

PATIENT'S GUIDE

Software version: 2020.1



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INTENDED USE PRECAUTIONS

It has been stated repeatedly that active participation in rehabilitation programs increases the benefit and effectiveness of therapy. The use of repetitive and sometime boring tasks produces a significant reduction in patient motivation. To combine therapy with appealing games, then, is not only a matter of creating entertainment, but a real necessity for recovery.

FEATURES & FUNCTIONS

VAST.Rehab, an innovative video capture virtual reality system, offers functional therapy using movement and position recognition proprietary technology. The touch-free (without external accessories there is no danger of contamination spreading or sterilization need) motion-activated solutions for virtual reality rehabilitation are used by clinicians in all rehabilitation health professions. The system is suitable to be used to treat a wide variety of patients, with a full library of interactive tasks and activities that can be tailored for children or seniors. VAST.Rehab supports medical professionals in following functionalities: Evaluation, Treatment, Feedback, Documentation.



INTENDED USE PRECAUTIONS

EVALUATION

VAST.Rehab allows patients assessment, using a personally tailored appropriate configuration to the patient's ability, evaluation of results and development of treatment plans (e.g. evaluation tasks: Reach test, Angles evaluation, Stability test, Romberg's test, Unterberg's test, Dynamic test).

TREATMENT

VAST.Rehab uses a wide variety of therapeutic tasks to enable training in all rehabilitation domains:

MUSCULOSKELETAL

- Range of motion
- Strength
- Endurance
- Fitness and cardiovascular training

NEUROLOGICAL

- Movement quality (gross and fine motor skills)
- Movement awareness and proprioception
- Bilateral movements in response to bilateral stimulation

BALANCE AND EQUILIBRIUM

- Trunk and postural control
- Anticipatory postural responses
- Adequate reactions to stimuli and distractors placed in preplanned positions or random
- Crossing the midline



INTENDED USE PRECAUTIONS

FEEDBACK

The augmented Feedback in VAST.Rehab provides real-time functional feedback (knowledge of results and knowledge of performance) in a motivating game like environment. By monitoring movements, it guides the patient through exercises specifically designed for therapy. It encourages and motivates the patient to achieve a higher number of repetitions, which helps improving the compliance and the therapy outcome. The exercises are adjustable according to the patient's needs and progress, and therefore provide a challenging and effective therapy.

DOCUMENTATION

VAST.Rehab software captures the patient's training activity and progress providing relevant documentation about the therapy process and the patient's compliance. Furthermore, the stored documentation offers information such as training accuracy, duration and frequency. Allowing accurate monitoring of the patient's training progress, the VAST.Rehab documentation supports clinical decision making. The Therapist in charge has the sole responsibility for a rehabilitation treatment and decides whether a patient is fit for a specific treatment. In particular, the therapist must weigh in each individual case possible risks and side-effects of the treatment against the expected benefit. In addition, the patient's individual situation plays just as important a role as the basic risk assessment for specific patient groups. The person in charge of using the system is responsible to adapt the training sessions and the course of therapy to the patient's abilities. Being a scientific discipline, medicine and rehabilitation are subject to constant advances of knowledge and treatment principles. The therapist in charge must continually keep his knowledge up-to-date by reading the latest scientific literature and must monitor changes in use recommendations during the course of treatment.



VAST.Rehab is a medical device and must be used in strict adherence to this document and software manuals. Failure to do so may result in serious personal injury. It is strongly recommended to regularly check VAST.Rehab website for the latest available information. Please contact if you have any question.

VAST.Rehab is to be used only under the supervision of qualified medical personnel. However, VAST.Rehab can be in certain conditions marketed for home use and must be strictly used according to the recommendations of your medical care provider who is knowledgeable about your specific needs. Read this document and software manuals for appropriate product designation. Failure to obtain and follow the recommendations of your medical care provider may result in serious personal injury.

