCD
3. SD Card	10. USB-A Drive
4. Power ON/OFF Button	11. Speakers (not visible as shown)
5. P.A.L. Sensor Module Port	12. Battery door beneath the device (not shown)
6. SD Card port	13. Optional 4x Type C Batteries (not shown)
7. Power Supply Port	

### 3.2 Design In-Depth

#### 1 P.A.L. Player Design

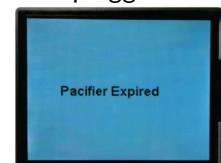
- The P.A.L. Device comes standard with 15 lullabies on three tracks (approximately 50 minutes of music) on an SD card.
- The preloaded lullabies are formatted with the most “active” music at the beginning of play. “Active” music being the most complex (12 chord) lullabies which descend in the playlist from 12 chords to 9, 6 and the least complex (3 chord) music at the end.
- The P.A.L. Device has a USB port that supports a standard USB flash drive. It allows music or voice recordings downloaded in MP3 format from another source to be played as well.

**NOTE:** a music file must be in .mp3 format with a sampling rate of 44.1kHz, bit rate of 128 kbps and stereo mode (2 channels) to be compatible with the P.A.L.. Please record audio using the P.A.L. Music Service. See section 9.3 for more details.

- The P.A.L. Device automatically defaults to the SD port, if both the SD port and USB port are connected. The screen will display “Media Select” - you highlight your choice and press SELECT. If either the SD drive OR the USB drive is in and you want to change modes, P.A.L. will not change modes unless you insert the new mode (SD or USB) and restart the machine.
- The P.A.L. Device is formatted with an automatic 5 sec RAMP ON/RAMP OFF mode of play in Non-Contingent Mode and a 1 sec RAMP ON/RAMP OFF in Contingent Mode. The music will not start or stop abruptly it, ascends on & descends off to avoid any startle of the infant.
- While the music is in PLAY, the screen will display a **GREEN PLAY ARROW** symbol. When the music stops, the screen will display a **RED PAUSE** symbol.
- There is a BATTERY ICON that will be lit during play, if the unit is running on battery power. If a red line appears across the battery icon, the batteries should be replaced as soon as possible. However, if the unit is in play, the current P.A.L. session will not be interrupted.
- A PLUG ICON will display if the unit is plugged in.
- The maximum music level is set at 65dBC (+/- 3dBC). The level of volume is measured based on the P.A.L. Device unit being 6 in. from the top of the midline between the infant's ears.
- The P.A.L. Device monitors the infant's sucking strength and sends this information back to the P.A.L. Player. The P.A.L. Player interprets the data and compares this data to the preset threshold. Music plays for a predetermined length of time, at a set volume, when the infant activates the pacifier by sucking at the pre-set levels.

## 2 P.A.L. Sensor Design

- The P.A.L. Sensor contains sensors that measure the infant's sucking force and frequency of sucks per burst. The sensors deliver information on the sucks when plugged into the P.A.L. Player.
- The P.A.L. Sensor is designed to fit securely into the opening of Soothie pacifiers (Phillips Soothie / NICU Soothie / Wee Soothie / Super Soothie) designed for hospital use.
- The caregiver must hold the P.A.L. Sensor in the infant's mouth during the P.A.L. session, as the infant will not be able to maintain the pacifier in its mouth for any extended length of time.
- Each sensor can be used for a 90-minute accrued period after which an automatic lockout is triggered, and the P.A.L. Sensor must be replaced.
- There are two modes of play:
  - CONTINGENT Mode
    - Default mode,
    - Requires active participation from the infant throughout the session
    - P.A.L. Sensor must be attached to P.A.L. Player
    - **NOTE: Use time is accrued on the P.A.L. Sensor when the P.A.L. sensor is plugged into the P.A.L. player**
  - NON-CONTINGENT Mode
    - This mode plays music for a period of time set by the operator with no participation from the infant.
    - Pacifier not needed
    - Time does not accrue on the P.A.L. Sensor
- In CONTINGENT Mode, the P.A.L. Device will not operate unless the P.A.L. Sensor is plugged in. The screen will display "waiting for pacifier" if the P.A.L. Sensor is not plugged in. Once the sensor is plugged in, the P.A.L. will proceed to play.
- When sensor exceeds 90 mins of use during a P.A.L. session, the P.A.L. Player will complete that session & not show the sensor as “expired” until the session has ended by restarting P.A.L. Device.
- The P.A.L. Sensor contains a circuit board. Dispose of expired P.A.L. Sensors in accordance with local regulations or contact manufacturer for advice.



