



Synchrony

Equipment User Manual

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Synchrony

ACP manufactures a premier line of rehabilitation technologies to assist health care professionals with improved outcomes and quality-of-life for patients. The ACP product line includes Pain Control Systems, Muscle Stimulators, Interferential Therapy, Therapeutic Ultrasound, Pulsed Shortwave Diathermy devices, and advanced Therapeutic Exercise Systems. Our **OMNICYCLE®**, **OMNISTAND®**, **OMNISWD®**, **OMNIVR®**, **OMNIVERSA®**, **SYNCHRONY** and **OMNIeEMG™** products represent the most recent worldwide advances available for therapeutic application of electro medical devices and other rehabilitation technology.

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INDICATIONS & CONTRAINDICATIONS

Indications for Use

Synchrony consists of a Dysphagia Cart, Omnistim® FX2 Portable PENS, and an OMNI sEMG™ surface electromyography (sEMG) biofeedback system. These devices are used in adjunct to oral motor and swallowing exercise and treatment. sEMG biofeedback has been found to assist clinicians and patients with the following:

- Facilitate relaxation of tense or hypertonic muscles
- Discriminate among different types of muscle activity
- Differentiate effects of posture or other variables on muscle activity
- Learn new behaviors
- Learn unfamiliar behaviors
- Learn behaviors difficult to conceptualize or identify under normal circumstances

Contraindications

Treatment should be paused or terminated should the clinician observe any of the following patient behaviors:

- Chest pain
- Severe shortness of breath
- Significant blood pressure changes
- BP > 200/110
- Lightheadedness; BP drops > 20mmHg
- Severe headache
- Sudden onset of numbness or weakness
- Onset of confusion
- Ataxia
- Pallor
- Cyanosis
- Cold and clammy skin
- Noticeable changes in heart rhythm
- Patient requests the exercise/activity be stopped

WARNINGS & PRECAUTIONS

Warnings

- Use the product according to its indications.
- Avoid connecting the sensors to the charger with inverted polarity, as this may damage the sensors. The correct polarity is shown on the charger station.
- Do not immerse components in water.
- Only apply the electrodes on undamaged skin according to electrode labeling.
- Use appropriate hypoallergenic double-sided tape, compatible with the usage on undamaged skin for brief periods of time to hold wires or skin jowling in place during treatment.
- Periodically test the integrity of the device and of its components.
- Should elements of the device, such as the transducers be dropped, or appear to be damaged in any way, retest them immediately for proper function. If they are non-functioning, do not attempt any kind of internal maintenance of the device. Always seek authorized technical support.
- In addition to the users' instructions, the prescriptions regarding accident prevention and technical regulations regarding occupational safety must also be complied with. The appertaining national regulations and standards of the country of use, with regards to prevention of accidents and environment, are an extension of the users' instructions.
- The device uses a lithium ion battery. Battery replacement and disposal should only be performed by the ACP Service Center or an authorized repair facility.
- If the power cable for your Synchrony equipment appears damaged or frayed, please don't use it and contact our Customer Support department for a replacement.

Precautions

Synchrony is a professional rehabilitation tool intended for patients of all ages who have been diagnosed with dysphagia or are experiencing difficulty in the oral or pharyngeal phase of swallowing. Synchrony requires the skills, knowledge and judgment of a qualified practitioner licensed in the state of practice, such as a Speech and Language Pathologist. Their guidance and supervision is required for the safe and efficacious use of Synchrony with patients.

Synchrony cannot monitor nor guarantee patient safety. The practitioner should judge whether a particular individual is able to perform a specific exercise or activity, and monitor the patient's performance and safety throughout the treatment session.

Additional specific "Precautions" are noted below:

- Do not apply any electrode gel or equivalent directly on the sensor snap terminals.
- Always use ACP electrodes as a medium between the sensor and the skin surface.
- Make sure to remove electrodes from sensor lead wires immediately after use.
- Do not connect third party sensors directly into instrument inputs.
- Use only ACP sensors, cables and electrodes.
- Use appropriate infection control and cleaning.

SYNCHRONY and OMNIsEMG™ Introduction

Synchrony incorporates a virtual reality augmented biofeedback rehabilitation unit called the OMNIsEMG™ (sEMG) which has been specifically designed to accommodate patients with difficulty swallowing as a result of oral or pharyngeal muscle dysfunction. Synchrony provides swallowing data and interactive exercise activities are displayed on a color monitor using specialized computer software. Research supports the use of virtual reality augmented sEMG biofeedback in conjunction with traditional Speech and Language Pathologist (SLP) therapy techniques. Specifically, patients appear to benefit from what is referred to as the “virtuous cycle”, where patients perform more exercise repetitions when they are motivated by the positive feedback provided in an interactive “virtual reality” based environment.

Delivery of Synchrony and OMNIsEMG™

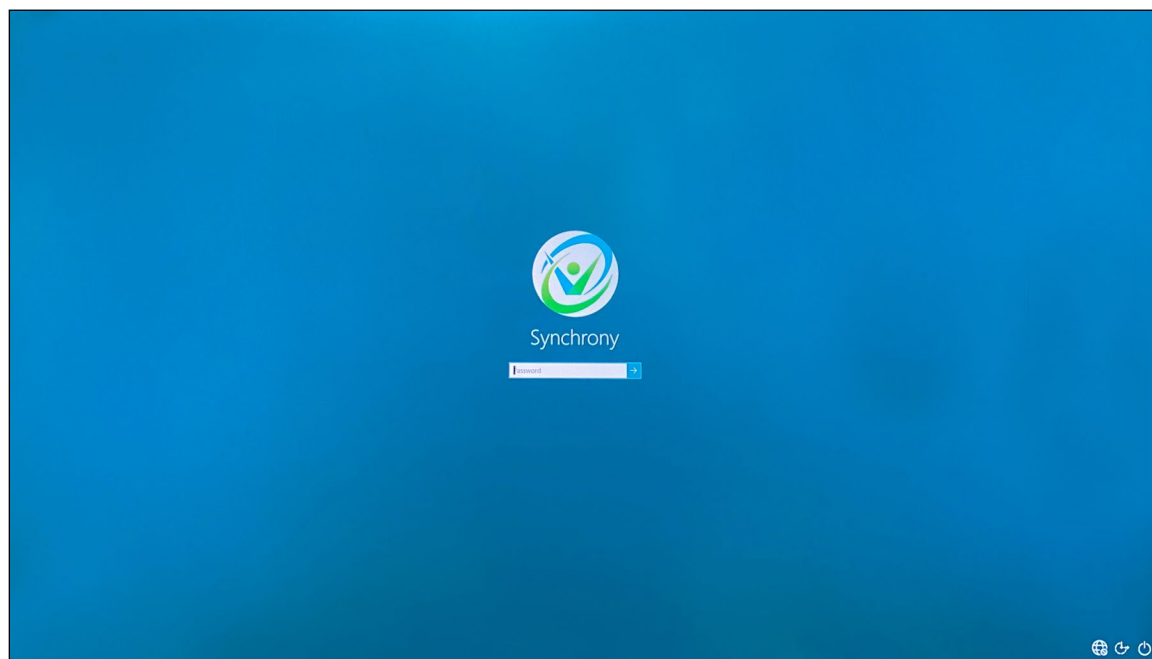
Upon receipt of Synchrony, inspect the shipping container and contents for any obvious or concealed damage. All ACP products are packaged carefully for rapid, safe delivery. We guarantee delivery in perfect condition to the postal or delivery services. However, any damage or loss incurred during transportation or delivery is the postal or Delivery Company’s responsibility. If damage or loss to the product and/or container is obvious or suspected, appropriate notation must be made on the signed freight bill at the time of delivery. All damage claims should be promptly filed with the delivering carrier and must be initiated by the addressee where the package was to be delivered. Retain the original shipping container and inserts for validation of damage claim or use at a later date. Please contact your ACP Clinical Program Consultant or call ACP Customer Service at 800-350-1100 to report any damage.

NOTE: *The purpose of this manual is to acquaint medical and therapy professionals with Synchrony. Please read the manual carefully before attempting to operate Synchrony. If questions remain unanswered, contact your ACP Clinical Program Consultant or call ACP Customer Service at 800-350-1100. Outside the USA, call 1-775-685-4000.*

OPERATION OF SYNCHRONY

To Turn ON Synchrony

1. The Synchrony cart should be plugged in when not in use to allow the OMNIsEMG™ sensors to remain charged. Ensure the charging station is turned on and the sensors are plugged in properly and charging. Fully charged sensors should be available at the start of the day. Replace the sensors on the charger cradle after each use so they remain fully charged.
2. Turn on the computer by pressing the green (GO) button on the front of the computer module located in the top tray storage compartment.
3. Turn on the monitor (as needed).
4. Enter password. Your SLP rep or Customer Support will supply you the password.
5. The Main Menu screen will appear automatically after a series of start-up screens load.



