



RePHAGIA
by SILVERFIT

User Manual

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TABLE OF CONTENTS

Warnings and safety instructions	3	Dashboard	11	Edit Parameters	26
Indications	3	General screen layout	11	s-EMG parameters	26
Contraindications	3	Dashboard layout	11	Timing	26
Important safety measures	3	Patient record	12	Markers	27
The therapist should take the following into account..	4	Patient information	12	Results	27
Immediately stop the exercise if..	4	Swallow scores	13	Repetitions	27
Hygiene and cleaning	4	Treatment progression	13	Perfect time deviation	28
Materials and essentials	5	Outcome details	13	Deviation in the preparatory phase	28
Components in the suitcase	5	Session history	13	Repetition duration	28
Moving the system	5	Exercise overview	14	Integrated sEMG	28
Additional essentials	5	Introduction and Assessment	14	Administrator	29
General use	6	Exercises: Pharyngeal phase	15	The administrator page	29
Switching on the system	6	Exercises: Oral phase	16	Manage patients	29
Switching off the system	6	Bolus type and volume	16	Manage therapists	29
Switching on the sensors	7	Set-up assistant	17	Solving clinical problems	30
Switching off the sensors	7	Calibration	18	Examples of possible problems	30
Charging the sensors	7	Objective	18	How you can help the client	30
Connecting the sensors to the electrode	8	Execution	18	Manage bolus consistencies	30
Placing the electrode	8	Bolus type	18	Manage bolus labels	30
Objectives of the treatment	9	Visualisation overview	19	Change bolus label	30
Examples of objectives	9	Visualisations in detail	20	Use less bolus types	30
How the SilverFit Rephagia works	9	Bar graph	20	Show in graph	30
Main menu	10	Trace display	21	Save or restore	30
Starting a session	10	Work-rest cycles	22	Solving problems	31
Introduction	10	Bow and arrow	23	Where to begin	31
Add a therapist	10	Kangaroo	24	Warnings	31
Starting a new treatment session	10	Diver	25	Unable to switch on the computer	31
Continue with a treatment session	10			No display on the screen	31
Continue with a discharged patient	10			Unable to find the sensors	31
Changing a patients basic data	10			The baseline signal is chaotic	31
Archive a patient after completing treatment	10			Sound is not working	31
Assign a single exercise to a patient	10				

WARNINGS AND SAFETY INSTRUCTIONS (1 of 2)

Indications

The SilverFit Rephagia is a virtual therapy system. It offers exercises that focus on the revalidation of swallowing difficulties.

The SilverFit Rephagia is indicated for:

- Revalidation after a CVA
- Revalidation after oncological therapy
- Revalidation after traumatic brain injury
- Revalidation after artificial respiration or feeding
- Dysphagia combined with intellectual disabilities

And in case of specific aspects of swallowing disorders such as:

- Delayed swallow initiation
- Reduced swallowing strength
- Insufficient bolus transport
- Reduced pharyngeal wall contraction
- Problems in the preparatory oral phase

Contraindications

The Rephagia cannot be used for:

- Patients who, according to the therapist's assessment, are unable to swallow safely
- Patients who, according to the therapist's assessment, do not benefit from muscular exercises; for instance, patients with (later stages of) ALS
- Patients who, as shown during a FEES evaluation for example, aspirate while swallowing instead of prior or after swallowing
- Patients who aspirate consistently; various food consistencies and/or conditions for oral intake must be reviewed.
- Patients who, as a result of skin problems or other reasons, are unable to use the OmniSEMG sensors and electrodes. Examples: in case of a damaged/irritated skin; After radiotherapy it should be individually assessed for each client whether it is possible to attach the electrode. Only place the electrodes on undamaged skin and place them in such a way that removing them will not cause damage to the client.
- There is no contraindication concerning possible negative effects of the sensors on a pacemaker. The sensors register and do not apply electro stimulation. In case of doubt you should consult a doctor.
The manual of the OmniSEMG sensors will provide more information about possible electromagnetic interference.

If clients are unable to see or interpret the system's visualisations, the system can be used as support/imaging system for the benefit of the therapist.

By offering auditive cues, the therapist can stimulate the client to perform specific actions that will be visualised for the benefit of the therapist, whereby 'markers' will be made that will be used to display clinical outcome measures.

The therapist is responsible for contraindications that are fitting in case of logopedic therapy of swallowing disorders, such as:

- Intensive motor exercises in case of progressive disorders such as ALS, MS, etc.
- Consistent aspiration; in that case it will be necessary to review various food consistencies and/or the conditions for oral intake

Important safety instructions

The SilverFit Rephagia is a professional revalidation system for clients with dysphagia and possible additional cognitive disorders. The system requires the skill, know-how and opinion of a qualified (speech) therapist. Supervision and guidance from the therapist is necessary for a safe and efficient use of the Rephagia with clients.

The Rephagia offers the therapist and client insight into the timing and coordination of the swallowing motion. The system also provides possible exercises in the form of games.

SilverFit will in no event be held liable for any direct, indirect, incidental, special, consequential or other damage, including physical injury, resulting from negligent use of the SilverFit Rephagia.

Warnings laptop:

- Do not place the Rephagia on an unstable trolley, base or table. The device could drop and become severely damaged.
- The openings of the laptop are used for ventilation. These should not be blocked or covered.
- Ensure that the power cable and other cables are not lying in the path where you will walk.
- Ensure that the power supply adapter cannot make contact with the skin or any other object made of soft material (such as a pillow, clothes or a cloth) during use.



WARNINGS AND SAFETY INSTRUCTIONS (2 of 2)

The therapist should take the following into account:

Client instruction

When a client performs an exercise for the first time, it would be sensible to show how it is done and/or guide him or her with instructions, depending on the client's cognitive capacities.

Reduced cognition

Clients with a cognitive disability must be closely monitored for a safe and efficient use.

Recovery of tissue after surgery/radiation

Be careful in case of recent surgical procedures, or in case of recovery of soft tissue. Muscle contractions could disrupt the healing process. Also be careful in case of sensitive, recovering skin in relation to cleaning the skin and attaching the electrodes. In case of doubt, delay the treatment with Rephagia.

Over-sensitivity

In rare cases the client could show signs of fear, nausea, reduced balance or other problems when doing exercises in a virtual environment. In these cases it is recommended to continue the treatment in a different manner or to provide intensive guidance, to be judged by the therapist.

Exercise room

Safe use of the SilverFit Rephagia demands a room that is adjusted to the client, whereby over-excitement is prevented. It is possible to exercise in treatment rooms. It is also possible to perform a bed-side treatment, whereby the therapist is responsible for a safe posture.

Problems in the equipment

If the SilverFit Rephagia is damaged/defective, if there are error messages on the screen or if the screen fails, try to shut down the SilverFit Rephagia in the correct manner or, if necessary, pull the plug from the power outlet. Contact the SilverFit technical service.

sEMG sensors and electrodes

Only use the original supplied sensors, electrodes, accessories and cables. Do not use the electrodes after their use by date. Do not re-use the electrodes.



Immediately stop the exercise if:

- The patient repeatedly starts coughing when offering a specific consistency
- There are consistent clinical symptoms of aspiration, such as watery eyes, discolouring of the face, etc.
- Suspicion of silent aspiration
- Dizziness; blood pressure drop >20mmHg
- Oxygen saturation < 90%
- Severe headache
- Occurrence of confusion
- Increasing tiredness whereby a reduction in swallowing strength can be measured
- The client asks you to stop



Hygiene and cleaning

- It is recommended to keep the laptop and accessories clean after use by means of 'a daily cleaning routine', to prevent the spread of infections.
- The equipment including sensor and electrode wires can be cleaned by means of 'disposable' cleaning wipes.
- Prevent cleaning with alcohol, this could affect the equipment's material.
- Do not clean the laptop and other electronic components with water or other liquids.

MATERIALS AND ESSENTIALS

Components in the bag:



Laptop



Laptop adapter



Mouse



Charging unit



Electrode sticker



Sensors (2x)



Charging unit adapter



Signal receiver



sEMG elektrode cable (2x)

Moving the system

The SilverFit Rephagia is a mobile system and can be moved for use at different locations.

If you want to move the system, you must first fully shut down the laptop (as described below 'General Use'), before you store the laptop in the suitcase.

Additional essentials

Before you start working with a client, there should be sufficient liquid and food ready for use during the training. The food consistencies and the materials by means of which these consistencies are offered, e.g. adapted cutlery, beakers, etc., are selected by the therapist. The therapist is responsible for the selection that is made on the basis of the client's possibilities and the desired difficulty level during the exercise.

GENERAL USE (1 of 3)

Switching on the system



1

Connect the adapter to the laptop and insert the plug in the power outlet.



2

Place the signal receiver in the USB connection of the laptop and fold open the laptop. Caution! It is important to place the signal receiver in the laptop before the laptop is folded open and switched on.



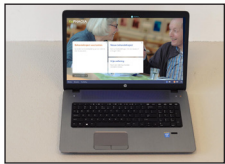
3

Switch on the computer by pressing the computer's on/off button. The computer and the Rephagia programme will start.



4

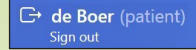
When the computer starts, a white led will light.



5

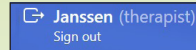
The main menu appears.

Switching off the system



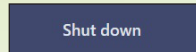
1

In the upper right corner you can log off the patient.



2

In the upper right corner you can log off the therapist



3

In the lower left corner you can shut down the system.



4

While the system shuts down, you will remove the signal receiver.



5

Wait until the system has shut down, before storing the laptop in the bag.

GENERAL USE (2 of 3)

Switching on the sensors



- 1 The sensor led can light in different colours. If the led does not light, the sensor is off.



- 2 Carefully slide the sensor over the 'swipe' strip at the bottom of the charging unit.



- 3 When the led lights white, the sensor will be on, it will send information to the signal receiver.



- 4 After a few seconds, the battery symbol in the bottom right corner of the screen will light up. The number of stripes in this symbol will indicate whether the sensor's battery has been charged. If the battery is (almost) empty, you must use the other sensor or charge the sensor before you start.

Switching off the sensors



The sensor can be switched off in two ways:

- By pressing the sensor on the 'swipe strip' in the charging unit for 3 seconds. When you remove the sensor, the led will stop lighting.
- OR
- Place the sensor in the charging unit. Switch the charging unit on and off using the on/off button at the rear of the charging unit.

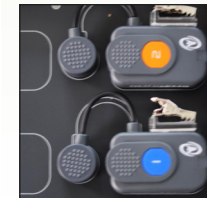
Charging the sensors



- 1 Check whether the plug of the charging unit has been connected.



- 2 If the charging unit is on and the sensor is attached, the led will light blue. This means that the sensor is off and is being charged.



- 3 If the blue led goes off while the sensor is attached to the connected charging unit, the sensor is fully charged.

GENERAL USE (3 of 3)

Connecting the sensors to the electrode



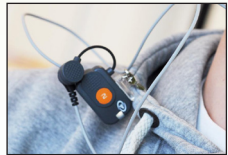
- 1 Place the electrode on the throat, as described in chapter 'Placing the electrodes'.



