Usability Engineering File

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Revision History

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Introduction

This Usability Engineering File validates a user interface (including labeling and training) that meets the needs of the specified users and allows them to use the Healthcare Application (HA) efficiently, effectively, and safely for the specified use in the specified use environment.

1.1 Scope

This document is the Usability Engineering File of the TeOra platform.

Use Specification

With this HA, patients are able to perform exercises focusing on daily activities. The virtual world of HA offers patients various tasks like making a cup of coffee, sorting the fridge, or handling cash in different realistic scenarios. Using this method, patients are able to train for everyday life in a safe, gamified, and fully controlled scenario. The training is carried out by interacting with the virtual world and accomplishing various tasks and exercises. In order to enable the interaction, patients use the provided controllers.

2.1 Intended Medical Indication

HA is designed to control the process of patient rehabilitation.

HA enables physicians to get information or updates about patients undergoing rehabilitation, both stationary and aftercare, related to completing tasks and making progress.

HA is intended for use by physicians in a clinic in order to:

- create plans for patients;

- view information about completed training and training that must be completed, as well as about patient progress;

- view available scenarios with exercises for rehabilitation and assign them to patients;

- view patient progress and adjust rehabilitation plans if necessary.

2.2 Intended Patient Population

Patients with cognitive function issues who undergo rehabilitation – from adults to seniors.

2.3 Intended User Profiles

2.3.1 Physician

- An experienced specialist of any gender with higher education who speaks English or German;

- Works in a clinic.

Common activities:

- Creates an account;

- Manages and updates profiles;

- Manages patients (views the list of patients, adds/deletes patients, views patient details/progress/plans/sessions, updates patient information, adds/removes patient devices, reassigns patients to another specialist);

- Manages training scenarios (views available scenarios for patients, suggests new scenarios, leaves feedback about a scenario);

- Gets notifications;

- Views patient progress information.

2.3.2 Platform Admin

An IT support specialist of any gender with higher education who speaks English or German.

Common activities:

- Has authorization privileges;

- Views profiles;

- Manages clinics (views the list of clinics, adds/deletes a clinic, adds an admin to a clinic, manages clinics' devices, switches on/off features);

- Manages devices (views the list of devices, activates devices, deactivates devices);

- Creates reports.

2.3.3 Clinic Admin

- An experienced specialist of any gender with higher education who speaks English or German;

- Works in a clinic.

Common activities:

- Has authorization privileges;

- Manages profiles (views profiles, updates profiles, deletes profiles, changes passwords);

- Connects with support;

- Creates accounts;

- Views statistics;

- Gets reports;

- Manages super doctors.

2.4 Intended Use Environment

Desktops in clinics.

2.5 Operating Principle

HA is a web app that works via browsers. A stable Internet connection is required. All popular browsers (Chrome, Opera, Firefox, Safari, etc.) are supported.

3.1 Characteristics Related to Safety and Potential Use Errors

1. Authorization

2. Add a new patient

3. Reassign patients

4. View a patient's details

5. Configure a plan for stationary patients

6. Configure a plan for aftercare patients

7. View a patient's plan

8. View a patient's progress and a patient's sessions

9. Deactivate a clinic

10. Delete a physician's account

11. Make a patient inactive

Risk Assessment

Table 1 – Authorization (sign-up)	
Action	The user opens the Sign-up screen.
Reaction of the system	The Sign-up screen is opened.
Use errors (PCA*)	P. The user may not understand how to find the Sign-up screen. C. The user may not understand what to enter. C. The user may forget the password rules. A. The user may forget to push Sign-up. A. The user may forget to read the Privacy Policy. A. The user may forget to read Terms and Conditions.
Root causes	The user is not familiar with HA.
Hazardous situation	The inability to get access to HA can cause a delay in rehabilitation.
Risk control measures	• The system sends the link to the Sign-up screen with instructions; • The user needs to use their email as the login; • The system shows information about password requirements; • The system issues a notification when a wrong password is entered; • The system notifies the user about connection issues; • The system asks the user to read the Privacy Policy and Terms and Conditions; • The system shows error notifications in case of a system error (system unavailable); • The sign-up process is only finished successfully if a user signs the Privacy Policy and Terms and Conditions.

* PCA stands for Perception, Cognition, and Action and is applicable to all tables here.