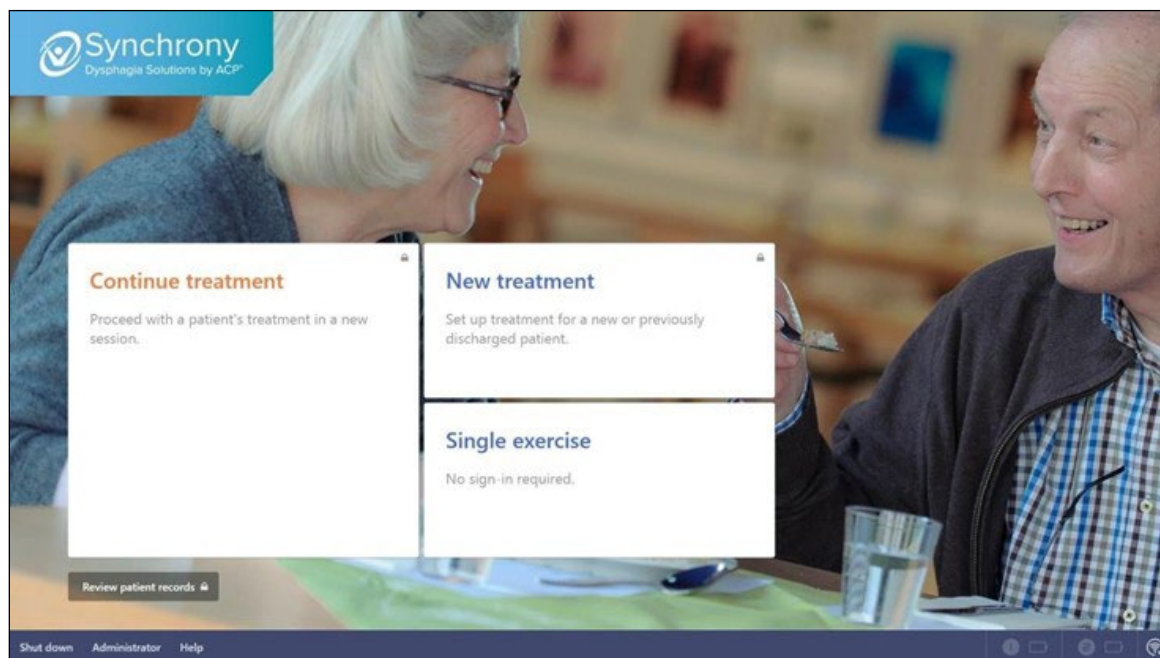
To Turn OFF Synchrony

1. Click the 'Shut down' command button located in the lower left corner of the Main Menu screen.
2. A message appears asking for confirmation. Click OK to confirm the intent to turn off the computer.
3. Remove the power strip plug from the wall outlet if the cart is being transported. Otherwise, leave the cart plugged in, to charge the OMNIsEMG™ sensors.

NOTE: Do not remove power cord from the wall outlet before Synchrony is powered "OFF" using the procedure above. Synchrony may remain "on" for extended periods, including overnight, without harming it or reducing the unit's longevity.

Main Menu – Software version v4.0

The Synchrony home screen is created in simple workflow modules explained below.



Continue treatment – selecting the intended patient to continue treatment. – continue an existing patient's treatment. Clinicians may be prompted to sign-in prior to selecting the intended patient to continue treatment.

New treatment – create a new patient for treatment with Synchrony. Clinician may be prompted to sign-in prior to creating new patient treatment.

Single exercise – allows the user to perform an exercise and decide to save the data to a patient record during or at the completion of the exercise session.


Review patient records – access to the Synchrony database of patients. Clinician will be promoted to sign-in prior to accessing the database.

System tray items

Shut down – select to power down the Synchrony system

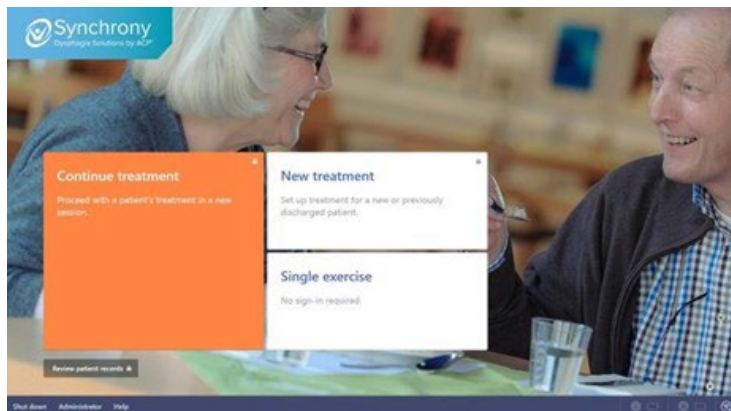
Administrator – provides access to the Synchrony Administrator

Help – provides access to informational items pertaining to the use and operation of Synchrony

Sensor 1 and 2 connections –  when a sEMG sensor is connected its battery icon will display with its current level of charge, as in sensor 1 example. If not connected, as in the example of sensor 2, the sensor will appear faded out.

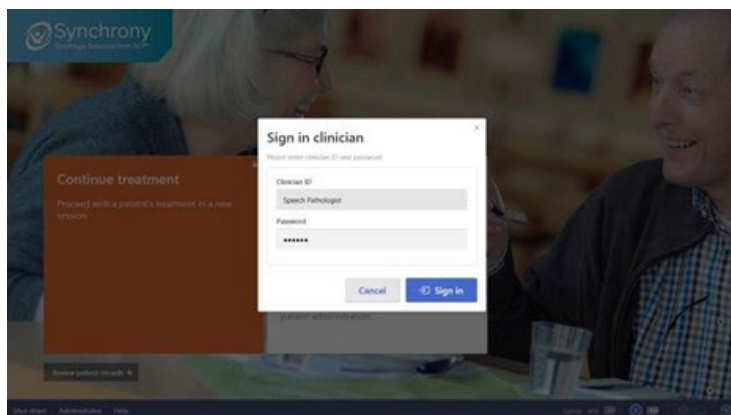
Improve connectivity –  optimizes the Wi-Fi connection of the sEMG sensor to the computer.

Continue treatment



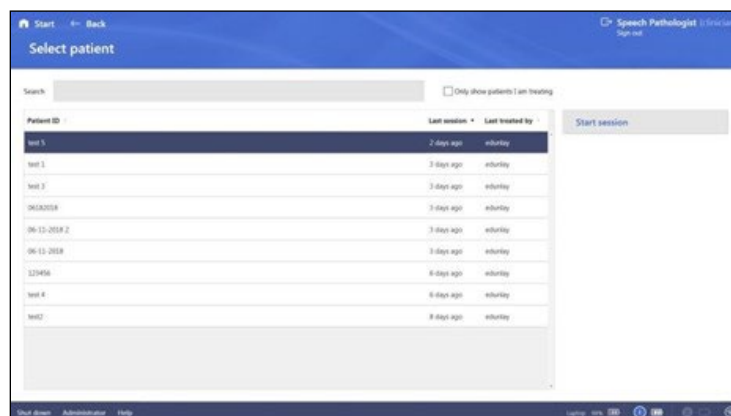
Hover the mouse over the Continue treatment section and click to continue

If not signed in, the therapist will be prompted to enter their **Clinician ID** and **Password**



Enter assigned **Clinician ID** and **Password**. When signed in, the current database of patients is presented

Note – clinician ID and Password are case sensitive

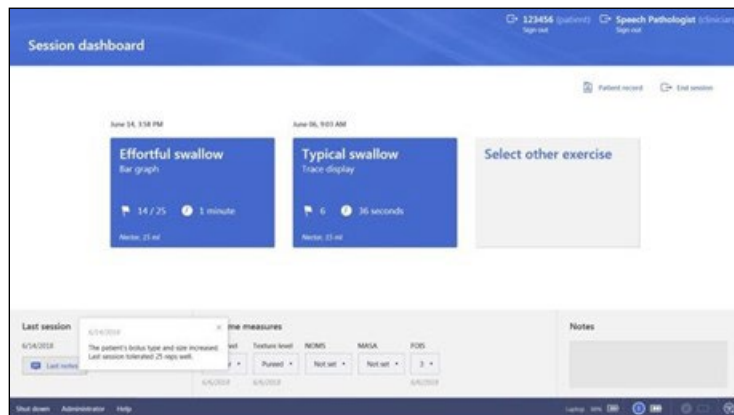


Select patient – select the patient to continue treatment and either double click their **Patient ID** or click **Start session** to continue

Note – the **Clinician ID** who is signed in will be displayed in the top right of the screen

Session dashboard

When selecting an existing patient to continue treatment, the selected patient's Session dashboard is displayed. The Session dashboard is an at a glance display of recent patient activity. The dashboard will always display the Patient ID in the upper right of the screen and the two most recent exercises performed in the middle of the screen. Other items accessible from the Session dashboard include; Patient record, date and notes from the last session, outcome measures directly linked to the patient record, and a new "Session Notes" field.



Session dashboard

Select existing exercise – to continue a previous exercise type, click on the specific exercise

From the System admin start screen, select **Select other exercise** – provides access to the the library of therapeu

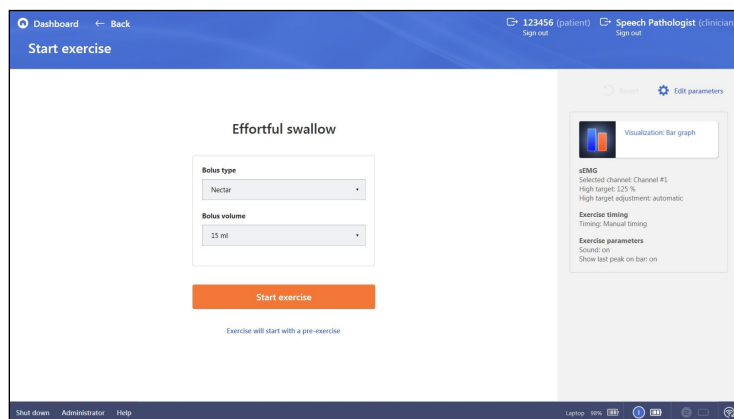
Manage patient's option tic exercises, assessment and "Set-up Assistant" Left click the patient account to be edited and then left

Last session – click the the date and recorded notes

Manage patient's button from the last session are displayed in the lower left of the screen

Continuing a previous exercise

After selecting an exercise to continue, the specific exercise's visualization, exercise parameters as well as the last bolus type and volume used will be displayed. All of these can be edited and changed.



Start exercise

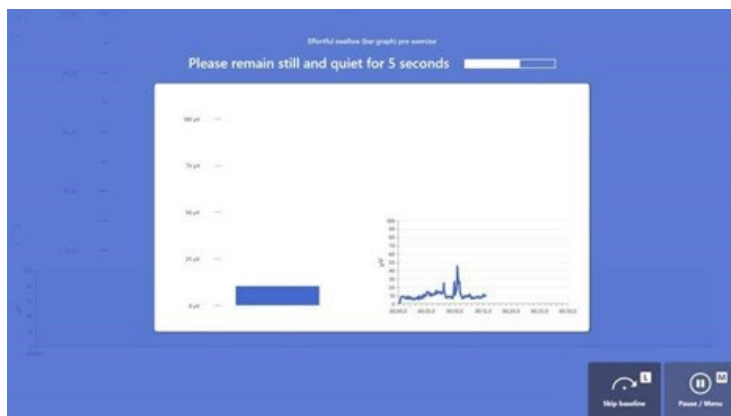
Bolus type and volume – the bolus type and volume used in the last session are displayed. To change, click on the dropdown arrow in either box.