- 2 Connect the electrode cables to the sensor.



- 3 Attach the clips of the electrode cables to the electrode.



- 4 Attach the sensor to the client's clothes using the peg, so that there will be no tensile force on the electrode cable and the electrode.

Placing the electrode

Depending on the client, you can attach the electrode on different locations.

- Prior to attaching the electrode, the skin must be cleaned with a cleaning wipe contained in the packaging. Ensure that the skin is properly dried after cleaning, before attaching the electrode.
- First remove the central strip from the adhesive layer and attach the electrode to the skin. Then remove the side strips from the adhesive layer and fully attach the electrode.



- 1 Oral placement: Use for oral motor exercises (e.g. lip closure). This placement uses two sensors.



- 2 Submental: Use to measure the tongue activity during the oral and pharyngeal phase of swallowing as well.

In the case of this placement, the signal will be the strongest, but a lot of tongue activity can be seen. This placement uses one sensor.



- 3 Suprahyoid: Use to measure all-round oropharyngeal muscle activity. This is the most common placement. This placement uses one sensor.



- 4 Infrahyoid: Use to display a pure signal of the pharyngeal muscle activity. The tongue activity is not visible, but the amplitude of the signal is smaller.

In the case of some clients, the signal can be too weak to be able to exercise. This placement uses one sensor.

OBJECTIVES OF THE TREATMENT

The SilverFit Rephagia offers the therapist a wide range of data and visualisations of muscles that are involved with swallowing. In combination with clinical observations, this will allow the therapist to determine the quality of swallowing, particularly in relation to the timing of the swallow and the possibilities/limitations of the client.

The Rephagia offers games/visualisation that fit specific treatment objectives drawn up by the therapist. It is possible to save the patient's performances and to map out improvements (or deteriorations) during the treatment.

Research showed that, irrespective of the pathology, clients with swallowing disorders are predominantly confronted with one or more of the following problems:

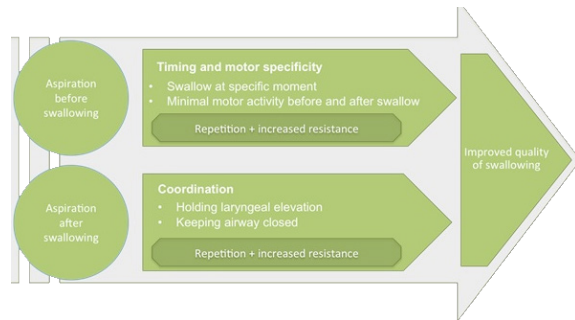
- sensibility problems.
- problems with bolus propulsion.
- passage problems.

This could lead to one of the following three symptoms:

- aspiration prior to the swallow (60-65%).
- aspiration after the swallow (30-32%), whereby food remains in the larynx after swallowing. This is often diffuse residue or very specific, e.g. in the *sini piriformes*.
- aspiration during the swallow (rare).

These symptoms can be mapped out by means of the FEES examination. These cannot be observed directly by means of SilverFit Rephagia.

Figure 1: Treatment for different symptoms.



Clients who aspirate prior to initiation of the swallow, often have difficulties timing and controlling the swallow initiation. These clients show a 'delayed' swallow initiation. This is often accompanied with a lot of compensation behaviour in order to force a swallow initiation. Clients who are having problems to transport the food bolus adequately through the pharynx/larynx, have difficulty to retain the larynx elevation/pharynx wall contraction in a coordinated way, after inciting a swallow reflex.

Examples of objectives

On the basis of observed symptoms you will be able to formulate treatment objectives related to the timing of the swallow initiation, repeatedly exercising the swallow, and/or retaining the swallow. The Rephagia has exercises for this and will record outcomes. You will be able to read more about this in the chapters concerned.

In case of aspiration during the swallow, it will usually not be possible to provide treatment with the Rephagia.

Examples of objectives:

- Shortening the delay (the time between the visual cue and the swallow initiation) / Increasing control of the swallow initiation. This is made visible by a reduction in the delay.
- Shortening/reducing compensation behaviour prior to the swallow initiation.
- Extending the duration of the swallow.
- Increasing the maximum force of a swallow.
- Increasing the number of repetitions/swallows within a described time frame.
- The client can perform a described exercise with a consistency with an increased resistance.
- Increasing the oral control of a described food consistency.

It is possible to draw up specific objectives based on clinical symptoms, logopedic interpretations, number of repetitions, and/or variables that can be specifically measured by the SilverFit Rephagia.

How the SilverFit Rephagia works

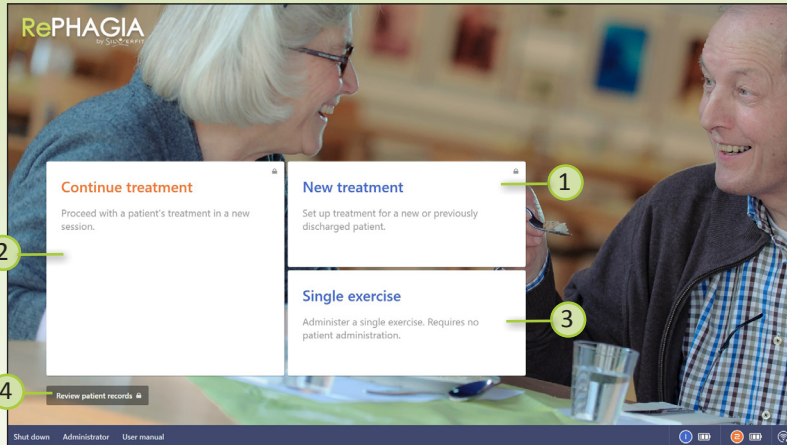
The SilverFit Rephagia offers intuitive visualisations, by means of which clients (also with cognitive limitations) can be challenged and motivated to perform the exercises. Due to the intuitive nature of the visualisation, there will be many more 'swallows' during a session, than when a client must constantly be cued verbally to swallow. The Rephagia is also able to visualise the timing (time between cue and onset) of a swallow or Mendelsohn (start to finish of a swallow) in an intuitive way. As a result, the patient will be able to work on the quality of the swallowing motion.

If specific treatment objectives are established, the Rephagia will be able to record relevant outcomes and map them out in the course of time.

Thanks to the structured method of working with the SilverFit Rephagia, the therapist will also be provided with insight into the progress in relation to the amount offered and the food consistencies.

The SilverFit Rephagia offers a structural approach and a dynamic difficulty level for exercising specific treatment objectives.

MAIN MENU



- 1 New treatment:**
Start a new treatment for a new patient or a discharged patient. Signing in with a therapist ID and password is necessary.
- 2 Continue treatment:**
Continue the treatment of an existing patient with a new session. Signing in with a therapist ID and password is necessary.
- 3 Single exercise:**
Directly start an exercise without signing in a patient or therapist.
- 4 Review patient records:**
Review the patient records of existing patients. Signing in with a therapist ID and password is necessary.

START A SESSION

Introduction

In the client administration you will create a profile of the client. When the client starts doing the exercises, the scores achieved will be saved in a profile. These can be viewed at a later time and/or edited.

Add a therapist

New therapists can be added at the Administrator page. The administrator page can be accessed by the button 'Administrator' in the lower left corner. Signing in with the administrator ID and password is necessary. More information can be found on page 29.

Start a new treatment

At the main menu you choose 'New treatment'. You are asked to fill in the base data of the patient. You can start directly with an exercise. After the exercise diagnostic data of the patient can be registered and monitored in the patient record.

Continue with an existing patient

At the main menu you choose 'Continue treatment'. You can select the patient from a list.

Continue with a discharged patient

At the main menu you choose 'New treatment' and then 'Continue with discharged patient' at the bottom of the field. You can select the patient from a list of all discharged patients.

Changing a patient's basic data

The patient ID and year of birth can be changed by the administrator. The administrator page can be accessed by the button 'Administrator' in the lower left corner. Signing in with the administrator ID and password is necessary. Choose 'Manage patients' and select the patient from a list. The diagnostic data of a patient can be adjusted in the patient record.

Archive a patient after completing treatment

The client data can be archived after all treatment sessions. The client data are saved in the 'Discharged clients' folder. In this way you will make the client non-active. The client is no longer visible in standard search screens. An archived client file can still be looked up when you are logged on as system administrator.

Assign a single exercise to a patient

Directly after completing a single exercise, the data can be assigned to an existing or new patient. At the results page you choose 'sign in patient' in the upper right corner. Next you are asked to sign in as a therapist first and then to sign in a patient. You can also choose to register a new patient. Clicking on the button 'start session' will show a notification asking whether you would like to assign the exercise to the patient.

DASHBOARD

After signing in a patient, the patient dashboard will appear. Here you have an overview of the last two sessions and you can start a new session.

The screenshot shows a patient dashboard with a blue header. At the top right, it displays 'de Boer (patient) Sign out' and 'Janssen (therapist) Sign out'. Below the header, there are three exercise cards: 'Effortful swallow' by Kangaroo (dated 30 May, 11:15), 'Mendelsohn Maneuver' by Diver (dated 17 May, 11:56), and a 'Select other exercise' button. The bottom section contains 'Last session' (05/06/2018), 'Swallow scores' (Liquid level: Nectar, Texture level: Pureed, FOIS: 5), and 'Notes'. A bottom navigation bar includes 'Shut down', 'Administrator', and 'User manual' buttons, along with system icons. Numbered callouts 1-6 point to various UI elements.

General screen layout:

- 1 Sign out patient/therapist:**
At the upper right corner you can see which patient and therapist are signed in. Here you can sign out a patient after completing a session or change the therapist.
- 2 Shut down:**
The Rephagia program and the computer will shut down completely.
Administrator:
To access the administrator page, signing in with the administrator ID and password is necessary. The following actions can be performed:
 - Edit or delete existing patients
 - Manage therapists
 - Change the administrator password
 - Manage bolus consistencies
- 3 Sensors:**
The icons in the lower right corner show whether the sensors are connected and the batteries charged.
- 4 Last sessions:**
The two last sessions that are performed with this patient are shown on the dashboard with a short summary of the session. Clicking the button will start the same exercise again. It is possible to change the parameters of the exercise.
- 5 Select other exercise:**
This button enables you to start another exercise. This is further explained at page 14.
- 6 Patient record:**
This button opens the patient record. Here you can manage and monitor the diagnostic data of the patient. The patient record is further explained at page 12.

Dashboard layout:

- 4 Last sessions:**
The two last sessions that are performed with this patient are shown on the dashboard with a short summary of the session. Clicking the button will start the same exercise again. It is possible to change the parameters of the exercise.
- 5 Select other exercise:**
This button enables you to start another exercise. This is further explained at page 14.
- 6 Patient record:**
This button opens the patient record. Here you can manage and monitor the diagnostic data of the patient. The patient record is further explained at page 12.

This section shows information and notes of the previous session.

