Pacifier Activated Lullaby (PAL ®)

Instructions for Use

IFU English
500055 Rev C

Caution: Federal Law (U.S.) restricts this device to sale or use by or on the order of a physician (or properly licensed practitioner).

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User Responsibility

PAL will perform in conformity with the description contained in the instructions for use, 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 LLC 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 PAL® Sensor has been designed for use with the Soothie Pacifiers manufactured by Children's Medical Ventures. Use with any other pacifiers will be ineffective and may result in PAL® not functioning properly.

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

Chapter 1: About this Manual

1.1 Indications for Use

The Pacifier Activated Lullaby (PAL®) encourages and reinforces 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.

1.2 Intended Users

This 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 "Pacifier Activated Lullaby," (PAL®) 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. PAL® 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 PAL® System 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 Pacifier Activated Lullaby ("PAL®") has a player module, pacifier sensor module and power supply. The pacifier sensor module 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 pacifier module 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 a speaker to the infant contingent on his/her sucking on the pacifier transmitter. This action occurs when the sucking strength and duration exceeds preset values. The user can control the sensitivity of the transducer.

The PAL® has been designed to fit within an incubator or bassinet and to be placed at the top of the crib, six inches above the baby's head. The PAL® delivers music binaurally (equally to both ears). The caregiver must hold the PAL® Pacifier Sensor Module in the infant's mouth during the PAL® therapy session, as the infant will not be able to maintain the pacifier in his/her mouth by himself/herself for any extended length of time. Hardware will keep time of usage of the sensor module and disable after 4 hours have elapsed. PAL therapy should 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 Service Manual, 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 with air.
	Type B.F. Applied parts
	Symbol placed next to **CAUTION** or **WARNING** to alert the users to important statements.
IP0X	Not for exposure to dust or moisture.

	Keep the device away from sunlight.
	Keep the device dry.
	Single-use only. Do not reuse.
	Hazard of severe electric shock or burn
	Non Sterile
	Class II Equipment
WARNING	A **WARNING** statement is used when the possibility of injury exists.
CAUTION	A **CAUTION** statement is used when the possibility of damage to the equipment exists.
IMPORTANT!	Instruction provided to help ensure correct clinical results and provide quality assurance to the phototherapy procedures.
NOTE	Background information provided to clarify a particular step or procedure. Information in this category is not considered precautionary

2.2 Warnings

Before using the Pacifier Activated Lullaby (PAL®) 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 PAL® Module 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 PAL® System is disconnected and turned off prior to making any repairs or performing any maintenance procedures.

	**WARNING:** Failure to follow this instruction manual could result in injury to patient or provider.
	**WARNING:** Failure to follow this instruction could result in damage to the unit.
	**WARNING:** Do not remove back cover, non user serviceable. This unit should be serviced by factory authorized personnel.
	**WARNING:** PAL® should be used only in the presence of a caregiver.
	**WARNING:** PAL® therapy should be administered for 15 minutes once or twice a day until the infant is able to suck effectively.
	**WARNING:** PAL® therapy should be administered only with infants up to the adjusted gestational age of two months.
	**WARNING:** Infants should be swaddled during PAL® therapy.
	**WARNING:** Infants should be swaddled during PAL® therapy.
	**CAUTION**: If using the power supply, disconnect the unit prior to wipe down.
	**CAUTION:** Do NOT immerse in liquid.
	**CAUTION** Do NOT place or store device where it is at risk of falling or being pulled into a tub or sink.
	**CAUTION** Never force the plug into an outlet.

CAUTION:
Never operate the PAL® System if it has a damaged cord or plug.

CAUTION:
Keep all cords away from heat sources.

CAUTION:
Make sure that all cabling is routed away from the infant as to not impair movement.

CAUTION:
Any unauthorized repair or tampering will void applicable warranties.

CAUTION:
Do not use speakers, power supplies, batteries, or any other accessory not supplied by the original manufacturer. This could result in injury as well as void all warranties and regulatory certifications.

CAUTION:
Dispose of batteries according to local regulations.

CAUTION:
The PAL® Player Module should be placed at the top of crib, six inches above the infant's head.

CAUTION:
Infants must be monitored when using the PAL® Pacifier Sensor Module.

CAUTION:
Use of the pacifier in the PAL® system should follow protocols for the use of any pacifier with the particular infant for whom a pacifier is appropriate.

CAUTION:
Do not leave the PAL® Pacifier Sensor Module 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 PAL® device from the crib when not in use.