Visualizations and parameters – the values for both are displayed on the right side of the screen. To edit, click on the Visualization box or Edit parameters icon.

Start exercise – clicking this advances to the live exercise screen

Pre-exercise process – Resting baseline

All initial exercises will start with a pre-exercise session unless the clinician indicates differently. The software prompts the patient to remain still and quiet for 5 seconds to obtain the “resting baseline.” To capture the resting baseline manually, select “Mark manually”. To skip the resting baseline, select “Skip baseline”



Automatic – requests patient to remain still and quiet for 5 seconds

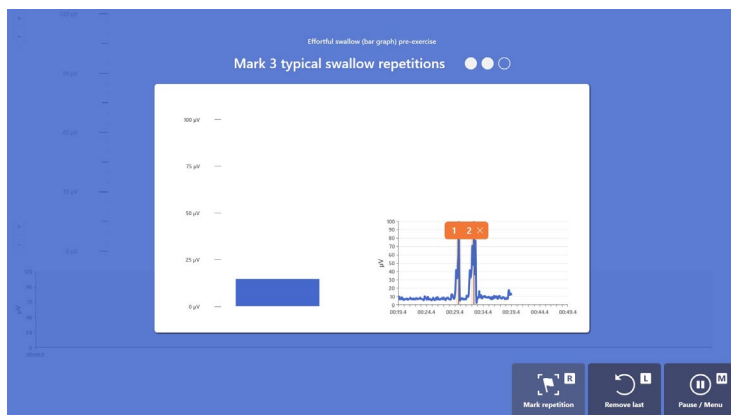
Mark manually – the therapist controls the start and stop time of the resting baseline

Skip baseline – the resting baseline will default to 10mV

Note – when footplate is attached the footplate command L-M-R are displayed on the command boxes.

Pre-exercise process – Mark 3 repetitions

The “Mark Repetitions” step will calibrate the exercise specific to the patient’s needs. Capturing three (3) typical swallows prior to beginning of the effortful swallow exercise customizes the exercise target level for the specific patient.



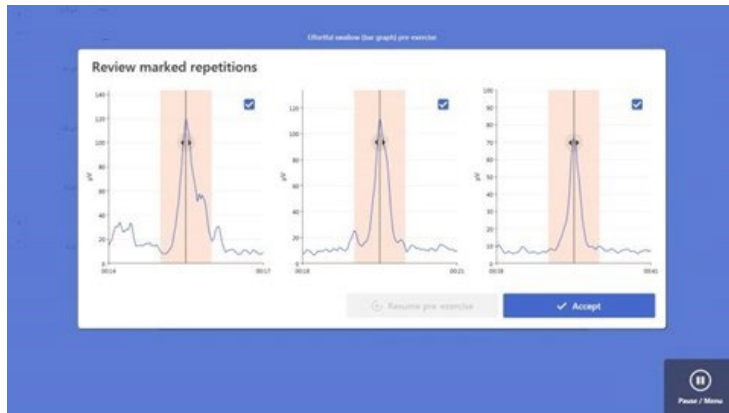
Mark repetition – use the footplate or mouse to mark 3 typical swallow repetitions.

Remove last – allows the therapist to remove the last captured/marked repetition

Pause/menu – pauses the pre-exercise process

Pre-exercise process – Review marked repetitions

After marking 3 typical swallow repetitions a review dashboard is provided. Each repetition can be edited or deleted. If a marked repetition is deleted, the opportunity to resume the pre-exercise is provided.



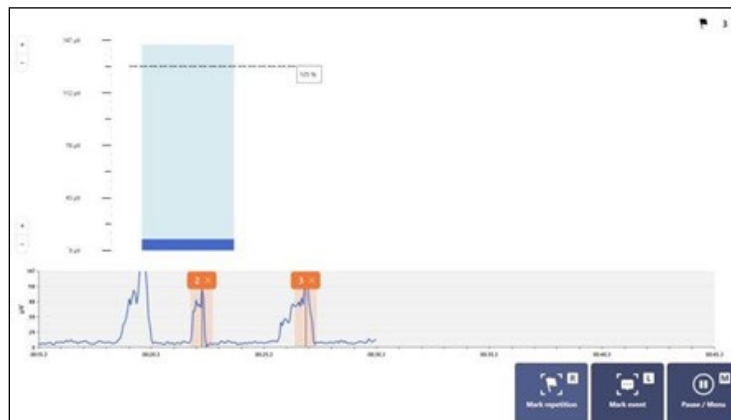
Editing a marked repetition - to edit a marked repetition, click on the repetition and reposition the repetition marker

Deleting a marked repetition – uncheck the blue box to delete a repetition

Pause/menu - pauses the pre-exercise process

Exercise display screen

The exercise display provides a way to observe the sEMG trace display along with the featured patient visualization. The exercise command boxes, Mark repetition, Mark event and Pause will always be located in the lower right of the screen for all exercises. When the footplate is connected, footplate commands (M, R and L) appear to aid in navigation.



Effortful swallow exercise screen

Progressive target – a 125% target is the starting goal and is progressive. The target will progressively increase or decrease based on the patient's performance during the exercise

Progressive increase of target – if during three consecutive swallows the patient reaches or exceeds the target, the target will reset higher by 10%

Progressive decrease of target – if during three consecutive swallows the patient does not reach the target, the target will reset lower by 10%

Pausing an exercise

All exercises can be paused and a menu of options — End exercise, Resume and Edit — is provided,



End exercise – exercise stops and advances to the “Exercise summary” page

Edit parameters – provides a way to save the current exercise and edit the desired parameters prior to re-starting

Resume – resumes exercise from the time the pause started.

Note: all pauses will be marked in the Graph display of the results

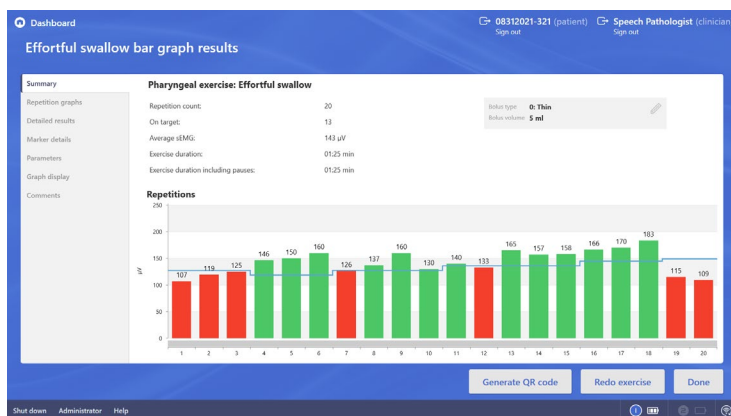
Editing parameters

All exercise parameters can be edited. When “Edit parameters” is selected a dialogue box offers the opportunity to “Save before editing”. This is recommended. When “Save” is selected, the screen advances to the exercise parameter screen to edit the selected exercise. After new parameters are set, advance to the exercise start screen which now incorporates the newly established parameters.



Exercise summary report

Upon completion of an exercise the exercise summary dashboard is displayed, providing multiple views of the completed exercise in a tabbed format. The default display is the Summary report providing an at-a-glance view of each repetition.



Summary – an overview of each repetition.

The bar-graphs in green represent activity that met or exceeded the exercise target values, those in red did not.

Multiple tabs – multiple ways to observe the exercise data are provided for editing and documenting purposes

Redo exercise – a direct pathway to the start page of the same exercise.

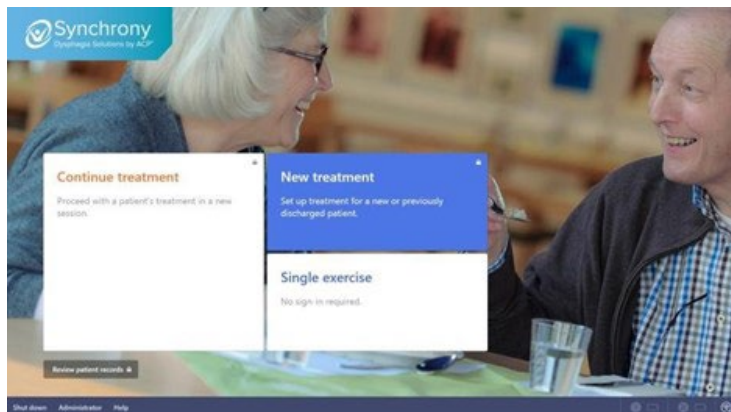
Done – returns to the patient's dashboard

Generate QR Code – At the end of a treatment session, a QR-code with embedded device information, protocol parameters and outcome results will appear. The QR-code can be scanned so this information can be added to the patient's Electronic Medical Record using the ACPlus application.



New treatment

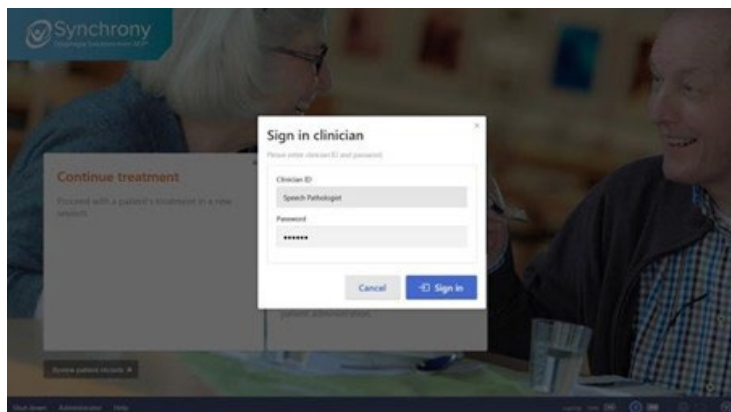
“New treatment” allows the addition of a new patient into the Synchrony database. When selected, the therapist will be prompted to sign-in if not already signed in. The process to add a new patient is simplified to only request the minimum information to establish a record for each patient. The Patient record can be accessed throughout the session or later to update all fields.



