

NTrainer System 2.0[®]

REF

IN-5000

IN-5001

IN-5002

IN-5003

Instructions for Use





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1. Section 1: Overview

1.1. About This Manual

This manual describes the features and functions of the NTrainer System® 2.0.

Section Overview:

Section 1: **Overview:** Provides an overview of NTrainer System® 2.0.

Section 2: **Operation:** Guides the user through the first time set-up, turning on the system, completing Assessments and Therapies, reviewing the data and managing users.

Section 3: **Care and Maintenance:** Guides the user through procedures for Service and Maintenance, Cleaning Directives, Troubleshooting, Returning and Disposing of the system.

Section 4: **Unboxing and Installation:** Guides the user through unpacking all components, as well as how to assemble and connect the system prior to use.

1.2. Introduction

1.2.1. Indications for Use

The NTrainer System® 2.0 reinforces non-nutritive suck (NNS) in newborns and infants born prematurely.

1.2.2. Intended Patient Population

The NTrainer System® 2.0 is intended for use in newborns and infants born prematurely with a gestational age (GA) at birth greater than 25 weeks and lacking an organized NNS.

1.2.3. Product Description

The NTrainer System® 2.0 is intended to be used in professional healthcare facility environments. No special skills, training, or knowledge required for operation of the NTrainer System 2.0.

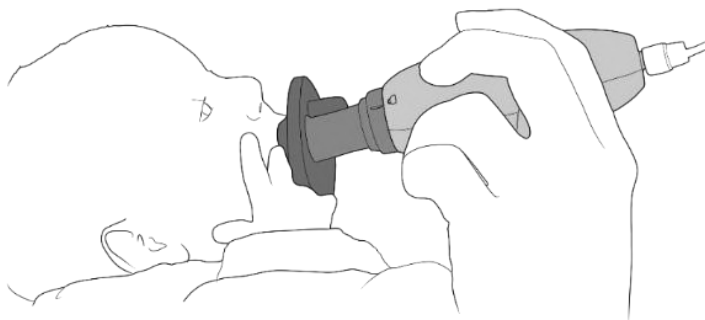
The NTrainer System® 2.0 assesses the infant's NNS skills and provides a sensory oral motor therapy to assist the infant with the development of organized non-nutritive sucking skills.

The NTrainer's patterned and frequency modulated oral stimulation (PFOS) therapeutic pulse entrains the infant's NNS oral motor skills. The NTrainer System® 2.0 is a pacifier system for assessing and a method of therapeutically stimulating the human orofacial system to reinforce NNS. The system includes a pacifier, connected to an air cylinder handset, with an integrated pressure transducer. In the assessment mode the pressure transducer serves to detect sucking intensity and time (frequency) of the suck. In the therapy mode, the NTrainer System® 2.0 provides patterned, rhythmic stimulation via the pacifier enabled-handset to the infant's orofacial system to



stimulate and entrain brain development. NTrainer System® 2.0 can be used on its own, during a nutritive gavage feeding or before/after breast or bottle feeds.

The use of the NTrainer System® 2.0 is underwritten by clinical evidence. The NTrainer System® 2.0 has no essential performance. The most up-to-date list of the scientific publications which support the benefits of the NTrainer System® 2.0 can be obtained at <http://www.innarahealth.com/research>. There are no known contraindications.





1.2.4. Unpacking

The NTrainer System® 2.0 and all necessary components are provided in 5 boxes. Quantities in boxes may vary depending on purchase order. All quantities shown here are to represent assembly only.

Box one contents:

- Monitor Enclosure
- AC Mains Cable (for UPS to Monitor Enclosure power)
- UPS Mount for Pole Cart
- Instructions for Use

Box two contents

- Uninterruptible Power Supply (UPS) with 6-ft cord packaged from vendor

Box three contents

- Pole Cart packaged from vendor

Box four contents

- Handpiece (x1)

Box five contents

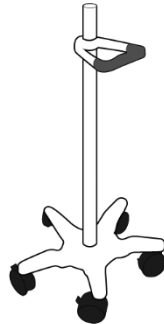

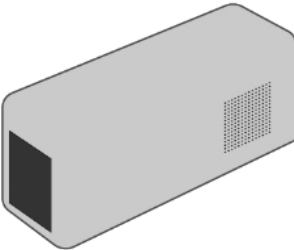
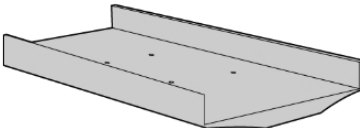
- Handpiece Tubing (x2)

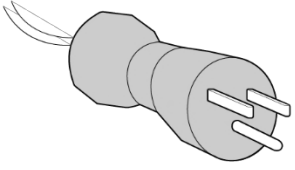

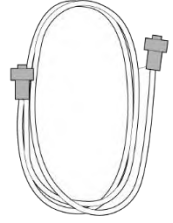

Contact Innara Health with any questions:

Website: www.innarahealth.com
Phone: (913)742-4456
Address: Innara Health, Inc.
10900 S Clay Blair Blvd.
Olathe, KS 66061

**Contents:**

Quantities in boxes may vary depending on the purchase order. All quantities shown here are to represent assembly only.

Part	Quantity	Image
Pole Cart	X 1	
Monitor Enclosure	X 1	
Uninterruptible Power Supply (UPS) with 6-foot Power Cord	X 1	
UPS mount for Pole Cart	X 1	

Part	Quantity	Image
AC Mains Cable (for UPS to Monitor Enclosure power)	X 1	
Handpiece	X 1	
Handpiece Tubing	X 1	
Instructions for Use	X 1	

1.2.5. Specifications

Physical

Size:	Pole Cart	21" X 21" X 43"(53.3 Cm X 53.3 cm X 109.2 cm) D X W X H
	UPS	13.7" X 5.4" X 6.4"(34.8 cm X 13.72 cm X 16.26 cm) D X W X H
	Handpiece	15.9" X 15.9" X 44.9"(40.37 mm X 40.37 mm X 113.97 mm) D X W X H
	Monitor Enclosure	89.3" X 169.5" X 147.9"(226.93 mm X 430.45 mm X 375.7 mm) D X W X H
Weight:	Pole Cart	10 lbs (4.5 kg)
	UPS	30 lbs (13.7 kg)
	Handpiece	0.13 lbs (0.06 kg)
	Monitor Enclosure	20 lbs (9.1 kg)



Service Life

NTrainer System® 2.0 is designed to provide a minimum of 3 years of service life.

Uninterruptible Power Supply (UPS)

Battery Type:	Uninterruptible Power Supply
Electrical:	550VA / 440W Capacity, 120 VAC Output, 12 V / 7 Ah Battery
Isolation:	Uninterruptible Power Supply provides means of isolation from supply mains.
Runtime:	40 minutes

Environmental

Operating Temperature: 16°C – 32°C

Operating Humidity: 30 to 60% relative, non-condensing humidity at an altitude up to 1600 meters (5,200 feet)

Storage Temperature: -10°C – 70°C

Storage Humidity: 10 to 80% relative, non-condensing humidity

Memory Capacity

Therapies	2920
Assessments	1460

Other

Display:	1920 x 1080 Pixel, LVDS
Monitor Material:	Cycology™ FR Resins C6600 (PC/ABS); AL 5052-H32
Handpiece:	Cycology™ FR Resins C6600 (PC/ABS)

1.3. Warnings

- Unauthorized modification of the Medical Electrical Equipment may lead to hazardous situations.
- Use only with Philips Soothie Pacifiers. Use of unapproved pacifiers may result in ineffective treatment or patient injury.
- **Do not** stand or ride on the pole cart.
- **Do not** place infant in the utility basket.
- **Do not** drop device during assembly or servicing that could cause bodily harm.



- Cables should be positioned to avoid creating a tripping hazard.
- To avoid strangulation, **do not** wrap cables around user or patient.
- **Do not** open the main housing, as there are no user-serviceable parts inside. Opening of device may affect function of device and voids the warranty.
- **Do not** reuse disposable receiver tube and pacifier with more than one patient. The Patient Receiver Tube and Soothie Pacifier are single patient use. Change before switching patients.
- Unauthorized modification of the Medical Electrical Equipment may lead to hazardous situations.
- To reduce the risk of electric shock, do not remove the cover of the UPS. There are no user serviceable parts inside the UPS.
- To prevent the risk of fire or electric shock, install the battery in a temperature and humidity controlled indoor area free of conductive contaminants. (Refer to UPS user manual for acceptable temperature and humidity range).
- The infant should be continually observed by a healthcare professional during assessment and therapy. Should signs of stress, intolerance and/or autonomic instability be noted pause the intervention, follow your facility's protocol and re-assess if the baby is capable of continuing.
- Not recommended for use in an infant that is deemed unstable by the healthcare professional.
- **Do not** perform maintenance when the NTrainer System® 2.0 is in operation.
- Inspect the system for damage prior to use.
- Dropping the Monitor Enclosure during assembly or servicing may cause bodily harm

1.4. Precautions

- Rx Only. Federal law (USA) restricts this device to sale by or on the order of a licensed physician
- This Instructions for Use contains the recommended procedures for preparing and using the NTrainer System® 2.0. It is intended for physicians and other healthcare professionals who will use this device and contains pertinent information on the handling of the device. Please read and become familiar with this entire manual before using the NTrainer System® 2.0.
- There are no known contraindications, however, care should be delivered at the discretion of the clinician in regard to gestational age, diagnoses and simultaneous use with respiratory supports.
- Inspect the system for damage prior to and periodically during use.
- Inspect the system labeling for damage prior to and periodically during use.



- Inspect the AC Mains Cable for damage or wear prior to and periodically during use.
- Inspect the Handpiece and Handpiece tubing for damage or wear prior to and periodically during use.
- Inspect the Uninterruptible Power Supply (UPS) for damage or wear prior to and periodically during use.
- Inspect the Soothie Pacifier prior to use and discontinue Soothie if it becomes damaged or contaminated.
- **Do not** spill liquids on the product.
- **Do not** hang or place heavy items on pole cart handle as it is not intended to bear weight.
- **Do not** cover or block vents on the back of the UPS.
- **Do not** attempt to lift or carry the NTrainer System® 2.0.
- **Do not** use the Handpiece, Handpiece Tubing, Power Cord, or other Cable as means to move the device.
- Be aware of pinch points between the system and external surfaces (such as walls).
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- The equipment should not be connected to another multiple socket-outlet or to an extension cord.
- Monitor Enclosure should only be connected to the provided Uninterruptible Power Supply (UPS).
- Connecting equipment not specified or provided by the manufacturer of this equipment to the multiple socket-outlet on the Uninterruptible Power Supply (UPS) effectively leads to creating a Medical Electrical System and the result can be a reduced level of safety.
- For requirements applicable to a Medical Electrical System refer to IEC 60601-1 General requirements for basic safety and essential performance.
- System should only be used in a non-condensing environment.
- System not for use with flammable agents.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- **Do not** connect the Handpiece, Handpiece Tubing, or Monitor to any other tubing or equipment not specified in this document.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NTrainer System® 2.0, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- California Prop 65: This product can expose you to chemicals which are known to the state of California to cause birth defects or other reproductive harm. For more information go to www.P65warnings.ca.gov.
- **Do not** open or mutilate batteries. Released material is harmful to skin and eyes. It may be toxic.



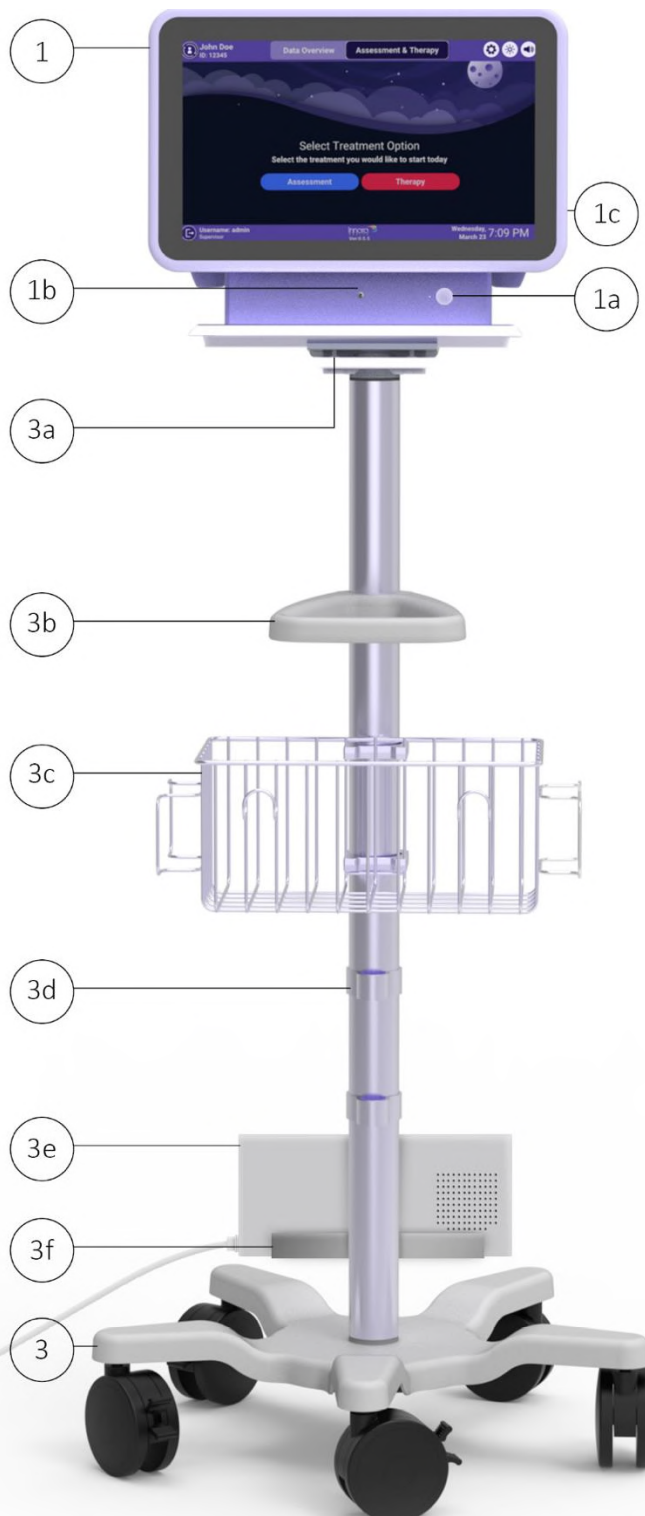
1.5. Notes

- NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Intended for use in healthcare facility only. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.
- NOTE: Regarding FCC compliance: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- NOTE: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