## Chapter 4: Operation

### 4.1 Preparation for Use

1. Remove the P.A.L. Player from the packaging.
2. The P.A.L. Player can be powered from the supplied wall power supply which is converted to DC or 4 C cell alkaline batteries.

3. To install the batteries, turn the unit over and remove the battery door. Install the batteries observing correct polarity as shown in the figure below. Replace the battery door and turn unit back over. Note: When batteries are exhausted, discard in accordance with local regulations.

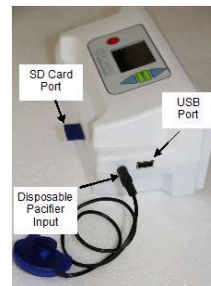


4. To use the wall supply, connect the DC plug on the power supply to the DC input jack on the side of the P.A.L. Player as shown in the figure below. Plug the unit into the wall outlet.

5. Remove a P.A.L. Sensor from its packaging and uncoil the cable. Attach Phillips Soothie / NICU Soothie / Wee Soothie / Super Soothie pacifier to the P.A.L. Sensor as shown below. Ensure that the back of the pacifier is flush against the face of the P.A.L. sensor.



6. Attach the P.A.L. Sensor 3.5mm plug into the jack on the side of the P.A.L. Player as shown in the figure below.



**CAUTION:** Ensure that the P.A.L. Sensor with the pacifier is plugged into the P.A.L. Player before powering up the device for accurate calibration and functionality.

7. The P.A.L. Player comes with an SD card installed with prerecorded lullabies. The SD card port is in the back of the unit as shown above. Check that the SD card is fully inserted. The P.A.L. Player also has the capability to play recorded MP3's from a standard USB flash drive. To use the USB port, insert the USB flash drive into the USB port on the side of the unit shown above.

## 4.2 Modes of Operation

### 4.2.1 Contingent Mode



#### TERMINOLOGY

- **Volume** - Settings are LOW, MEDIUM and HIGH: The maximum level being 65dB (+/- 3dB) C-Weighted SPL.
- **Duration** - This is the length of time the music is set to play; it is displayed in seconds for contingent mode (in minutes for non-contingent mode).
- **Threshold** - This is the sucking strength that is required to activate the music.
- **# Of Sucks** - The number of times the infant must suck on the pacifier at the required threshold to activate the music.

#### DEFAULT SETTINGS

SETUP	SCREEN DISPLAY
VOLUME (default = Medium)	low
	<b>Medium</b>
	high
DURATION (default = 10 sec)	<b>10</b>
	20
	30
	40
THRESHOLD Threshold (default = 4)	1
	2
	3
	<b>4</b>
	5
	6
	7
	8
	9
	10
# OF SUCKS (default = 1)	<b>1</b>
	2
	3
	4
	5

#### INSTRUCTIONS FOR USE

1. Insert the P.A.L. Sensor with the Soothie Pacifier (Phillips Soothie / NICU Soothie / Wee Soothie / Super Soothie)
2. Turn the device ON with the POWER button
3. Display will read CONTINGENT (default setting), press SELECT.
4. VOLUME will be highlighted. Default is medium. To change: Press SELECT, scroll with UP/DOWN arrows. When choice is highlighted, press SELECT again.
5. DURATION will be highlighted. The default setting is 10. To change: Press SELECT, scroll to desired time with UP/DOWN arrows. When choice is highlighted, press SELECT again.
6. THRESHOLD will be highlighted. Default is 4. To change: Press SELECT, scroll with UP/DOWN arrows. When choice is highlighted, press SELECT again.
7. # OF SUCKS will be highlighted. Default is 1. To change: Press SELECT, scroll with UP/DOWN arrows. When choice is highlighted, press SELECT again.
8. When Setup is complete, user must navigate to EXIT TO BEGIN. Press SELECT and P.A.L.

Device will be ready to play and will proceed to music display screen.

4.2.2 Non-Contingent Mode



TERMINOLOGY

- **Volume** - Settings are LOW, MEDIUM and HIGH: The maximum level being 65dB (+/- 3dB) C-Weighted SPL.
- **Duration** - This is the length of time the music is set to play; it is displayed in minutes for non-contingent mode (in seconds for contingent mode).