Hover the mouse (or use the touch screen) over the **New treatment** section and click

If not signed in a prompt will appear requiring **Clinician ID** and **Password**

Sign in clinician

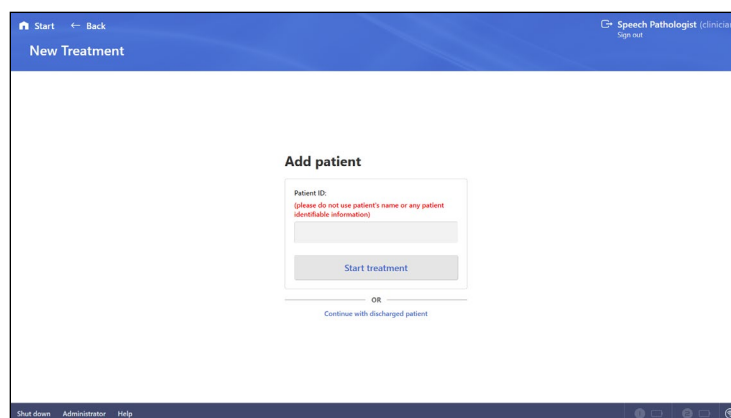


Enter assigned **Clinician ID** and **Password**. When signed in, the current database of patients is provided.

Note - clinician ID and Password are case sensitive

Add patient

Add patient requests the minimum amount of data to initiate a patient record. If the new patient is a patient previously discharged from Synchrony, click the blue text below the Start treatment area “Continue with discharged patients”. A list of discharged patients is provided to add onto caseload.



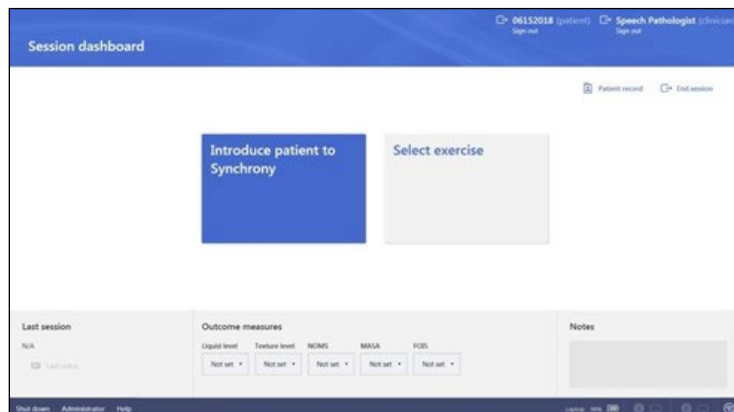
Patient ID – please use a unique and HIPPA compliant patient identification. Do not use any patient identifiable information.

Start treatment – advance to the patient dashboard.

Continue with discharged patient – presents a list of previously discharged patients to add back onto caseload.

Session dashboard

The new treatment session dashboard will always display the Patient ID in the upper right of the screen alongside the signed in treating clinician. The two main options, ‘Introduce patient to Synchrony’ and ‘Select exercise’ are discussed below. The Session dashboard also provides access to other tools including access to the Patient record, Outcome measures and a notes field.



Introduce patient to Synchrony – a free-form area intended to allow the therapist to introduce sEMG to the patient

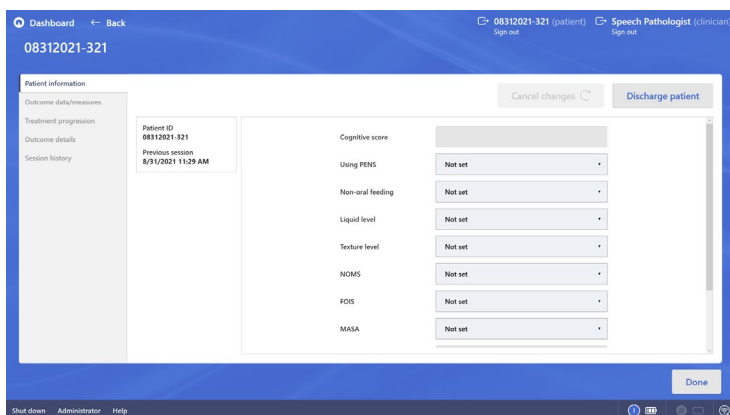
Select exercise – access to the library of pharyngeal and oral therapeutic exercises, Assessment and the Set-up Assistant feature

Outcome measures – a file directly linked to the patient record to allow the patient record to be kept current

Note - to access any of the dashboard functions, hover over the desired area and click to continue

Patient record

The Patient record provides several fields to track the patient’s progress and outcomes. It is suggested all the relevant information is recorded to facilitate complete documentation. All fields are completed by using the provided dropdown boxes or fields can be manually completed.



Patient information – Several fields of patient data intended to help track the patient’s progress and outcomes. Use the provided dropdown boxes to make quick selections.

Cancel changes – to cancel any changes made select the “Cancel changes” button.

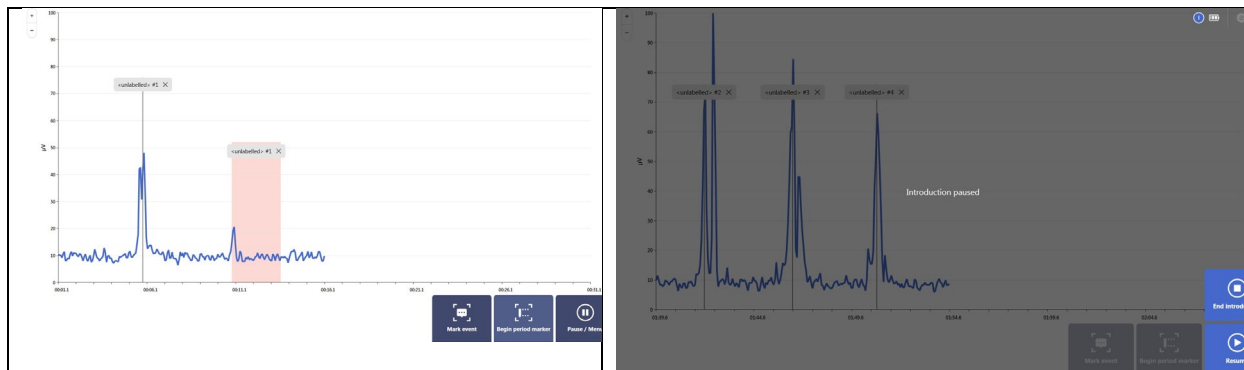
Discharge patient – to discharge a patient from Synchrony caseload click the “Discharge patient” box. A prompt will appear requesting the therapist update all the patient information.

Multiple tab views of patient data – As the patient is progressed through the use of Synchrony, progress can be reviewed by selecting the tabs.

Return to patient dashboard – To return to the Patient dashboard, use the Back arrow or click on the Dashboard icon

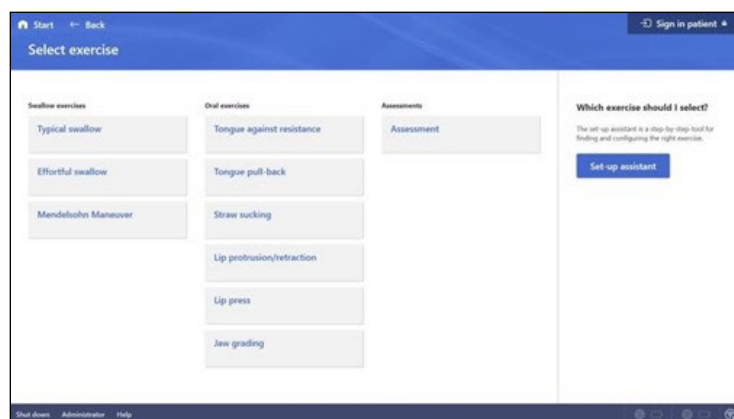
Introduction to Synchrony

Introduction to Synchrony allows the therapist to acquaint the patient to sEMG and swallowing exercise. Tools are provided to demonstrate how events are marked in individual repetitions or as period markers. At the completion of the Introduction, select “End introduction” and all the introduction data is removed and the screen will return to the Patient dashboard.



Select exercise

A library of Swallow exercises, Oral exercises, Assessment and Set-up assistant are provided. Each therapeutic exercises follows a common pathway of Pre-exercise set up, performing the exercise and viewing results.



Swallow exercises – offering includes Typical swallow, Effortful swallow and Mendelsohn Maneuver

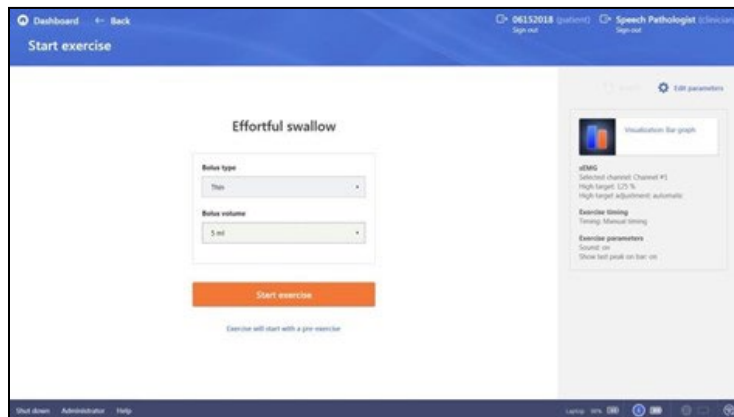
Oral exercises – offering includes Tongue against resistance, Tongue pull-back, Straw sucking and Jaw grading

Assessment – an open assessment area that allows the therapist to assess the patient’s performance in conditions clinically relevant for that patient

Set-up Assistant – a clinical pathway to help clinicians determine the clinically appropriate exercise based on functional impairment or the intervention the therapist desires to perform

Performing an exercise – Example Effortful swallow

All exercises follow the same process of pre-exercise, exercise delivery and results. Each exercise also provides the therapist with the recommended default visualizations and exercise parameter settings which can be edited and tailored to the needs of each patient. Prior to initiating the exercise, follow the patient preparation guidelines as presented in the “Innovations in Dysphagia Rehabilitation” course guideline. Refer to the Help Section of the software for assistance.



