Getting Started Guide

Product designation: SaeboVR-1

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GENERAL PRODUCT AND SAFETY INFORMATION

IMPORTANT: READ THIS ENTIRE DOCUMENT PRIOR TO USING THE SAEBOVR SYSTEM.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Indications for Use

A software system used with the Microsoft Kinect intended to be used to support repetitive task practice for rehabilitation of adults under supervision of a medical professional in a clinical or home setting. The system includes simulated activities of daily living (ADLs) for the upper extremity with audiovisual feedback & graphic movement representations for patients as well as patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.

U.S. Only – this product is cleared for use in the United States of America.

Principles of Operation/Features

SaeboVR is based on a simple premise, that the best way to acquire (or reacquire) the capability to perform a task is to practice that task. SaeboVR provides a virtual environment for the practice of activities of daily living (ADLs), presenting a form of repetitive task practice (RTP) for the shoulder and elbow that involves use of the impaired arm in meaningful tasks that evoke functional movements with graduated levels of difficulty. The activities are organized into a virtual "Road to Recovery" that traverses a series of four islands organized around a central theme. Currently-available activities include Grocery Shopping, Putting Away Groceries, Preparing Breakfast, Pet Shopping, Pet Feeding, Pet Bathing, Garden Planting, Garden Harvesting, Preparing Dinner, Organizing a Closet, and Volunteering at a Soup Kitchen.

SaeboVR software runs on a personal computer and uses a Microsoft Kinect sensor. From a seated position, the patient is challenged to perform integrated activities that involve picking up, placing, and manipulating virtual objects. When the patient moves his or her arm, the real-world shoulder and elbow joint movements are mimicked by an avatar (the patient's "virtual self") within the virtual activity. The range of motion and movement repetitions required to complete the tasks are determined by the medical professional. The level of cognitive challenge can also be adjusted.

Also included with the SaeboVR system is a Provider Dashboard application that enables the medical professional to view patient performance metrics and participation history. It is described in the included Provider Dashboard User's Manual.

Important Safety Instructions and Precautions

- A physician's order and guidance of a qualified medical professional are required prior to use.
- SaeboVR activities should be performed pain-free. If the patient experiences any pain when using SaeboVR, stop immediately and contact a medical professional prior to resuming use.
- Patients should be seated at all times when using SaeboVR.

- Patients should take frequent rest breaks.
- To use SaeboVR effectively, patients should be able to see a computer display and follow verbal instructions.
- Patients should wear their usual vision or hearing aids when using SaeboVR, e.g. prescription glasses.
- The cognitive difficulty levels have not been clinically evaluated and are to be used by the clinician to gauge the relative difficulty of each setting.
- Use all third party equipment in accordance with the original manufacturer's labeling and instructions.

Important Usage Instructions
- SaeboVR stores patient data using a non-identifying, system-generated access code. Only this non-identifying code is stored on disk. It is recommended that you record both the practitioner-selected user name and the system-generated access code in a secure location for retrieval if necessary.
- Exercise good data security practices. Connection of the SaeboVR system to a network should only be done by qualified and authorized IT personnel, and only in a manner consistent with the internal policies and standard operating procedures of the cognizant organization; and in compliance with all applicable policies regulations and statutes.
- The owning institution should implement a system access, account management, and data backup solution that complies with internal policies and standard operating procedures.

Package Contents
- Dell Alienware Alpha personal computer (preloaded with SaeboVR software)
- Dell Alienware Alpha power supply
- Microsoft Xbox One Kinect Sensor
- Microsoft Xbox Kinect Adapter for Xbox One and Kinect power supply
- Kinect TV Mount for Xbox One
- D-ring 1/4" Mounting Screw
- Logitech wireless keyboard
- HDMI cable
- Documentation including: Getting Started Guide; Patient Application User's Manual; Provider Dashboard User's Manual; and Third-party Labeling Package

Additional Required Equipment
- HDMI-compatible 1080p HDTV display monitor with a 16:9 aspect ratio (40" or larger recommended)
- Armless chair without casters and a low back that does not impede shoulder movement
- AC power outlet

GETTING STARTED

Unpack and verify contents

1. Unpack the shipping container and verify contents match the package contents list above.

Select a workspace

2. Use of the SaeboVR system should take place in a space with limited distractions and an area of open floor space of at least 6 feet x 6 feet.
3. Due to the potential for glare on the display monitor, the system should not be placed in a room with direct sunlight which cannot be blocked by curtains or shades.