Here you can fill in information about the usual food intake of the patient.

Here you can add notes about the current session. These notes are visible on the screen and can be read by the patient.

PATIENT RECORD (1 of 2)

Patient information



This button opens the patient record. Here you can register diagnostic patient data. The patient record also shows the treatment progress.

View specific information concerning the progress and treatment history of the client. See page 13

After completing the treatment, the patient can be discharged. The patient will not appear in the patients list but can be restored.

The screenshot shows a patient record form for 'de Boer'. The form includes a sidebar with navigation options: Swallow scores, Treatment progression, Outcome details, and Session history. The main content area contains the following fields:

Patient ID	de Boer
Gender	Male
Year of birth	1960
Previous session	05/06/2018 13:09
Primary diagnosis	Stroke
Cognitive score	
Enteral feeding	No
Liquid level	Nectar
Texture level	Pureed
FOIS	5
Notes	

Buttons at the top right include 'Cancel changes' and 'Discharge patient'. Buttons at the bottom right include 'Print' and 'Done'. The bottom navigation bar includes 'Shut down', 'Administrator', and 'User manual'.

Diagnostic data. The food intake of the patient is monitored over time. The consistency of the food can be selected from a list.

Extra information on the Functional Oral Intake Scale (FOIS)

Tube-feeding dependant (levels 1-3)

1. No oral intake
2. Dependant on tube-feeding with minimal/non-consistent oral intake
3. Dependant on tube-feeding with consistent oral intake

Fully oral intake (levels 4-7)

4. Full oral intake of a single consistency
5. Full oral intake of several consistencies; special preparation is required
6. Full oral intake with no special preparation, specific forms of food and drink must be prevented
7. Full oral intake without restrictions

Patient's basic data. This can be changed by the Administrator. See page 29.

If the system is connected to a printer, the patient record can be printed.

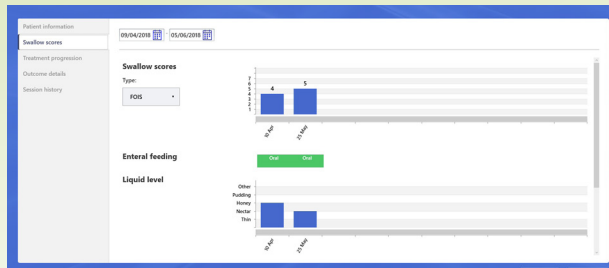
Save the changes and return to the patient dashboard.

PATIENT RECORD (2 of 2)

Swallow scores

The tab 'Swallow scores' shows information about the general food intake of the patient. This information can be registered each session in the patient record at the tab 'Patient information' or on the dashboard of the patient. (see page 11). You can monitor the progress over time by bar charts.

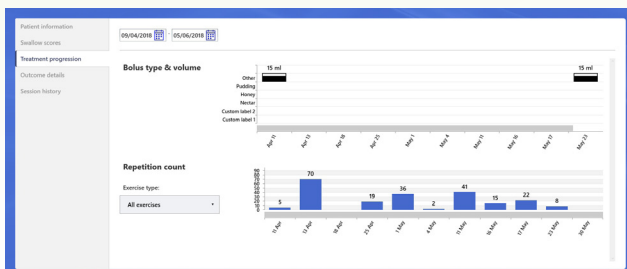
At the top of the page you can select a timeframe. The default timeframe is the entire treatment period.



Treatment progression

The tab 'Treatment progression' shows information on the treatment. Bolus type & volume shows information on the bolus that is used during the exercises. The consistencies that are shown can be changed. The names and the bolus types that are shown in the graph can be adjusted per institution. More information can be found on page 30.

'Repetition count' shows the amount of marked repetitions per day. At 'Exercise type' you can filter the results on a certain exercise type.



Outcome details

The tab 'Outcome details' shows the results for:

- Repetition count: the number of marked repetitions is shown per day
- Repetition duration: for oral exercises and the Mendelsohn maneuver, the average duration of a repetition is shown per day
- Deviation in preparatory phase: the average percentage of the deviation in preparatory phase is shown per day
- Perfect time deviation: for timing exercises, the average deviation from the cue is shown per day
- Integrated sEMG: for oral exercises and the Mendelsohn maneuver the average integrated sEMG of the repetitions is shown per day

At the top of the page you can select a timeframe. The default timeframe is the entire treatment period. It is possible to filter the results on exercise type.

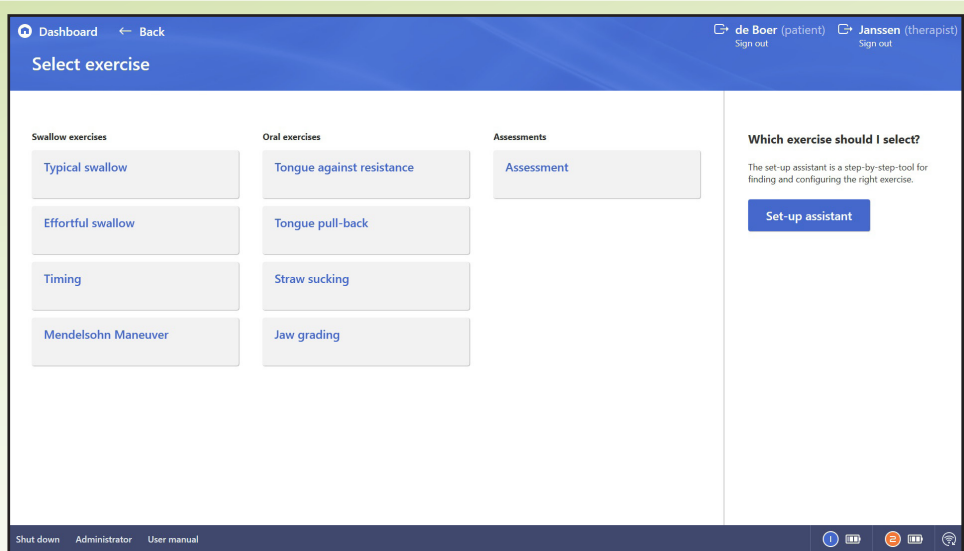
Patient information		17/05/2018				17/05/2018	23/05/2018	23/05/2018
Swallow scores		Exercise				Exercise	Exercise	Exercise
Outcome details	Settings	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal
Session history	Exercise	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal
	Typical swallow	Typical swallow	Typical swallow	Typical swallow	Effortful swallow	Typical swallow	Typical swallow	Typical swallow
	Visualisation	Visualisation	Visualisation	Visualisation	Visualisation	Visualisation	Visualisation	Visualisation
	Type display	Type display	Type display	Type display	Type display	Type display	Type display	Type display
	Bolus type	Purée	Purée	Purée	Unspecified	Purée	Purée	Purée
	Bolus volume	15 ml	15 ml	15 ml	Unspecified	15 ml	15 ml	15 ml
	Calibration outcomes	Average peak sEMG	47 µV	52 µV	104 µV	23 µV	31 µV	29 µV
		Repetition duration	00:06 min	00:10 min	00:18 min	00:44 min	00:22 min	00:20 min
		% on target	-	-	-	-	63%	-
		Repetition duration	-	-	-	3.4 s	-	-
		Deviation in preparatory phase	90%	6%	-	53%	16%	0%
		Integrated sEMG	-	-	-	70 µVs	-	27%
		Perfect time deviation	-	-	-	-	-	-
		Actions	Actions	Actions	Actions	Actions	Actions	Actions

Session history

The tab 'Session history' shows a summary of all sessions that are performed with this patient. At the right side is the most recent performed session, you can scroll to the left to see older sessions. The screen shows a summary of the session. The button 'Actions' allows you to view, edit or delete the session.

Patient information		17/05/2018				17/05/2018	23/05/2018	23/05/2018
Swallow scores		Exercise				Exercise	Exercise	Exercise
Outcome details	Settings	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal
Session history	Exercise	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal	Pharyngeal
	Typical swallow	Typical swallow	Typical swallow	Typical swallow	Effortful swallow	Typical swallow	Typical swallow	Typical swallow
	Visualisation	Visualisation	Visualisation	Visualisation	Visualisation	Visualisation	Visualisation	Visualisation
	Type display	Type display	Type display	Type display	Type display	Type display	Type display	Type display
	Bolus type	Purée	Purée	Purée	Unspecified	Purée	Purée	Purée
	Bolus volume	15 ml	15 ml	15 ml	Unspecified	15 ml	15 ml	15 ml
	Calibration outcomes	Average peak sEMG	47 µV	52 µV	104 µV	23 µV	31 µV	29 µV
		Repetition duration	00:06 min	00:10 min	00:03 min	00:44 min	00:22 min	00:20 min
		% on target	-	-	-	-	63%	-
		Repetition duration	-	-	-	3.4 s	-	-
		Deviation in preparatory phase	90%	6%	-	53%	16%	0%
		Integrated sEMG	-	-	-	70 µVs	-	27%
		Perfect time deviation	-	-	-	-	-	-
		Actions	Actions	Actions	Actions	Actions	Actions	Actions

EXERCISE OVERVIEW



In this screen you choose which exercise you offer. The assessment can be used to introduce the patient to the system. There are activities aimed at the pharyngeal phase and the oral phase. The set-up assistant helps you step by step to find the right exercise. More information about the set-up assistant can be found on page 17.

- The pharyngeal exercises are used to train in relation to repetitions, control of the swallow initiation (by means of timing exercises), or retaining the swallow (Mendelsohn maneuver). The exercises are of a constructive nature: a course of treatment starts with repetitions, possibly followed by exercises for timing and coordination. You can read more about this on the next pages.
- The oral exercises are aimed at treating different disorders in the oral phase of the swallow. Use these exercises in case of a specific problem in the oral phase. See the next pages for more details.
- The assessment is used to make the patient familiar with the system. The therapist will also get an impression of motor activity and control. The assessment is therefore predominantly used to provide insight. The visualisation for the assessment is always in the form of a line graph.

INTRODUCTION AND ASSESSMENT

Introduce patient to Rephagia

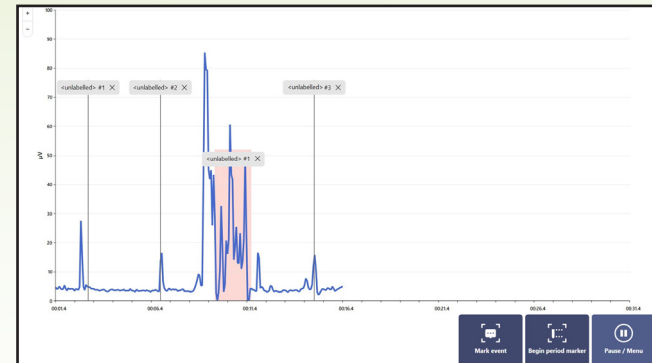
When starting with a new patient, the dashboard will show the option 'introduce patient to Rephagia'. The introduction is a shown as a trace display. It helps the patient to get to know the system and see the effect of the motor activity on the visualisation. The introduction data are not stored in the system.