DEFAULT SETTINGS

SETUP		SCREEN DISPLAY	
VOLUME (default = Medium)		low	
		Medium	
		High	
DURATION (default = 15 min)		15	
		30	
		45	
		60	
		75	
		90	
		105	
		120	

INSTRUCTIONS FOT USE

1. Turn the device ON with the POWER button. Do not attach P.A.L. Sensor.
2. Display will read Contingent (default). Press SELECT, scroll to Non-Contingent, press SELECT again.
3. VOLUME will be highlighted; Medium is the default. To change: Press SELECT, scroll to desired volume level, press SELECT again.
4. DURATION will be highlighted. 15 minutes is the default. To change: Press SELECT, scroll to desired time with the UP/DOWN arrows and press SELECT again. Once Setup is complete, user must navigate to EXIT TO BEGIN. Press SELECT and you will proceed to the music display screen.



## Chapter 5: Routine Maintenance Procedures

This chapter includes procedures for routine maintenance of the P.A.L. Device. These procedures may be performed after any of the following events and/or as prescribed by the institution's maintenance schedule:

- Initial receipt of the P.A.L. Device at the institution.
- P.A.L. Device has been visually damaged or subjected to mechanical shock (i.e., dropped).
- P.A.L. Device has been submitted for maintenance or scheduled performance verification.

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**NOTE:** Please follow your institution's protocol for infection control when cleaning the device.

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### 5.1 Maintenance

The P.A.L. Device does not require any maintenance beyond cleaning after each use and visually inspecting the unit and connected accessories for any wear or damage. If any wear or damage is noted, do not use. Contact the manufacturer for replacement parts.

### 5.2 Cleaning Procedure:

It is recommended that the P.A.L. Device be cleaned with alcohol wipes or a cleaning agent that is compatible with plastic (see list below). Unplug the unit from the wall prior to cleaning. Do not pour or spray any cleaners directly on the P.A.L. Device components. Wipe all surfaces with a damp cloth containing the cleaning agent. We also suggest that you wipe all surfaces with a sterile cloth with a little sterile water and allow to air dry completely after each use of the cleaning agent. This is so that the cleaning agent does not pool in crevices and on the plastic.

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**Acceptable cleaning agents:**

- Water (Do not immerse)
- Mild dish soap

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**Acceptable commonly available cleaning products:**

- Isopropyl Alcohol
  - Clorox commercial disinfectants that listed by the manufacturer as plastic compatible.
  - PDI Super Sani-Cloth Germicidal Wipes
  - Metrex CaviWipes
- 



**CAUTION:**

Unapproved cleaning products should not be used. These cleaning agents may cause damage to P.A.L. Device and the P.A.L. Sensors.

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**Unacceptable cleaning agents:**

- Ammonia
- Acetones
- Ketones
- Ethers
- Toluene
- Hydrogen peroxide

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**Unacceptable commonly available cleaning agents:**

- PDI Super Sani-Cloth AF3
- Aromatic hydrocarbons
- Low molecular weight aliphatic solvents
- Chlorinated and brominated solvents
- Ozone
- Ammonia
- Concentrated bases
- Inorganic Hypochlorites - including bleach
- Hydrofluoric acid
- Hydrochloric acid
- Sulfuric acid

**CAUTION:**

Unplug the device. Always turn off and disconnect the device (or remove the batteries) from the power outlet before cleaning

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**NOTE:**

Please follow your institution's protocol for infection control when cleaning the device

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### 5.3 Replacing P.A.L. Sensors

Tools and Materials Required
------------------------------

- |         |
|---------|
| 1. None |
|---------|
- 

**CAUTION:**

Only use the NeoLight issued P.A.L. Sensors replacements for the device as any other part may result in the device being ineffective or dangerous to the user

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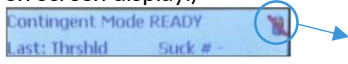

**CAUTION:**

Ensure that the device is turned off and unplugged before proceeding

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- 
1. Turn off the device and then unplug the P.A.L. Sensor
  2. Unpack the new P.A.L. Sensor and insert the 3.5 mm audio pin into the port shown above
  3. Turn on the device by pressing the power button for at least 1 second
-