Risk Assessment

Table 2 – Authorization (log-in)	
Action	The user opens the Log-in screen.
Reaction of the system	The Log-in screen is opened.
Use errors (PCA)	P. The user may not understand how to find the screen. C. The user may not understand what to enter. C. The user may forget their password. A. The user may enter the wrong password.
Root causes	The user is not familiar with the application. The password is complicated.
Hazardous situation	Inability to get access to the application can cause the delay of rehabilitation.
Risk control measures	• The initial screen is the Log in screen; • Fields contain hints for login and passwords (gray font); • The login for all users is their email; • The system checks whether all fields are filled in; • The system removes the spaces before and after the email address in the login field; • The system issues a notification when an incorrect login or password is entered; • The user can reset their password using the link to the password reset feature ("Forgot Password?") on the Log-in screen; • The system shows error notifications in case of a system error (system unavailable).

Risk Assessment

Table 3 – Add a new patient	
Action	The user opens the form for adding a new patient.
Reaction of the system	The modal screen is opened.
Use errors (PCA)	P. The user may not understand how to find the "Add a new patient" form; C. The user may not understand what to enter; C. The user may forget to enter their diagnosis or clinical summary; C. The user may specify the wrong rehabilitation type; A. The user may forget to save the form; A. The user may create a duplicate patient; A. The user may enter a wrong diagnosis or clinical summary.
Root causes	A large amount of data that the user has to enter correctly.
Hazardous situation	Incorrectly entered data can cause misdiagnosis, leading to incorrect or delayed rehabilitation.
Risk control measures	• The system refuses to save the form with empty required fields; • The system shows hints under fields where necessary; • The system displays a notification about whether the action is completed successfully or not; • The system assigns a status to a patient – the default status for new patients is STATIONARY; • A combination of Name+DOB+Gender+Identification number to avoid duplicates; • The system displays a notification that the created patient already exists in the system; • A drop-down list of diagnoses; • The system displays the "Patient added successfully" notification; • The system displays the "Patients has not been added. Please try again" notification; • The system displays the "Please fill in all required fields" notification.

Risk Assessment

Table 4 – Reassign patients	
Action	The user (physician) opens a patient profile.
Reaction of the system	A patient profile is opened.
Use errors (PCA)	P. The user may open the wrong patient profile; C. The user may not understand how to reassign the patient; A. The user may reassign the wrong patient; A. The user may reassign a patient to the wrong physician (without an account).
Root causes	A large amount of data that the user has to enter correctly.
Hazardous situation	Wrong patient assignment can cause the absence or delay of rehabilitation.
Risk control measures	• A patient's personal information is displayed at the top of their profile; • Patient profiles have the "Change the physician" button; • A drop-down list of physicians; • The user needs to confirm the assignation of patients to another physician; • The physician receives a notification that a new patient is assigned to them, as well as all information about this patient and their treatment; • The former physician receives a notification that a patient was reassigned to another specialist; • A super doctor function which can reassign all patients; • A dashboard displaying the percentage of new patients.

Risk Assessment

Table 5 – View patient's details	
Action	The user (physician) opens a patient profile.
Reaction of the system	A patient profile is opened.
Use errors (PCA)	P. The user may not find the needed patient;
	The user may open the wrong patient profile;
	C. The user may not recognize the rehabilitation type;
	C. The user may not recognize the diagnosis or clinical summary;
	C. The user may not understand what device has been added;
	A. The user may forget to assign a training plan.
Root causes	A large amount of data that the user has to understand.
Hazardous situation	An unclear diagnosis can lead to incorrect rehabilitation.
Risk control measures	• The list of assigned patients on the left side of a profile;
	• The user can see both active (undergoing treatment) and inactive (having completed treatment) patients;
	• Filtering by rehabilitation type;
	• Special symbols are used:
	• stationary
	• aftercare
	• A patient's personal information is displayed at the top of their profile;
	• The user can update the information about diagnoses;
	• The user can update the clinical summary;
	• The user can see the device that has been added to a patient (only for AFTERCARE patients);
	• The user can mark a patient as inactive (for patients who have completed their plans).