CAUTION:
To avoid the risk of the PAL® Player Module tipping, the caregiver should not lean his/her hand on the PAL® Player Module while the PAL® Player Module is in the crib.

CAUTION:
No component is provided sterile and the pacifier sensor module is single use, disposable.

CAUTION:
The PAL Player Module should only be used with the supplied medical grade power supply. Only PAL Pacifier Sensor Modules should be used. The PAL Player Module will play MP3's from a compatible SD card or standard USB flash drive plugged into the USB port.

CAUTION:
Do not plug the PAL® Pacifier Sensor Module into any device other than the PAL® Player Module.

CAUTION:
Ensure that the PAL® Pacifier Sensor with the Pacifier is plugged into the PAL® Player before powering on the device for accurate calibration and functionality

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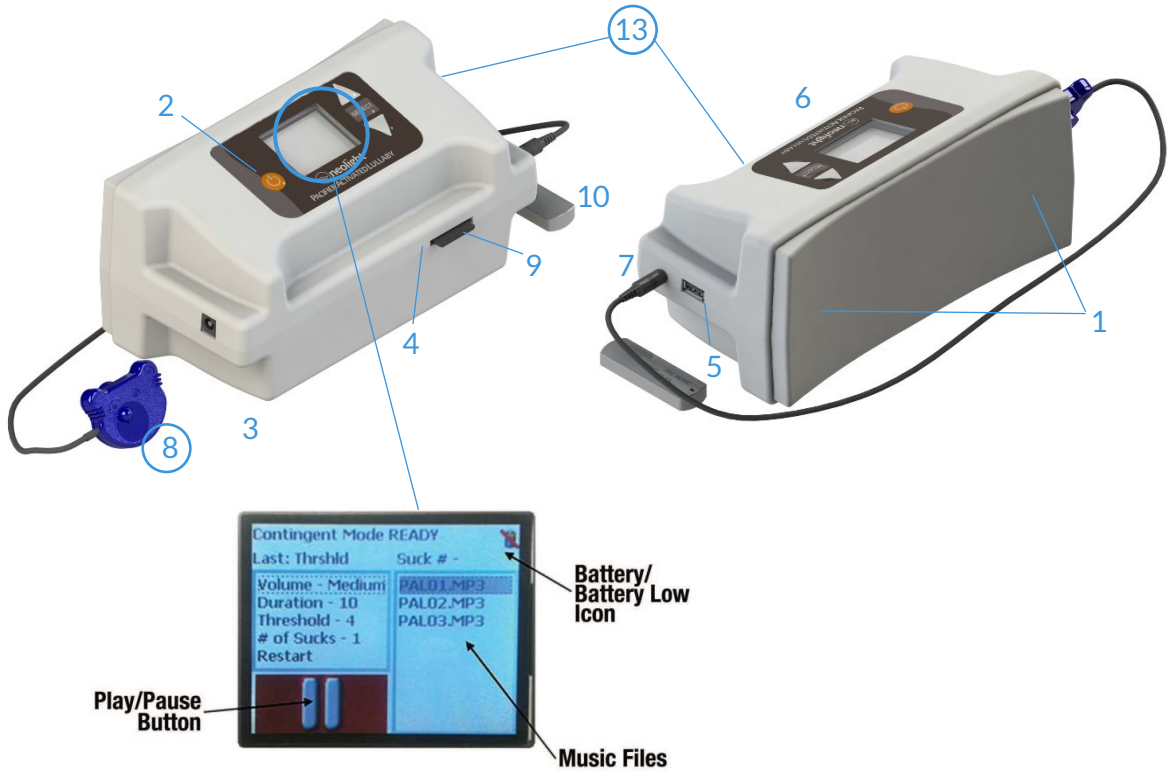
Chapter 3: Components and Controls

3.1 System Components:



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

3.2 Design In-Depth

8 PAL® Sensor Unit (Single Patient Use) Design

- The Pacifier Sensor Module (bear head) contains the sensors that when attached to a specified pacifier will measure the level of sucking strength and the number of sucks per burst. The sensors will deliver that information to the PAL® player module when plugged into the PAL® Player Module.
- The Pacifier Sensor Module (bear head) is designed to fit securely into the opening of specified pacifiers designed for hospital use.
- The caregiver must hold the PAL® Pacifier Sensor Module in the infant's mouth during the PAL® therapy session, as the infant will not be able to maintain the pacifier in his/her mouth by himself/herself for any extended length of time.
- Each sensor can be used for a 4-hour accrued period after which an automatic lockout is triggered, and the Pacifier Sensor Module (bear head) must be replaced.