2. Section 2: Operation

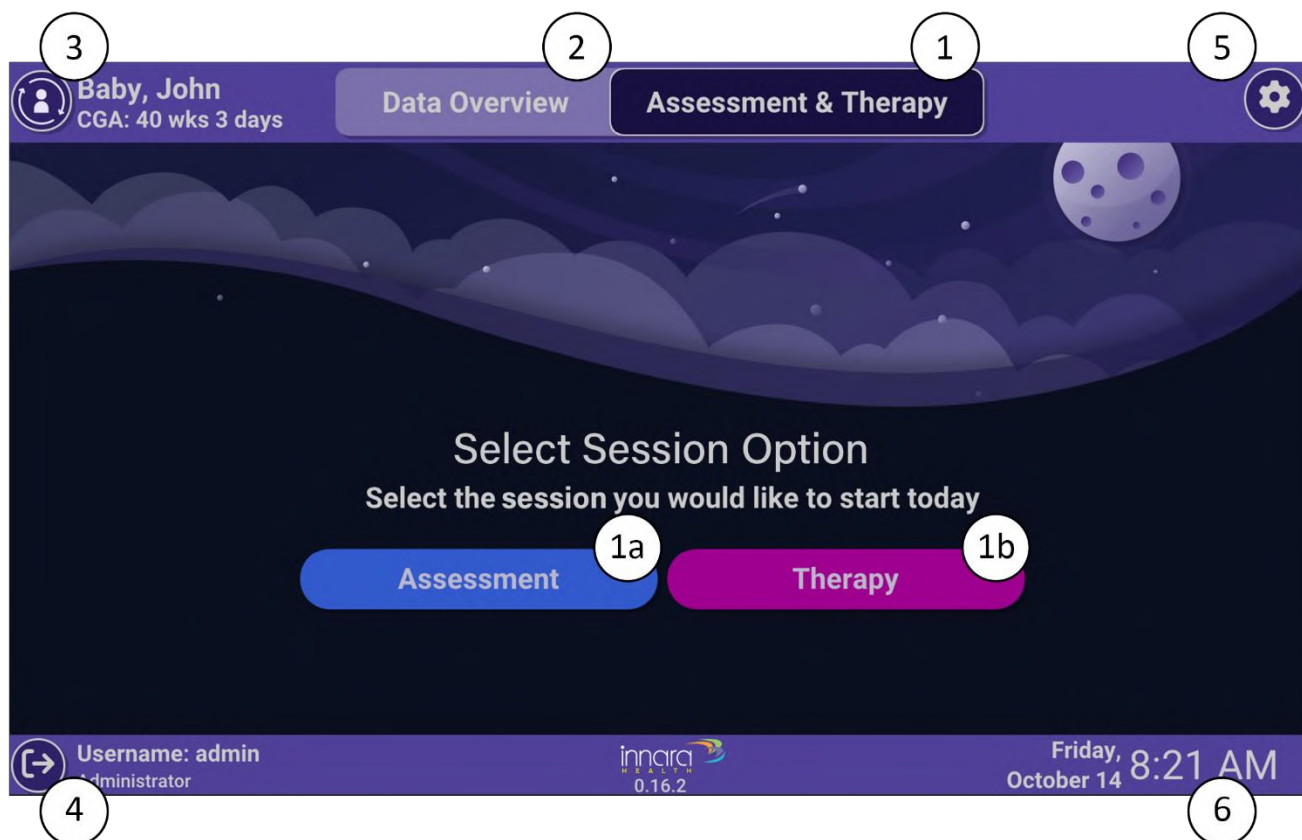
2.1. Device Parts

- 1 **Monitor Enclosure**
 - a. Power Button
 - b. Handpiece Tubing Connection
 - c. Monitor Housing
- 2 **Handpiece**
 - a. Patient Receiver Tube
 - b. Start/Pause Button
 - c. Soothie Pacifier
 - d. Handpiece Tubing Connection
- 3 **Pole Cart**
 - a. Mounting Plate for Monitor Enclosure
 - b. Handle
 - c. Utility Basket
 - d. Cable Clips
 - e. Uninterruptible Power Supply (UPS)
 - f. UPS Mount for Pole Cart



2.2.Screens Guide

2.2.1. Home Screen



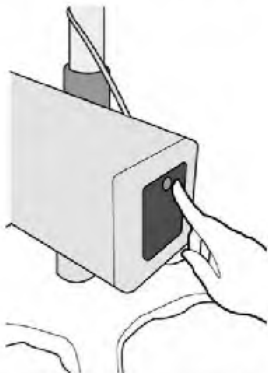
- 1 Assessment & Therapy Tab
 - a. Run an Assessment Session
 - b. Run a Therapy Session
- 2 Data Overview Tab
 - View Total Number of Sessions
 - Review patient progress
 - Review notes and waveforms
 - View multiple assessments
- 3 Patient Icon
 - To the right view currently opened Patient File
 - Log Out Patient
- 4 Log Out Icon
 - To the right view currently logged in User
 - Power Off
 - System Log Out
- 5 Settings Icon
 - Manage NTrainer
 - o Manage Users
 - Add New User
 - Edit User
 - Remove User
 - o Manage Patients
 - Mark Patient Inactive
 - Edit Information
 - Export Report
 - o Utilization Report
 - o Settings
 - Pair Handpiece
 - About
 - Run Self-Check
 - Reset My Password
 - o Advanced
 - Change Date/Time
 - Adjust Volume
 - Adjust Brightness
- 6 Date and Time



2.3. Getting Started

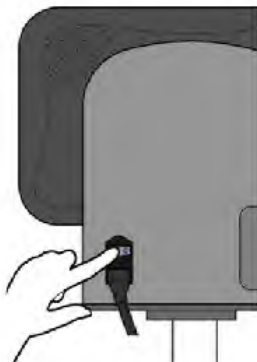
2.3.1. Power On the System

Step 1: Turn on UPS



Make sure the 6-foot power cord is plugged into the wall and the AC Mains Cable is connected to the back of the Monitor Enclosure. Then press the UPS power button on.

Step 2 : Turn on Monitor Enclosure



Turn on the Monitor Enclosure using the back power switch. Make sure it is flipped to "I".

Step 3 : Turn on Touch Screen



Press and hold the button on the front of the Monitor Enclosure until the green light illuminates and the display lights up.

The NTrainer System® 2.0 should be plugged in at all times during use and storage. It can be unplugged during transport between storage space and patient bedsides.

2.3.2. User Log In

Step 1: Start-Up Screen



Once the system is on the Start-Up Screen will appear. Touch anywhere on the the screen to begin the log in process.

Step 2 : Log in to User Account



Type in username and password and select the "Log In" button. **Note:** The UP arrow toggles between lower and upper case letters.

Step 3 : View Main Screen



Once logged in you can go to the Settings icon or proceed to create a "New Patient" or to an "Existing Patient" file.

2.3.3. Pair the Handpiece

Step 1 : Select Settings Icon



Select the Settings icon in the top right corner.

Step 4 : Select Handpiece



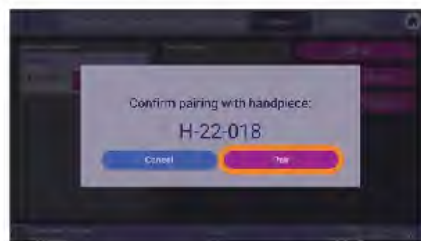
On the left side of the screen find the correct handpiece to pair and then select "Pair". **Note:** The Serial Number should flash when the button on the Handpiece is pressed.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

Step 5 : Pair Handpiece



Confirm the Handpiece and then select "Pair". If it is incorrect select "Cancel" to return to the Settings window.

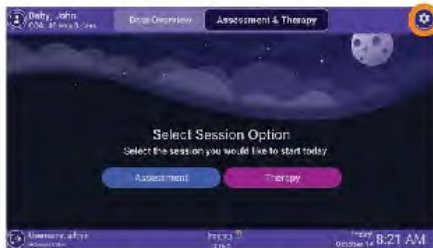
Step 3 : Press Hanpiece Button



Select "Settings" from top menu. Press the button on the Handpiece.

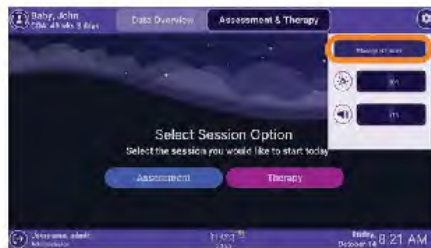
2.3.4. Set Up System Users

Step 1 : Select Settings Icon



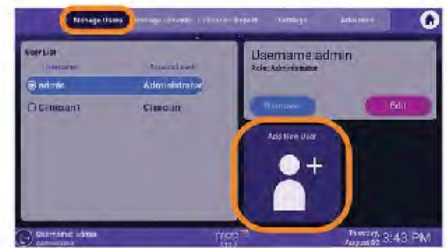
Select the Settings icon in the top right corner.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

Step 3 : Add User



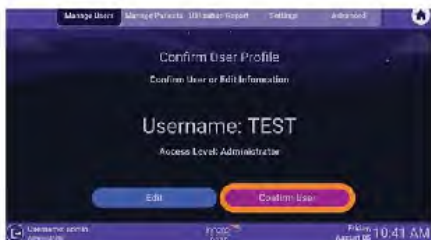
Select "Manage Users" from the top menu. Select the "Add New User" button.

Step 4 : Input User Information



Input the Username, Password and Access Level. Once finished select the "Create" button in the bottom right corner.

Step 5: Confirm New User



Confirm all the information is correct and select "Confirm User". To change the information select "Edit".

- System Users must be hospital clinicians or staff members, not parents/caregivers.
- Patient information stored on the NTrainer System® 2.0 is private, personally identifiable information subject to USA Federal HIPAA safeguards. This law requires access to the NTrainer System® 2.0 be controlled by password protected user accounts.
- Each user should have a unique password and should not be shared with other users.

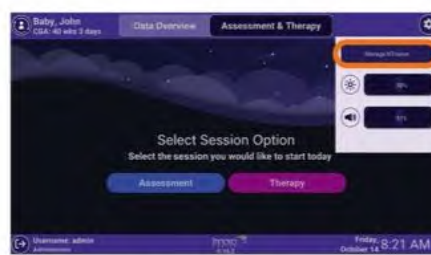
2.3.5. Set Date and Time

Step 1 : Select Settings Icon



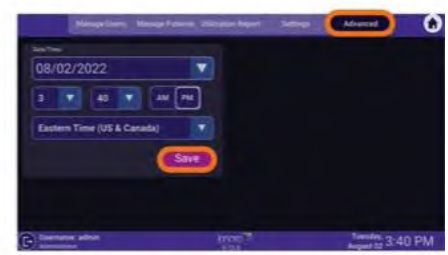
Select the Settings icon in the top right corner.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

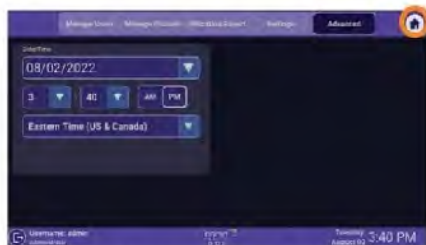
Step 3 : Change Date and Time




Select "Advanced" from the top menu. Change the information using the drop-down menus to reflect the current date and time. This task must be completed manually because the system is not connected to the Internet. Press "Save" when done.

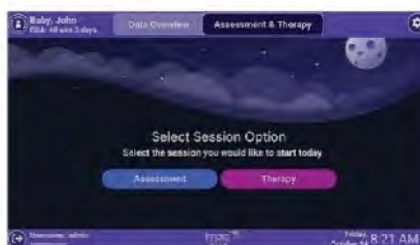
2.3.6. Return to Home Screen

Step 1 : Return Home



Select  icon to return to the home screen.

Step 2 : Home Screen 1



If you are logged into a patient you will be returned to the Assessment/Therapy screen (as seen above).

Step 3 : Home Screen 2



If you are not logged into a patient you will be returned to the New or Existing Patient screen (as seen above).

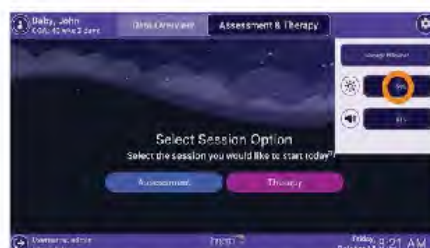
2.3.7. Adjust Screen Brightness


Step 1 : Select Settings Icon



Select the Settings icon in the top right corner.

Step 2 : Drag Wheel Right and Left



Use the scroll to the right of the  icon to adjust the brightness.

2.3.8. Adjust Volume


Step 1 : Select Settings Icon



Select the Settings Icon in the top right corner.

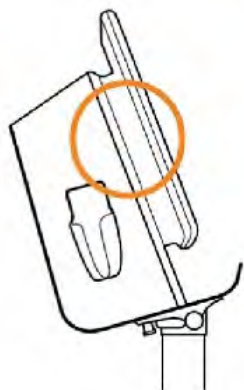
Step 2 : Drag Wheel Right and Left



Use the scroll to the right of the  icon to adjust the volume.