Setup hardware

4. Mount the display monitor per the manufacturer's instructions such that the center of the display is approximately 4' above floor height (see Figure 1).
5. Center the armless chair on the display monitor at a distance of approximately 5 feet.

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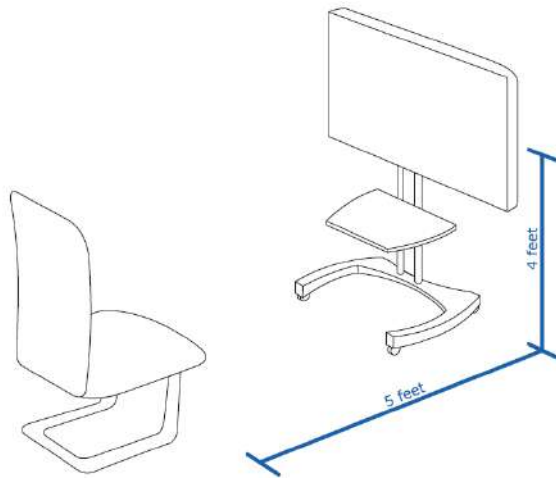
Figure 1. Setup of monitor and chair

6. Following the included manufacturer's instructions for the Kinect TV Mount (in the Third Party Labeling Package), apply sufficient force to adjust the back arm of the TV Mount so that the back arm sits firmly against the back of the TV. Place the Kinect Sensor on the display monitor following manufacturer's instructions. Alternatively, if using a display mounting system with an over-TV platform, mount the Kinect Sensor directly to the platform (without the Kinect TV Mount) using the provided D-ring 1/4" Mounting Screw.
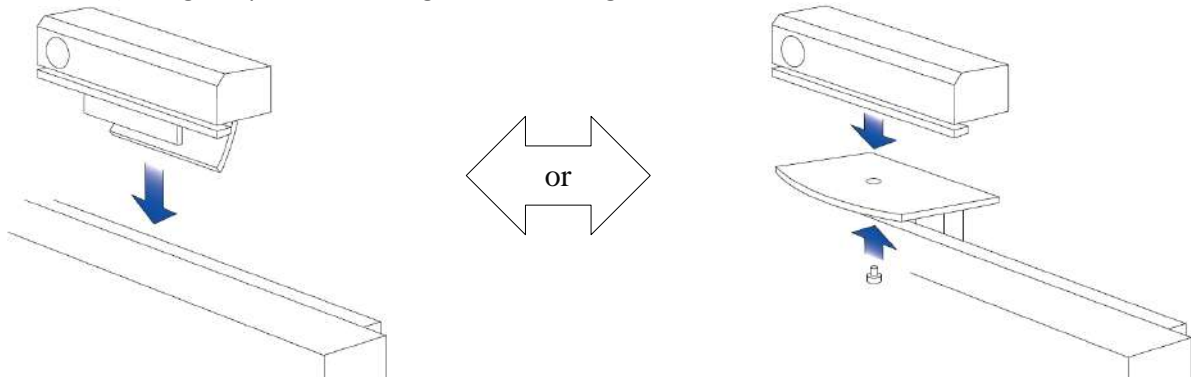
Figure 2. Placement of Kinect