Start exercise

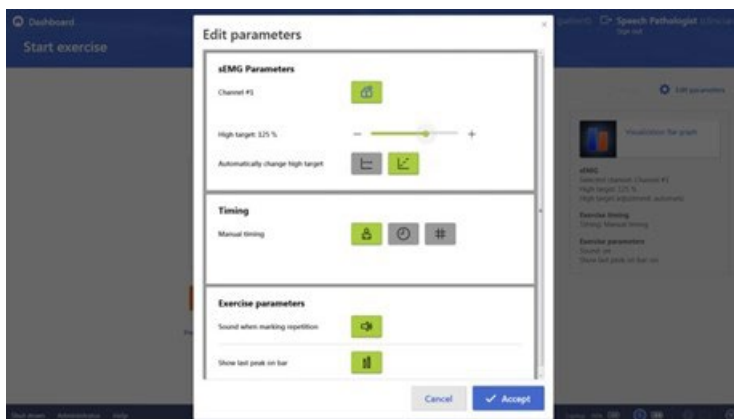
Bolus type and volume – the exercise bolus type and volume can be set from the list using the dropdown box in each section.

Exercise visualizations and parameters – all exercises have clinician recommended visualizations and parameters visualization and exercise parameters default settings. To edit, click on the Visualization box or “Edit parameters” icon.

Start exercise live exercise screen – clicking advances to the

Editing exercise parameters

When “Edit exercise” is selected, the selected exercises parameters are displayed with the default setting and values highlighted in green. When changing the default settings, screen text appears, informing the therapist of the proposed changes. It is suggested the therapist become familiar with the various parameters to optimize the exercise experience.



sEMG Parameters

Channel #1 – display of the sEMG sensor in use, either channel 1 or 2

High target: 125% - the percentage of the target setting used in the exercise. To change, use either use the + or – icons or the slide bar

Automatically change high target – the high target automatically changes higher or lower depending on the response of the patient. If this is changed, the exercise high target value can be adjusted manually prior to starting the exercise and throughout the exercise

Timing

Manual timing – the therapist controls the timing of the exercise duration (when the exercise starts and stops). Other options include exercise duration based on time or number of repetitions.

Exercise parameters

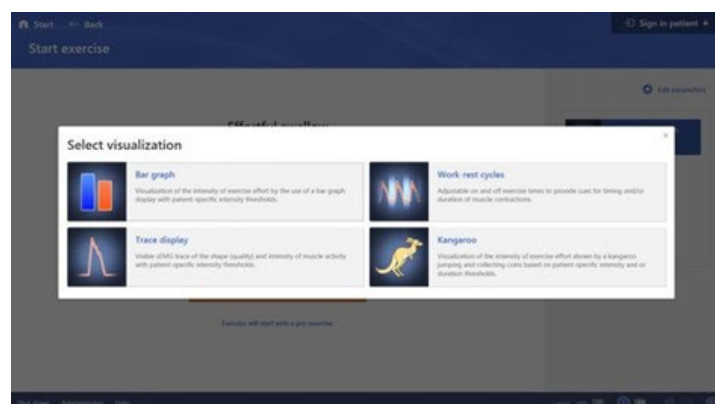
Sound when marking repetition – the system default is a sound when a repetition is marked. This can be set on or off.

Show last peak on bar – shadow of the prior repetition is displayed on the screen. This can be set on or off.

NOTE – Isometric based exercises will allow the therapist access to rest time and isometric work time

Changing exercise visualization types

Multiple exercise visualizations are provided for each exercise. The default visualization has been found to be the clinician's choice when initiating the exercise with a new patient. Not all visualizations are available for each exercise. The visualization examples displayed here are for the Effortful swallow exercise. A video demonstration of each visualization is provided within the Help section of the software.



Bar graph – visualization of the intensity of the exercise effort by the use of a bar graph

Trace display – visible sEMG trace of the shape (quality) and intensity of muscle activity

Work-rest cycles – adjustable on and off exercise times to provide cues for timing and or duration of muscle contractions

Kangaroo – animated visualization of the intensity of the exercise effort shown by a kangaroo jumping and collecting coins

Pre-exercise process – Resting baseline

All initial exercises will start with a pre-exercise unless the clinician changes the setting. The resting baseline is automatic, requesting the patient to remain still and quiet for 5 seconds. To capture the resting baseline manually, select “Mark manually.” To skip the resting baseline, select “Skip baseline.”



Automatic - request patient to remain and quiet for 5 seconds

Mark manually – the therapist controls the start and stop of the resting baseline

Skip baseline – the resting baseline will be set at 10mv

Note - when footplate is attached the footplate command L-M-R are displayed on the command boxes.

NOTE: Any button with an L, M, or R in a box format indicates the foot switch can be used in place of the mouse by simply tapping the left, middle, or right pedals.

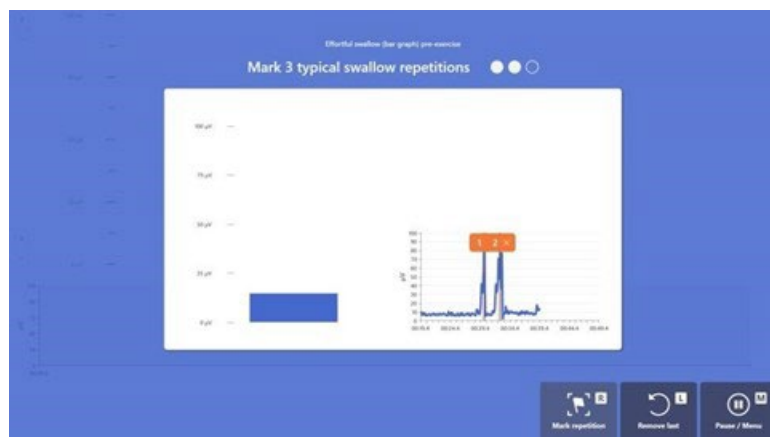
L Left foot pedal

M Middle foot pedal

R Right foot pedal

Pre-exercise process – Mark repetitions

The Mark repetitions step will calibrate the exercise specific to the patient's needs. Capturing three typical swallows prior to beginning of the effortful swallow (bar graph) pre-exercise assures the exercise target levels will be set to the patient's level.



Mark 3 Typical swallow repetitions

Mark repetition – use the footplate or the mouse to mark 3 typical swallow repetitions.

Remove last – allows the therapist to remove the last captured/marked repetition

Pause/menu – pauses the pre-exercise process

Pre-exercise process – Review marked repetitions

After marking 3 typical swallow repetitions a review dashboard is provided in which each repetition can be edited or deleted. If a marked repetition is deleted the opportunity to resume the pre-exercise is provided.



Review mark repetitions

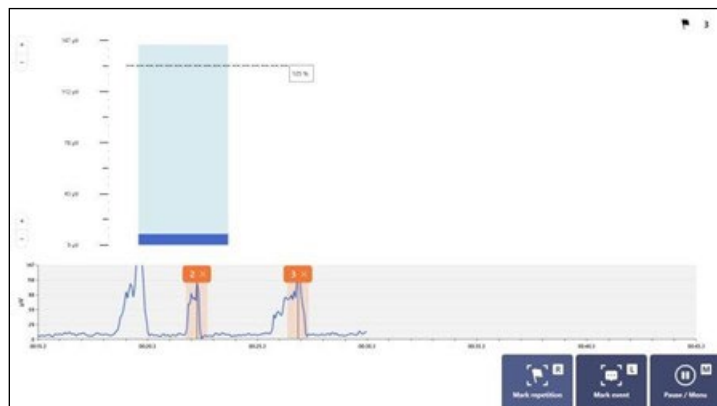
Editing a marked repetition - to edit a marked repetition, click on the repetition. This opens a submenu, allowing the therapist to reposition the repetition marker

Deleting a marked repetition - uncheck the blue box to delete a repetition

Pause/menu - pauses the pre-exercise process

Exercise display screen – Effortful Swallow exercise

The exercise display provides a way to observe the sEMG trace display along with the featured patient visualization. The exercise command boxes — Mark repetition, Mark event and Pause — are located in the lower right of the screen for all exercises. When the footplate is connected, Footplate commands (L, M, R) appear to aid in navigation.



Progressive target – a 125% target is the starting goal and is progressive. The target will progressively increase or decrease based on the patient's performance during the exercise

Progressive increase of target - if during three swallows the patient reaches or exceeds the target, the target will reset higher by 10%

Progressive decrease of target - if during three consecutive swallows the patient does not reach the target; the target will reset lower by 10%

Pausing an exercise

All exercises can be paused and a menu of options is provided: End exercise, Resume and Edit



End exercise – exercise stops and advances to the exercise summary page

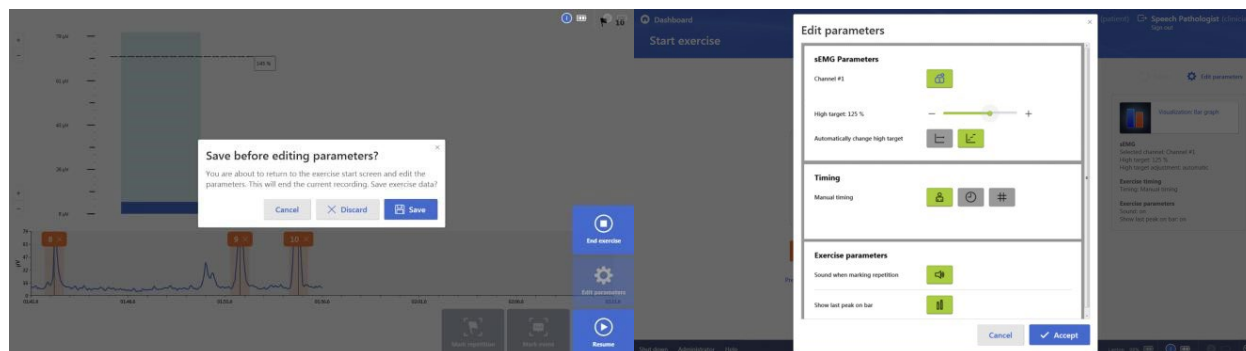
Edit parameters – selecting Edit will provide a way to save the current exercise and edit the parameters desired prior to re-starting

Resume – resumes exercise from the time the pause started.