2.3.9. Adjust Screen Tilt

Step 1 : Adjust Screen Tilt

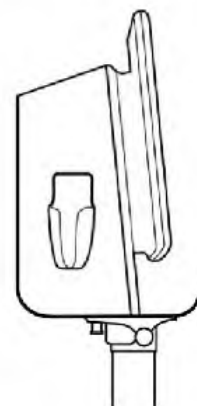


Using the sides of the Monitor Enclosure tilt forward or backward until you have reached the desired viewing angle.



You can also use the handle attached to the bottom of the Monitor Enclosure to make tilt adjustments.

Troubleshooting



If you can't easily adjust the screen due to too much or too little resistance, contact Biomed for assistance.

2.4. User Access Guide

The system has two types of users: a system administrator and a clinician. While both roles can access patient files only an administrator role can access certain system settings.

2.4.1. Feature Access Breakdown

Function	Details	Role	
		Administrator	Clinician
Assessment	<ul style="list-style-type: none"> Objectively captures full oral motor NNS skill data Infant's interactions with a neutral pacifier are recorded, and displayed in graph form Measures infant's NNS skill development over time Contributes to feeding readiness and advancement decisions 	X	X
Standard Therapy	<ul style="list-style-type: none"> Neuromuscular intervention to strengthen and organize NNS skills Impacts neurological pathways for oral muscular activity Provides consistent oral stimulation via a proven pulse pattern designed to mimic healthy NNS 9-minutes of therapy provided over 10 minutes 3-minute paced segments of 6 simulated sucks separated by a 2-second pause 3, 3-minute segments separated by 30-second quiet nipple periods 	X	X
Short Interval Therapy	<ul style="list-style-type: none"> Neuromuscular intervention to strengthen and organize NNS skills Impacts neurological pathways for oral muscular activity Provides consistent oral stimulation via a proven pulse pattern designed to mimic healthy NNS 9-minutes of therapy provided over 10 minutes 1.5-minute paced segments of 6 simulated sucks separated by a 2-second pause 6, 1.5-minute segments separated by 10-second quiet nipple periods 	X	X
Extended Therapy	<ul style="list-style-type: none"> Neuromuscular intervention to strengthen and organize NNS skills Impacts neurological pathways for oral muscular activity Provides consistent oral stimulation via a proven pulse pattern designed to mimic healthy NNS 9-minutes of therapy provided over 20 minutes 3-minute paced segments of 6 simulated sucks separated by a 2-second pause 3, 3-minute segments separated by 5.5-minute quiet nipple periods 	X	X
Data Overview	<ul style="list-style-type: none"> View Total Number of Sessions View Multiple Assessments to track progress View Assessment STI score and other metrics View Therapy Notes 	X	X
Create New Patient	<ul style="list-style-type: none"> Add Patient ID, Patient Name, Date of Birth, Gestational Age at Birth, Birth Weight and Sex 	X	X

Function	Details	Role	
		Administrator	Clinician
Sign in Existing Patient	<ul style="list-style-type: none"> Search existing patient by first or last name or by patient ID 	X	X
Create New System Users	<ul style="list-style-type: none"> Create Username, Password and assign role Clinician roles do not have access to certain settings* 	X	
Edit System Users	<ul style="list-style-type: none"> Change system user's password, role or username 	X	
Remove System Users	<ul style="list-style-type: none"> Delete system user from system 	X	
Edit Patient Details	<ul style="list-style-type: none"> Adjust Patient ID, Patient Name, Date of Birth, Gestational Age at Birth, Birth Weight and Sex 	X	X
Mark Patients as Inactive	<ul style="list-style-type: none"> Mark existing patient as inactive and reactivate inactive patients 	X	X
Pair Handpiece	<ul style="list-style-type: none"> Pair new Handpiece to system 	X	X
Reset Personal Password	<ul style="list-style-type: none"> Enter existing password and new password twice 	X	X
Run System Self Check	<ul style="list-style-type: none"> Review system health and possible errors 	X	X
View System Information	<ul style="list-style-type: none"> View system memory and age 	X	X
Change Time and Date	<ul style="list-style-type: none"> Select time zone, time and date 	X	

2.5.Patient Files

2.5.1. Create a New Patient File

Step 1 : Select New Patient



Select the "New Patient" button.

Step 2 : New Patient's Information



Fill in the patient's information and then select "Save" button.

Step 3 : Confirmation



Confirm the information is correct and select "Confirm Patient". If the information is incorrect select the "Edit" button.

2.5.2. Open an Existing Patient File

Step 1 : Select Existing Patient



Select the "Existing Patient" button.

Step 2 : Search Existing Patient



Search for an Existing Patient by First or Last Name, or by Patient ID. Select the name of the patient you are looking up.

Step 3 : Confirmation



Confirm the Patient Profile and select "Confirm Patient". If the information is incorrect, select "Incorrect Patient".

2.5.3. Edit Patient File

Step 1 : Select Settings Icon



Select the Settings icon in the top right corner.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

Step 3 : Select Patient



Select Manage Patients from the top menu. Select the patient you need to correct, then select "Edit".

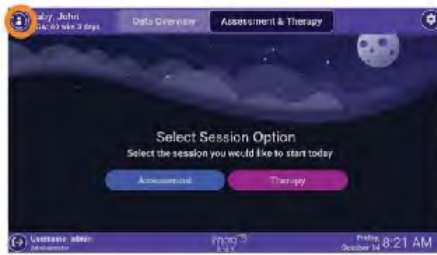
Step 4 : Edit Patient



Edit the patient's information and then select "Save". This will return you back to the Manage Patients window.

2.5.4. Switch Patient Files

Step 1 : Select Patient Icon



Select Patient icon in the top left corner of the screen.

Step 2 : Select Log Out Patient



Select "Log Out Patient" from the drop-down menu.

Step 3 : Confirm Log Out



Confirm "Log Out" or select "Cancel" to remain in the patient's file.

Step 4 : Choose New or Existing Patient



Open up a "New Patient" or "Existing Patient" file, as seen in section 2.5.

2.5.5. Mark Patient as Inactive

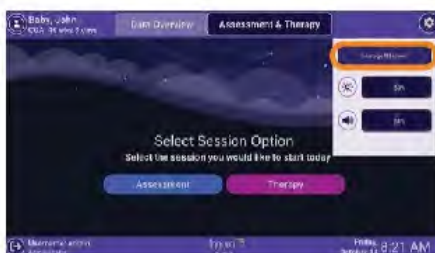
Note: Marking a patient as Inactive will remove them from the search list, but all their information will still be saved on the system.

Step 1 : Select Settings Icon



Select the Settings icon in the top right corner.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

Step 3 : Select User

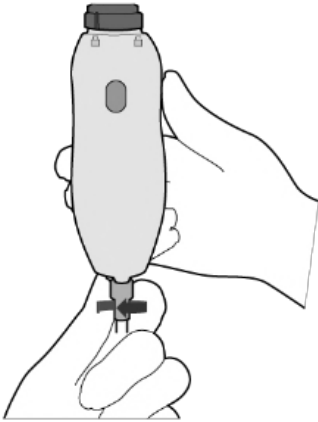


Select "Manage Patients" from top menu. Select the correct patient and then select "Mark Patient Inactive".

2.6. Set Up the Handpiece for Use

- WARNING: The Patient Receiver Tube and Soothie Pacifier are single patient use. Change Patient Receiver Tube and Pacifier, and switch to clean gloves before using the Handpiece on another patient.

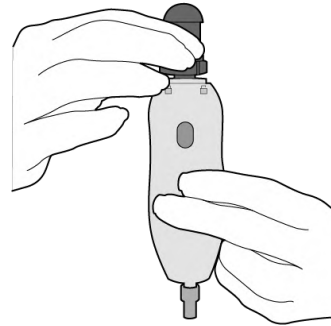
- Ensure the Handpiece Tubing is only connected to the Monitor Enclosure and Handpiece per the first two drawings below, and no other Luer-lock devices.



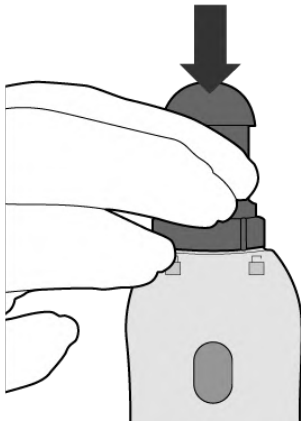
Step 1: Twist one end of the Handpiece Tubing onto the bottom of the Handpiece.



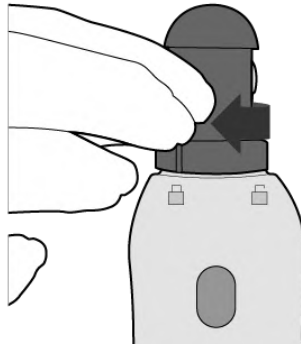
Step 2: Twist the other end of the Handpiece Tubing onto the front of the Monitor Enclosure.



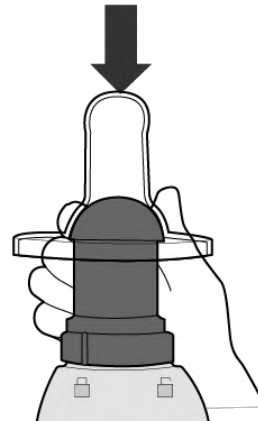
Step 3: Line up the Receiver Tube with the Handpiece.



Step 4: Push down the Receiver Tube.



Step 5: Twist Receiver Tube to locked position.



Step 6: Attach Soothie Pacifier onto the top of the Receiver Tube, be sure to fully cover the lip.



2.7. Supporting the Infant Before, During and After an Assessment or Therapy Session

The infant's interaction with the NTrainer System® 2.0 is designed to be a positive pleasurable developmental experience. The ideal state for learning is when the infant is calm, awake, and alert.

Be aware of external environmental stimuli which will negatively impact the experience. Try to perform session in a quiet, dimly lit area.

The infant should be continually observed by a healthcare professional during assessment and therapy. Should signs of stress, intolerance and/or autonomic instability be noted pause the intervention, follow your facility's protocol and re-assess if the baby is capable of continuing.

Swaddle the infant loosely so breathing is not restricted and the infant's hand can easily move up to the face or mouth. Use developmental support to position the infant with arms and legs in flexion and hold in side-lying feeding position with support to the head/neck, bottom, and legs.

With the pacifier attached to the NTrainer System® 2.0 Handpiece, gently brush the pacifier to the infant's cheek or lips to encourage a rooting response.

- If the infant does not readily accept the pacifier, place the nipple midline on the top lip and wait for the infant to show signs of acceptance, for example, a noticeable release of the clenched jaw and loosening of the pursed lips. Slowly introduce pacifier into the infant's mouth from the side making sure to place the nipple on top of the tongue, neither pushing down on the tongue or up on the palate.

If the infant demonstrates a brief gag response to the pacifier remove the pacifier and allow the infant to recover. Re-introduce the pacifier slowly.

Keep the NTrainer System® 2.0 Handpiece still during both assessments and therapies.

While it may be tempting to move the NTrainer System® 2.0 Handpiece to encourage sucking, the NTrainer System® 2.0 therapy intervention is specifically programmed. Extraneous movement will affect the desired assessment or therapy and may provide conflicting signals to the infant.

2.8.Run an Assessment

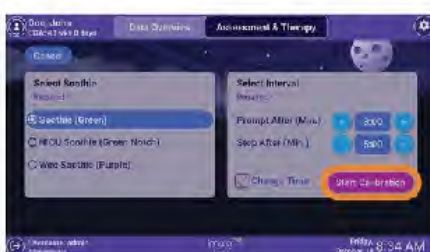
- Objectively captures full oral motor NNS skill data
- Infant's interactions with a neutral pacifier are recorded, and displayed in graph form
- Measures infant's NNS skill development over time
- Contributes to feeding readiness and advancement decisions
- An initial Assessment should be performed to determine if the patient is a candidate for Therapy, and if yes, will serve as a baseline to compare later Assessments to
- Additional Assessments can be incorporated into existing bedside feeding and developmental evaluations done with each patient
- As a recommendation, one Assessment may be provided every 3-7 days to track progress

Step 1 : Select Assessment



From the Assessment and Therapy window select the "Assessment" button.

Step 2 : Select Correct Settings



Select the Soothie Pacifier you will be using. To change the Prompt and Stop times, select the "Change Time" button and use the plus or minus buttons to adjust as needed. Proceed to "Start Calibration".

Step 3 : Start Calibration



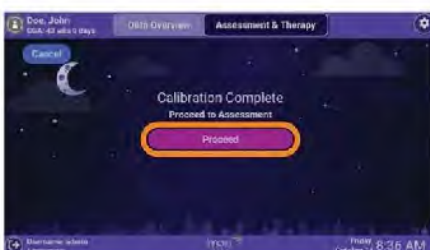
Select "Begin Calibration" to start the calibration process. **Note:** The hand-piece must be prepared and connected prior to calibration.

Step 4 : Calibrate



The calibration is an automatic process. No steps are necessary during this time.

Step 5 : Calibration Complete



Once calibration is complete, select "Proceed". To go back select the "Cancel" button in the top left corner.

Step 6 : Begin Assessment



Start the Assessment by pressing the button on the handpiece or the Start/Pause button on the screen. Select the "END" button if the Assessment is finished.

Step 7 : Patient State



Select the patient's state and then select "Confirm".

Step 8 : Add Assessment Documentation



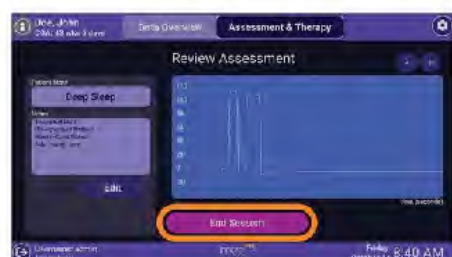
Add autogenerated documentation. If custom notes are needed, select the "+ Custom Note" button on the bottom right. If finished select "Confirm".

Step 9 : Custom Notes



Input the custom, free-hand documentation, then select "Add Notes" to finish.

Step 10 : Review Assessment



Review the patient's assessment. If edits are necessary select the "Edit" button. Once finished select "End Session".