7. Adjust the alignment of the Kinect sensor such that it is facing approximately towards the back of the user's chair.
8. Place the personal computer on a stable flat surface near the display monitor.
9. Plug USB connector (labeled with a red dot) on the Kinect Adapter to the USB port (also labeled with a red dot) on the personal computer (see Figure 3).
10. Plug the connector on the power cable on Kinect power supply to an AC power outlet (e.g. plug into a power strip).
11. Attach one end of the HDMI cable (labeled with a green dot) to the HDMI port (also labeled with a green dot) on the personal computer.
12. Connect the free end of HDMI cable to an HDMI connector on the display monitor.
13. Connect the barrel connector (labeled with a blue dot) on the computer power supply to the power connector (also labeled with a blue dot) on the personal computer.
14. Plug the connector on the power cable of the computer power supply to an AC power outlet (e.g. plug into a power strip).
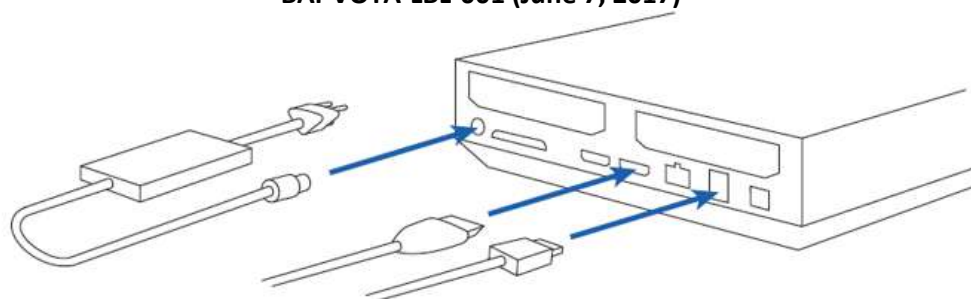
Figure 3. Attachment of connectors

Power up system

15. Turn on the display monitor and set the input to same HDMI channel as the connection used for the SaeboVR HDMI cable (e.g. using input/source button on the TV remote).
16. Press power button on personal computer to turn it on.
17. Verify the battery pull tab has been removed on the wireless keyboard. Slide the power button on the wireless keyboard to the ON position.

Windows login

18. The following default Windows login credentials have been created (case sensitive).

> Username: saebovr
> Password: adlfun

19. Login to Windows using your credentials.

Login to SaeboVR

20. Double click on the SaeboVR Patient App icon to launch the application.
21. At the SaeboVR Login window, either type an existing patient user name or select New User to create a new user account (note that the SaeboVR login user name is NOT the same as the Windows login username).
22. If creating a new account, record the SaeboVR user name and the system-generated access code in a secure location.
23. The first time a new user code is used, an introductory scene will play.

Use SaeboVR

24. Go to the avatar selection view by selecting "MENU" and then "Avatar Selection."
25. Verify that the avatar's arms are tracking the arm movement of the patient. If not, use the "P" key on the keyboard to change the person being tracked by the Kinect. Note that if there are many people in the sensor's view, you may have to do this multiple times until you are tracking the desired person.
26. If the avatar's arms do not appear to be correctly tracking the patient, use the "K" key to reset Kinect tracking.
27. If tracking difficulties persist, please refer to the Troubleshooting section of this guide.
28. Select an avatar for the patient using the ← and → on-screen arrows.
29. Click "OK" to save preferences and return to the Player Dashboard view.
30. Click "MENU" and the "Settings" to open the settings menu.
31. Select the desired Cognitive Difficulty by clicking "Easy," "Med," or "Hard." See Guidance on Difficulty Settings below.
32. Select the desired Motor Difficulty by clicking "Easy," "Med," or "Hard." See Guidance on Difficulty Settings below.
33. Next to "Impaired Arm," click on the "Left" or "Right" button to select which arm to use in the SaeboVR exercises.
34. Leave "Easy Interactions" set to "Yes" and Auto Complete to "No." Please consult the SaeboVR Patient Application User's Manual for more information on these options.
35. Click "CLOSE" to return to Player Dashboard view.
36. Click "MENU" and "Practice" to go to a practice activity involving placing ball in boxes. Use this simple activity to allow patient to become familiar with interacting with virtual objects. Click "Return to Dashboard" when done.
37. Play! Click "START" to begin. The software automatically takes the player to the first activity (or next activity in the recommended sequence in subsequent logins).
38. On completion of each activity, the player is given a summary of results and then returned to the Player Dashboard.

THE USER SHOULD BE OFFERED A BREAK AFTER EACH ACTIVITY.