Assessment

The assessment can also be used in preparation to the therapy. The data of an assessment can be stored in the system. The assessment is also shown as a trace display and can be used to provide insight. There is no exercise linked to the assessment, the therapist is free to choose which assignment he or she will give.

Pharyngeal vs. Oral

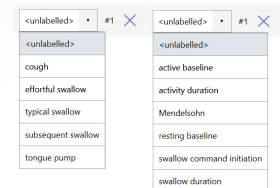
In the pharyngeal phase, swallowing will be at the centre of the exercises. Therefore, functional motor movements will also be performed and marked during the assessment. The oral phase particularly relates to isolated motor movements of, for example, the tongue, jaw or the lips.



Marking box:

During or after the assessment you will be able to place markers. This can be event markers or period markers. In the results overview after completing the assessment can be specified which activity is marked. Each marker has a menu window.

In the text box you will be able to select one of the pre-programmed activities by clicking on the drop-down box or you can add your own text to give a name to the activity or behaviour. By means of the arrow, it will be possible to move the marker in the graph to the left or right. In this way, it is also possible to change the length of a period marker.



EXERCISES: PHARYNGEAL PHASE

Clinical reasoning with the SilverFit Rephagia

The Rephagia offers many types of exercises as a tool to determine the treatment objective and to select visualisations. In the pharyngeal phase it is possible to choose four courses of treatment: Typical swallow, Effortful swallow, Timing (control of the swallow initiation) and Mendelsohn (coordination). We recommend these exercises for the following situation(s):

<p>Typical swallow</p>	<p>We are dealing with a low swallow frequency and/or insufficient fitness to perform 25 swallow repetitions. When there are problems with consciously initiating the swallow, it is highly probable that compensation behaviour can be observed prior to the swallow initiation. The initiation of a swallow will consistently occur with a delay or is very hard to achieve, in spite of visible efforts by the client.</p> <p>The assessment shows that the client finds it very difficult to initiate the swallow in spite of visual and verbal cues. Clinical observations consist of a low frequency spontaneous swallow, 'seeking' mouth behaviour and over-active tongue movements. These problems also often occur in the case of clients receiving liquid and food 'for a long period of time' via a nose-stomach or PEG tube and in the case of weak clients.</p> <p>This course of treatment can be used as a starting point for each treatment.</p>
<p>Effortful swallow</p>	<p>We are dealing with insufficient effort and/or insufficient fitness to perform 25 swallow repetitions effortfully. The peak value of the repetitions should remain above 80% of the average peak value of a typical swallow, as measured during calibration.</p> <p>The 'Typical swallow' exercise shows that the patient finds it very difficult to perform an effortful swallow in spite of visual and verbal cues. When there are problems with consciously initiating an effortful swallow, it is highly probable that compensation behaviour can be observed prior to the swallow initiation. The initiation of an effortful swallow will consistently occur with a delay or is very hard to achieve, in spite of visible efforts by the client. Clinical observations consist of a low frequency spontaneous swallow, 'seeking' mouth behaviour and over-active tongue movements. These problems also often occur in the case of clients receiving liquid and food 'for a long period of time' via a nose-stomach or PEG tube and in the case of weak clients.</p> <p>This type of exercise is particularly important if FEES or a different type of diagnostics shows that aspiration occurs prior to swallowing.</p>

<p>Timing</p>	<p>We are dealing with insufficient control of the swallow initiation. If a client is able to perform 25 or more swallow repetitions, but shows problems in controlling the initiation of the swallow, it is possible to use timing exercises to improve this conscious control. If the assessment shows that a client is able to initiate the swallow, but the initiation is consistently too early or too late in relation to a cue (verbal or visual).</p> <p>Clinical observations consist of 'seeking mouth behaviour or over-active tongue movement, whereby a client attempts to initiate the swallow. Offering small bites or sips of a safe consistency, will often speed up a swallow initiation in an uncontrolled manner. These problems often occur in the case of clients who have neurological injuries and/or have received a nose tube during a longer period for the additional or full replacement of oral intake.</p> <p>This type of exercise is particularly important if FEES or a different type of diagnostics shows that aspiration occurs prior to swallowing.</p>
<p>Mendelsohn maneuver</p>	<p>If the client has sufficient control of the initiation of his swallow, but there are problems with the adequate transportation of a food bolus towards the esophagus and stomach, coordination exercises will be performed with the aid of the Mendelsohn maneuver. In this way it is attempted to retain the contraction of the muscles involved with swallowing (particularly the pharyngeal wall contraction) in a coordinated manner.</p> <p>The assessment shows that the client is able to control the swallow initiation (with different consistencies). But is unable to consciously retain the muscle contraction as created during a swallow reflex. Clinical observation or diagnostic examination shows that there is a problem with the bolus propulsion, whereby food remains in the throat after swallowing, with a hazard of aspiration and penetration.</p> <p>These problems particularly occur in the case of clients that find it easier to process thin liquid consistencies, but particularly experience problems with firmer food consistencies. These clients suffer from a lot of coughing in case of solid food and indicate that food gets stuck in the throat. Thick liquid food can accumulate in the throat without noticing, whereby the client starts to sound fuller after a few bites and aspirates when the oral intake of this consistency continues.</p> <p>This type of exercise is particularly important if FEES or a different type of diagnostics shows that aspiration occurs after swallowing.</p>

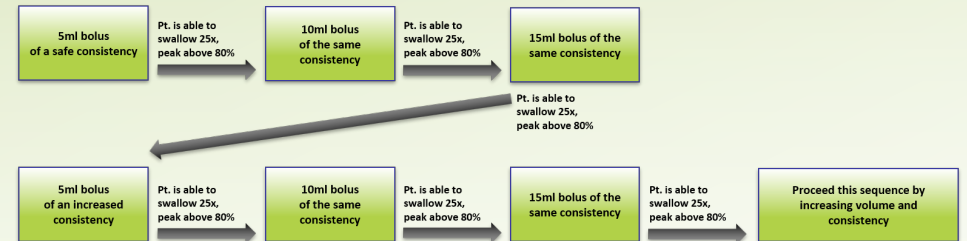
EXERCISES: ORAL PHASE

Available exercises for the oral phase particularly focus on improving the mobility and strength of the muscles that are involved with food manipulation, chewing and lip closure. The exercise types are: Tongue against resistance, Tongue pull-back, Straw sucking and Jaw grading. We recommend these exercises for the following situation(s):

<p>Tongue against resistance</p>	<p>If a patient has insufficient control over the tongue while holding a food bolus, there are problems with the adequate transportation of a food bolus towards the esophagus and stomach, or problems in the preparatory phase with the food bolus on the tongue. This exercise attempts to coordinate the contraction of the tongue.</p> <p>Clinical observation or diagnostic examination shows that there is a problem with the bolus propulsion, whereby food remains in the throat after swallowing, with a hazard of aspiration and penetration.</p> <p>These problems particularly occur in the case of clients that find it easier to process thin liquid consistencies, but particularly experience problems with firmer food consistencies. These patients have trouble gaining control over these consistencies or with swallowing the mouth completely empty. They suffer from a lot of coughing in case of solid food and indicate that food gets stuck in the throat.</p>
<p>Tongue pull-back</p>	<p>If a patient has trouble with tongue base retraction or there is no or reduced epiglottic inversion. This exercise attempts to increase the hyoid lift and coordinate the contraction of the tongue base.</p>
<p>Straw sucking (Coordination)</p>	<p>If a patient has insufficient control over the lips which causes problems with holding food in the mouth. These visualisations can train a combination of power and mobility. The patient is stimulated to perform the movements powerfully and controlled in a certain time frame.</p>
<p>Jaw grading</p>	<p>If a patient experiences problems with grinding a food bolus or with the preparation of a food bolus on the tongue. This exercise attempts to increase the coordination of the jaws over a food bolus.</p> <p>These problems particularly occur in the case of clients that find it easier to process thin liquid consistencies, but particularly experience problems with firmer food consistencies. These patients have trouble gaining control over these consistencies or with swallowing the mouth completely empty. They suffer from a lot of coughing in case of solid food and indicate that food gets stuck in the throat.</p>

CONSISTENCY AND VOLUME BOLUS

For exercises in the pharyngeal phase, an increase in bolus type and volume is advised. By choosing different exercises with other objectives, the patient keeps being challenged, the bolus type and volume of have an influence on that as well. During the treatment process the consistency of the bolus will become thicker. A thicker consistency will cause more resistance, and thus more training, than a thinner consistency. Naturally it is intended that over time, the patient is able to safely swallow thinner consistencies as well. By means of an FEES or other diagnostic tool can be evaluated whether a patient is safely able to swallow thinner consistencies. This cannot be performed with the Rephagia. It is advised to start with a volume of 5ml and a consistency that is safe for the patient to swallow (see scheme below).



Resistance increase

To motivate the patient to increase effort or hold the effort for a longer period it is important to gradually adjust the resistance of the consistency. The figure above shows schematically how to adjust the consistency during the treatment. The therapist checks whether the patient is able to swallow 25 times with a certain bolus type and volume. If the patient is able to do so, the bolus will be adjusted. It is important that the therapist keeps the abilities of the patient into account so the chances of aspiration during the treatment are as low as possible. At the same time it is important that the patient keeps training with a consistency that provides such a resistance that the muscle power increases.

Consistency in general food intake and during treatment

At the patient dashboard can be indicated which consistencies do not lead to aspiration in the general food intake of the patient. The Rephagia uses the IDSSI structure (2015, iddsi.org) for the naming of the different consistency levels. In the patient record the progress of the used consistencies in the general food intake is quickly visible.

The bolus type that is used during the exercise can be indicated before starting the exercise. This does not have to be the same consistency as used for the general food intake. Because the consistencies are offered under supervision of a therapist, it is possible to offer a harder bolus type to the patient. The patient record shows this as a graph, where the progress in bolus type and volume are quickly visible to the therapist.

Swallow scores		
Liquid level	Texture level	FOIS
Nectar	Pureed	5
25/05/2018	25/05/2018	25/05/2018

Bolus type

Puree

Bolus volume

15 ml

Electrode placement

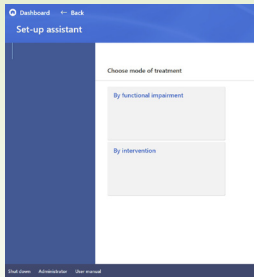
Suprahyoid

SET-UP ASSISTANT

The set-up assistant is a tool which helps the therapist in selecting an exercise.

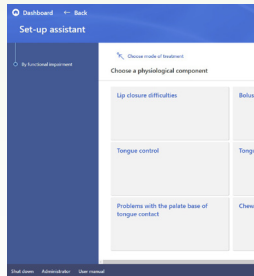
The right side of the screen offers different options. When you have passed all the clinical steps, the system will advise some possible exercise types and visualisations. These exercises are an advice, the therapist is always able to choose another exercise or change the parameters. The therapist remains responsible for the safety of the treatment and the treatment objective, if either one is at stake the therapist should intervene.