This document provides details about a medical product which may not be available in all countries and may not have received approval or market clearance by all governmental regulatory bodies throughout the world. Nothing herein should be construed as a solicitation or promotion of the product or of an indication of any specific use for the product which is not authorized by the laws and regulations of the country where the reader of this information resides.



VAST.Rehab purpose is to support functional therapy for patients who have lost the function of or have restricted function in their body or cognitive functions caused by cerebral, neurogenic, spinal, muscular or bone-related disorders. Considering the contraindications and every patient's individual profile, the device is used in the case of:

- Cerebrovascular Accidents
- Multiple Sclerosis
- Cerebral Palsy
- Parkinson's Disease and Extrapyramidal Syndromes
- Brain-tumor operations
- Spinal cord injuries
- Traumatic brain injury
- Muscular atrophy
- Deconditioning Muscle weakness due to lack of mobility
- Endoprosthesis for hip, knee, elbow and shoulder joints
- Following stable fractures of vertebra and/or extremities
- Limb amputations with or without prosthesis
- Balance and Equilibrium disturbances

Just as for any other therapy, the therapist in charge is always responsible for the indication. Functional training with VAST.Rehab is not possible or indicated in every case. In general, the device must not be used in the following cases to avoid causing harm to the patient. The following precautions must therefore be observed in particular:

- Severe osteoporosis
- Contractures affecting the relevant extremity
- Skin lesions in the area of the relevant extremity
- Joint subluxation or severe pain in the target joint
- Severe spasticity
- Severe spontaneous movements, e.g. ataxia, dyskinesia, myoclonic jerks
- Severe postural instability
- Cardiac arrhythmia, hypotension or severe hypertension
- Confused or non-cooperative patients
- Severe cognitive deficits
- Patients requiring isolation due to infections
- Severe visual problems (patient is not able to see displayed elements on the computer screen)



The following contraindications must therefore be observed in particular:

- Not controlled epileptic seizure within the past two years, or photosensitive patients
- Retinal disease which may be exasperated by watching video games
- Bone instability (non-consolidated fractures in vertebrae or extremities)
- Osteomyelitis or other inflammatory/infectious diseases
- Bone Cancer, including spinal tumors or metastases to vertebrae or joints
- Pronounced, fixed contractures affecting the relevant extremity
- Open skin lesions in the area of the relevant extremity
- Non-stable vital functions: Pulmonary or cardio-circulatory contraindications
- Spondylolisthesis (second degree or higher) or with neurological signs



The above list does not claim to be exhaustive. In case of patients with chronic diseases and/or patients with illnesses coexisting with the one in which therapy VAST.Rehab's support is used and/or patients who have been immobile for a long period of time, special attention is required and short training sessions are recommended to begin with. An over-reaction is expected from these patients if training sessions are too long. On the other hand, patients often tend to have a certain euphoric reaction after the initial treatment, and want to have longer and/or more frequent training sessions. This can result, in the case of the patients described above, in excessive strain being exerted on ligaments, tendons and joints.

The decision as to whether a patient is suitable for treatment always comes under the remit of the therapist in charge, who has sole medical responsibility for the treatment. As part of this, he must evaluate in particular, in each individual case, possible risks and side-effects of the treatment against the benefit gained from it. In addition, the patient's individual situation plays just as important a role as the basic risk assessment for specific patient groups.





INFORMATION CLAUSE FOR VAST.REHAB PRECAUTIONS

According to art. 13 section 1 and 2 of the General Data Protection Regulation dated on 27 April 2016, we inform you that:

- The administrator of your personal data is BRONTES PROCESSING Sp. z o.o. Ul. Przewozowa 32, 44-100 Gliwice, Poland.
- Your personal data is processed for the purpose of establishing an online account in the VAST.Rehab software platform and for statistical purposes. The processing takes place on the basis of Article 6 (1b) and (1c) and article 9 (1h) of the GDPR.
- The recipient of your personal data will be the entities authorized by the controller of the personal data, entities authorized by law and external entities under signed contracts.
- Your personal data will be kept for a period consistent with applicable law.
- You have the right to access your personal data and the right to rectify, delete, limit processing, the right to data transfer, the right to object, the right to withdraw consent at any time without affecting the legality of processing, which was made on the basis of consent before its withdrawal.
- You have the right to lodge a complaint with the supervisory body when you feel that the processing of personal data concerning you violates the provisions of the General Data Protection Regulation of 27 April 2016.
- Providing personal data is a prerequisite for the purpose of processing. If you do not provide your personal information, it will not be possible to process it.
- Your personal data will not be subject to automated decision making or profiling.