RECOMMENDED TRAINING

Prior to using the SaeboVR software system with patients, it is recommended that the medical professional read the entire SaeboVR Getting Started Guide (this document) as well as the SaeboVR Patient Application User's Manual and SaeboVR Provider Dashboard User's Manual provided with each system.

Additionally, it is recommended that each medical professional participate in at least one role playing practice session involving one or more pairs of individuals. One medical professional in each pair should initially assume the role of clinician while the other plays the role of a patient.

1. Each medical professional should first read and verbally review the entire Getting Started Guide (this document), including: GENERAL PRODUCT AND SAFETY INFORMATION, GETTING STARTED, RECOMMENDED TRAINING (this section), IMPORTANT TIPS, and TROUBLESHOOTING.

2. The medical professional initially playing the role of clinician should perform steps 19-38 in the GETTING STARTED instructions (above), guiding the second medical professional (playing the role of patient) through completion of at least two SaeboVR activities.

3. The medical professionals should then switch roles and repeat steps 19-38.

4. The medical professionals should follow the Getting Started instructions in the SaeboVR Provider Dashboard User's Manual to become familiar with the Provider Dashboard tools.

The medical professionals should then discuss how SaeboVR can be used to support patient treatment, including appropriateness for different diagnoses.

It is estimated that the above-described training and practice session should take approximately 2 hours.

IMPORTANT TIPS

1. **Torso movement is ignored**

   SaeboVR only recognizes shoulder and elbow movements. Instruct the user to avoid leaning forward, backward, or side-to-side.

2. **Motor and Cognitive Difficulty settings**
   a. The medical professional should use sound therapeutic judgement to select Motor and Cognitive Difficulty settings that are appropriate for the individual patient.
   b. It is recommended that both Motor and Cognitive Difficulty be set to Easy while a new player is becoming familiar with the game and interactions with the virtual world through arm movements.
   c. Some individuals may be able to quickly advance from Easy to Medium to Hard. Others may progress more slowly.
   d. Once selected, the difficulty settings for a user will persist until changed using the settings menu.

   Motor Difficulty

   e. The Motor Difficulty setting adjusts the amount of repetition and range of arm motion required to complete tasks within the different SaeboVR activities.
   f. To perform SaeboVR activities without assistance at the Easy setting, patients should have antigravity elbow range of motion of greater than 45 degrees of active flexion and antigravity shoulder strength of greater than 30 degrees in active flexion, greater than 30 degrees in abduction/adduction, and greater than 15 degrees in active rotation. Patients at a lower level of function may complete activities with therapist's physical assistance or by using hand over hand techniques.
   g. Motor Difficulty should be advanced when, in the judgement of the medical professional, a patient is not sufficiently challenged by the motor demands of the current difficulty setting.

h. Motor Difficulty should be reduced if, in the judgement of the medical professional, a patient is being challenged beyond his or her capabilities, and/or use at the current level would lead to overexertion, fatigue, and/or soreness.
i. The patient should be offered the opportunity to take frequent breaks.

Cognitive Difficulty

j. The Cognitive Difficulty setting adjusts the degree to which an activity challenges the patient's memory, visual-spatial planning, attention, and executive function.
k. Cognitive Difficulty should be advanced when, in the judgement of the medical professional, a patient has demonstrated a degree of mastery in responding to the visual-spatial planning, memory, and attentional requirements of activities in current difficulty setting.
l. It is recommended that the Cognitive Difficulty setting not be advanced beyond the Motor Difficulty setting. This ensures a more balanced feel to the virtual activities.

3. **Selecting activities**

    a. Clicking "START" will automatically take the user to the next activity on the virtual Road to Recovery.

    b. Alternatively, the user may click on a different lily pad (activity icon along the path) to choose any activity. The activities on different islands can be accessed by clicking on an island on the far left of the dashboard.