It is at every moment possible to return to the previous clinical step. As an example, an exercise will be chosen based on a functional impairment.

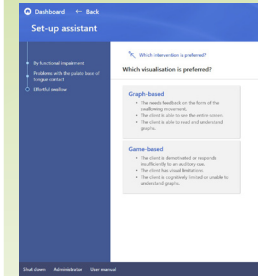
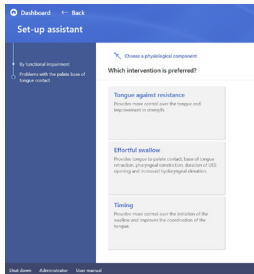


Here you can choose a treatment mode. A treatment objective can be set which reasons from a functional impairment or an intervention.

Here you can select a functional impairment, for example problems with the palate base of tongue contact.

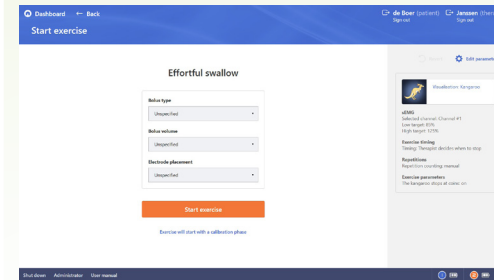
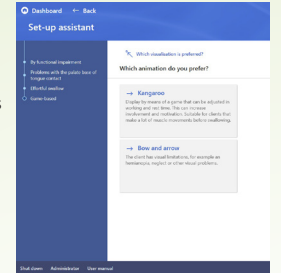


Select an intervention. You can read for each intervention in which cases it is applicable.



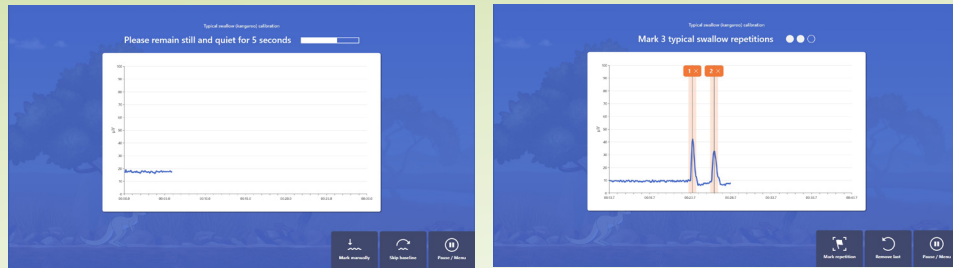
Select a visualisation type. You can read under both types for which patients the type is suitable.

Select a visualisation. You are advised in which cases for example the kangaroo is suitable.



By the chosen options, you have navigated to the start and parameters screen of the selected exercise.

CALIBRATION



Objective:

Prior to an exercise a calibration will be executed. By performing a calibration, the threshold values of the exercises are set. These threshold values are determined based on the effort of a swallow and the tonus at rest of the measured muscles.

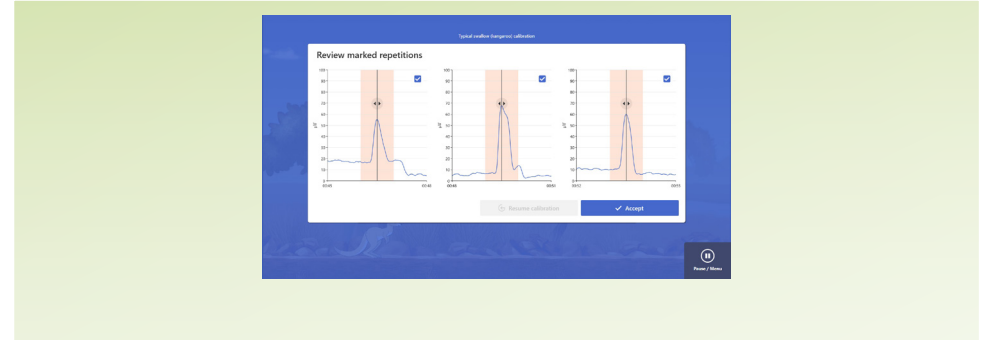
Execution:

When you click 'start exercise' the calibration will start directly. During the calibration, instructions will appear on the screen.

Baseline calibration:

The baseline calibration determines the tonus at rest. There are multiple ways to perform a baseline calibration.

- Automatic baseline calibration: Ask the patient to sit still for 5 seconds. On the screen appears a time indicator that automatically restarts when too much movement is detected. After 5 seconds the mean base tonus (μV) of the patient is automatically calculated.
- Skip baseline calibration: If it is not possible to capture a signal without movement in 5 seconds, the calibration can be skipped. A default value of $10 \mu\text{V}$ will be used as baseline value.
- Manual baseline calibration: If it is not possible to automatically capture a baseline and $10 \mu\text{V}$ is not a suitable value to use, the baseline can also be manually captured. You can mark the begin and ending of the calibration period with the mouse. Afterwards the graph with the marked area will be shown. You can manually slide the marked area to the right period, based on the marked area the average base tonus (μV) will be determined.



Repetition calibration:

To determine the threshold values of a repetition, the patient is asked to perform three typical swallows repetitions. With the mouse you can mark a repetition. For the swallow repetitions the marker is automatically placed at the peak. For period-repetitions (for example the Mendelsohn maneuver) you can indicate the begin and end of the work period.

After marking three repetitions the system automatically navigates to a page where the markings can be adjusted. You can slide a marker to the left or right to indicate the right position. With the blue checkbox in the corner you can indicate which markers are included in the calculation. If needed, you can mark a new repetition with the button 'Resume calibration'

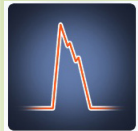
Bolus types:

During the calibration, it is important to offer the same consistency as during the exercises. In case of a more solid consistency, the resistance and required strength to swallow it will increase, resulting in a higher measured peak value.

The exercise starts directly after calibration.

VISUALISATION OVERVIEW

Depending on the chosen exercise, different visualisations are available.



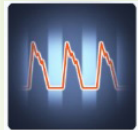
Trace display

Free exercise without time periods. Also suitable for use with an auditive cue provided by the therapist. With this visualisation it is possible to give a patient more specific feedback on the swallow.



Bar graph

Free exercise without time periods, also suitable for auditive cueing. With this visualisation it is possible to give a patient more specific feedback on the swallow.



Work-rest

Trace display that visually shows when the swallow or other movement must be initiated (i.e. there is a visual cue). With this visualisation it is possible to give a patient more specific feedback on the swallow



Kangaroo

Game based visualisation: A kangaroo jumps and collects coins at the moment the patient swallows. Dependent on the exercise, one or more coins are visible and the kangaroo stops at coins or directly jumps along. This visualisation motivates the patient to a better performance.



Bow and arrow

Game based visualisation: When the patient swallows, an arrow is shot with which a target can be hit. Dependent on the exercise these targets move or stand still. This visualisation motivates the patient to a better performance.



Diver

Game based visualisation: During the work period the diver will swim up to collect shells. This visualisation is available for oral exercises and focuses on mobility and the coordination between work and rest periods. This visualisation motivates the patient to a better performance.

Pharyngeal

	Trace display	Bar graph	Work-rest	Kangaroo	Bow and arrow	Diver
Typical swallow	x	x		x	x	
Effortful swallow	x	x		x	x	
Timing			x	x	x	
Mendelsohn	x	x	x	x		

Oral

	Trace display	Bar graph	Work-rest	Kangaroo	Bow and arrow	Diver
Tongue against resistance		x	x	x		x
Tongue pull-back		x	x	x		x
Straw sucking		x	x			
Jaw grading		x	x			

VISUALISATIONS IN DETAIL - BAR GRAPH

Bar graph

Objective: Making the strength and duration of the measured muscle activity visible in very simple and vertically moving bars.

Indication: If only strength has to be made visible and the time during which it is retained.

Contraindication:

- When dealing with visual and/or cognitive limitations, as a result of which the client does not understand the display.
- When the client is insufficiently able to see the screen.

Description: This visualisation shows the signal by vertically moving a bar. The more powerful the measured muscle activity, the higher the bar will reach. If the muscle strength reduces, the bar will go down again, but a shadow of the maximum result will remain visible. This is a very simple and clear visualisation of 'strength'. By means of the set thresholds, which can be moved up and down during the exercise, the client can be challenged to perform the required activity with more strength. The client will get direct visual feedback of his attempts. This visualisation can be used for different exercises and disorders.



Visualisation: You can see a blue or red bar in the centre of the screen (depending on the selected sensor), which makes vertical movements when the muscle strength increases. Two target values/thresholds are visible. The thresholds can be adjusted at the discretion of the therapist by pressing the 'grey bullet' buttons next to the threshold. Making changes that are fitting for the clinical purposes of the exercise. The y-axis shows the measured voltage in microvolt. Below the bar graph it is possible to show a downsized line graph.


When the 'bar graph' becomes too small or too large in the screen, you can adapt the display by pressing the 'plus' or 'minus' button.





Parameters

sEMG Parameters

Channel #1  

High target: 125% 


Automatically change high target  


High target: The high target can be made visible for some exercise types to get direct insight in the performance of an activity. The therapist can adjust this value.

Low target: For some exercises it is possible to show the low target on the screen to help a patient train between two target levels.

Automatically change high target: For the bar graph and the trace display it is possible to let the system automatically change the high target value. If the patient reaches the high target multiple times, the high target will be adjusted to a higher level. It is also possible that the therapist changes the high target manually during the exercise.

Exercise parameters

A sound is played when a repetition is marked 

Last peak is displayed on bar 

Last peak is displayed on bar: For most exercise types it is possible to show a shadow of the maximum result (peak value in μV). When the measured output drops after the swallow, this result remains visible for the patient and the therapist. This can be used as a reference for the next swallow. This option is not available for typical swallow because this exercise type does not use cues.

VISUALISATIONS IN DETAIL - TRACE DISPLAY

Trace display

Objective: The line graph can be used to provide the client and therapist insight into the possible differences between motor activities, such as compensation behaviour of the tongue and the motor activity of a swallow. Another objective is to entice a large number of swallowing repetitions during a treatment.

Indication: When increasing strength and extending the number of repetitions is necessary. The line graph is also suitable to make use of auditive cues to provide insight into muscle activity during intention and rest.

Contraindication:

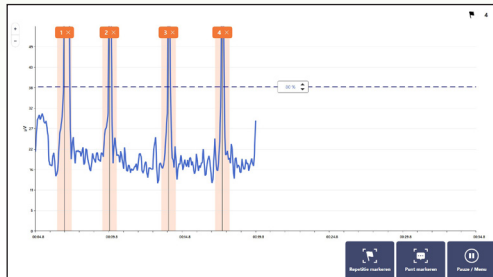
- When dealing with visual and/or cognitive limitations, as a result of which the client does not understand the display.
- When the client is insufficiently able to see the screen.