2.9.Run a Therapy

- Neuromuscular intervention to strengthen and organize NNS skills
- Impacts neurological pathways for oral muscular activity
- Provides consistent oral stimulation via a proven pulse pattern, contracting 6 times followed by a 2-second pause, designed to mimic healthy NNS
- As a recommendation, therapy should be done during gavage feedings or prior to oral feedings 2-4 times per day until oral feedings are established, as determined by the healthcare professional

Types of Therapy:

Standard	<ul style="list-style-type: none"> • 9-minutes of pulses over 10-minutes • two 30-second pauses
Short Interval	<ul style="list-style-type: none"> • 9-minutes of pulses over 10-minutes • five 10-second pauses
Extended	<ul style="list-style-type: none"> • 9-minutes of pulses over 10-minutes • two 5.5-minute pauses

Step 1 : Select Therapy



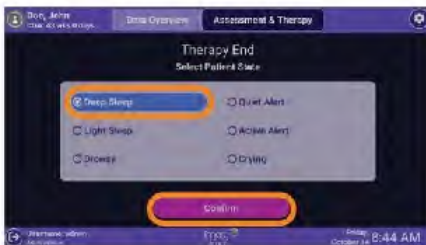
From the "Assessment & Therapy" window select the "Therapy" button.

Step 4 : Calibrate



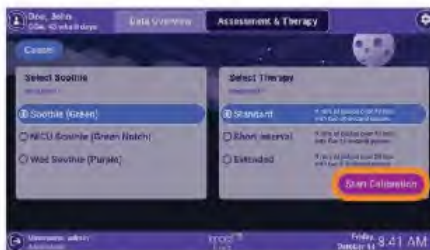
The calibration is an automatic process. No steps are necessary during this time.

Step 7 : Patient State



Select the patient's state and then select "Confirm".

Step 2 : Select Correct Settings



Select the Soothie Pacifier you will be using and the therapy you will be running. Then proceed to "Start Calibration".

Step 5 : Calibration Complete



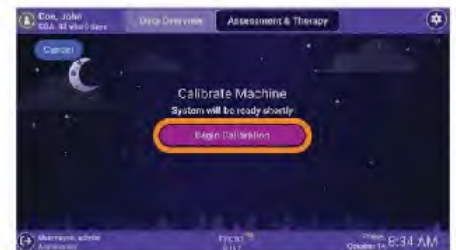
Once calibration is complete, select "Begin Therapy". To go back select the "Cancel" button in the top left corner.

Step 8 : Add Therapy Documentation



Add autogenerated documentation. If custom notes are needed, select the "+ Custom Note" button on the bottom right. If finished select "Confirm".

Step 3 : Start Calibration



Select "Begin Calibration" to start the calibration process. **Note:** The handpiece must be prepared and connected prior to calibration.

Step 6 : Begin Therapy



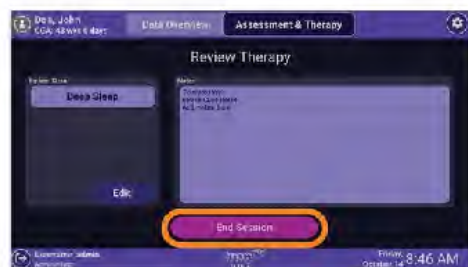
Start the Therapy by pressing the button on the handpiece or the Start/Pause button on the screen. Select the "END" button if the therapy is finished.

Step 9 : Custom Notes



Input the custom free-hand documentation then select "Add Notes" to finish.

Step 10 : Review Therapy



Review the patient's therapy. If edits are necessary select the "Edit" button. Once finished select "End Session".

2.10. Data Overview

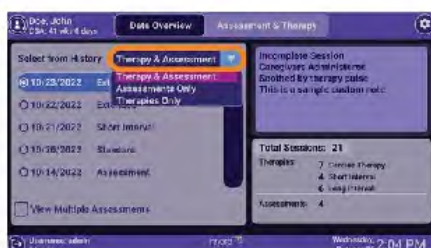
2.10.1. View Data

Step 1 : Data Overview



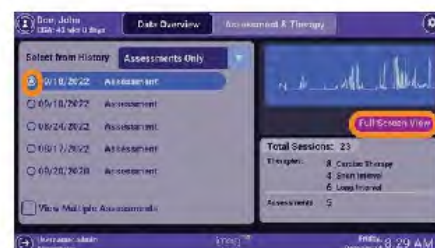
Select the "Data Overview" button on the top panel.

Step 2 : Select Data



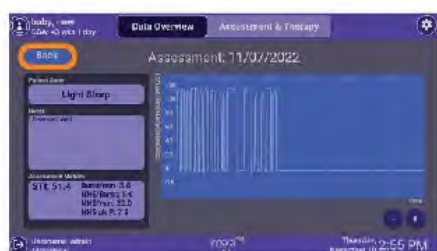
To filter the data by Therapy, Assessments or both, select appropriately from the drop-down menu.

Step 3 : Filter Data



Select the data to be viewed. The data is presented on the right side of the screen. Select "Full Screen View" to analyze waveforms in greater detail.

Step 4 : View Data



While viewing the data the plus and minus buttons in the bottom right corner allow zooming in and out of the waveform. Once finished select "Back".

2.10.2. View Multiple Assessments

Step 1 : Select Assessments



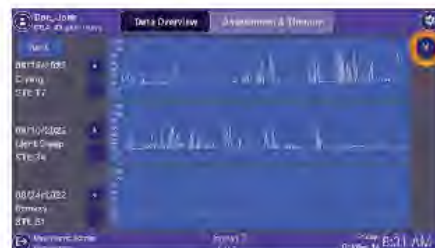
From the "Data Overview" screen select Assessments from the drop down menu.

Step 2 : View Multiple Assessments



Check the "View Multiple Assessments" in the bottom left corner. Select "Full Screen View" to analyze waveforms in greater detail.

Step 3 : Full Screen View



While viewing the data the plus and minus buttons to the left of the waveform allow zooming in and out. Once finished select the "X" in the top right corner to exit the assessment data.

2.11. Access a Utilization Report

Step 1 : Select Settings Icon



Select the Settings icon in the top right corner.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

Step 3 : Review Report



Select "Utilization Report" from top menu. Review the current month's report. To review previous months select the "Previous" button. To review the next month, select the "Next" button.

2.12. User Log Out

Step 1 : Select Log Out Icon



Select the "Log Out" icon in the bottom left corner.

Step 2 : Select System Log Out



Select the "Log Out" button.

Step 3 : Confirm Log Out



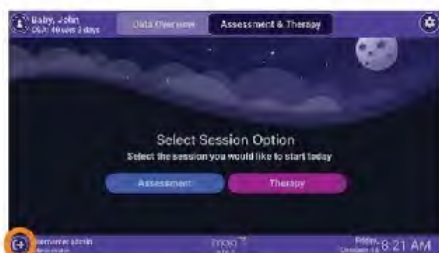
Confirm "Log Out" or to go back select "Cancel".

Always Log Out between patients to ensure patient confidentiality and to prevent non-users access to protected health information.

Do not leave patient screen visible in public areas.

2.13. System Power Off

Step 1 : Select Log Out Icon



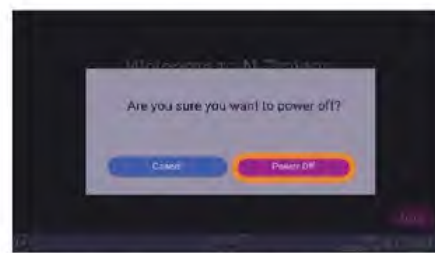
Select the "Log Out" icon in the bottom left corner.

Step 2 : Select Power Off



Select the "Power Off" button.

Step 3 : Confirm Power Off



Confirm "Power Off", or to go back select "Cancel".

2.14. Administrator Accessible Settings

2.14.1. Add a New System User

See Section 2.3.4 – Set Up System Users

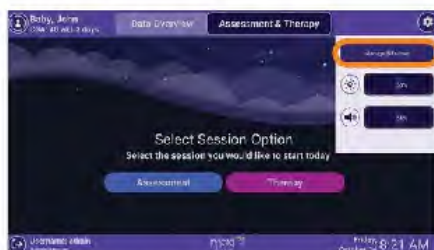
2.14.2. Edit System Users

Step 1 : Select Settings Icon



Select the Settings icon in the top right corner.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

Step 3 : Select User



Select "Manage Users" from top menu. Select the correct user, and then select the "Edit" button.

Step 4 : Edit User Details



Type in the updated user name. To change the user's access level select the drop down menu in the middle right of the screen, then select "Save". Select "Reset Password" to change that user's password.

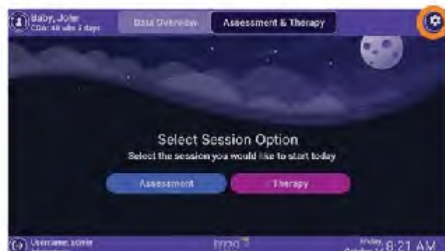
Step 5 : Change Password



Create new password and then select "Reset".

2.14.3. Remove System Users

Step 1 : Select Settings Icon



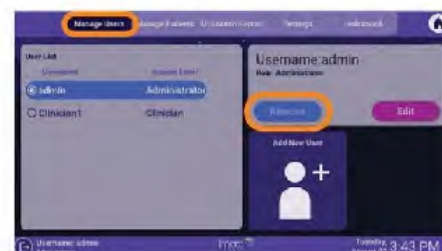
Select the Settings icon in the top right corner.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

Step 3 : Select User



Select "Manage Users" from top menu. Select the correct user, and then select the "Remove" button.

Step 4 : Remove User



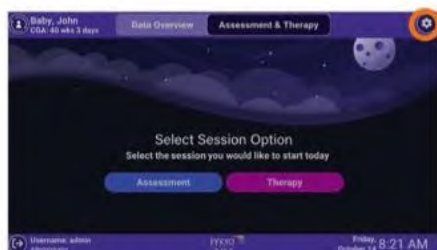
Confirm the user you want to remove and select "Remove", to go back select "Cancel".

2.14.4. Change the Date and Time

See Section 2.3.5 - Set Date and Time

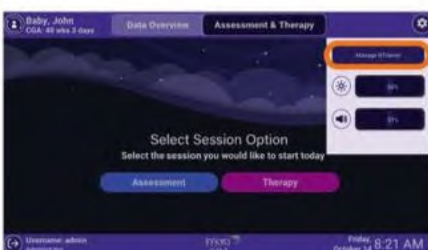
2.15. Reset Password

Step 1 : Select Settings Icon



Select the Settings icon in the top right corner.

Step 2 : Select Manage NTrainer



Select "Manage NTrainer".

Step 3 : Reset Password



Select "Settings" from top menu. Select the "Reset My Password" button. This is for the currently logged in user.

Step 4 : Input Information



Fill in the Old Password and then input the New Password, once finished select the "Save" button.



3. Section 3: Care and Maintenance

3.1. Maintenance and Servicing

The NTrainer System® 2.0 should be inspected for signs of damage prior to every use. If signs of damage are observed, contact Innara Health. The NTrainer System® 2.0 has no serviceable parts. Internal batteries in the UPS not intended to be replaced over the life cycle of the system. Periodically inspect all fasteners associated with each part of the Pole Cart Assembly. Tighten as necessary for optimal operation and safety.

Warning: Do not perform maintenance when the NTrainer System® 2.0 is in operation.

3.1.1. Part Replacement

If the Handpiece, Handpiece tubing, Uninterruptible Power Supply, or other components display signs of damage or wear, they should be replaced to maintain intended performance. For information on part replacement, contact Innara® Health.

Website: www.innarahealth.com
 Phone: (913)742-4456
 Address: Innara Health, Inc.
 10900 S Clay Blair Blvd.
 Olathe, KS 66061

3.2. Cleaning and Disinfecting

To clean and disinfect the NTrainer System® 2.0, PDI Super Sani-Cloth Wipes should be used according to the manufacturer's instructions on the following parts: Monitor Enclosure, Handpiece, Receiver Tube, and Pneumatic Tubing. PDI Easy Screen Cleaning wipes should be used on the touchscreen portion of the Monitor Enclosure. The device should be cleaned and disinfected after every patient use.

Do not allow water or cleaning solvent to enter the internal parts of the Handpiece or Monitor Enclosure. Do not immerse the system in liquid or water. Do not use cleaning solvents other than PDI Super Sani-Cloth Wipes or PDI Easy Screen Cleaning Wipes. If cleansing wipe feels over-saturated, squeeze off excess liquid to prevent cleaning solvent from entering the internal parts.

The Patient Receiver Tubes are designed for single patient, multiple use. Per manufacturer's instruction, pacifiers should be disposed after 4 weeks, or after discharge, whichever comes sooner. All Patient Receiver Tubes should be disposed after patient discharge. Prior to use, they may be cleaned per hospital procedure .

Soothie Pacifier is a single-patient use component. Prior to use, they may be cleaned per hospital procedure and the manufacturer's labeling.



Caution: Disconnect Power Cord from power source before cleaning. After cleaning, **do not** re-connect to power source until the Monitor Enclosure, AC Mains Cable and Power Cord are thoroughly dry.

Cleaning of the Pole Cart Assembly, in which the NTrainer System® 2.0 attaches to, must be performed as follows:

- Each part of the Pole Cart Assembly may be cleaned with most mild, non-abrasive solutions commonly used in the hospital environment (e.g. diluted bleach, ammonia, or alcohol solutions).
- The surface finish will be permanently damaged by strong chemicals and solvents such as acetone and trichloroethylene.
- Do not use steel wool or other abrasive material to clean the any part of the Pole Cart Assembly.
- We recommend that you test any cleaning solution on a small area of the mounting assembly that is not visible to verify compatibility.
- Never submerge the Pole Cart or allow liquids to enter any part of the Pole Cart Assembly. Wipe any cleaning agents off the Pole Cart Assembly immediately using a water-dampened cloth. Dry all parts of the Pole Cart Assembly thoroughly after cleaning.