## Chapter 6: Troubleshooting

System Indicators	Trouble Shooting Steps
<b>Functionality Issues</b>	
Battery icon will not display (There is a "battery low" indicator on screen display.) 	Check and replace batteries. Unit will complete session if battery low indicator comes on, but will not restart a new session 
Screen is dim or not lit	Plug the P.A.L. Player in using power supply
Screen display reads "waiting for pacifier".	In CONTINGENT mode, make sure the P.A.L. Sensor is attached to the unit
Screen display reads "Pacifier Expired".	Obtain a new P.A.L. Sensor
P.A.L. Sensor is attached, but P.A.L. Device does not recognize connection.	Check that the P.A.L. Sensor is securely fit in the opening of the pacifier
In CONTINGENT mode, the infant is sucking below the set threshold and/or # of sucks.	At any time during a CONTINGENT mode session, you can scroll through the window settings and change what is needed without having to restart the unit
Music won't play from flash drive in USB port.	Music Files must be in .mp3 format with the following specs to be compatible with the P.A.L.: <ol style="list-style-type: none"> <li>1. Sampling Rate: 44.1 kHz</li> <li>2. Bit rate: 128 kbps</li> <li>3. Channels: 2 (stereo)</li> <li>4. Metadata title field length:               <ol style="list-style-type: none"> <li>a. Artist: Less than 30 characters</li> <li>b. Album: Less than 30 characters</li> <li>c. Year: Less than 5 characters</li> <li>d. Comment: Less than 31 characters</li> <li>e. Leave other metadata fields empty</li> </ol> </li> </ol> Neolight recommends using P.A.L. Music Service (See section 9.3) to generate songs compliant to specifications listed above. The P.A.L. device will not recognize recordings in other formats. Restart P.A.L. Player with MP3 USB in USB port
The P.A.L. Device says there is a USB in the device, but it doesn't show the playlists/songs.	The recording was probably not fully exported as an MP3 file. If you use other online converters, they sometimes don't fully rewrite the file to an MP3. Make sure you see the program write the file to a MP3
The P.A.L. Device doesn't give me the option for an MP3 on the main menu	It could be that your USB flash drive isn't formatted correctly. If you work for a hospital system and IT ordered the flash drive, they could have formatted the flash drive

## Chapter 7: Accessories and Replacement Parts

Please contact NeoLight Customer Service for any replacements and parts needed. The following parts are critical components to the efficacy and safety of our products and must be replaced as directed.

Part Name	Catalog Number	Recommended Replacement Time
P.A.L Starter Kit	PAL-HOS	End of use-life
P.A.L. Player	PAL-PLR, PAL-PLR-2T-EN	Replace when damaged and unusable
USB-A 2.0	PAL-USB	
SD Card	PAL-SDC	
Power Brick and Blade (Type A)	PAL-PWR	
Power Blade Type C	PAL-PWR-C	
Power Blade Type I	PAL-PWR-I	
Power Blade Type G	PAL-PWR-G	
P.A.L. Sensor, 10 pk	PDS-10	Replace every 90 minutes or between patients, whichever comes first
Pacifier Soothie	Order from Philip Medical Venture Part #: 96004-N/989805607151	
Pacifier NICU Soothie	Order from Philip Medical Venture Part #: 1029232/989805604551	
Pacifier Wee Soothie	Order from Philip Medical Venture Part #: 96003-N/989805607121	

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Producer: The Florida State University College of Music

Recording Engineer and Editor: Brian Gaber

Vocalist and English Language Developer: Jennifer Jarred Peyton

**The use of non-NeoLight accessories with the P.A.L. Device may reduce treatment efficacy. NeoLight LLC declines all responsibilities for any damages or consequences resulting in using unauthorized parts with our P.A.L. Device.**



### **WARNING!**

The use of accessories, replacement parts, or power cords other than those specified by the manufacturer may affect the unit's performance. It could damage the unit or unsafe conditions for the patient and the operator