Note: all pauses will be noted in the Graph display tab in the results section

Editing parameters

All exercise parameters can be edited. When “Edit parameters” is selected a dialogue box offering the opportunity to “Save before editing”. This is recommended. When “Save” is selected the screen advances to the “Exercise parameters” screen to edit the selected exercise. After new parameters are set and “Accept” is selected the Start exercise screen is presented, incorporating the newly established parameters.



Exercise summary report

At the completion of an exercise the exercise summary dashboard is displayed, providing multiple views of the completed exercise in a tabbed format. The default display is the Summary report providing an at-a-glance view of each repetition.



Summary – an overview of each repetition. The bar-graphs in green represent contractions that met or exceeded the exercise target values, those in red did not

Multiple tabs – multiple ways to observe the exercise data are provided for editing and documenting purposes

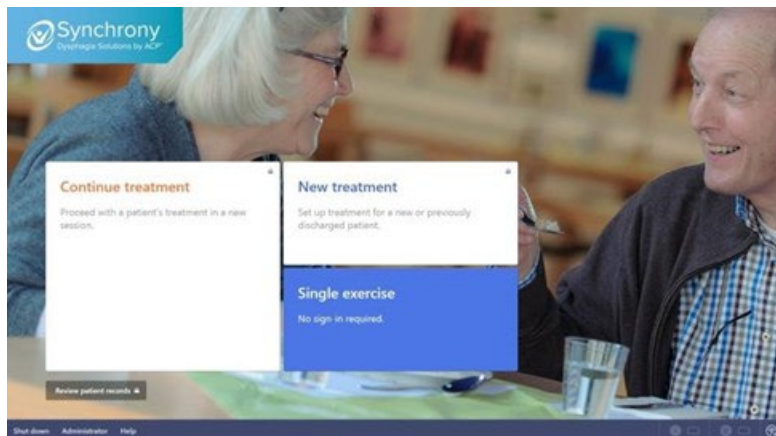
Redo exercise page of the same exercise – a direct pathway to the start

Done – when selected the screen returns to the patient’s dashboard

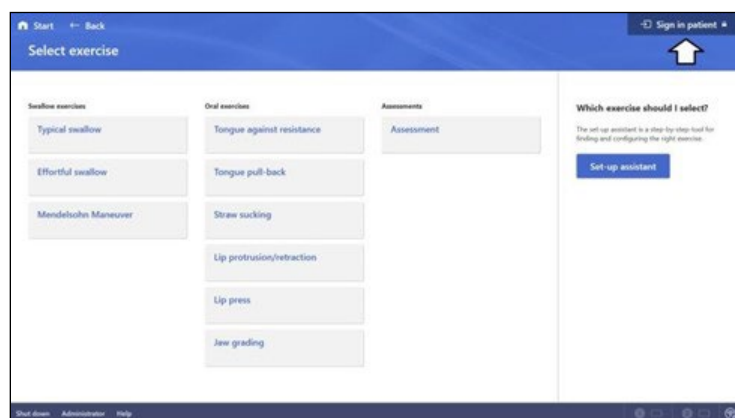
Generate QR Code – At the end of a treatment session, a QR-code with embedded device information, protocol parameters and outcome results will appear. The QR-code can be scanned so this information can be added to the patient’s Electronic Medical Record using the ACPlus™ application.

Single exercise

Single exercise is intended to be an express pathway to initiate an exercise or assessment. The Single exercise setup follows the same setup process as reviewed in prior sections of this document.



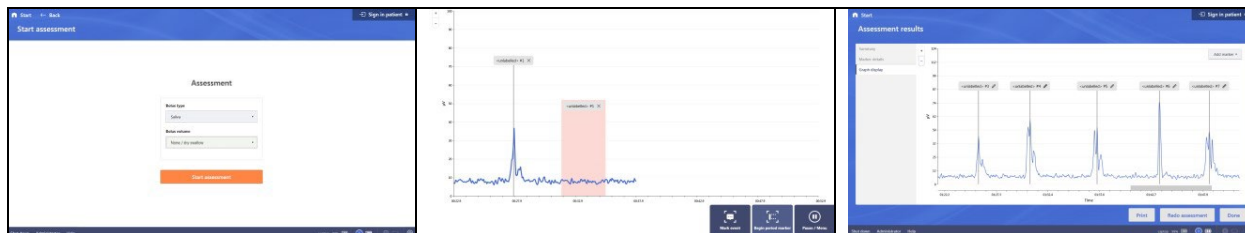
Throughout the single exercise path of use, up into the reviewing of results, the therapist can link the exercise data to an existing patient or new patient record by selecting the Sign in patient box.



Sign in patient – throughout the Single exercise path of use, up into the display of the exercise results, the therapist has the opportunity to link the exercise to an existing patient or new patient record

Performing an Assessment

A patient assessment is typically performed in order to validate sensor performance and the patient's abilities. It is used to measure and quantify specific swallow activity (e.g. typical swallow, swallow duration, effortful swallow, pre-motor time, etc.) or oral motor activity.



The flow of the assessment pathway will allow the clinician to capture repetition and period based markers and observe the patient results in several views within the Assessment results section

NOTE: Any button with an L, M, or R in a box format indicates the foot switch can be used in place of the mouse by simply tapping the left, middle, or right pedals.



Left foot pedal



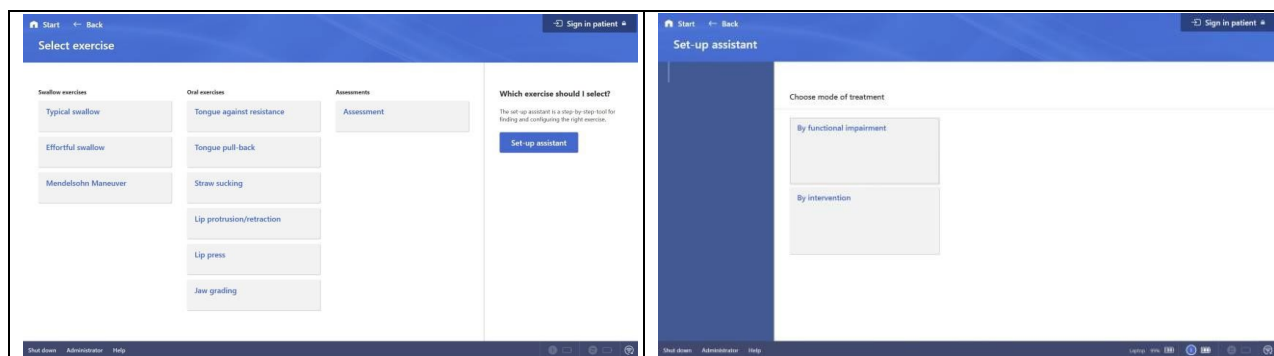
Middle foot pedal



Right foot plate

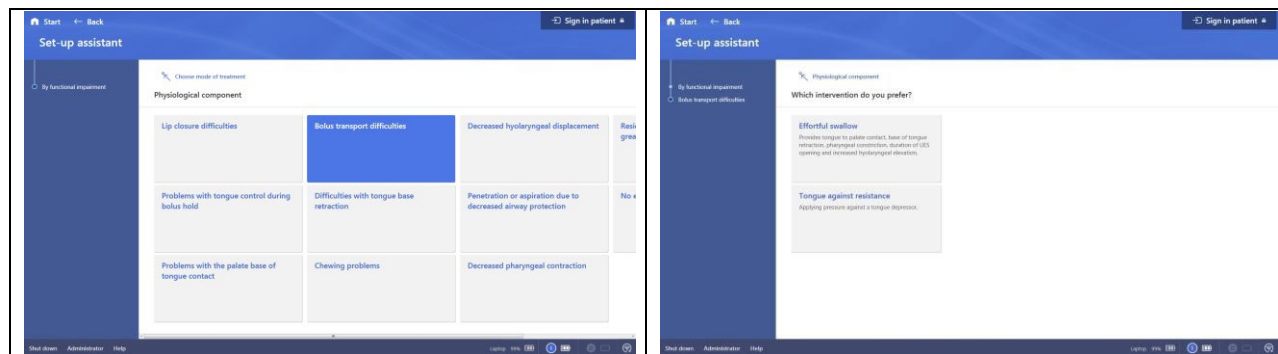
Set-up Assistant

Set-up Assistant is a clinical pathway to assist in the selection of a therapeutic exercise based on either the “Functional impairment” presented or the “Intervention” (swallow exercise or oral exercise) the therapist desires to perform.