3.3.Troubleshooting

3.3.1. Common Issues

Symptom	Probable Cause	Corrective Answer
System Won't Turn On	Not Holding Front Power Button for Long Enough	Hold Power Button down for 5 second minimum.
	Rear Power Switch is not turned on	Flip Power Switch to "I" State.
	Uninterruptible Power Supply (UPS) is not turned on	Press UPS Power Button on
	System is not plugged in	Plug UPS into AC power supply, and ensure proper connection between UPS and Monitor Enclosure via the AC Mains Cable.
Handpiece Won't Work	Handpiece is Not Paired	Go to Manage NTrainer > Settings > Push Handpiece Button > Pair Handpiece.
System Unable to Calibrate	Handpiece Tubing Not Connected Correctly	Ensure that Handpiece Tubing is correctly connected to both the Monitor Enclosure and Handpiece and that the Receiver Tube is twisted into place.
	Handpiece Tubing Damaged	Check the Handpiece Tubing and all connections for signs of damage. Replace if damaged.
	Patient Receiver Tube Not Connected Correctly	Remove and reattach Patient Receiver Tube.
	Soothie Pacifier not Attached Correctly or Damaged	Remove and reattach Soothie Pacifier, or replace the Soothie Pacifier.
Frozen Screen	Software Malfunction	If the software is unresponsive or frozen, hard reset the system by turning off the power switch at the back of the Monitor Enclosure. Wait 1 minute and then turn back on and go through the start up process again.
Unable to Log In	Incorrect Password	Contact System Admin for a Password Change.
	Incorrect Username	Contact System Admin for a Username Change.
Exits Therapy Unexpectedly	Damage to Internal Pump	Contact Innara Health Customer Service.



3.3.2. Error Messages

Displayed Message	Description	What to Do
Unable to Pressurize Pneumatic System	Pneumatic system not pressurizing	Check all Handpiece tubing connections for possible leak and restart assessment or therapy. If message persists, contact Innara Health
Power on self-test failed	System start up self-test failed	Restart system. If message persists, contact Innara Health
Failed to connect to database	Database connection error	Restart system. If message persists, contact Innara Health
Error during therapy. Check connections for possible leak	Error during therapy	Check all tubing connections for possible leak and restart therapy. If message persists, contact Innara Health
Warning: Less than 10% of space available on device	Data storage drive has less than 10% of capacity remaining	Contact Innara Health
Handpiece error. Check connections for possible leak	Handpiece leak detected	Check all tubing connections to the Handpiece. Ensure Receiver Tube and Soothie Pacifier are securely attached. Restart therapy or assessment. If message persists, contact Innara Health
System unable to vent. Discontinue use	System failure to vent detected	Check all tubing connections for possible leak and restart assessment or therapy. If message persists, contact Innara Health
Unknown Error	Error of undetermined means	Contact Innara Health.
System Failure Unknown	Displayed during therapy when the internal pump temperature interlock activates	Contact Innara Health Customer Service.

3.4. Return or Disposal Procedure








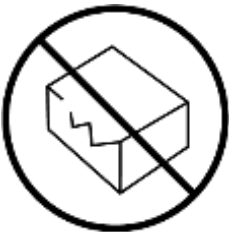
Return Procedure

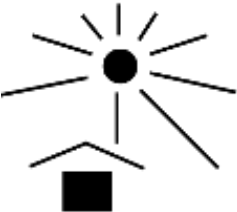
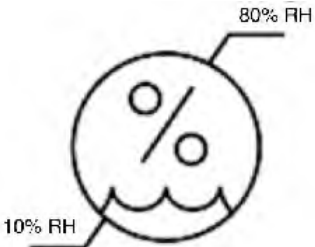
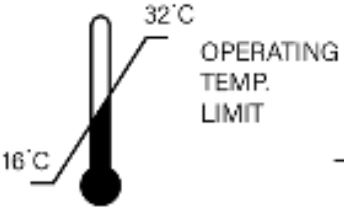
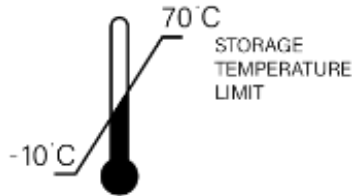

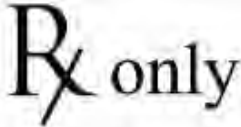
Should a malfunction occur, contact Innara Health. If Innara determines that the NTrainer System 2.0 should be returned, you will be assigned a return authorization number and be provided shipping instructions.







Disposal Procedure



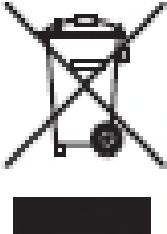
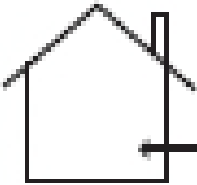


Dispose of an NTrainer System 2.0 in accordance with the regulations applicable in your country. For information about correct disposal, please contact your local council or authority.



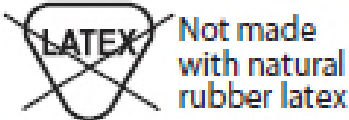
3.5.Symbols Glossary

Symbol	Symbol Title	Explanatory Text
	Manufacturer	Indicates the medical device manufacturer. ISO 7000-3082
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified. ISO 7000-2493
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified. ISO 7000-2498
	Lot Number	To identify the batch or lot code. ISO 7000-2492
	Quantity	To identify the quantity of units in the package.
	Ingress Protection	Indicates the ingress protection level of the unit.
	Keep Dry	Indicates a medical device that needs to be protected from moisture. ISO 7000-0626
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information. ISO 7000-2606

Symbol	Symbol Title	Explanatory Text
	Keep away from direct sunlight	Indicates a device that needs protection from light sources. ISO 7000-0624
	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed. ISO 7000-2620
	Operating Temperature Limits	Indicates the temperature limits to which the medical device can be safely exposed. ISO 7000-0632
	Storage Temperature Limits	Indicates the temperature limits to which the medical device can be safely stored. ISO 7000-0632
	Country of Manufacture	To identify the country of manufacture products. IEC 60417-6049
	Perscription Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Symbol	Symbol Title	Explanatory Text
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read. ISO 7010-M002
	Refer to Operating Instructions	To signify that the operating instructions must be read. ISO 7000-1641
	Type B Applied	To identify a type B applied part complying with IEC 60601-1. IEC 60417-5840
	Single Patient Multiple Use	Indicates a medical device may be used multiple times (multiple procedures) on a single patient. ISO 7000-3706
	TÜV SÜD Certification Mark	To identify a product has been certified by TÜV SÜD.
	No Pushing	To prohibit pushing against an object. ISO 7010-P017

Symbol	Symbol Title	Explanatory Text
	Alternating current	Indicates that the equipment is to be powered by alternating current. IEC 60417-5032
	Non-sterile	Indicates a device that has not been subjected to a sterilization process
	Dispose of as Electrical or Electronic Waste	Indicates the product should be separately collected and not disposed of as unsorted municipal waste.
	Caution for Indoor Use Only	For indoor use only
	MR Unsafe (Magnetic Resonance)	Indicates the device would be unsafe in any MR environment
	Do Not Immerse in Any Liquid	Not water resistant

Symbol	Symbol Title	Explanatory Text
	Non-ionizing Electronic Radiation	Non-ionizing electromagnetic radiation
	Not Made with DEHP	Indicates product does not contain PHT / DEHP.
	Not Made with Natural Rubber Latex	Indicates product does not contain natural rubber latex.



3.6.Cybersecurity

The NTrainer System® 2.0 has security measures in place to prevent unauthorized access, modification, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. The NTrainer System® 2.0 is not connected to internet, and relies on the transport of information via a secured USB port.

Access to features pertaining to the management of device and user information should only be granted to system administrators or privileged device users.

Never share device log-in information, leave the device logged-in or trust an unauthorized USB. If you see any suspicious behavior or have any additional questions pertaining to cyber security measures put into place for the NTrainer System® 2.0, contact Innara Health®.

Website: www.innarahealth.com
Phone: (913)742-4456
Address: Innara Health, Inc.
10900 S Clay Blair Blvd.
Olathe, KS 66061



4. Section 4: Unboxing and Installation

4.1. Packaging Breakdown

Quantities in boxes may vary depending on purchase order. All quantities shown here are to represent assembly only.

Box 1 – Pole Cart packaged as-is from the vendor

Box 2 – UPS (Uninterruptible Power Supply) packaged as-is from the vendor

Box 3 – Includes:

- 1 Monitor Enclosure
- 1 AC Mains Cable (for UPS to Monitor Enclosure power)
- 1 UPS Mount for Pole Cart
- 1 Instructions for Use

Packaged Separately:

- Patient Consumables/Receiver Tubes
- Handpiece
- Handpiece Tubing Sets
- NICU/Wee Soothies (pacifiers)

4.2. Assembly Instructions

The NTrainer System® 2.0 is comprised of three primary units; the pole cart, the Uninterruptible Power Supply and the Monitor Enclosure. To assemble the device, follow the assembly instructions in this order:

1. Assemble Pole Cart
2. Assemble UPS Mount
3. Mount the UPS
4. Assemble Monitor Enclosure

Be sure to follow the detailed instructions for each step.

Once you've assembled all the primary units you will then need to connect the AC Mains Cable from the back of the Monitor Enclosure to the UPS, as well as connect the 6ft power cord that runs from the UPS into the power outlet in the wall.

4.2.1. Cart Assembly Instructions

Quantities in boxes may vary depending on purchase order. All quantities shown here are to represent assembly only.

Tools Required:

5/32" [4 mm] Hex Wrench

2.5 mm Hex Wrench

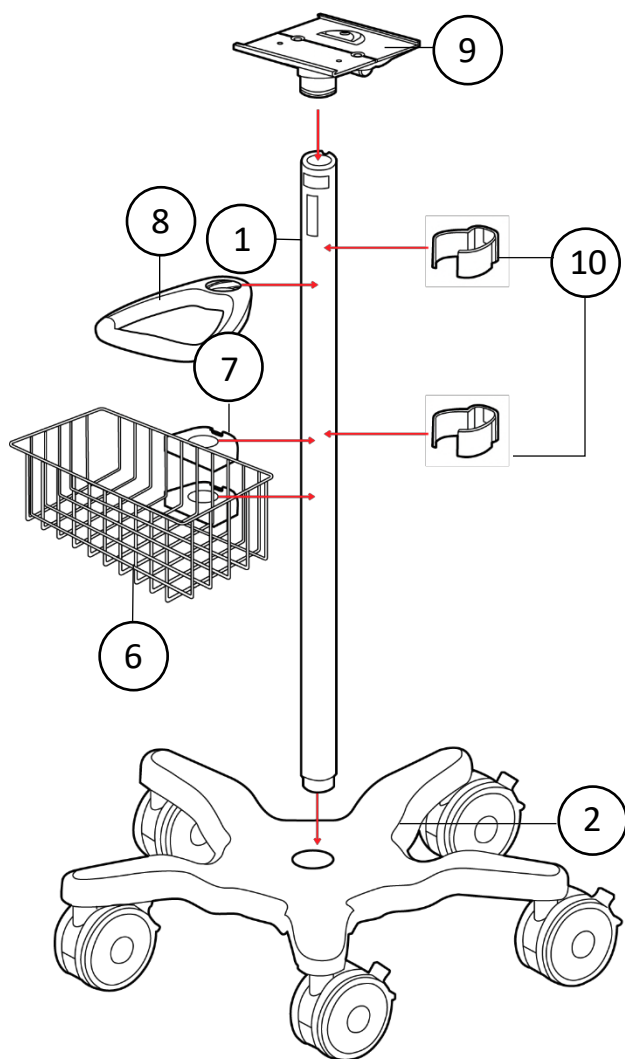
Tools Not Required:

Phillips Screwdriver

1/2" [13mm] Wrench

Manufacturer Part #: GCX: RS-0006-64

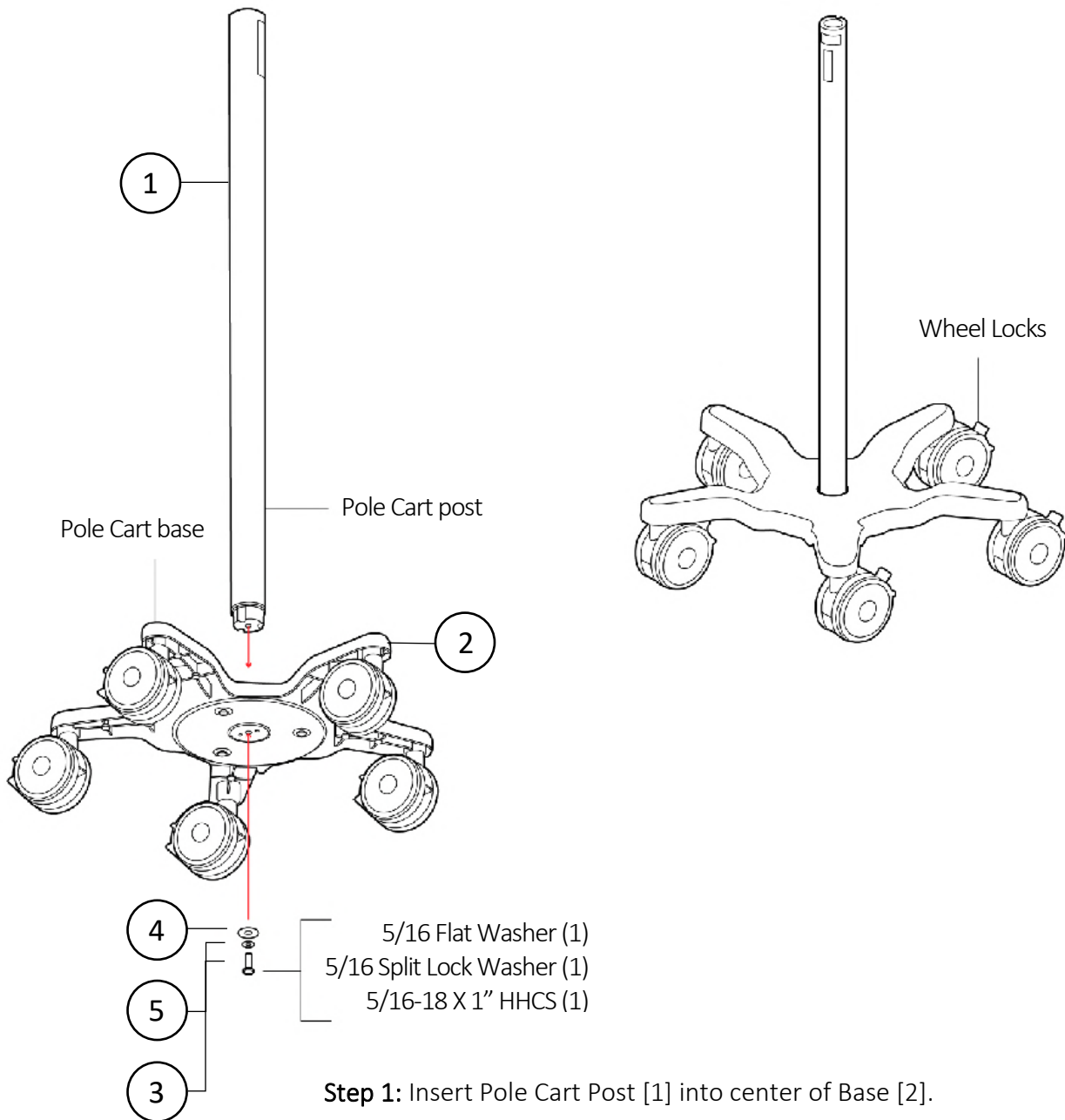
Innara Health Part #: IN-2047



Item #	Description	Qty
1	Pole Cart Post	1
2	Pole Cart Base with 10 lbs/4 kg Counterweight	1
3	5/16-18 x 1" Hex Head Cap Screw (HHCS)	1
4	5/16 Flat Washer	1
5	5/16 Split Lock Washer	1
6	Utility Basket (includes mounting hardware)	1
7	Nylon Clips	2
8	Handle (includes mounting hardware)	1
9	Mounting Plate for Monitor Enclosure	1
10	Cable Clips	2
11	5/32" Hex Wrench	1
12	2.5 mm Hex Wrench	1
13	#8-32 Pan Head Machine Screws (PHMS)	2
14	#8-32 Hex Nuts	2
15	#10-32 x 9/16" PHMS	2

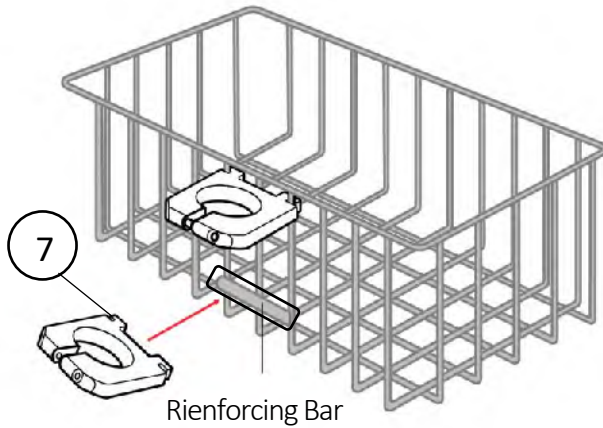
Note: Throughout the instructions, any numbers seen between [] represents item numbers to match the table on this page. Any numbers seen between () represent quantities.

4.2.1.1. Assembling Pole Cart

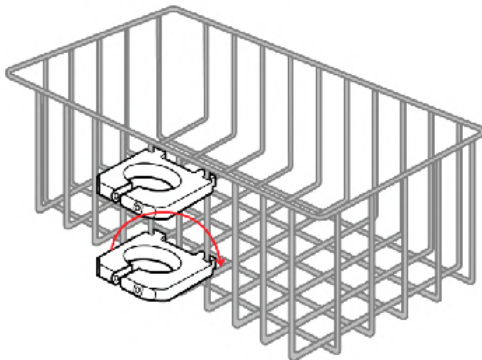


4.2.1.2. Installing Utility Basket on Post

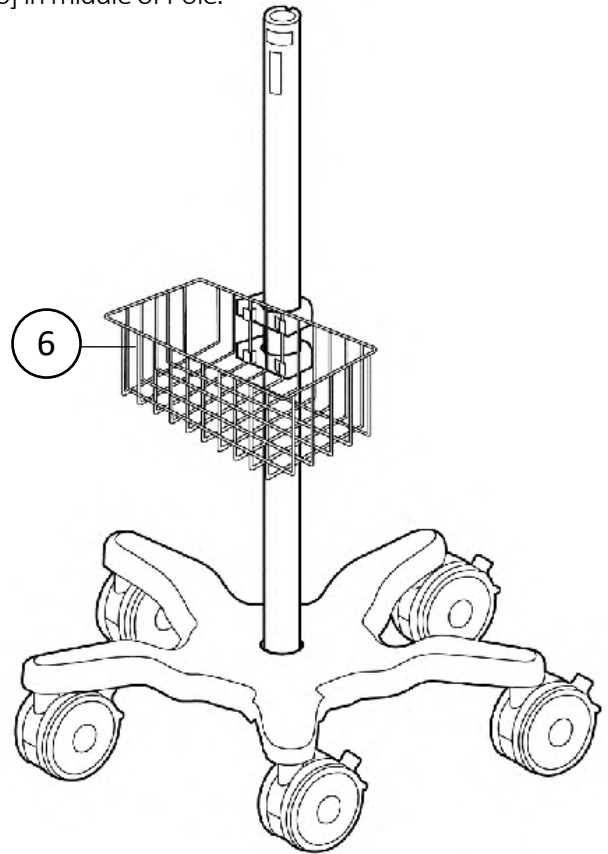
Step 1: Install Nylon Clips [7] at an angle, in center of basket [6] above the Reinforcing Bar.



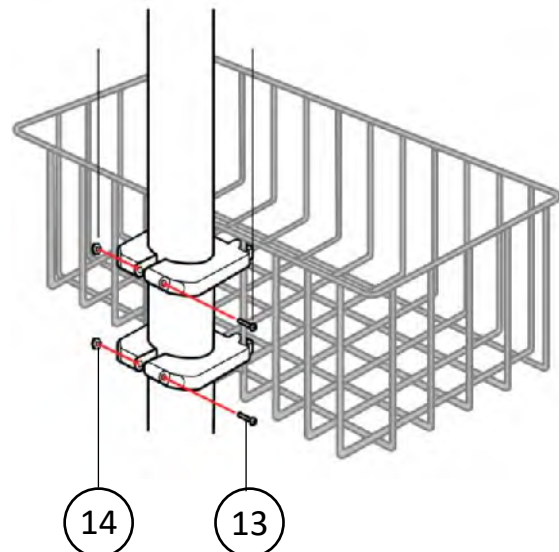
Step 2: Rotate Nylon Clips [7] until both are horizontal. Slide Clips [7] to the top and bottom of Basket [6].



Step 3: Slide end of Post [1] through Nylon Clips [7]. Position Basket [6] in middle of Pole.

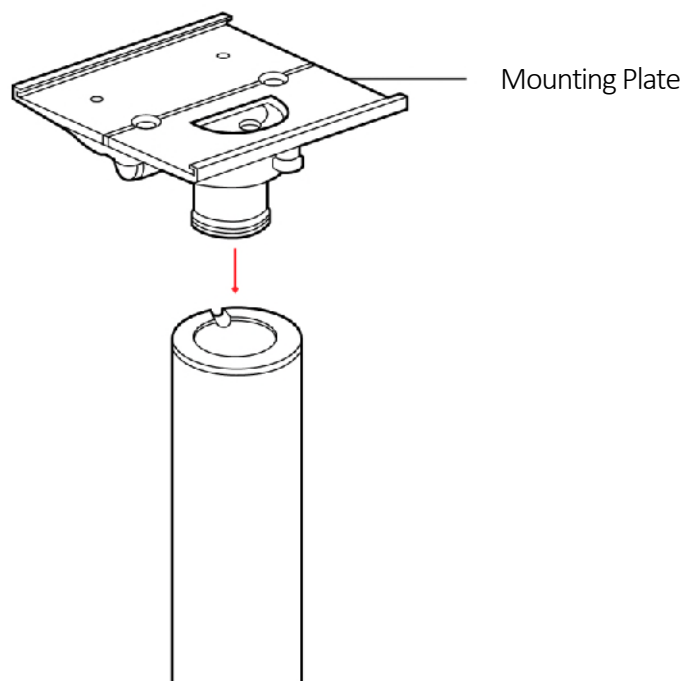


Step 4 : To secure the Basket [6], install two (2) #8-32 pan head machine screws (PHMS) [13] and #8-32 hex nuts [14] as shown, using #2 Philips Head Screwdriver. Tighten screws until Basket [6] does not rotate on Post [1].

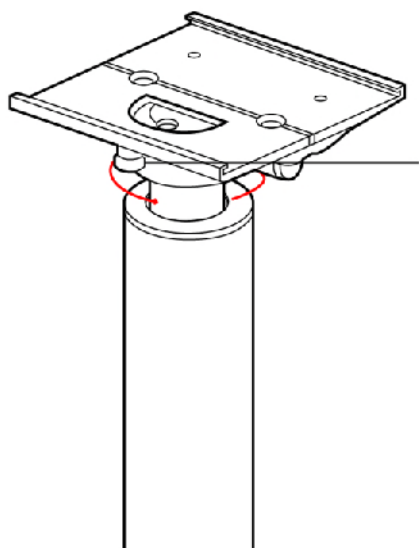


4.2.1.3. Installing Mounting Plate on Pole Cart

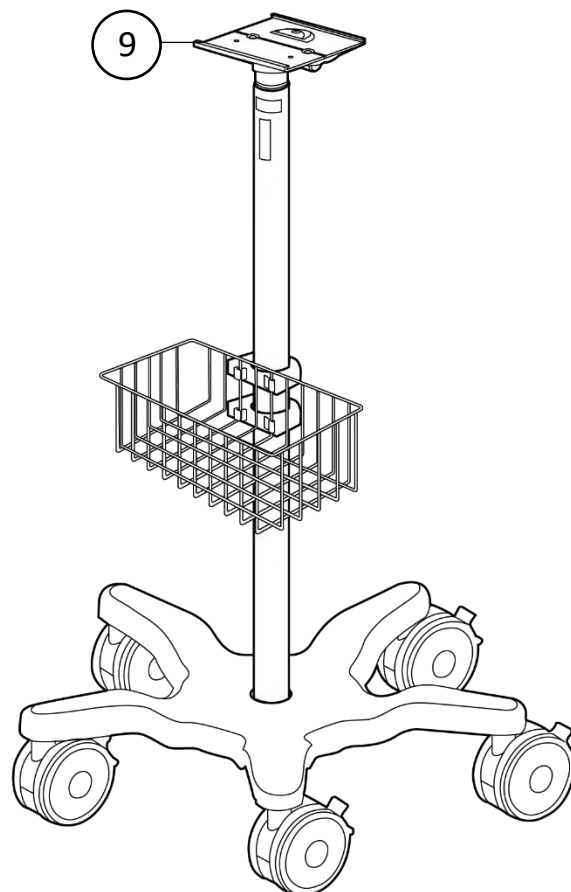
Step 1: Insert Mounting Plate [9] on top of Post [1].



Step 2: Press downward while twisting until the Mounting Plate [9] snaps into place.



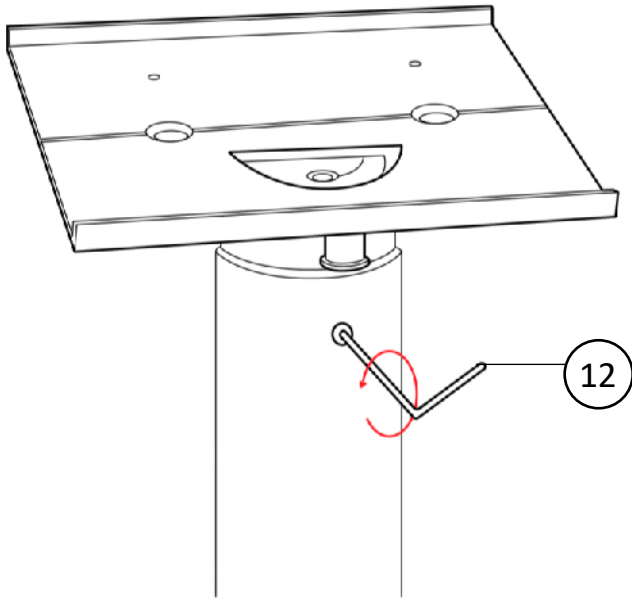
Step 3: Swivel the Mounting Plate [9] until the spring-loaded plunger is toward the back of the Pole Cart [1].



4.2.1.4. Adjusting Swivel and Tilt Angle of Mounting Plate

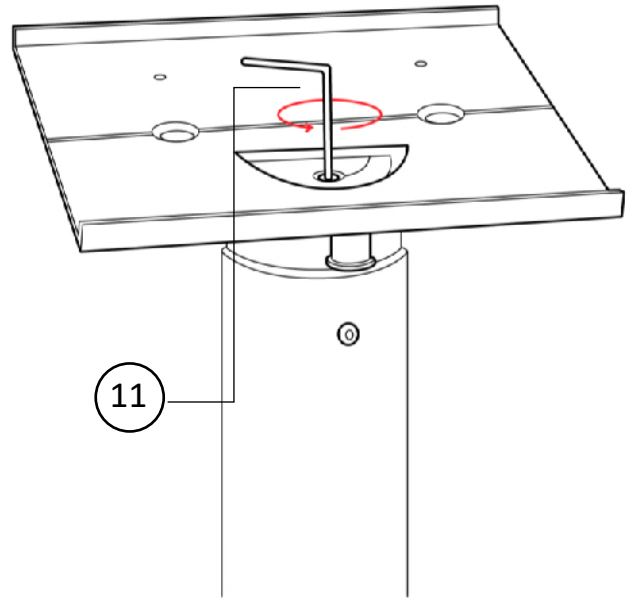
Swivel Tension Adjustment

Adjust **Swivel** tension by tightening or loosening the socket set screw **on the back** of the Pole Cart Post. A 2.5mm hex wrench [12] is provided for this adjustment.