## Chapter 8: Product Specification

<b>Electrical (AC Power)</b>	
AC Power:	Input: 100-240V~, 50-60HZ, 0.5A; Output: 9VDC, 0.66A,
Type of Protection against Electrical Shock:	Class II Equipment
Degree of Protection against Electrical Shock:	Type B.F. Applied Part
Degree of Protection against Ingress of Water:	IPOX
Mode of Operation:	Continuous
<b>Electrical (Battery Power)</b>	
Battery Type	Type C 1.5V Alkaline Battery
Number	4
<b>Physical (P.A.L. Player)</b>	
Device Dimensions	8.25" L x 4.12" W x 3.95" H (20.96 x 10.46 x 10.03 cm)
Device Weight	< 3 lbs. (1.36 Kg)
Communication	Via wired bus with P.A.L. Sensor Module
Display	LCD graphic display visible from a distance < 6 feet
Memory	Secure Digital (SD) Card (FAT format) USB-A 2.0 (FAT Format)
Control Interface	4 buttons interface (UP, DOWN, SELECT and POWER)
Speakers	65 dB (±3) maximum C-Weighted SPL
Biocompatibility	All patient contacting materials used in the P.A.L. are biocompatible
<b>Physical (P.A.L. Sensor Module)</b>	
Sensor	Piezo
Length of wire lead	17.72 in (45 cm) with 3.5 mm stereo plug
Biocompatibility	All patient contacting materials used in the P.A.L. are biocompatible
<b>Transportation and Storage</b>	
<p>The P.A.L. Device should be transported and stored in temperatures between -4°F and 185°F (-20°C and 85°C), atmospheric pressures between 50 and 106 kPa (7.25 psi to 15.37 psi) and relative humidity between 10% and 93% R.H.</p> <p>Each module is designed to continue operation after being exposed to vibration levels as defined in IEC60068-2-6 (Vibration), IEC 60068-2-35 (Random Vibration Wide Band), and IEC 60068-2-27 Shock</p>	
<b>Operating Conditions</b>	
<p>The P.A.L. Device should be operated in temperatures between 32°F and 104°F (0°C and 40°C), atmospheric pressures between 50 and 106 kPa (7.25psi to 15.3psi), and relative humidity between 15% and 90% R.H non-condensing</p>	

## Chapter 9: Technical Reference

### 9.1 Working of P.A.L. In Depth

The primary users of the P.A.L. are premature infants. In P.A.L. Device Contingent mode, active participation from the infant is required (infant driven) to activate the music or mother's voice. In this mode, the infant activates the music when he/she hits the strength and duration of sucking set by the operator. The operator can select the required sensor strength/threshold level (levels 1-10) and the # of sucks (1-5) that best fits the infant's needs. When the infant hits these preset levels, music or mother's voice will play but only for the length of time set by the operator (10, 20, 30, or 40 seconds). If the infant wants to hear music or mother's voice again, the infant must again achieve the preset strength and duration level. Thus, the operator has control over several behavioral factors in the P.A.L. Contingent Mode: (1) Control over the sucking strength required to trigger the music (2) The length of time the music plays when activated by the infant; (3) The number of sucks required to turn on the music. The P.A.L. Sensor monitors the infant's sucking strength and transmits this information back to the Player Module. The P.A.L. Player Module interprets the data and compares this data to the preset threshold. Music plays for a predetermined length of time, at a set volume (High, Medium, Low) when the infant activates the pacifier by effective sucking. The maximum music sound level is set at 65dB +/- 3dB C-Weighted SPL. The level of volume is measured based on the P.A.L. Device being 6 inches from the top of the infant's ears. The music can be in two formats: Music from a USB (MP3 format) or a pre-recorded SD. To avoid alerting the infant when the music is stopped, the Player Module uses a ducking circuit to fade the music 15 seconds prior to ending it.

In addition to the P.A.L. Contingent mode, the system can also provide music in a non-contingent mode. The exact time the music can play is user adjustable, however, with an initial default setting of 15 minutes. To avoid alerting the infant when the music is stopped, the Player Module uses a ducking circuit to fade the music 15 seconds prior to ending it. Also, when the music ends, the unit changes back to P.A.L. Contingent mode.

### 9.2 Protocol for the Use of P.A.L. Device to Encourage or Reinforce Development of Effective Non-nutritive Sucking

**Goals:** Encourage and reinforce non-nutritive sucking endurance and effectiveness.

**Objectives:**

- To increase sucking endurance.
- To develop sucking bursts
- To develop sucking strength.
- To develop pacing for oral feedings.
- To increase feeding rate as a result of better sucking when nipping.