WHAT IS THE PATIENT PANEL USED FOR? INTRODUCTION

VAST.Rehab Patient Panel is the gamified part of the system. It is designed to keep the patient engaged while performing the exercises. Usually, the patient learns to use VAST.Rehab while working one to one with the therapist, and at the later stage, he will be able to perform preplanned sessions by himself without his therapist's supervision (e.g. at home). Each of the therapeutic tasks offers lots of configuration options. That's why - while exercising - the patient always has a small picture presenting the movement pattern that he is expected to perform in the currently running task.



HOW DO I INSTALL THE PATIENT PANEL?

All our applications are available in Microsoft Store. You can simply search for "VAST.Rehab" and the list of available apps will be displayed. You can also paste the following URL to your web browser:

https://www.microsoft.com/store/apps/9N9MV3R0RMFF



HARDWARE REQUIREMENTS

WHAT IS NEEDED?

Necessary hardware depends on the VAST.Rehab modules assigned to the considered Patient Station. Some modules require stronger PC and some will work even on tablet powered by Android or on an iPad. For specific hardware requirements you need to check documentation for the modules/devices you are going to buy.



HOW TO EXERCISE? SCENARIOS FOR PATIENT

Therapy with VAST.Rehab requires physical activity to interact with elements in virtual world presented on your screen. When Workout is started you will see elements presented below.



- 1) Movement pattern you are expected to perform
- $(\mathbf{2})$ Instruction for currently running Therapeutic Task
- 3) Outer circle presents time left in the Workout
- $(\mathbf{4})$ Inner circle presents time left in the current Therapeutic Task
- 5 Number of points collected



SIGN IN MANUALLY SCENARIOS FOR PATIENT

You need to have your login and password in order to use Patient Panel. You shall receive them from your therapist.

Please log in Use your login and password	VAST. Rehab REHABILITATION IN VIRTUAL REALITY	¢ ×
Active to: 2020-12-31		2
Anonymous Create Mode account		Sign in using Sign in face recognition

1 Provide your login and	l password
(2) Click to proceed	



SIGN IN MANUALLY SCENARIOS FOR PATIENT

When authorized you'll see Patient Panel's main menu screen. It is described below.



- (1) Timeline of Workouts scheduled in your calendar
- 2) Click to start Workout scheduled for today
- 3) Click to generate a Workout without Therapist Panel



MANUALLY START WORKOUT PREPARED BY YOUR THERAPIST

SCENARIOS FOR PATIENT

When your therapist assigns you a Workout that can be started today - you can start it manually as described below.



(1) Click to start Workout scheduled for today



MANUALLY START WORKOUT PREPARED BY YOUR THERAPIST

SCENARIOS FOR PATIENT

Here you can see list of Therapeutic Task your Workout contains

Workout details Following therapeutic tasks are inclu	ded	John Green 🔅 🗙
Name Quick Start Duration 15 min Preview Os V	Airplane Vampires	Insects
		Start

Duration of big instructions before each Therapeutic Task
 Click to proceed



MANUALLY START WORKOUT PREPARED BY YOUR THERAPIST

SCENARIOS FOR PATIENT



(1) Click to proceed



EDIT YOUR PERSONAL DATA SCENARIOS FOR PATIENT

If you need to update your personal data (e.g. your name) you can do it manually as described below.



20

(1) Click to navigate



EDIT YOUR PERSONAL DATA SCENARIOS FOR PATIENT

Modify data in the form below.