- There are two modes of play: (1) CONTINGENT Mode - This is the default mode and it requires active participation from the infant throughout the session; it is "baby driven"; (2) NON-CONTINGENT Mode - This mode plays music for a period of time set by the operator regardless of whether or not the infant is sucking on the pacifier.
- Note: The Pacifier Sensor Module does not accrue time in Non-Contingent Mode.
- In CONTINGENT Mode, the PAL® unit will not operate unless the Pacifier Sensor Module (bear head) is plugged in. The screen will display "waiting for pacifier" if the Pacifier Sensor Module is not plugged in. Once the sensor is plugged in, the PAL® will proceed to play.
- If a Pacifier Sensor Module (bear head) has accrued 4 hours of Contingent Mode use, the device screen will read "pacifier expired" alerting the user to replace the sensor.

- If the sensor exceeds 4 use hours during a PAL® session, the PAL® Player Module will complete that session and will not show the sensor as "expired" during the session.
- The PAL® Pacifier Sensor Module contains a circuit board. Dispose of expired Pacifier Sensor Modules in accordance with local regulations or contact manufacturer for advice.

13 PAL® Player Unit Design

- The PAL® comes standard with 15 lullabies on three tracks (approximately 50 minutes of music) on an SD card.
- Music is formatted in ascending to descending order 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 PAL® 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.
- PAL® 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, PAL will not change modes unless you insert the new mode (SD or USB) and restart the machine.
- The PAL® is formatted with an automatic 5 second RAMP ON/RAMP OFF mode of play in Non-Contingent Mode and a 1 second RAMP ON/RAMP OFF in Contingent Mode. This means that the music will not start or stop abruptly it, ascends on and descends off to avoid any startle of the infant.
- While the music is in PLAY, the screen will display a GREEN PLAY ARROW. When the music stops, the screen will display a RED PAUSE INDICATOR.
- 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 PAL® session will not be interrupted.
- A PLUG ICON will display if the unit is plugged in.
- The maximum music level is set at 65dB (+/- 3dB in scale C). The level of volume is measured based on the PAL® unit being 6 inches from the infant's ears.
- The PAL® monitors the baby's sucking strength and sends this information back to the PAL® Player Module. The PAL® 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, when the infant activates the pacifier by sucking at the pre-set levels.

Chapter 4: Operation

4.1 Preparation for Use

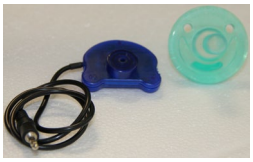
1. Remove the PAL® Player Module from the packaging. Do not attach Pacifier Sensor Module.

2. The PAL® Player Module can be powered from the supplied wall power supply which is converted to DC or 4 C cell alkaline batteries.

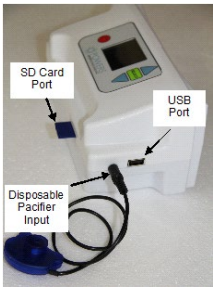
3. To install the batteries, turn the unit over and remove the battery door. Install the batteries observing correct polarity as shown in the figure below. Replace the battery door and turn unit back over. Note: When batteries are exhausted, discard in accordance with local regulations.

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

5. Remove a PAL® Pacifier Sensor Module (bear head) from its packaging and uncoil the cable. Attach a Soothie, NICU Soothie or WeeSoothie pacifier to the bear head sensor as shown below. Insure that the back of the pacifier is flush against the face of the bear head



6. Attach the PAL® Pacifier Sensor Module 3.5mm plug into the jack on the side of the PAL® Player Module as shown in the figure below.



CAUTION: Ensure that the PAL® Pacifier Sensor with the pacifier is plugged into the PAL® Player before powering up the device for accurate calibration and functionality

7. The PAL® Player Module 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 PAL® Player Module 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

- **Sensor Threshold** – This is the sucking strength that is required to activate the music playing.
- **Volume** - Settings are LOW, MEDIUM and HIGH: The maximum level being 65dB in scale C (+/- 3dB).
- **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).
- **# 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
DURATION (default = 10 sec)	**10**
	20
	30
	40
VOLUME (default = Medium)	low
	Medium
	high
THRESHOLD Sensor Threshold (default = 4)	1
	2
	3
	4
	5
	6
	7
	8
	9
	10
# OF SUCKS (default = 1)	**1**
	2
	3
	4
	5