Tilt Tension Adjustment

Adjust **Tilt** tension by tightening or loosening the socket set screw **on the top** of the Pole Cart Post. A 5/32" hex wrench [11] is provided for this adjustment.

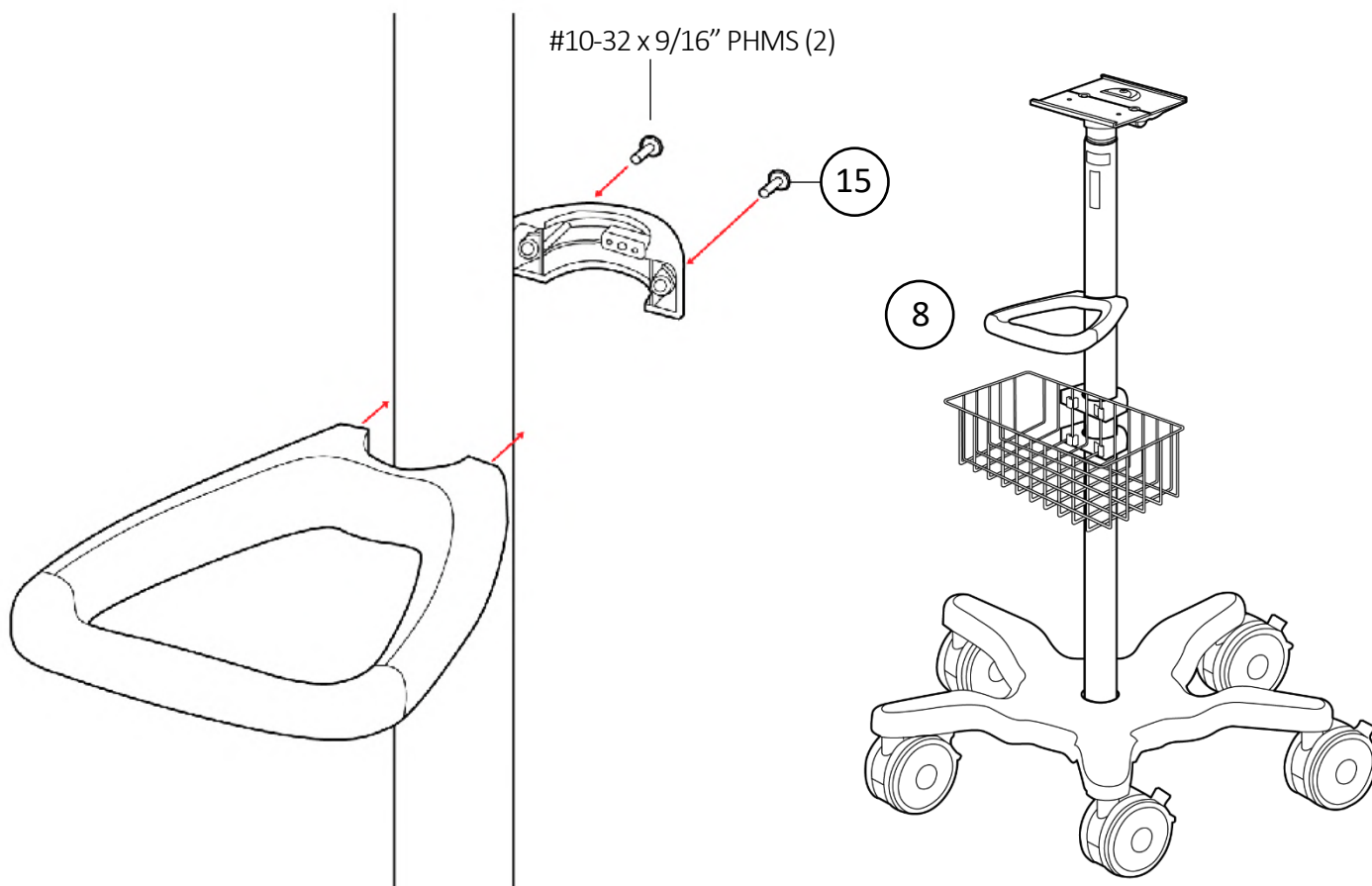


Tip: The Monitor Enclosure will sit on the Mounting Plate so you will want to ensure the Pole Cart and Mounting Plate are stable enough to support its weight.

4.2.1.5. Attaching the Pole Cart Handle

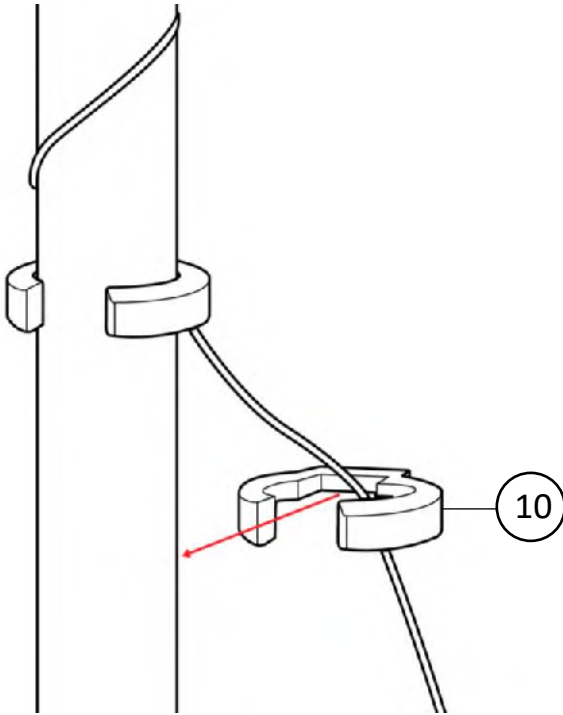
Step 1: Fasten Handle [8] to Pole Cart Post [1] with two (2) #10-32 x 9/16" PHMS [15] as shown.

Step 2: Alternately tighten Handle screws until Handle does not rotate around Post.



Tip: Handle position shown is typical, but Handle may be attached at any desired location on the Post.

4.2.1.6. Attaching Cable Clips



Place loose cables inside Cable Clip [10] and slide the Clip onto Post [1] as shown.



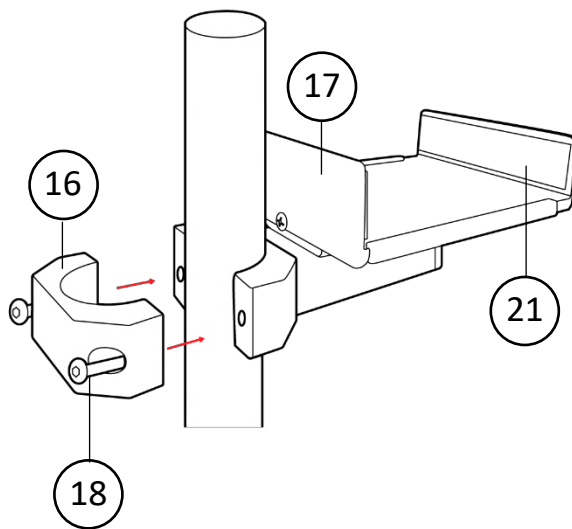
4.2.2. Assembling UPS Mount

Manufacturer Part #: GCX: RS-0024-02C

Innara Health Part #: IN-2048

Tools Required:

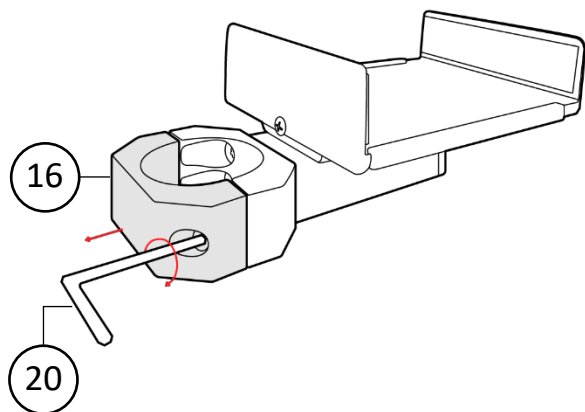
- 3/16" hex wrench



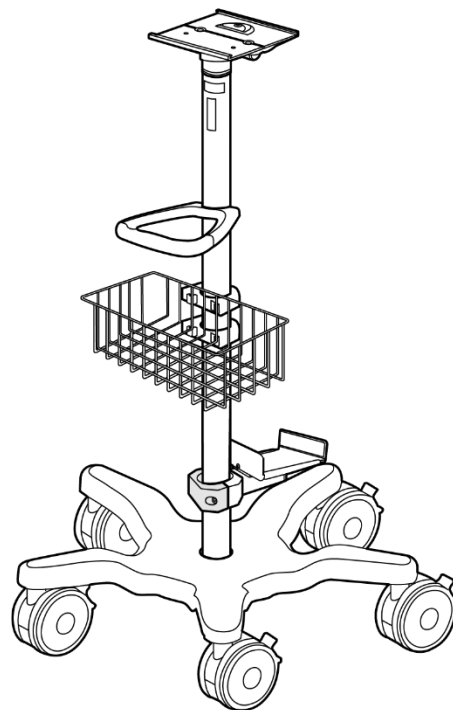
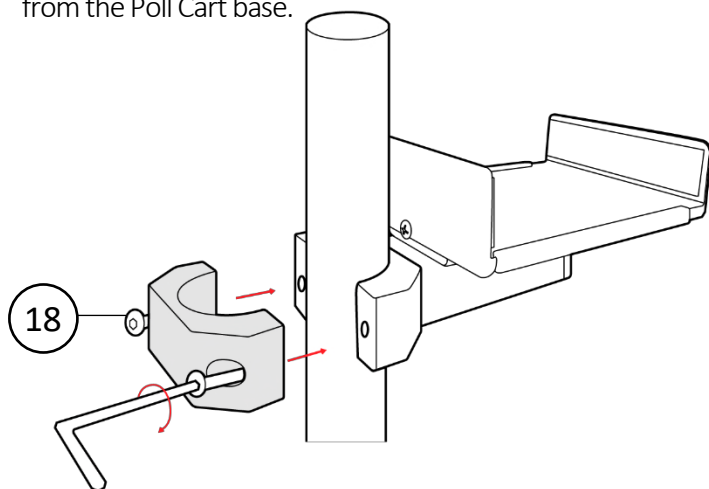
Item #	Description	Qty
16	Detachable Post Arm	1
17	Side Clamp	2
18	¼-20 x 3/4" SHCS	2
19	#10-16 X 2" OHSMS	1
20	3/16" hex wrench	1
21	Velcro Strip Pairs	2

4.2.2.1. Installing UPS Mount

Step 1: Remove Detachable Post Arm [16] from subassembly by unscrewing (2) ¼-20 x 3/4" SHCS [18] using the 3/16" hex wrench [20].



Step 2: Reassemble the Detachable Post Arm [16] around the post of the Pole Cart [1], at a height of no more than 6 inches from the Pole Cart base.

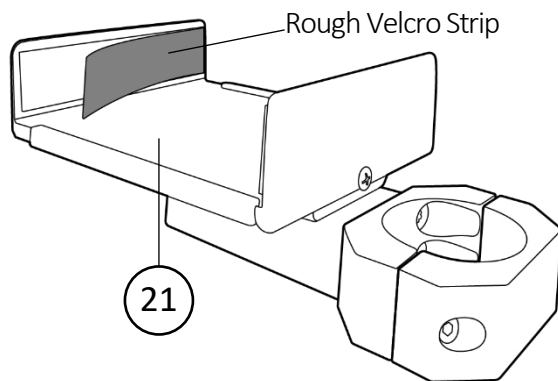


4.2.3. Mounting UPS

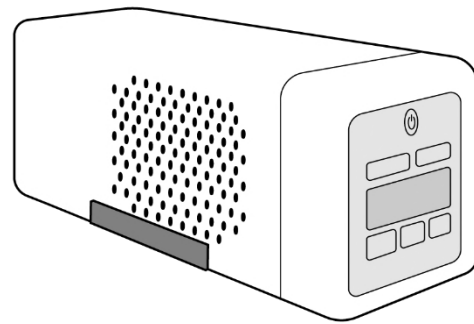
Manufacturer Part #: K01-0000614-04

Innara Health Part #: IN-2048

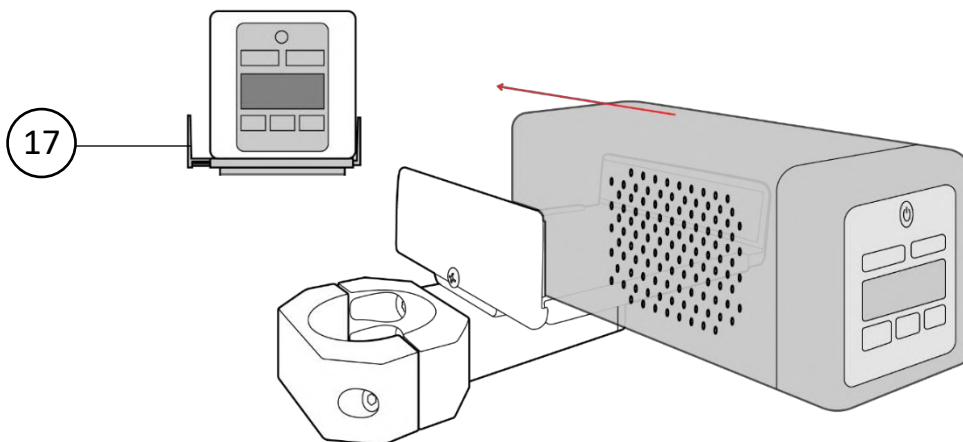
Step 1: Remove one side of the Velcro Strip Pair [21] from UPS Mount. Peel off the lining to expose the adhesive side. The Velcro Strip Pairs will help secure the UPS into the Mount.