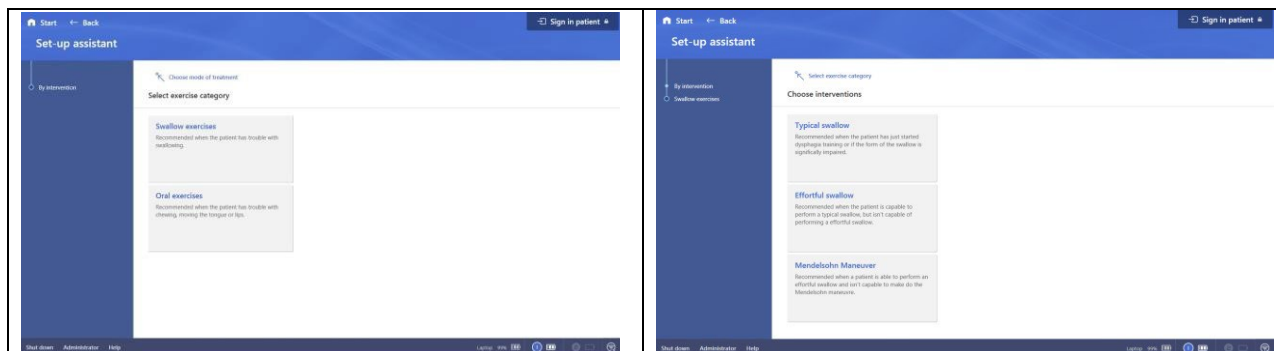
Set-up assistant – Functional impairment

The Set-up assistant – Functional impairment option presents eleven common functional impairments encountered in clinical practice. After selecting the impairment to address in the session, the therapist is presented with a group of research based therapeutic exercise options.



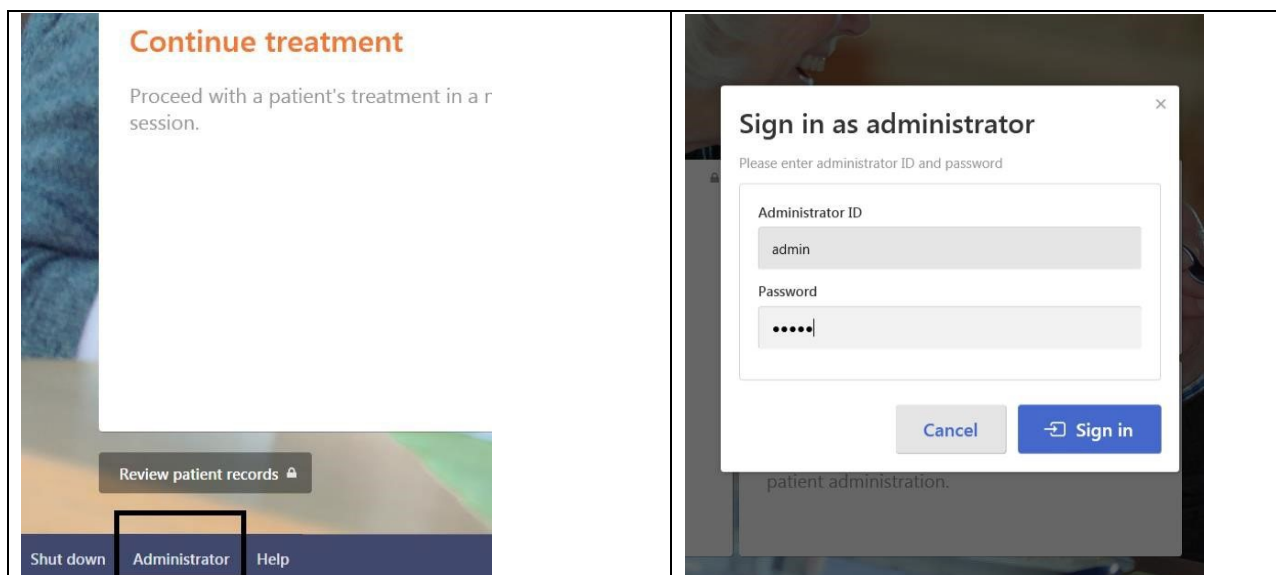
Set-up assistant – Intervention

The Set-up assistant – Intervention option questions the therapist if the desired intervention is for swallowing exercise or oral exercise. After the user's response, common therapeutic exercises are presented.



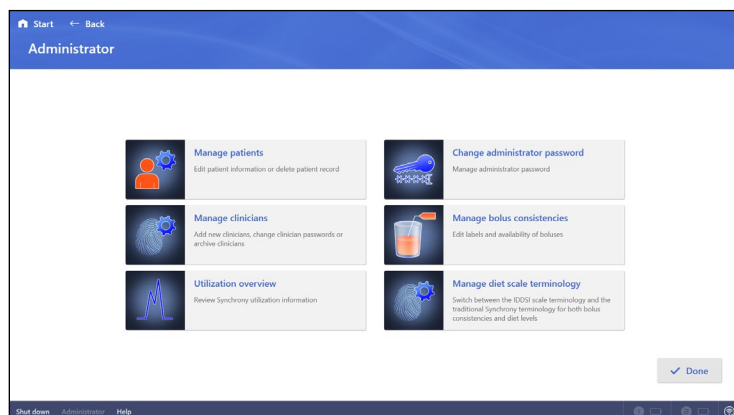
Administrator section

The Administrator section is a user ID and password controlled area intended to be used by the individual identified as the Synchrony administrator. The administrator has access to a control panel of system administrative fields, including ways to manage the patient database, provide clinicians credentials to access Synchrony, review system utilization data and to manage and edit bolus names.



Administrator control panel

The Administrator control panel provides multiple administrative tools to clinically manage the Synchrony system.



Manage patients – access to the patient database to edit or delete patient information

Manage clinicians – provides access to edit or delete clinicians from the database of previously entered clinicians and enables the addition of new Synchrony users

Utilization review – access to the treatment effect and utilization data

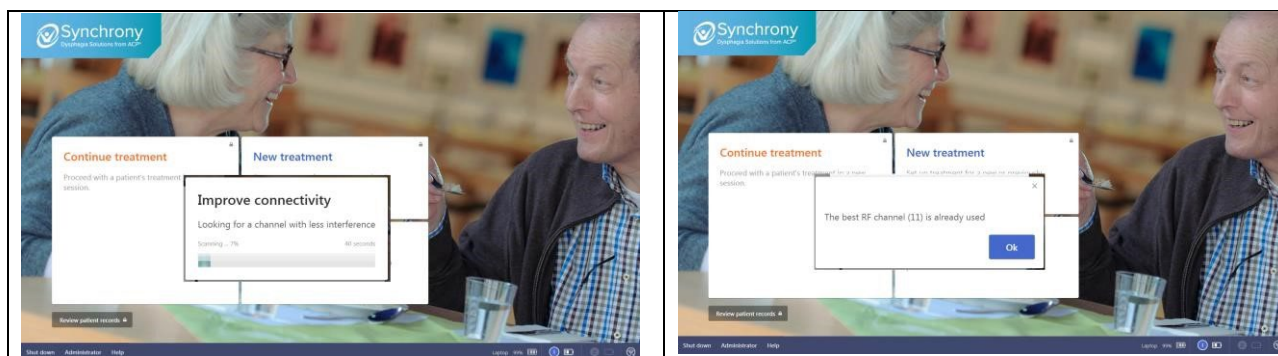
Change administrator password – access to ways to change the Administrator password

Manage bolus consistencies – access to the preset bolus types used with Synchrony

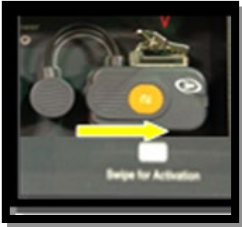


Manage diet scale terminology – Switch between the IDDSI diet level framework terminology and the traditional Synchrony terminology for both bolus consistencies and diet levels.

Improving connectivity

When activated, the Improve connectivity feature scans the available Wi-Fi fields to find the optimum channel with the least traffic. When activated, the scanning process takes about 40 seconds and when finished will acknowledge the selected channel. The improve connectivity feature should be used if the therapist suspects slow or poor communication between the sEMG sensors and the Synchrony software.



Electrode Setup – Connecting the sEMG Sensors

- Remove OMNI sEMG™ sensor from charging station and swipe over the magnet on the charging station to activate (slowly flashing white LED = active).
- Snap two lead wires into the sensor and then remove the electrode patch from the plastic liner card.
- Attach the lead wire to the electrode snap by squeezing the clip and releasing onto the post.
- Prepare the patient's skin by thoroughly cleaning the area of application using the included Prep Pad. Allow the skin to fully dry before applying the electrode.
- Clip the OMNI sEMG™ sensor to the patient's clothing in a location that minimizes stress on the lead wires.
- Review the electrode labeling for care and use of electrodes, including application, removal and re-use if applicable.

INFECTION CONTROL EQUIPMENT AND PRINCIPLES OF USE

Definitions

- Barrier Film – One-time use, disposable plastic film for use over touch/operator surfaces of equipment to reduce risks of cross-contamination and need for high level disinfection of equipment between patients.
- Germicidal Disposable Wipe – Low level and/or intermediate level disposable germicidal disinfectant wipe for use on electrotherapeutic devices and accessories.
- Plastic Lead Wire Sleeve – Barrier to be used on electrical stimulation lead wires, covering the junction of lead wire and electrode wire.

Universal Precautions – Body Substance Isolation

Universal Precautions (UP) must be implemented in the care of all patients to protect employees from occupational exposure to blood borne pathogens. Personal protective equipment (gloves, masks, gowns) should be available and worn by staff when occupational exposure to blood, body fluids containing blood, semen and vaginal secretions is likely to occur. Health care workers with exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves. Equipment must be cleaned/disinfected and protective barriers used when appropriate.

Cleaning / Disinfecting of Synchrony and OMNI[®]EMG™

All Synchrony equipment and OMNI[®]EMG™ components shall be cleaned / disinfected per facility infection control policy. ACP recommends the following guidelines:

Cleaning and Low-Level Disinfection

This is a recommended daily housekeeping practice to keep the equipment clean and free of contaminants which could contribute to transmission of infection. The following practices are recommended for use when treating intact skin without the presence of physiologic fluids such as blood and urine.

- Clean equipment daily with ACP germicidal wipes. At the end of the day, wipe common contact surfaces, such as control panel and lead wires, with germicidal disposable wipe and allow to air dry. This technique will inactivate *M. tuberculosis* as well as most bacteria and viruses. This will also facilitate removal of organic material contaminants from equipment.
- Disposable and Reusable electrodes are for individual patient use only and are not to be used on multiple patients.

Intermediate Level Disinfection and Barriers

This method is recommended to keep the equipment clean and free of contaminants when used between patients for treatment of non-intact skin or incontinence management, where there is an increased risk of patient cross-contamination. The following are the recommended practices.