4. **Keyboard Hotkeys**

    The following key sequences on the wireless keyboard are useful for controlling the SaeboVR software.
    - K   Reset Kinect tracking
    - P   Change person being tracked by the Kinect
    - Esc   Pause/Unpause the Game
    - Shift+Esc   Exit activity and return to the Player Dashboard
    - Alt+Fn+F4   Force SaeboVR program to quit

TROUBLESHOOTING

1. **No Kinect tracking or tracking appears to freeze**
    If the avatar does not appear to be moving in response to the movements of any person in view of the Kinect sensor, perform the following sequence of steps (stop when the problem is resolved):
    a. Verify that the Kinect is not tracking the wrong person (see number 2 below).
    b. Verify that the Kinect is connected per the instructions above and that it is connected to an active power outlet.
    c. Verify that the Kinect sensor is not obstructed by an object or person.
    d. Verify that the Kinect sensor is aligned such that it is facing the back of the user's chair.
    e. Close and restart the SaeboVR program.
    f. Unplug the Kinect sensor from the computer's USB port and then re-connect.
    g. Shut down and restart the personal computer, and relaunch SaeboVR.

2. **Avatar tracking the wrong person**
    If the avatar is not following the movements of the patient, or is following the movements of a person other than the patient, do the following:
    a. Click on "MENU" and then "Avatar Selection" to go to the avatar selection view.
    b. Ask the user to "wave" at the Kinect with either hand (while others in the sensor view remain stationary).
    c. Click the P key on the wireless keyboard until you see the avatar moving with the user.

3. **Poor Kinect tracking**
   If the avatar's arm movements are inaccurate or jittery, perform the following sequence of steps (stop when the problem is resolved):
   a. Verify that the Kinect sensor is not obstructed by an object or person.
   b. Verify that the lens of the Kinect sensor is not dirty or smudged. If necessary, use a microfiber cloth to gently wipe the lens in a circular motion until it is clean.
   c. Verify that the user is not wearing clothing items that might impair the Kinect sensor's ability to see the arm (for example a draping sweater or bulky jacket).
   d. Reset the tracking system by clicking the K key on the wireless keyboard.
   e. Close and restart the SaeboVR program.
   f. Shut down and restart the personal computer, and relaunch SaeboVR.

4. **Program freezes or experiences an unrecoverable error**
   In the unlikely event this occurs, perform the following sequence of steps (stop when the problem is resolved):
   a. Close and restart the SaeboVR program.
   b. Shut down and restart the personal computer, and relaunch SaeboVR.

5. **Patient lacks sufficient strength or range of motion to complete a task**
   a. The medical professional may instruct the patient to perform "self-assist" using their opposite hand.
   b. The medical professional may provide hand-over-hand assistance from a position behind or to the side of the patient so as not to block the sensor.
   c. The task can be completed using a mouse click on the target object (employing the touchpad on the keyboard).
   d. Note that Motor Difficulty should be reduced if, in the judgement of the medical professional, a patient is being challenged beyond his or her capabilities, and/or use at the current level would lead to overexertion, fatigue, and/or soreness.
   e. The patient should be offered the opportunity to take frequent breaks.

6. **The patient "misses" the target object**
   New users will sometimes "over reach," resulting in their virtual hand passing through or beyond the intended target. When this happens, you will see the avatar hand turn blue.
   a. Instruct the patient to retract the hand towards the body until it no longer appears blue.
   b. If necessary, the medical professional may provide hand-over-hand assistance to reinforce the desired movement. Hand-over-hand assistance should be provided from a position behind or to the side of the patient so as not to block the sensor

7. **The patient experiences difficulty reading text or seeing graphics**
   a. Verify that the user is wearing any doctor-prescribed vision correction;
   b. If necessary, move the user's chair closer to the screen (but no closer than 3 feet away); and/or
   c. Use a larger TV display (40" or larger recommended).

8. **The patient experiences difficulty hearing audio**
   a. Verify that the individual is wearing any doctor-prescribed hearing aids; and/or
   b. If necessary, increase the volume on the display monitor and/or personal computer.

PLEASE SEE THE SAEBOVR PATIENT APPLICATION USER'S MANUAL FOR ADDITIONAL DETAILS ON THE DESIGN AND USAGE OF THE SAEBOVR SOFTWARE.

PLEASE SEE THE SAEBOVR PROVIDER DASHBOARD USER'S MANUAL FOR DETAILS ON THE MEDICAL PROVIDER'S APPLICATION FOR ACCESSING PATIENT PERFORMANCE METRICS.

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