Description: In this visualisation, the muscle activity is displayed in the form of a line. Cues, targets or other visual characteristics are not used. This will provide the therapist with insight into the signals that fit specific motor behaviour of the client. This visualisation can be used to discuss (unwanted) motor behaviour, such as compensation behaviour, with the client. The client learns what this looks like on the screen and can try to adapt this where necessary and reduce compensation behaviour.

Visualisation: Muscle activity is represented by a blue or red line in the centre of the screen. If muscle activity takes place, this will be visible through vertical movement of the line. The y-axis shows the measured voltage in microvolt. The x-axis shows the time.

Two target values/thresholds can be made visible. These can be adapted by the therapist during the exercise or in the detailed menu.

The activated sensor (Channel #1 or Channel #2) determines whether the signal is displayed as a red or blue line. When the signal becomes too large or too small in the screen, you can adapt the display by pressing the 'plus' or 'minus' button.



Parameters

EMG Parameters

Channel #1



High target: 80%



Low target: 40% (hidden)



High target: The high target can be made visible for some exercise types to get direct insight in the performance of an activity. The therapist can adjust this value.

Low target: For some exercises it is possible to show the low target on the screen to help a patient train between two target levels.

Automatically change high target: For the bar graph and the trace display it is possible to let the system automatically change the high target value. If the patient reaches the high target multiple times, the high target will be adjusted to a higher level. It is also possible that the therapist changes the high target manually during the exercise.

Exercise parameters

A sound is played when a repetition is marked



A sound is played when a repetition is marked: You can indicate whether a sound should be played when a repetition is marked. When repetitions are counted automatically a sound will be played when the peak value exceeds the high target. When repetitions are counted manually, a sound will be played when you mark a repetition.

VISUALISATIONS IN DETAIL - WORK-REST CYCLE

Work-Rest Cycle

Objective:

- More control of the swallow initiation by consciously timing the swallow initiation on the basis of visualisation.
- Reduction of preparatory/compensation behaviour prior to swallowing.

Indication: When the client finds it difficult to initiate the swallow consciously; in case of compensation behaviour prior to the swallow initiation.

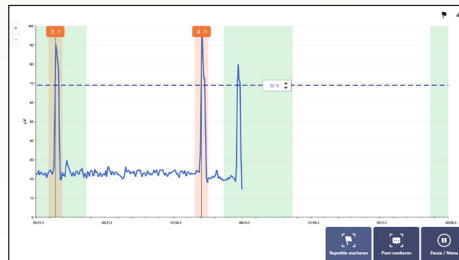
Contraindication:

- If the client is not yet able to make at least 25 swallow movements without signals of tiredness or signs of aspiration when swallowing a safe consistency.
- When dealing with visual and/or cognitive limitations, as a result of which the client does not understand the animation.
- When the client is insufficiently able to see the screen.

Description: This visualisation is very similar to the line graph, but has been extended with visible and adjustable work and rest periods. These periods create visual cues for the client to perform a required activity at a certain moment. As the client is able to see exactly when the swallow must be initiated, the client is able to prepare himself physically and mentally. By adapting the work and rest period, the exercise can be made more difficult or easier. The work periods can be used as a time period in which a required muscle activity takes place; alternatively, the client can be instructed to retain the activity as long as the work period takes (see Mendelsohn). This visualisation can be used for different exercises. In addition to required motor behaviour, unwanted motor activity is also made visible, such as preparatory 'compensation behaviour' by the tongue.

As this is also visible, recognition will occur, through which an attempt can be made to reduce this behaviour.

Visualisation: The activity of the client is represented in the same way as in the line graph. During the work-rest cycle, the rest period is displayed with a white background and the work period with a green background. The set threshold values are displayed by a dotted line.



The activated sensor (Channel #1 or Channel #2) determines whether the signal is displayed as a red or blue line.

When the signal becomes too large or too small in the screen, you can adapt the display by pressing the 'plus' or 'minus' button.

Parameters

sEMG Parameters

Channel #1



High target: 80%



Low target: 40% (hidden)



High target: The high target can be made visible for some exercise types to get direct insight in the performance of an activity. The therapist can adjust this value.

Low target: For some exercises it is possible to show the low target on the screen to help a patient train between two target levels.

Exercise parameters

A sound is played when a repetition is marked



Rest duration 10 seconds



Work duration 5 seconds



Work duration: The time period during which swallowing should take place to get a positive reward can be set longer or shorter by setting the duration of this period. During the exercise, the 'work duration' will be visible as a green block. The longer the work time, the wider the green block.

Rest duration: The rest duration is the time that the patient has before the next swallow must be initiated. During the rest duration the patient can prepare himself for the next swallow.

VISUALISATIONS IN DETAIL- BOW AND ARROW

Bow and arrow

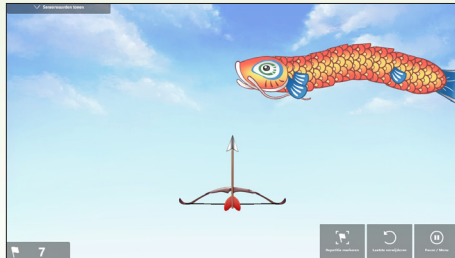
Objective: increased control of the swallow initiation by consciously timing the swallow initiation by means of a visual cue and reduction of preparatory compensation behaviour prior to swallowing.

Indication: When the client finds it difficult to initiate the swallow consciously; in case of compensation behaviour prior to the swallow initiation.

Contraindication:

- If the client is not yet able to make at least 25 swallow movements without signals of tiredness or signs of aspiration when swallowing a safe consistency.
- When dealing with visual and/or cognitive limitations, as a result of which the client does not understand the display.
- When the client is insufficiently able to see the screen.

Description: This visualisation as a game provides the client with a visual cue, on the basis of which the swallow initiation must be timed adequately. This visualisation specifically aims to improve the timing of the swallow initiation. It is possible to set many parameters in the detailed menu, in order to make the exercise more difficult or easier (see parameters).



Visualisation: The client is represented by a bow, visible in the centre of the screen. When the client performs a required motor activity (swallowing), the arrow will be shot. In the top of the screen, 'figures' (or balloons; adjustable parameter) float towards and over the bow. If the visual targets are hit, a visual reward will take place. The visual targets disappear from the screen and you wait for the next visual cue.

Score screen Games with a break will show an intermediate ranking screen during this break. The intermediate ranking screen also shows how many repetitions have occurred. When this is set, the amount of remaining time before the exercise is finished is also shown here.

When closing the exercises, a summary of the results achieved will be visible that is based on the selected visualisation. This summary will show a 'score'. This score is coupled to the quality by means of which the intended objective of the exercise was achieved. For example, the better the client is able to time the swallow, the more points he earns in a certain time frame.



Parameters

Exercise parameters

- 1 10 seconds between cue and required swallow ————— +
- 2 Targets enter on the right and move left → ← ↔
- 3 Patient has between 10 and 12 seconds to complete swallow
- 4 Patient has to swallow at the correct time to be rewarded
- 5 Rest period between swallows is 15 to 20 seconds
- 6 Targets are paper animals

- 1 **Speed of the visual cue:** The target is able to move faster or slower through the screen.
- 2 **Direction of the cue:** The direction of movement of the visual cue can be adjusted to take into account possible visual limitations or to make the exercise more dynamic and more difficult.
- 3 **Work time:** The time period during which swallowing should take place in order to achieve a positive reward can be made dynamic or static or made longer or shorter by placing the two sliders on different positions on the bar indicating the time.
- 4 **Rewards:** The reward takes place at each swallow initiation, or when the swallow is perfectly timed in relation to the visual cue.
- 5 **Rest time:** The rest time can be made static (always the same time) or dynamic with a min. and max. time. The computer will randomly select a rest time from the set values.
- 6 **Normal or simplified graphics:** In order to avoid over-excitement or distraction, a simplified display of the visualisation is available.

VISUALISATIONS IN DETAIL - KANGAROO

Kangaroo

Objective: increased control of the swallow initiation by consciously timing the swallow initiation by means of a visual cue and reduction of preparatory compensation behaviour prior to swallowing. Improving the coordination of muscles involved with swallowing, particularly developing the ability to retain the pharynx wall contraction after the swallowing reflex has extinguished. It is possible to perform the Mendelsohn maneuver with this game.

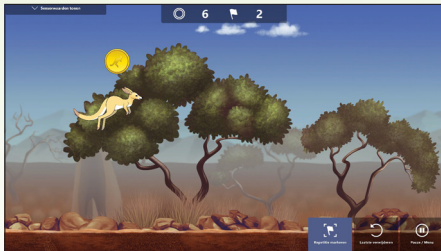
The kangaroo game can also be used to induce repetitions in a relatively easy way.

Indication: The kangaroo game is indicated for all objectives that can be worked on using the Rephagia.

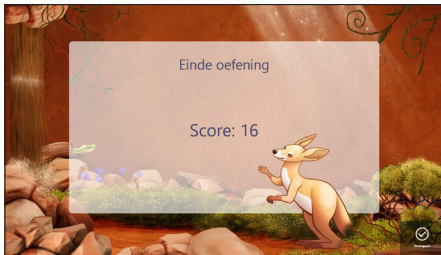
Contraindication:

- When dealing with visual and/or cognitive limitations, as a result of which the client does not understand the display.
- When the client is insufficiently able to see the screen.

Description: This visualisation as a game provides the client with a visual cue, on the basis of which the swallow initiation must be timed or retained/coordinated adequately.



Visualisation: The client is represented by a Kangaroo (left in the picture). When the client performs a required motor activity, the kangaroo will jump. At the top of the screen you can see floating coins. Depending on the selected 'exercise', one, three or a range of coins are displayed. The respective objective is to time the initiation of the motor activity in such a way that the coins are collected by the kangaroo and/or the activity is retained, so that the kangaroo continues to float and collects a range of coins. Once the kangaroo lands again, the coins will disappear and the kangaroo will continue until the next cue appears.



When closing the exercises, a summary of the results achieved will be visible that is based on the selected visualisation. This summary will show a 'score'. This score is coupled to the quality by means of which the intended objective of the exercise was achieved. For example, the better the client is able to time the swallow, the more coins he earns in a certain time frame.

Parameters

sEMG Parameters

Channel #1

High target: 80%

Low target: 40%

High target: The high target determines at what percentage of the calibrated value the kangaroo jumps. It depends on the exercise type whether this is above (effortful swallow) or below the calibrated value.

Low target: The low target is used for the Mendelsohn maneuver and oral exercises. The kangaroo returns to the ground when the signal becomes lower than the low target after a motoric activity.

Exercise parameters

Work duration 5 seconds

Rest duration 10 seconds

Active time: The time period during which swallowing should take place to get a positive reward can be set longer or shorter by setting the duration of this period. During the exercise, the 'Active time' will be visible as a row of subsequent coins. The longer the work time, the more coins must be collected.

Rest time: The rest time is the time that the client has before the next swallow must be initiated. During the rest time the client can prepare himself for the next swallow.