- After each use, clean common contact surfaces, such as control panel and lead wires with ACP germicidal wipes.
- With a second ACP germicidal cloth, wipe again leaving surfaces wet for at least 5 minutes. Allow the surface to air dry before patient use.
- Barriers should also be used on the equipment for treatment of non-intact skin or incontinence management. This technique will inactivate *M. tuberculosis* as well as most bacteria and viruses.

Use of Barriers – Intermediate Level Disinfection

The use of an all-purpose barrier film provides surface protection from cross-contamination resulting from a variety of applications. This precaution should be used whenever dealing with non-intact skin or the chance of coming in contact with bodily fluids. Barrier film is designed to cover any surface that may be touched during a patient treatment, in order to help prevent cross-contamination. Barrier film is for single-use only. The film is discarded after each patient treatment. The procedure for use is as follows:

1. Wash hands.
2. Apply Intermediate Level Disinfection prior to barrier application.
3. Select, tear or cut with clean scissors a length of barrier film to fit over the operator surfaces.
4. Prepare any items which may become in contact with the therapist during treatment, such as ultrasound gel, pens, assessment tools, cart handles, etc.
5. Set up the patient per guidelines for the procedure.
6. Provide treatment as appropriate.
7. Discard all disposables.
8. With clean gloves, remove the plastic film from the unit and discard.
9. Remove the plastic sleeve from the lead wire by sliding it toward the electrode. Remove the electrode and discard with the sleeve.
10. Use intermediate level disinfection of the device prior to the next treatment application.

TECHNICAL SPECIFICATIONS

| OMNIsEMG™ Transmitter / Sensor | |
|--|--|
| Geometry | Variable |
| Electrodes | Standard sensing electrode with clip connection |
| Battery | Rechargeable lithium ion |
| Dimensions | 17mm x 36mm x 8mm |
| Weight | <9g battery included |
| Frequency | ISM band 2.4GHz (standard IEEE802.15.4) |
| Input Impedance | >10G Ohms |
| CMMR | >110db @ 50–60Hz |
| Resolution | 16bit |
| Acquisition frequency | Up to 4KHz |
| Sensitivity | 1 μ V |
| OMNIsEMG™ Receiver / Dongle | |
| Dimensions | 152mm x 82mm x 22mm |
| Weight | 240g |
| OMNIsEMG™ | |
| Ambient conditions for operation | -20 °C to +45 °C 50 to 80% Rh, non-condensing |
| Ambient conditions for storage or transportation | 0 °C to +40 °C 50 to 80% Rh, non-condensing |
| Altitude | 0 to 2000M |
| Autonomy | Up to 24 hours with rechargeable battery |

ACP reserves the right to change technical specifications and product availability without notice.

TROUBLESHOOTING

Service Center

For repair or service of ACP Products and accessories, please call (800) 350-1100 and follow the prompts. Normal hours of operation are 6:00am to 5:00pm Pacific Standard Time. After hours, please leave a message and a technician will return your call during the next scheduled workday.

The following table lists problem symptoms and possible areas to check for the problem causes. If these suggested measures do not correct the problem, call your ACP Customer Service Representative.

General

| PROBLEM | CAUSE | REMEDY |
|--|--|---|
| OMNIsEMG™ dongle will not reconnect | The computer may not recognize the dongle | Unplug the dongle and reinsert into a different USB port in the computer. A message will pop up telling you to plug in the dongle and press enter. Follow the message and retest for connectivity. |
| | The software may not be configured to accept the COM port for the dongle | Click on the ACP logo and enter code 1593. Verify the COM port is configured in the setup menu. The Com port will be the highest number in the drop down listing (i.e. COM 5). Save, exit, and test connectivity. |
| OMNIsEMG™ sensors are not working | Make sure the sensors are charged | Plug the sensor into the charging tray and verify the blue light comes on. Once the blue light goes out, the sensor is charged. |
| | Sensors are configured and ready for use | Run the sensor across the magnetic section of the charging tray. This will activate the sensor. It will show active and ready with a white flashing light. |
| Sensor / electrode noise | The site has not been cleaned and skin debrided properly to eliminate artifact in the signal | Remove electrodes and clean the patient's skin with ACP pumice based skin prep pad. The OMNIsEMG™ electrodes are designed for one-time use, so new electrodes should be used to reassess the signal quality. |
| | The patient's skin could be oily or the skin has residue from makeup or lotions | |
| Printer not printing | Make sure the printer is turned on | Verify the power status light is illuminated (blue light) and the power connection cable is secure. |
| No image from monitor | Video source not set to HDMI | Using the monitor controls on the back of the monitor, press the input button. Then select the video source and ensure the source is set to HDMI. If not, use the up and down arrows to select the HDMI option, and press the plus (+) sign to save settings. |
| No audio from monitor | Audio source not set to HDMI | Using the monitor controls on the back of the monitor, press the input button. Then select the audio source and ensure the source is set to HDMI. If not, use the up and down arrows to select the HDMI option, and press the plus (+) sign to save settings. |
| | Monitor Speakers turned OFF | Find the external speaker switch on the left rear side of the monitor. Turn on the speakers and test audio |
| The unit will not power-on | Damaged power cable | Examine the power cable, and if it appears damaged or frayed, discontinue its use and contact our Customer Support department for a replacement. |

STANDARD LIMITED PRODUCT WARRANTY

The warranty information provided in this section is applicable only to products purchased from ACP, directly or through an authorized dealer. This section does **not** apply to leased products. The terms of maintenance and repair of any leased products are detailed in the separately executed agreement between the parties.

Warranty Coverage

This warranty provides coverage, for Equipment purchased, against manufacturer's defects in material and workmanship, and extends to the original owner of the product during the warranty period for that product. Only those items returned to the ACP Service Center within the warranty period, and also within thirty (30) days after notification to ACP of the defect, shall be eligible for repair under the Standard Limited Product Warranty. Buyer is responsible for shipping cost associated with sending the Equipment to the ACP Service Center. ACP shall ship Equipment to Buyer after repair at no cost to the Buyer provided repair is deemed to be under warranty. ACP may, at its discretion and only for valid warranty claim, repair or replace any part(s) that prove to be defective during the warranty period.

Warranty Exclusion

Any and all warranty coverage will be void if any of the following have occurred:

1. The product contains repairs or replacement parts not furnished by ACP.
2. The product is damaged resulting from misuse or negligence.
3. The product has been tampered with and/or altered, including serial number alteration.
4. The product was used with accessories and/or supplies, including electrodes, not approved by ACP for use with the product.

Warranty Period

The following coverage is provided at no additional cost to the Buyer:

New Equipment / Product. Products purchased as new from ACP are warranted against manufacturer's defects in material and workmanship for a period of two (2) years from the date of purchase.

Refurbished Equipment / Product. Products purchased specifically as Refurbished Equipment are warranted against manufacturer's defects in material and workmanship for a period of one (1) year from the date of purchase.

Accessories. All accessories for ACP equipment / products are warranted against manufacturer's defects in material and workmanship for a period of three (3) months from the date of purchase.

Warranty Validation

The following information needs to be provided to the ACP Customer Service representative prior to the product being returned under warranty coverage:

1. Buyer name or account number as it appears under the "Bill TO" on the ACP or recognized ACP Dealer invoice.
2. Invoice Date and Number.
3. Model number, description, and serial number of equipment.
4. Detailed description of the problem.

Return of Defective Equipment

Any Equipment returned to the ACP Service Center under warranty coverage must have the Warranty coverage validated and must receive authorization from ACP Customer Service prior to being received at the Service Center.

Shipping charges, insurance, and any other costs incurred in sending product to ACP Service Center is the responsibility of the customer and will not be refunded. ACP shall cover the shipping charges and related costs to return the unit to the customer, provided repair is deemed to be under warranty.

ACP is not responsible for any loss or damage to the Equipment prior to receipt at the ACP Service Center. Equipment returned for warranty service must be shipped complete with all accessories (except for manuals), in its original packing or equivalent so as not to be damaged while in transit.

NOTE: Any Equipment sent to the ACP Service Center that is not covered by the ACP Limited Product Warranty is subject to a minimum service and handling fee.

IMPORTANT:

DO NOT SHIP THE EQUIPMENT TO ACP SERVICE CENTER WITHOUT FIRST SECURING AUTHORIZATION TO DO SO. EQUIPMENT SENT IN WITHOUT AUTHORIZATION FROM ACP CUSTOMER SERVICE WILL NOT BE ACCEPTED.

SYNCHRONY AND OMNIsEMG™ ACCESSORIES

| ITEM | ITEM NO. | DESCRIPTION |
|---|----------------|--|
|  | 300800A | <p>Synchrony</p> <p>Synchrony incorporates a virtual reality augmented biofeedback rehabilitation unit called the OMNIsEMG™ which has been specifically designed to accommodate patients with difficulty swallowing as a result of oral or pharyngeal muscle dysfunction.</p> |
|  | 39593 | Mouse, Wireless, M325 |
|  | 59441 | Keyboard, Wireless, K400 |
|  | 18669 | Charging Station, OMNIsEMG™ |
|  | 64187 | Sensor, OMNIsEMG™ |
|  | 93477 | Dongle, OMNIsEMG™ |

SYNCHRONY AND OMNIsEMG™ ACCESSORIES (cont.)

| ITEM | ITEM NO. | DESCRIPTION |
|---|---|---|
|  | https://acplus.com/acp-technology-user-manuals | Synchrony Equipment User Manual DOC# 290SYN |
|  | 74921 | Electrodes, Face & Neck – PENS w/snap, 10packs/box |
|  | 34184 | Electrodes, Pharyngeal sEMG, 1-Use 15/box |
|  | 61879 | Electrodes, Oro-Facial, sEMG, 1-Use 15/box |
|  | 69854 | Pad, Electrode Skin Prep Pad w/ Pumice 100/box |
|  | 34774 | Lead Wire, PENS, 4ft, 3mm pinch style |
|  | 61977 | Lead Wire, sEMG, 12in, 3mm. pinch style |