**Infant Criteria:**

- Infant should be 34 weeks adjusted gestational age (GA) and/or ready for oral feeding trials.
- Infant should be no more than two months adjusted gestational age
- Infants qualify if they:
  - Show little motivation to suck
  - Exhibit a weak suck
  - Experience early fatigue during PO feeds
  - Demonstrate frantic, short sucking bursts followed by fatigue during PO feeds
  - Are not having success with PO feeds for any other reason

**Protocol:**

1. Establish that the infant meets the above criteria.
2. Request and receive an order for a P.A.L. Session signed by ARNP or Physician.
3. Begin implementing a P.A.L. session prior to feeding. (Research indicates that infants have the best outcomes when a P.A.L. session is provided prior to feeding – approximately 30 minutes to 90 minutes prior to feeding.)
4. A P.A.L. session should be implemented for 15 minutes once or twice/day depending on the GA of the infant. A P.A.L. session should be withdrawn if the infant ceases to suck for 1 minute with mild stimulation of pacifier movement in his/her mouth or when signs of overstimulation are observed.
5. For the initial P.A.L. session use the lowest criteria or easiest settings on a P.A.L. Player to determine the infant's beginning sucking behaviors and allow the infant time to learn the music is contingent on the infant's suck. Infants with neurological damage or failure to demonstrate a suck reflex should be given longer periods of time at the lowest criteria settings.
6. As the infant begins sucking consistently and showing progress, gradually increase the settings, increasing the difficulty or criteria for music reinforcement.
7. If the infant is not successful at the increased criteria or settings, return to previous easier setting for the remainder of the session. Ensure the infant shows success at the lower setting again before increasing the settings.
8. Continue a P.A.L. Session until infant demonstrates periods of 15 minutes of effective NNS and the infant's oral feeding improves.
9. Following the P.A.L. session, remove the P.A.L. Sensor from the infant's crib. Remove the Soothie pacifier from the P.A.L. Sensor, use approved cleaning agents to clean and store the P.A.L. Sensor for future use by this infant (single-patient-use).
10. Remove the P.A.L. Player from the crib. Use approved cleaning agents wipes to clean the P.A.L. Player.
11. Store P.A.L. Player unit.

**NOTE:** If during P.A.L. session another patient is having an alarm needing intervention and no other caregiver is available to handle the alarm situation, before leaving the patient, the caregiver should assure the safety of the P.A.L. patient by:

- Making sure bedrails are up or incubator doors closed.
- Contain the patient so he/she feels secure.
- Take P.A.L. Player and P.A.L. Sensor out of the crib/isolette and place on bedside table.
- Go to patient needing intervention.
- When patient needing intervention is addressed, return to the patient and continue administering the P.A.L. session.

### 9.3 Use of P.A.L. Device for Recording & Using Mother's Voice

As units continue to move to a family center care approach, the use of mother's voice also continues to increase. While it can seem complicated, it is a simple, easy service that we can provide to our families in the NICU.

**The purpose of utilizing mother's voice is to:**

- Promote mother and infant bonding
- Provide parent education
- Empower mother
- Increase parental involvement in the infant's care

- Increase the infant's exposure to appropriate auditory stimulation

**Participation:**

- ALL MOTHERS CAN PARTICIPATE
- Prior music skills are NOT required
- Ensure that the mother has recovered from giving birth and she is healthy and stable.
- Especially encourage mothers with transportation and work issues that don't allow them to be at the bedside every day.

**Suggestions for how to get mothers to participate:**

- Explain that no prior music skills/singing ability are needed
- Remind mom that she is the infant's favorite voice. This is her time to be a "star"
- Reassure mom that you will be there to help coach her through the whole process.
- Remind her that you will sing the songs for her first and then she will sing them back (or she can listen to records of the songs first).
- Explain to mom that how she sings these songs will be the "right" way to the infant since the infant has never heard these before.
- Remind her that the infant and you, and maybe an occasional nurse will be the only ones who hear the recording.

**9.3.1 P.A.L. Music Service**

***Recommended method to record mother voice and prepare lullabies for P.A.L.***

The P.A.L. Music Service by Neolight, is a platform designed to empower parents in supporting their baby's treatment journey. This service allows parents to create personalized audio files for the P.A.L. System to enrich their child's therapeutic experience.