VISUALISATIONS IN DETAIL - DIVER

Diver

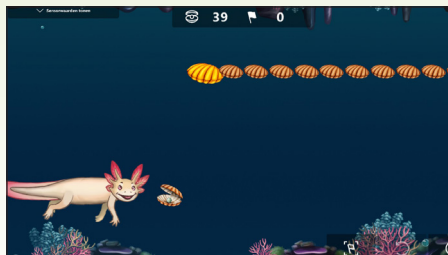
Objective: Increased strength and mobility of different facial muscles and tongue muscles.

Indication: The Diver game is indicated for clients with problems in the preparatory oral phase of swallowing. Particularly reduced mobility and strength:

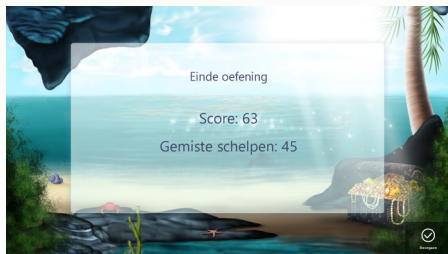
Contraindication:

- Clients with progressive neurological or muscular diseases, whereby strength training will be counter productive.
- When dealing with visual and/or cognitive limitations, as a result of which the client does not understand the display.
- When the client is insufficiently able to see the screen.

Description: This visualisation can be used to train strength and mobility of the tongue muscle, for example. Clients showing an increased tone or a lot of compensation behaviour can try to actively acquire rest in specifically measured muscles and to activate these muscles in a controlled manner on the basis of a visual cue.



Visualisation: The patient is represented as a swimming creature that is moving vertically when the muscle activity increases or decreases. There are shells coming towards the patient that can be collected by reinforcing or weakening the intensity of the motor activity in such a way that the creature continuously swims at the correct height. The collected shells are counted and displayed in the score screen.



Parameters

Exercise parameters

Swim speed of diver: 1

Pearls are placed in a work-rest cycle pattern

Rest period: 10 seconds

Work period: 10 seconds

Swim speed of diver: The speed by means of which the diver moves. As a result, it seems that the game is going faster, making it more difficult for the patient.

Shell pattern: During the game, the shells can be displayed in a static/predictable or more dynamic pattern. It is also possible to display the shells in a dynamic (unpredictable) pattern during the exercise.

Rest period: The rest time is the time during which the client must relax. When the motor activity remains minimal, the diver continues to swim near the bottom.

Work period: The time period during which the motor activity must be retained in order to achieve a positive reward. This time can be made longer or shorter.




PARAMETERS



Overview parameters returning for every visualisation



All parameters have a default value for every visualisation. If needed the therapist can adjust these to every patient. After selecting an exercise and visualisation, via the button 'Edit parameters' adjustments can be made in the sensor values (sEMG parameters), in ending the exercise (Timing) and some visualisation specific parameters. This section contains an overview of the parameters that are available for every visualisation.

sEMG parameters:

sEMG Parameters

Channel #1   

High target: 80% -  + 




Low target: 40% (hidden) -  + 



Here you choose the sensor that you wish to use. The values measured by this sensor are used during the exercise. When both sensors are selected this is shown as 'both channels'. It depends on the exercise and visualisation whether one or both sensors should be used.

The system records a 'swallow', when the signal/peak value of motor activity is greater than 80% of the set peak value. The games will respond on the basis of these values and accompanying threshold, and the activity is rewarded or not. For the therapist it is important that he sets the threshold correctly and assesses which motor behaviour could possibly cause 'noise'. Always set the upper threshold in such a way that only a 'swallow initiation' exceeds the threshold. You could think of motor behaviour like chewing, talking, coughing, tongue pressing, etc. If the upper threshold is set correctly, the client is also prevented from deploying compensation behaviour in order to have a positive effect on the game.

Timing:

Timing

Therapist decides when to stop   

Therapist has to count repetitions with the mouse  

End the exercise:

You can indicate when to end the exercise. There are multiple options:

- The exercise is ended manually: you decide when to stop the exercise
- The exercise is ended automatically: before starting the exercise you can indicate a timing of the exercise or the number of repetitions that should be performed

Repetition count:

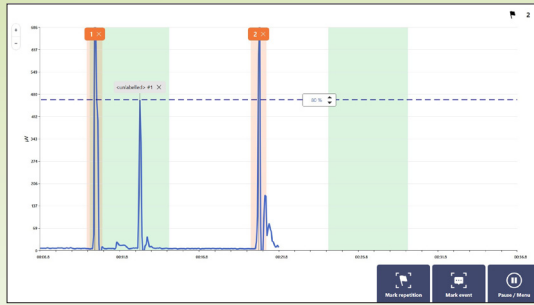
You can indicate how the repetitions should be counted during the exercise:

- Manually: you indicate each repetition with a mouseclick
- Automatically: Every signal that exceeds the high threshold is automatically registered as a repetition/swallow. This setting only works well when there is not much noise in the signal.

Exercise parameters:

Visualisation specific parameters are further explained at the concerning visualisation.

MARKERS



The Rephagia is able to record and analyse the results of an assessment or training session. Markers will have to be placed for this purpose. The marker indicates what the client was doing at a certain moment, so that the data can be interpreted correctly.

The therapist is able to place the markers at two moments:

1. During an assessment, calibration or exercise. This can be entered by the therapist by means of the mouse.
2. After termination of an assessment, calibration or exercise.

Markers can also be placed automatically by the system, you can choose this option in the Edit parameters section (see page 26). This is only possible during exercises, and not during a calibration or assessment. The automatic detection will only work if there is little noise in the signal; which means that the client is making few compensatory movements and that the swallow movement provides a clear signal in relation to other motor behaviour.

There are two types of markers:

1. An event marker indicates a particular moment. Examples are: peak marker, repetition marker (except in the case of the Mendelsohn and certain oral exercises), cough, laugh, etc.
2. A period marker. This marker has a start and end point. Period markers are used during calibration in order to mark the rest value. In the case of the Mendelsohn maneuver and certain oral exercises where the duration of the contraction is important, they will mark the repetition.

Add marker ▾

- Add repetition marker
- Add event marker
- Add period marker
- Add print zone

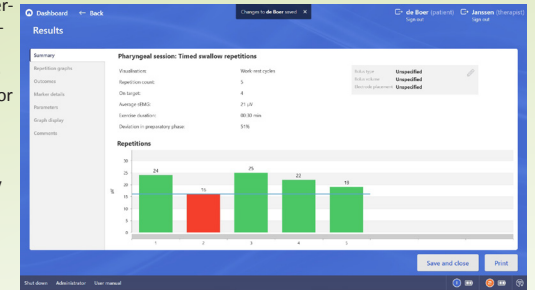
In all cases, the therapist will be able to adjust the markers after the session in the “Graph” tab of the result overview.

By default, each marker will get a label. The therapist is able to change this by selecting a label from the drop-down menu or by typing in a new name. Caution: each label is analysed separately by the system. Only if the ‘Mark repetition’ button is used for marking a swallow, will it be automatically displayed in the result overview as clinical outcome measures.

RESULTS (1 of 2)

Overview of results

A number of basic results are visible after closing an exercise, which are based on added ‘event’ or ‘period’ markers. These are visible under the ‘Graph per repetition’, ‘Data per marker’ and ‘Parameters’ tabs. The ‘Complete Graph’ tab is available to add markers after an exercise or to adapt markers that were made during the exercise.



Clinical outcome measures

The Rephagia can provide information about the quality of the swallowing function. For this, it is necessary that repetitions are marked as such.

A distinction is made between outcome measures that are fitting for the respective courses of treatment

‘Typical swallow’ (swallowing frequency), ‘Effortful swallow’ (power during a swallow), ‘Timing’ (control of the swallow initiation), ‘Mendelsohn’ (coordination) and exercises aimed at the tongue, lips and jaws. After each exercise, the outcome measures are shown in the summary of the exercise. These outcome measures are also summarised on the client dashboard. Here, it will be possible to view the development over time of the client’s swallow function.

Below you will find an explanation of the outcome measures that are fitting for the courses of treatment.

Repetitions

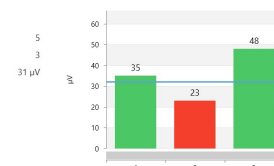
Total: You will be given an overview of all marked swallow movements. These are displayed in a bar graph, with the measured peak value.

Repetitions above target: he bar has a green colour when the strength reaches above the 80% threshold of the measured peak value during the calibration. If the strength reduces and the peak value is below the 80% threshold, the bar will be coloured red. In this way you can immediately see how many repetitions were performed during an exercise and whether the strength decreases (tiredness increases) during the exercise. For a ‘Typical swallow’ exercise all bars are orange because no target values are used.

Average peak sEMG: the system calculates the average value of all marked repetitions.

Repetitions

Total: 5
 Repetitions above target: 3
 Average peak sEMG: 31 µV

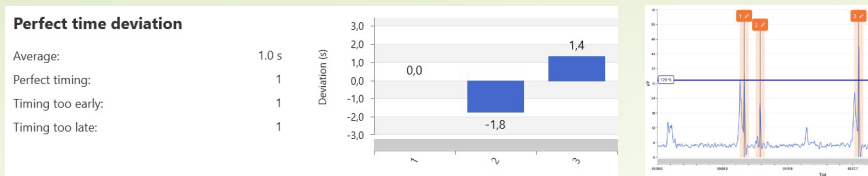


RESULTS (2 of 2)

Timing (control of the swallow initiation)

In the 'Timing' course of treatment, the Rephagia provides extra information concerning control of the swallow initiation.

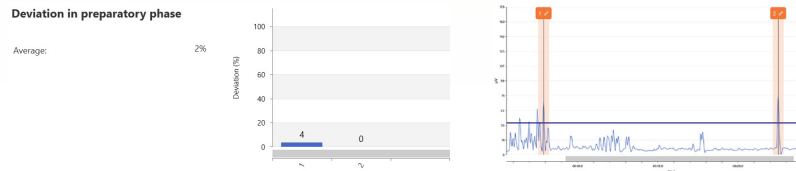
On the basis of the visual cue in the exercise, the swallow can be initiated too soon or too late respectively. By adding a marker during a swallow, the 'timing' of the swallow in relation to a visual cue will be measured, whereby an average is measured and displayed under the 'Outcome measures' tab. When control of the swallow initiation increases, the 'timing' will improve. The Rephagia shows information on average timing, perfect timing, timing too early and timing too late.



Deviation in preparatory phase

When a swallow is marked, the Rephagia also measures the motor muscle activity that precedes swallowing. This motor muscle activity is considered compensation behaviour or a motor activity to initiate the swallow. In the case of a 'healthy' person this will be absent, as the swallow can be initiated at command with no preparation. When a client has a reduced control of the swallow initiation, it is highly likely that preparatory motor behaviour is present when swallowing on the basis of a visual cue. Compensatory movements prior to swallowing will often be coupled to a delayed initiation.