INSTRUCTIONS FOR USE

1. Turn the device ON with the POWER button
2. Display will read CONTINGENT (default setting), press SELECT
3. DURATION will be highlighted with the default being 10. To change: Press SELECT, scroll to desired time with UP/DOWN arrows. When choice is highlighted, press SELECT again
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. THRESHOLD - Default is 4. To change: Press SELECT, scroll with UP/DOWN arrows. When choice is highlighted, press SELECT again.
6. # OF SUCKS - Default is 1. To change: Press SELECT, scroll with UP/DOWN arrows. When choice is highlighted, press SELECT again
7. When Setup is complete, EXIT TO BEGIN will be highlighted. Press SELECT and PAL® 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 in scale C (+/- 3dB).
- **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 Pacifier Sensor Module.
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, EXIT TO BEGIN will be highlighted. 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 PAL® system. 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 PAL® at the institution.
- PAL® has been visually damaged or subjected to mechanical shock (e.g., dropped).
- PAL® has been submitted for maintenance or scheduled performance verification.

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

5.1 Maintenance

The PAL® system 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 and Disinfection Procedure (for both professional and home use):

It is recommended that the PAL® system be cleaned with alcohol wipes or a disinfectant 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 PAL® system components. Wipe all surfaces with a damp cloth containing the disinfectant. 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 disinfectant. This is so that the disinfectant does not pool in crevices and on the plastic.

Acceptable cleaning agents:	**Acceptable common available cleaning products:**
• Water (Do not immerse) • Mild dish soap	• Isopropyl Alcohol • Clorox commercial disinfectants that listed by the manufacturer as compatible with plastic.

Unacceptable cleaning agents:	**Unacceptable common available cleaning agents:**
• Ammonia • Acetones • Ketones • Ethers • Toluene • Hydrogen peroxide	• PDI Super Sani-Cloth AF3 • PDI Super Sani-Cloth Germicidal Wipes • Metrex CaviWipes • 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:
The use of unacceptable cleaning agents such as the ones listed above may cause a reduction in structural integrity of the plastic material in the Player enclosure that can lead to cracks and eventual failure of the Player enclosure.

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

CAUTION:
Products such as PDI Sani-Cloth AF3, PDI Sani-Cloth, and CaviWipes Surface Disinfectant should not be used. These cleaning agents may cause damage to PAL® and the PAL® sensors.

CAUTION:
Cleaning agents such as petroleum-based solvents, or disinfectants containing aldehydes, phenols or amines as active ingredients should not be used.

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

5.3 Replacing PAL Sensor Modules

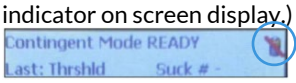
Tools and Materials Required
1. None

CAUTION:
Only use the NeoLight issued PAL Sensor Modules replacements for the device as any other part may result in the device being ineffective or dangerous to the user.

CAUTION:
Ensure that the device is turned off and unplugged before proceeding.

1. Turn off the device and then unplug the PAL Sensor Module.
2. Unpack the new PAL sensor module 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
Functionality Issues	
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 PAL® Player Module in using power supply.
Screen display reads "waiting for pacifier".	In CONTINGENT mode, make sure the Pacifier Sensor Module is attached to the unit.
Screen display reads "Pacifier Expired".	Obtain a new sensor module (Bear Head).
Pacifier Sensor Module is attached, but PAL® unit does not recognize connection.	Check that the "Bear Head" is securely fit in the opening of the pacifier.
In CONTINGENT mode, the baby 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.	Verify that the downloads are in MP3 format. The PAL® device will not recognize recordings in other formats. Restart PAL® Player Module with MP3 USB in USB port.
The PAL® says there is a USB in the device, but it doesn't show the playlists/songs.	The recording was probably not fully exported as a MP3 file. If you use other online converters, they sometimes don't fully rewrite the file to a MP3. Make sure you see the program write the file to a MP3.

The PAL® 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
PAL® Player Module	PAL-PLR	Replace when damaged and unusable
USB-A 2.0	PAL-USB	
SD Card	PAL-SDC	
Power Brick	PAL-PWR	
PAL® Sensor Module, 10 pk	PDS-10	Replace every 4 hours 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	

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 PAL® System may reduce treatment efficacy. NeoLight LLC declines all responsibilities for any damages or consequences resulting in using unauthorized parts with our PAL® System.