- Visit the following website to access the service
  - Link: [bit.ly/3KFXprX](https://bit.ly/3KFXprX)
  - QR Code:



**P.A.L.**  
Music  
Service



### 9.3.2 Alternate Method to Record Mother Voice

#### Technology:

- Handheld digital voice recorder with USB connection or memory card slot
  - Sony High Resolution Portable Audio Recorder
  - Philips DVT
  - Sony ICD – UX
  - Olympus WS
- Other portable more high-tech recording devices:
  - iZotope Inc. Spire Studio
  - Zoom H6 Six-Track Portable Recorder
- Blank SD memory cards
  - SanDisk Standard Flash Memory Card
- Blank USB 1 GB flash drives (FAT formatted) only
  - SanDisk Cruzer Glide
  - PNY Classic Attaché
  - Super Talent RM Swivel
  - In bulk: VICFUN 20 Pack from Amazon
- Editing Software
  - Garage Band (on a MacBook)
  - Audacity

**NOTE:** When recording mother's voice to play at the bedside and use on a speaker, it is ok to use an iPad or iPhone without needing the recording to go through a Mac computer. If you are planning to use the recording on the P.A.L. Device, it is recommended that even when recorded and edited on an iPad that it is transferred to a Mac computer. This is because the P.A.L. Device will only play files that are fully converted to an mp3 format. This is best done on Garage Band on a Mac computer. Due to IT and logistical issues, most P.A.L. Device users have found it easier to record on a voice recorder and then process/edit the recordings in Garage Band on a Mac computer.

#### How to Record Mother:

1. Have a song list (with lyrics) for mom to help her pick out songs to sing.
2. Let mom pick 4 to 5 songs to sing.
3. Record the songs in order from simplest to the most complex.
4. Sing the 1st song and have mom sing with you. (Tip: Pat your leg or conduct to help mom learn correct tempo)
5. Sing song with mom until she feels comfortable.
6. Have mom record song through just one time if it is a short song like "Twinkle, Twinkle Little Star." Have mom sing several verses if it is a longer song like "Wheels on the Bus."
7. If you need to sing with mom while she is recording, put the mic close to mom and sing softly, further away from the microphone in order to capture only mom's voice.
8. If mom is singing by herself, it is still helpful to provide a visual for the correct tempo.
9. Repeat these steps (4-8) for each song that mom selected.
10. Make sure to let mom know that if she makes a mistake to pause and look up at you. Then you can tell mom where to come back in. Reassure her that all mistakes will be cut out of the final recording

#### How to process Recording:

1. Transfer the recording onto the Mac computer.

2. Use Audacity to take out any white noise/room noise. (Easiest way to learn this is through YouTube Videos)
3. Put edited file from Audacity into Garage Band.
4. Cut the recording into individual songs and delete any unnecessary blank recording time.
5. Edit any individual songs to take out mistakes.
6. Loop each song 3 to 4 times so that each song lasts at least 3 min.
7. Loop the entire recording AFTER looping each song if the recording isn't 15 minutes long.
8. Export the song as an MP3.
9. Put the recording onto the USB (only 1GB in storage size) or Scan Disk drive to us in the P.A.L.®.

If you attempt mother's voice and are having issues please look at the below troubleshooting section.

## Chapter 10: Compliance Declaration

AAMI ES 60601-1, 2005/(R) 2012 and A2: 2010/(R)2012	Medical Electrical Equipment- Part 1: General Requirements for basic safety and essential performance
IEC 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
FCC Part 15b	Equipment authorization of unintentional radiators
ICES-003	Issue 4 for a Class B Device – Digital apparatus
ISTA-6	Testing Packaging Product Weighing up to 150 lbs.


### Electromagnetic Compatibility (EMC)

This equipment has been tested and found to comply with the limits for a Class B device. The equipment was tested to IEC 60601-1-2:2007/AC 2010. It was also tested for U.S. FCC emissions to CFR Title 47, Part 15, Subpart B, and Canada CSA to ICES-003 Issue 4, February 2004 in accordance with CISPSR 22:02.