Step 2: Attach it to the center-bottom rim of the UPS so that it lines up with the Velcro Strip on the Mount.

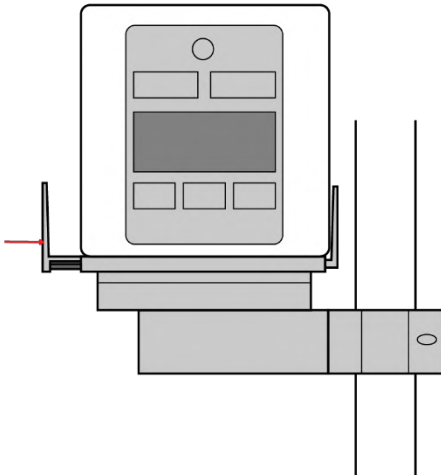


Step 3: With side clamp [17] fully extended, slide UPS onto mount lining up velcro strips.

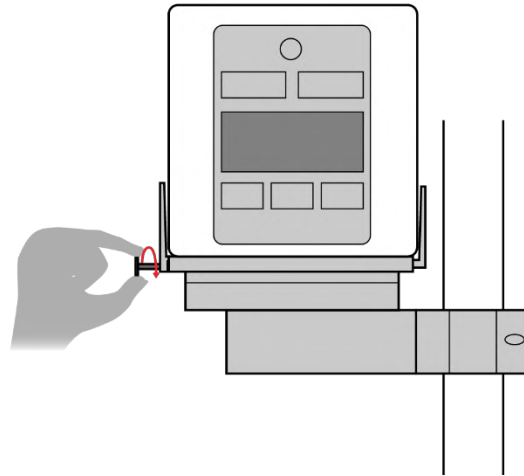


CAUTION: UPS weighs 13.65 kg (30 pounds). Seek assistance as necessary.

Step 4: Slide Side Clamp towards post until it securely hugs UPS.



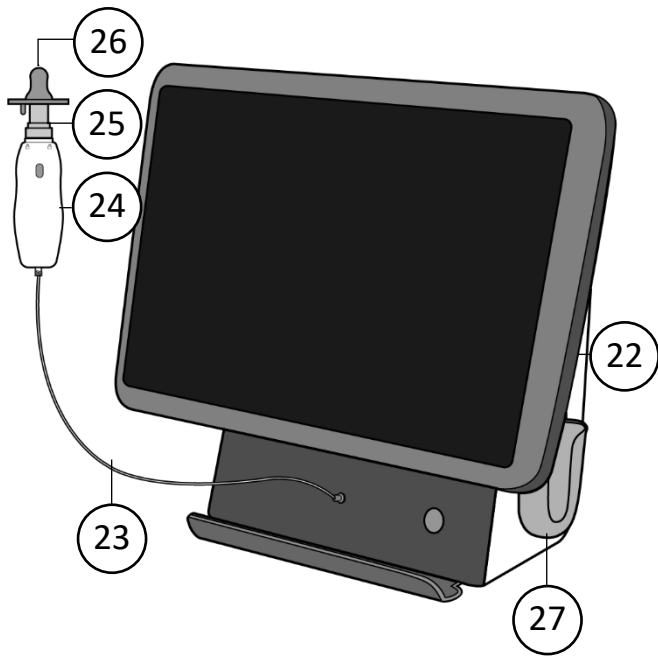
Step 5: Twist #10-16 X 2" OHSMS with hand into track. **NOTE:** Adjustment Screws must always be engaged at least 1/2" in the track at all times.



For more information on the UPS use and operation go to www.cyberpower.com or follow the QR code



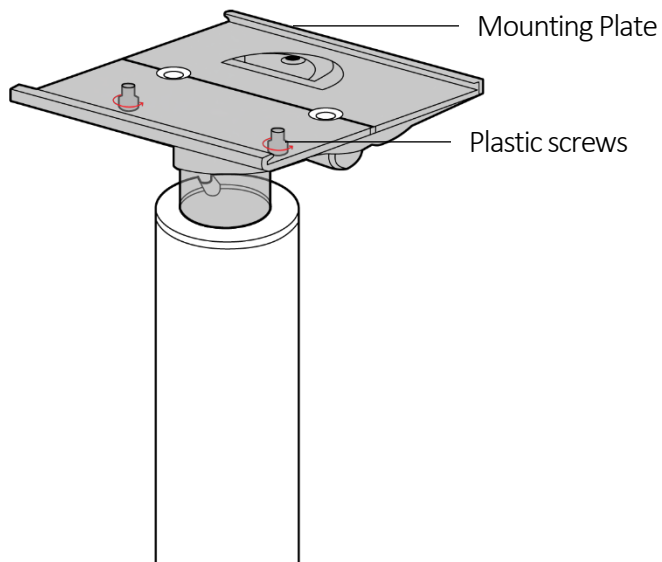
4.2.4. Assembling Monitor Enclosure



Item #	Description	Qty
22	Monitor Enclosure	1
23	Handpiece Tubing	1
24	Handpiece	1
25	Patient Consumable/ Receiver Tube	1
26	Phillips Soothie Pacifier	1
27	Handpiece Holders	2
28	AC Mains Cable for UPS to Monitor power (boxed with UPS)	1

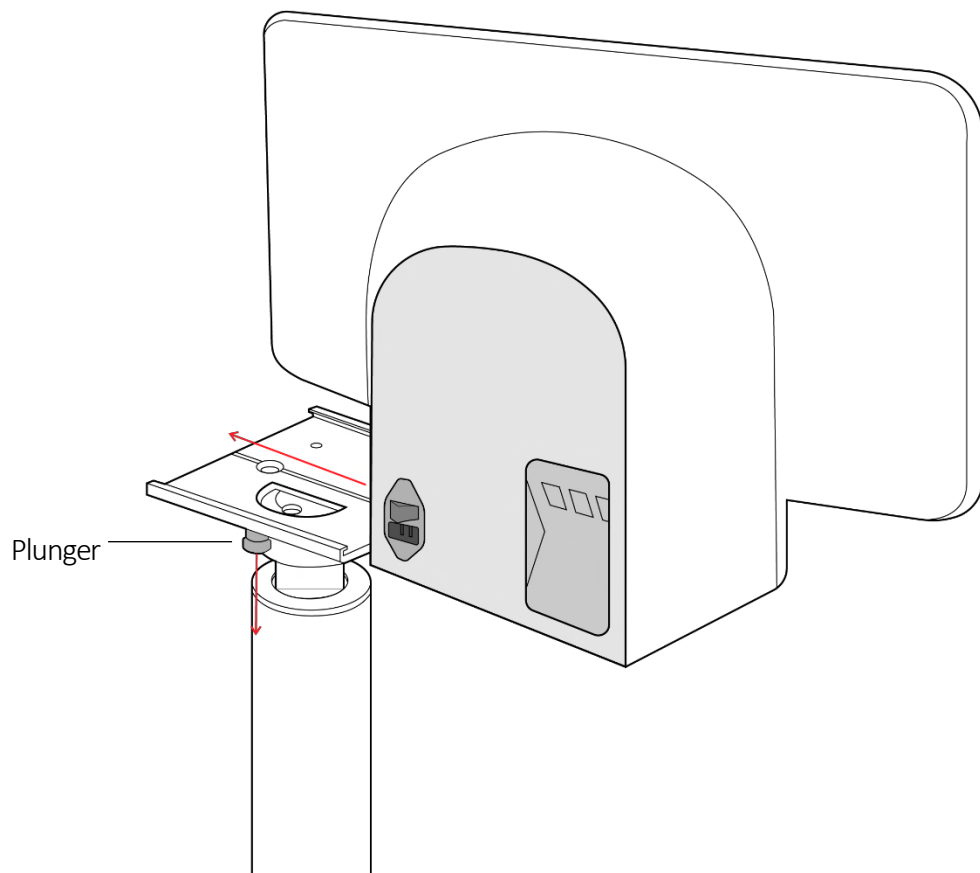
4.2.4.1. Mounting Monitor Enclosure

Step 1: Ensure plastic screws on the front of the Mounting Plate are loosened.



Step 2: Pull plunger down as you slide the Monitor Enclosure onto the Mounting Plate.

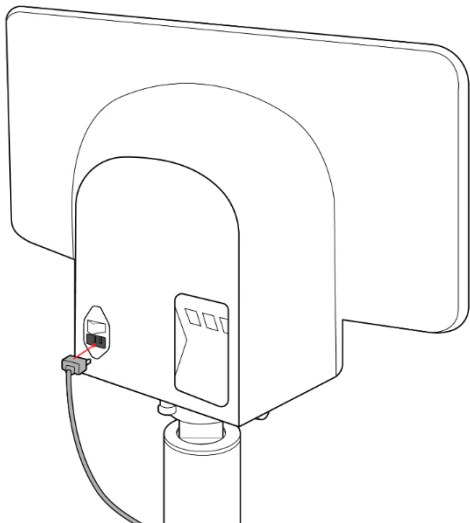
WARNING: Dropping the Monitor Enclosure during assembly or servicing may cause bodily harm.



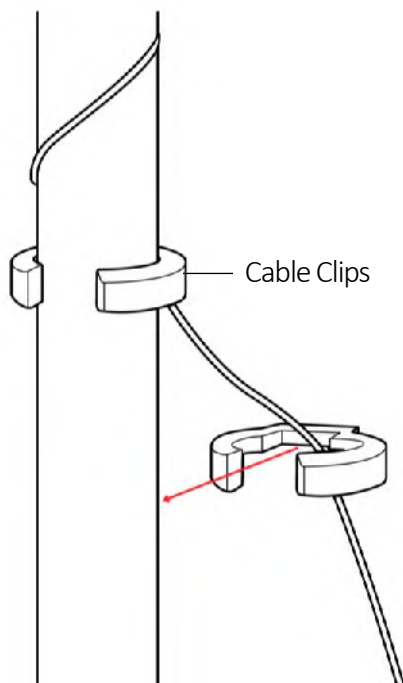


4.2.4.2. Connecting the System

Step 1: Plug one end of the AC Mains Cable [28] to the back of the Monitor Enclosure [22].

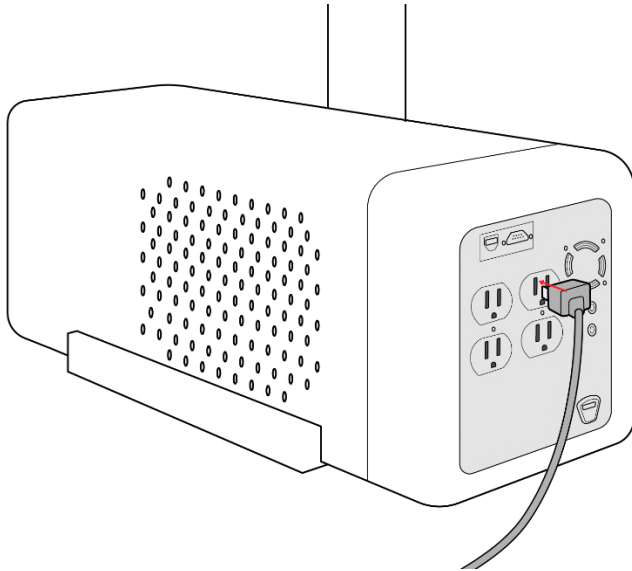


Step 2: Wrap AC Mains Cable [28] down the Pole Cart Post [1], using the Cable Clips [10] to secure in place.



Step 3: Plug other end of the AC Mains Cable [28] into the UPS System. Ensure the 6-foot Power Cord is plugged into the wall prior to use.

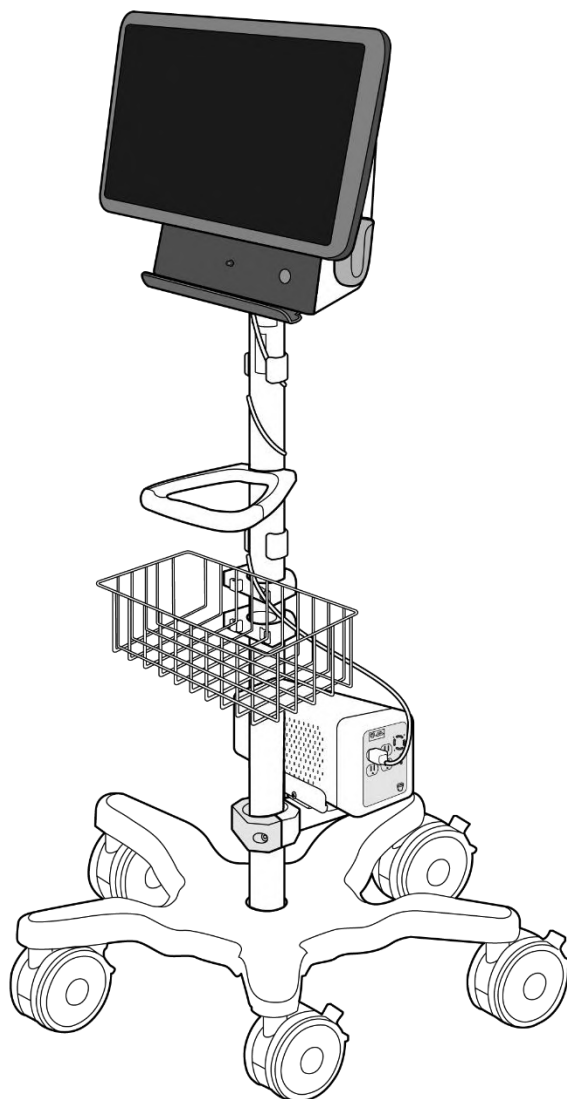
CAUTION: Inspect the 6-foot Power Cord for damage or wear prior to use.





4.3.Assembled Unit

WARNING: Inspect the system for damage prior to use.



Innara Health, Inc.
10900 S Clay Blair Blvd.
Olathe, KS 66061, USA
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IN-P000 Rev 3

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