ъ	Edit account	data				φ×
name	First name *	John	External Id			
'n	Last name *	Green	External Id 2			
	Password change reminder		Country	Poland	~	
	Language *	English 🗸				
	Gender *	Male 🗸				
	Birth date *	1950-01-01 🗸				
	Height *	171 cm				
	Weight *	70 kg				
	Phone					
	E-mail					
						Apply

(1) Click to proceed



WRITE MESSAGE TO YOUR THERAPIST SCENARIOS FOR PATIENT

If you need to contact your therapist (e.g. to ask some questions) you can do it as described below.



(1) Click to navigate



WRITE MESSAGE TO YOUR THERAPIST SCENARIOS FOR PATIENT

Type your message in the form below.

Messages	1	2	John Green 🔅 🗙
Unna		MM	~
No messages		Enter message text	
			3
Refresh			Send

- 1 History of your communication
- 2) Select institution you want send the message to
- $\mathbf{3}$ Click to proceed



When an institution (e.g. hospital) decides to use VAST.Rehab it must decide how many Patient Stations (computers running Patient Panel) they need. Each Patient Station has then unique identifier and can have different modules assigned to it. Activation means assigning a specific Patient Station identifier to the computer.









(1) Click to proceed



Provide your VAST.Rehab Administrator account credentials to initialize activation.

Please login as administrator Welcome to VAST.Rehab Automatic network discovery	Admin login:
Internet Server Local Server	
	Sign in

1 The default option is 'Internet Server'. In case your computers can't be connected to the Internet you will need to choose 'Local Server'. When 'Local Server' is used you'll need to install additional software called 'VAST.Rehab Local Server' which needs a special USB dongle to work.

2 Click to proceed



Below you can see all the Patient Stations that are available on your VAST.Rehab Administrator account. Each Patient Station displays list of modules that are assigned to it.



- 1) Select Patient Station you want to activate
- 2) Choose name for this Patient Stations when listed in your Therapist Panel
- 3 Click to proceed



CREATE NEW PATIENT SCENARIOS FOR THERAPIST

Although you are normally expected to use Therapist Panel for managing patients database - you can create patient's account directly in Patient Panel.

Please log in Use your login and password	*	×
	Login: Password:	
Active to: 2020-12-31 Careate Mode account	Sign in using face recognition	





CREATE NEW PATIENT SCENARIOS FOR THERAPIST

Fill the form

p	Create accou	unt					¢ ×
name	First name *				External Id		
Ъ	Last name *				External Id 2		
	Login *				Country	Poland 🗸	
	Password *				Legal information	User has been familiarized with	
	Password confirmation *					Show legal documents	
	Password change reminder					Send in an e-mail	
	Language *	English		~			
	Gender *	Male		~			
	Birth date *	1950-01-0	1 ~				
	Height *	170	cm				
	Weight *	70	kg				(1)
	Phone						
	E-mail						
							\sim
							\checkmark
							Create

(1) Click to proceed



GENERATE A QUICK WORKOUT FOR PATIENT 1/4 SCENARIOS FOR THERAPIST

Although you are normally expected to use Therapist Panel to build Workouts for your patients - you can generate a Workout directly in Patient Panel as described below.

Start screen Welcome on board		1 ^{oh)} Green	ά×
Today Workout 15 Workout Workout 15 + min	start workout Start scheduled workout		MESS
Tomorrow (Workout 15 + min		Not active	REPC

(1) Click to generate a Workout without Therapist Panel



GENERATE A QUICK WORKOUT FOR PATIENT 2/4 SCENARIOS FOR THERAPIST

Adjust settings according to your needs.



- **1**) Select device
- 2) Filter control modes (standing and/or sitting)
- **3** Select physical difficulty
- $\mathbf{4}$) Select cognitive difficulty
- 5) Set workout's duration
- $\overline{\mathbf{6}}$ Set duration for each therapeutic task



GENERATE A QUICK WORKOUT FOR PATIENT 3/4 SCENARIOS FOR THERAPIST

Based on your decisions in previous step system suggested some Therapeutic Tasks and Control Modes to be used. The disabled elements will not be used in the Workout by default, but you can activate them manually.