### Warnings

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the equipment. Medical equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the medical equipment should be observed to verify normal operation in the configuration in which it will be used.
- This equipment uses and can generate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer. Modifications or use of accessories not expressly approved by the manufacturer are prohibited and may void the user's authority to operate the equipment

Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The Pacifier Activated Lullaby (P.A.L) Model PAL-HOS is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Emission Tests		Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11		Group 1	The Pacifier Activated Lullaby (P.A.L) Model #PAL-HOS 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 Pacifier Activated Lullaby (P.A.L) Model #PAL-HOS 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
R.F. emissions CISPR 11		Class B	
Harmonic emissions IEC 61000-3-2		Compliant	
Voltage fluctuations / flicker emissions IEC 61000-3-3		Compliant	
Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Pacifier Activated Lullaby (P.A.L) Model PAL-HOS is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U <sub>T</sub> (>95 % dip in U <sub>T</sub> ) for 0,5 cycle  40 % U <sub>T</sub> (60 % dip in U <sub>T</sub> ) for 5 cycles  70 % U <sub>T</sub> (30 % dip in U <sub>T</sub> ) for 25 cycles  < 5% U <sub>T</sub> (95 % dip in U <sub>T</sub> ) for 5 s	< 5 % U <sub>T</sub> (>95 % dip in U <sub>T</sub> ) for 0,5 cycle  40 % U <sub>T</sub> (60 % dip in U <sub>T</sub> ) for 5 cycles  70 % U <sub>T</sub> (30 % dip in U <sub>T</sub> ) for 25 cycles  < 5% U <sub>T</sub> (95 % dip in U <sub>T</sub> ) for 5 s	The Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME Equipments or ME systems] requires continued operations during power mains interruptions, it is recommended that the [ME Equipments or ME systems] be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U <sub>T</sub> is the A/C mains voltage prior to application of the test level.			
Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Pacifier Activated Lullaby (P.A.L.) Model PAL-HOS is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Pacifier Activated Lullaby (P.A.L) Model # PAL-HOS, including cables, than the recommended separation distance calculated from the
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			<p>equation applicable to the frequency of the transmitter</p> <p><b>Recommended separation distance</b>  <math>d=1.2\sqrt{P}</math>, 80 Mhz to 800 Mhz</p> <p><math>d=2.3\sqrt{P}</math>, 800 Mhz to 2.5 Ghz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey:</p> <p>a. should be less than the compliance level in each frequency range.</p> <p>b. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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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

<sup>a</sup> 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 Pacifier Activated Lullaby (P.A.L) Model #PAL-HOS is used exceeds the applicable RF compliance level above, the Model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Pacifier Activated Lullaby (P.A.L) Model # PAL-HOS. 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 Pacifier Activated Lullaby (P.A.L)

The Pacifier Activated Lullaby (P.A.L) Model PAL-HOS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Pacifier Activated Lullaby (P.A.L) Model # PAL-HOS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pacifier Activated Lullaby (P.A.L) Model # PAL-HOS as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
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 determined 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

## Chapter 11: Warranty

NeoLight, LLC ("NeoLight") warrants to the initial Purchaser ("Purchaser") that each Covered Component of each new Product, as such terms are defined below, purchased hereunder will be free from defects in workmanship and materials for the applicable period of indicated below (each, a "Warranty Period") from the date of the Product's initial shipment to Purchaser.

- One years for the P.A.L. Device (the "Product"), including all components of the Product, excluding the Disposable Parts (collectively with the P.A.L. Sensors, the "Covered Components").

The P.A.L. Sensors or other expendable or disposable parts of the Product are the "Disposable Parts."

NeoLight will replace your P.A.L. Device free of charge, provided the system:

- Has been used for its intended purpose by the original owner and in the manner described in this manual.
- Has regular periodic maintenance and service, disposable parts are replaced, and repairs are made according to the service or user manual.
- Has not been connected to an unsuitable power source.
- Has not been subjected to misuse.
- Has not been modified or repaired by any unauthorized party without prior consent from NeoLight.

Such warranties are extended only with respect to the first purchase of the P.A.L. Device directly from NeoLight or NeoLight's authorized dealers as new merchandise and are extended to the Purchaser thereof; such warranties do not apply to any resale of the Product.

## Chapter 12: Customer Service:

Don't hesitate to get in touch with Customer Service if you need assistance setting up, using, or maintaining your P.A.L. Device(s) or to report any unexpected operation or events. NeoLight Customer Service can be reached at:



[support@theNeoLight.com](mailto:support@theNeoLight.com)



Customer Support: + 1-866-934-8945 x 1  
Technical Support: + 1-866-934-8945 x 2

When returning any products, please include your name, address, phone number, and Return Material Authorization (RMA) number provided by Customer Service. All product returns should be mailed to:



NeoLight LLC  
1475 N Scottsdale Rd,  
Suite 110,  
Scottsdale, AZ 85257



**P.A.L.**  
by neolight

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