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

Electrical (AC Power)	
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:	IP0X
Mode of Operation:	Continuous
Electrical (Battery Power)	
Battery Type	Type C 1.5V Alkaline Battery
Number	4
Physical (PAL ® Player)	
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 PAL ® 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
Biocompatibility	All patient contacting materials used in the PAL are biocompatible
Physical (PAL ® Sensor Module)	
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 PAL are biocompatible
Transportation and Storage	
The PAL 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. 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.	
Operating Conditions	
The PAL system 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	

Chapter 9: Technical Reference

9.1 Working of PAL In depth

The primary users of the PAL are premature infants. In PAL®'s contingent mode, active participation from the baby is required (baby driven) to activate the music or mother's voice. In this mode, the baby 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 baby's needs. When the baby 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 baby wants to hear music or mother's voice again, the baby must again achieve the preset strength and duration level. Thus, the operator has control over several behavioral factors in the PAL 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 Pacifier Sensor Module monitors the baby's sucking strength and transmits this information back to the Player Module. The 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 scale C. The level of volume is measured based on the PAL® being 6 inches from the baby's head. 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 PAL 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 PAL Contingent mode.

9.2 Protocol for the Use of PAL® 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 nippling.

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 PAL® Therapy signed by ARNP or Physician.
3. Begin implementing PAL® Therapy prior to feeding. (Research indicates that infants have the best outcomes when PAL® Therapy is provided prior to feeding – approximately 30 minutes to 1 hour prior to feeding.)
4. PAL® Therapy should be implemented for 15 minutes once or twice/day depending on the GA of the infant. A PAL® Therapy 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 PAL® Therapy session use the lowest criteria or easiest settings on PAL® Player Module 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 PAL® Therapy until infant demonstrates periods of 15 minutes of effective NNS and the infant's oral feeding improves.
9. Following the PAL® session:
10. Remove the PAL® Pacifier Sensor Module from the infant's crib. Remove the blue pacifier sensor (bear head) from infant's pacifier, use disinfecting wipes to clean and store this sensor for future use by this infant (single-patient-use).
11. Remove the PAL® Player Module from the crib. Use disinfecting wipes to clean the PAL® Player Module.
12. Store PAL® Player Module unit.

NOTE: If during PAL therapy another patient is having an alarm needing intervention and no other caregiver is available to handle the alarm situation, before leaving PAL® patient, the caregiver should assure the safety of the PAL patient by:

- Making sure bedrails are up or incubator doors closed.
- Contain the patient so he/she feels secure.
- Take PAL player module and sensor out of the crib/isolette and place on bedside table.
- Go to patient needing intervention.
- When patient needing intervention is addressed, return to PAL patient and continue therapy.

9.3 Use of PAL® 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 baby'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 baby and you, and maybe an occasional nurse will be the only ones who hear the recording.

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 PAL®, it is recommended that even when recorded and edited on an iPad that it is transferred to a Mac computer. This is because the PAL® 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 PAL® 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 PAL®.

The above is the easiest way to ensure that recording will play on the PAL®. 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 (PAL®) 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 (PAL®) 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..
R.F. emissions CISPR 11	Class B	The Pacifier Activated Lullaby (PAL®) 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.
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 (PAL®) 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_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5% U_T (95 % dip in U_T) for 5 s	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5% U_T (95 % dip in U_T) for 5 s	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_T is the A/C mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Pacifier Activated Lullaby (PAL®) 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Pacifier Activated Lullaby (PAL®) Model # PAL-HOS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter

			Recommended separation distance d=1.2sqrt(P), 80 Mhz to 800 Mhz **d=2.3sqrt(P), 800 Mhz to 2.5 Ghz** where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in 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 Pacifier Activated Lullaby (PAL®) 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 (PAL®) 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 (PAL®)

The Pacifier Activated Lullaby (PAL®) 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 (PAL®) 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 (PAL®) 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=1.2sqrt(P)	d=1.2sqrt(P)	d=2.3sqrt(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 PAL® (the "Product") including all components of the Product, excluding the Disposable Parts (collectively with the PAL® Disposable Sensors, the "Covered Components").

The PAL® Disposable Sensors, or other expendable or disposable parts of the Product are the "Disposable Parts."

NeoLight will replace your PAL®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 and 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 PAL® System 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.

Customer Service:

Please contact Customer Service if you need assistance setting up, using, or maintaining your PAL® Unit(s) or to report any unexpected operation or events. NeoLight Customer Service can be reached at:

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