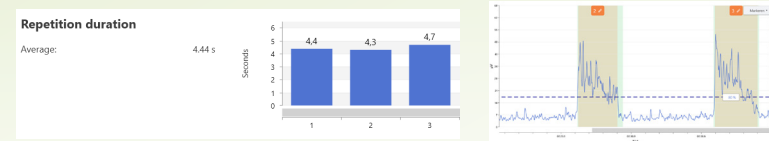
The amount of motoric muscle activity prior to the swallow initiation will be converted into a percentage and shown in a bar graph. A higher percentage relates to more compensation behaviour. This number will decrease during the course of the treatment, when the patient gains more control over the swallow initiation. The percentage does not provide information about the quality of the swallow. It is a measurement to display the amount of motor behaviour prior to the swallow. It helps the therapist to compare the patient with himself during the course of the treatment.



Repetition duration

The repetition duration is shown for oral exercises and the Mendelsohn maneuver. In the case of the Mendelsohn it shows the time (in seconds) in which the patient is able to retain the muscle contraction after swallowing in a coordinated way. The duration shows information about the quality of the coordination. This 'repetition duration' is shown in a bar graph.

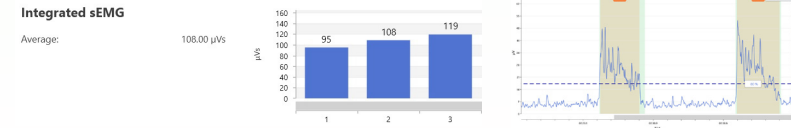
It is important that the therapist marks a valid Mendelsohn maneuver. The therapist should measure the amplitude from the moment that the 80% target is exceeded until the moment that the signal drops below the 40% target. When the amplitude drops below the 40% target and then increases there is still motoric muscle activity. However, this cannot be counted as a Mendelsohn maneuver which improves the general coordination of the swallow initiation.



Integrated sEMG

Integrated sEMG is shown for oral exercises and the Mendelsohn maneuver. This graph shows the surface under the signal during the swallow. This does not only provide a picture of the duration of the coordinated contraction, but also of the strength. The longer and more forceful the contraction is retained, the larger the surface under the signal, and the more effort is provided by the client. This outcome measure is displayed in a graph with a number. When the contraction is more powerful, the effort will increase. In this way, progress is clearly made visible.

The number by means of which the effort is displayed says nothing about the quality of the swallow. It is a measure by means of which the client during the course of the treatment can be compared with himself in order to record progress over time.



ADMINISTRATOR

The administrator page

Administrator

With this button you open the administrator page. To see the page you must sign in with the administrator ID and password.

The screenshot shows the Administrator page with a blue header containing 'Dashboard', 'Back', and user information for 'de Boer (patient)' and 'Janssen (therapist)'. The main content area has four management options, each with a callout box:

- Manage patients:** Edit patient information or delete patient record. Callout: "Here you can adjust the basic data of a patient or delete a patient from the system."
- Change administrator password:** Manage administrator password. Callout: "Here you can change the password of the administrator account"
- Manage therapists:** Add new therapists, change therapist passwords or archive therapists. Callout: "Here you can add a new therapist, (de)activate a therapist or change a password."
- Manage bolus consistencies:** Edit labels or availability of boluses. Callout: "Here you can adjust the names of the bolus types. More information can be found on page 29."

A 'Done' button is located at the bottom right of the main content area, with a callout: "Save the changes and return to the last opened page."

Manage patients

The system shows a list of all patients that are registered in the system. You can use the search bar to find the patient more quickly. The order of the list can be changed by clicking the headers of the list:

- Patient ID: the list will sorted alphabetically
- Last session: the list will be sorted on the most recent sessions
- Last treated by: the list will be sorted by therapist
- Status: the list will be sorted by treatment status (*on caseload* or *discharged*)

After selecting a patient you can choose in the menu on the right what you wish to do. You can change a patients basic data (patient ID, birth year, gender) or delete the patient from the system.

The screenshot shows the 'Manage patients' page with a search bar and a table of patients. The table has columns for Patient ID, Last session, Last treated by, and Status. Action buttons for 'Edit patient information' and 'Delete patient' are on the right.

Patient ID	Last session	Last treated by	Status
0001	3 months ago	1234	Discharged
0002	one month ago	1234	On caseload
0003	one month ago	1234	On caseload
0004	3 months ago	1234	On caseload
0005	3 months ago	1234	On caseload
0007	3 months ago	1234	On caseload
0008	3 months ago	1234	On caseload
Bakker	11 days ago	Janssen	On caseload
Blase	one month ago	1234	On caseload
de Boer	53 minutes ago	Janssen	On caseload
de Wit	54 minutes ago	Janssen	On caseload
Jansen	2 months ago	1234	On caseload

Manage therapists

The system shows a list of all therapists that are registered in the system. You can use the search bar to find the therapist more quickly. The order of the list can be changed by clicking the headers of the list:

- Therapist ID: the list will sorted alphabetically
- Active: the list will be sorted on active/non-active

After selecting a therapist you can choose in the menu on the right what you wish to do. You can add a new therapist, change the password of the therapist or (de)activate a therapist.

SOLVING CLINICAL PROBLEMS

Examples of possible problems:

- If the patient consistently only initiates the swallow when the work period has passed, the work period can be extended by adapting it in the parameters.
- When chewing results in a signal that is consistently above the 80% threshold of the peak value of a swallow reflex, the visualisation can be temporarily interrupted during chewing by pausing.
- If unwanted motor behaviour results in a situation where the signal consistently reaches above the 80% threshold of the peak value of a swallow reflex, the threshold or peak value can be adjusted in the parameters of the exercise, in order to avoid that this activity is rewarded positively during the exercise.
- If there is a lot of sunlight, you must use sunshades or curtains.
- If the patient is in bed, you should position the client in such a way in the bed, by adjusting the back rest, that the client is straight in front of the screen.
- Ensure the patient is sitting properly straight before starting the exercise.

How can you help the patient?

During the exercise the client can be verbally stimulated as soon as the visual cue appears; or when the moment nears at which the swallow must be initiated. The patient can be supported more intensively by counting down or by motivating verbally, when the strength must be retained after swallowing.

During functional exercising with different consistencies, the therapist is able to support the patient by offering a measured amount of the consistency to be practised. When explaining an exercise, it will be practical to sit next to a patient, so that the therapist is also able to see the screen. When the exercise starts, the therapist can explain what is happening on the screen and what is expected from the patient.

MANAGE BOLUS CONSISTENCIES

Level	Bolus type	Custom label	Available	In graph (%)
0	Saliva	Custom label 1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
1	Thin	Custom label 2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2	No-Steps	Custom label 3	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3	Sticky		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4	Honey		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5	Pudding		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6	Puree		<input checked="" type="checkbox"/>	<input type="checkbox"/>
7	Mechanical soft		<input checked="" type="checkbox"/>	<input type="checkbox"/>
8	Mixed		<input checked="" type="checkbox"/>	<input type="checkbox"/>
9	Regular		<input checked="" type="checkbox"/>	<input type="checkbox"/>

Manage bolus names:

The Rephagia uses a default list with bolus types you can select before starting a pharyngeal exercise. When your organization uses other bolus types, these names can be adjusted at the Administration page. Signing in with the administrator account is necessary.

Change bolus name:

To change a bolus name you can select the desired label and choose 'dja;dja;fj'. The adjusted name will appear in the column at the right of the default name. With the button 'delete label' you can delete the adjusted name. The first column shows the level of the label, these are sorted by the IDDSI-scale (more information on this scale can be found on www.iddsi.org). Make sure that the new label names are at the same level, this is also used to indicate the progress of the bolus types in the patient record.

Use less bolus types:

The column 'Available' indicates whether the label is used in the system. When your organization uses less bolus types than the 10 default labels, you can remove a label from the list in this column. These will not appear as a possible bolus type before starting an exercise.

Show in graph:

In the patient record, the progress in the used bolus types is shown in a graph. This graph has room for 5 bolus types, the other types will appear as 'Other' in the graph. In the column at the right you can indicate which 5 bolus types should be visible in the graph.

Save or restore:

Restore default values: with this button you can restore the list to the default values. All adjusted labels will disappear and the selections in the two columns on the right will be restored.

Undo changes: This button will put all values back to the last saved version

'Done': with this button you save the changes. You will return to the administrator page.

SOLVING TECHNICAL PROBLEMS

Where to begin?

Find the problem that you are confronted with in the table below. If your problem is not mentioned or if you do not succeed in solving it, please contact SilverFit.

Warning

The SilverFit Rephagia requires updates / service at least once per year. If this does not happen with the required frequency, SilverFit B.V. is unable to guarantee a correct functioning of the SilverFit Rephagia.

Never make adjustments to the hardware of SilverFit Rephagia yourself, except if it concerns actions described in this chapter. After this type of changes to the hardware, SilverFit B.V. is no longer able to guarantee the correct functioning of the SilverFit Rephagia.



Unable to switch on the computer

If you press the on/off button, a white led will light behind the button. You will also be able to hear a soft rustling noise from the internal fan.

If these things do not happen, check the following:

- is the plug properly attached to the power outlet?
- is the power strip on?
- has the power cable of the computer been connected correctly?

No display on the screen

Perhaps the screen is in standby mode. Press the on/off button of the laptop.

If no led lights on the screen, check the following:

- Is the plug properly connected to the power outlet and has the battery of the laptop been charged sufficiently?
- Is the power strip on?
- Has the power cable of the computer been connected correctly?

Unable to find the sensors

- The signal receiver must be connected to a USB port of the laptop before the computer is switched on. If this was not the case, you must restart the computer.
- When the sensors are moved over the magnet strip in the charging unit, the leds on the sensors should flash white. Then, the battery symbol at the top right of the screen should become green after a few seconds.

If the battery symbol does not turn green, please check the following:

- Is the signal receiver correctly connected to the USB port? If not, place it correctly and start the computer again.
- Has the sensor been charged properly? Swipe the sensor over the magnet strip of the charging unit. The led should flash white now. If not, place the sensor in the charging unit, connect it to the power supply and press the 'power button' at the back of the charging unit. The sensor shows a blue led and is being charged.

The baseline signal is chaotic

It is possible that the electrode is no longer properly attached to the skin, or perhaps the lead-wires have not been connected correctly.

If the signal shows a chaotic noise and does not provide a low baseline in case of a client in rest, check the following:

- Does the electrode properly connect to the skin?
- Have all three adhesion surfaces of the electrode been attached to the client's skin?
- Does the client have a beard, as a result of which the electrode is hanging freely from skin?
- Have the lead-wires been connected correctly to the metal bulbs of the electrode?
- Have the lead-wires been connected correctly to the sensor?

Sound is not working

Check the sound volume of the screen by pressing the volume buttons. If the volume is between halfway and full, but there is still no sound to be heard, try pressing the sound button on the mouse. Sometimes this button is pressed by accident and the sound is switched off.

SilverFit

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Carefully read this user manual
prior to using the device



MDD 93/42/EC