- (1) Select evaluations you want to be performed
- 2) Select gamified Therapeutic Tasks you want to be performed
- 3 Select Control Modes (movement patterns) you want to be performed. The larger the number you choose, the larger the share of the given Control Mode will be.
- (4) Click when you are happy with your settings



GENERATE A QUICK WORKOUT FOR PATIENT 4/4 SCENARIOS FOR THERAPIST

Here you can see list of Therapeutic Task your Workout contains



 $\stackrel{\frown}{1}$ Duration of fullscreen instructions before each Therapeutic Task

2 Click to proceed



START MULTIPLAYER WORKOUT SCENARIOS FOR THERAPIST

You can use VAST.Rehab to start Workout for 2 patients on the same Patient Station. Depending on the Therapeutic Task they will then play against each other or in cooperation. Please note that when multiplayer is used no statistics are collected. In order to start it - please follow the process described below.

Please log in Use your login and password		¢ X
	Rehab NVIRTUAL REALITY	
1 Active to: 2020-12-31	1	
Anonymous Create Mode account		Sign in using Sign in face recognition

 $\mathbf{1}$ Click to start anonymous Workout (single or multiplayer)



START MULTIPLAYER WORKOUT SCENARIOS FOR THERAPIST

Adjust settings according to your needs.



- 1) Select single or multiplayer mode
- 2 Click to proceed



GENERATE REPORT FOR PATIENT SCENARIOS FOR THERAPIST

Objective data is an important element that helps keep patient motivated. You can generate a simply report to discuss with your patient directly in Patient Panel. You can observe in which categories patient is getting better and in which is getting worse. In order to do it please follow the process described below.



- 1) Select time frame
- 2 Select progress treshold. Result will be displayed only if it is far enough from 0 (when progress is very small result will be hidden).
- **3**) Average progress achieved in all Control Modes in the category
- **4**) Progress achieved in the given Control Mode



HOW TO ADJUST SETTINGS? SETTINGS

Patient Panel has a dedicated settings view that lets you tailor the application according to your needs. In order to change some settings please follow the process described below.

Use your	se log in login and password		(1)*×
		Login: Password:	
Active to: 202	20-12-31		
Anonymous Mode	Create account		Sign in using face recognition

(1) Click to navigate



HOW TO ADJUST SETTINGS? SETTINGS

Settings are divided into several groups.



- (1) Set language, unit system, active monitor devices, ect.
- 2) Manage devices connected to this Patient Station
- **3**) Password protected options available for VAST.Rehab technicians only
- **4** Contact with VAST.Rehab producer
- 5) Set screen where application shall start and screen resolution
- 6) Change license activated on this Patient Station
- 7 Choose which camera shall be used to look for special code that can be used to perform basic actions during Workout



WHAT TO DO WHEN A PROBLEM OCCURS? TROUBLESHOOTING

If for any reason Patient Panel is crashing please follow the process described below to send to us description of the problem. System will automatically add to your message additional information collected when application crashed - they will help us solve the problem you are encountering.



(1) Contact with VAST.Rehab producer



WHAT TO DO WHEN A PROBLEM OCCURS? TROUBLESHOOTING

If for any reason Patient Panel is crashing please follow the process described below to send to us description of the problem. System will automatically add to your message additional information collected when application crashed - they will help us solve the problem you are encountering.

Feedb Contact us!	pack		×
Unnamec	VAST.Rehab Tag Brontes Processing 2020-02-20 13:47:24 1.0.7355.24822	https://vast.rehab	
1			
2	Your e-mail:	Log file size: 7,99MB	3 4
			Save Send

- 1) Describe your problem here
- 2) Type your contact details here
- **3**) Click to save the log file on your desktop. You can send it manually to the producer.
- 4 Click to proceed