Risk Assessment

Table 6 – Configure a plan for stationary patients	
Action	The user (physician) opens the "Configure session plan" form.
Reaction of the system	The modal screen is opened.
Use errors (PCA)	P. The user may not understand how to select an activated device; C. The user may not understand how to configure the plan; A. The user can forget to create a training plan.
Root causes	A large number of exercises.
Hazardous situation	The inability to create a training plan can lead to the absence of rehabilitation.
Risk control measures	• A drop-down list with activated devices; • A list of exercises available on the right side of the modal screen; • Text hint in brackets after the list of exercises; • The confirmation button at the bottom of the modal screen; • The system displays a notification asking the user to create a training plan; • The user can not select a completely empty plan; • The system displays the "Empty Plan cannot be created" notification; • The system displays the "Session plan is successfully created" notification.

Risk Assessment

Table 7 – Configure a plan for aftercare patients	
Action	The user (physician) opens the "Change rehabilitation type" form.
Reaction of the system	The modal screen is opened.
Use errors (PCA)	P. The user may not understand how to configure an aftercare plan; P. The user may not receive patient progress results; C. The user may not understand that the patient is not ready for aftercare (the patient hasn't finished their stationary training program); A. The user may prescribe aftercare to a patient by mistake; A. The user may assign the wrong training plan.
Root causes	• Unclear processes (before the configuration of the aftercare plan, the rehabilitation type needs to be changed); • Notifications about patient progress are either absent or displayed on another screen.
Hazardous situation	The wrong aftercare plan can cause injury or lead to incorrect rehabilitation.
Risk control measures	• The "Move to aftercare" button with the "add a device and create an aftercare plan" text hint; • The function to view patient progress/activity; • The button to confirm the change of rehabilitation type; • Search for activated devices and confirm with the confirmation button; • The user can see all scenarios that can be used by patients; • The user can specify the number of sessions for the patient; • The user can see the list of available scenarios/exercises for the patient; • The user cannot select a completely empty plan; • The system displays a notification asking the user to create a training plan; • A dashboard displays the latest stationary sessions of patients; • A function for generating a report about a patient's progress; • The system displays the "Empty plan cannot be created" notification; • The system displays the "Session plan is successfully created" notification.

Risk Assessment

Table 8 – View a patient's plan	
Action	The user (physician) opens the "Plan" screen.
Reaction of the system	The "Plan" screen is opened.
Use errors (PCA)	P. The user may open the wrong patient profile; P. The user may not receive patient progress results; C. The user may not know that exercises are included in each scenario; C. The user may not know that exercises were assigned to the patient; C. The user may not know that cognitive functions are trained with each exercise; A. The user may assign wrong scenarios; A. The user may forget to save changes.
Root causes	A lack of or too much information on the screen.
Hazardous situation	The wrong training plan can lead to incorrect rehabilitation.
Risk control measures	• A patient's personal information is displayed at the top of their profile; • A patient progress topbar; • A drop-down list of exercises (from a scenario); • The user can view selected scenarios (exercise availability switch); • View the total number of sessions; • The function to view patient progress/activity; • The user can edit the plan and add or remove exercises; • The user can view what cognitive function the exercise focuses on; • The user can only see the plans for AFTERCARE patients; • The "Save changes" button at the bottom of the screen; • The system displays the "Changes have been made. Are you sure you want to leave the page without saving them?" notification.

Risk Assessment

Table 9 – View a patient's progress and a patient's sessions	
Action	The user (physician) opens the "Activity/Progress" screen.
Reaction of the system	The "Activity/Progress" screen is opened.
Use errors (PCA)	P. The user may open the wrong patient profile; P. The user may not receive/find the patient's general progress; P. The user may not receive/find the patient's daily progress (detailed results); P. The user may not receive/find what sessions were completed; C. The user may not understand the results of rehabilitation; C. The user may not understand that rehabilitation is completed; A. The user may assign additional sessions; A. The user may stop the rehabilitation too early.
Root causes	A lack of or too much information on the screen.
Hazardous situation	Unawareness of patient progress can lead to a lack of or excessive rehabilitation.
Risk control measures	• A patient's personal information is displayed at the top of the screen; • The user can view the detailed progress of a patient; • The user can view the progress in three formats: 1. calendar, 2. table, 3. diagram (general progress). • The user can select a day in a calendar to view more details about treatment; • The user can view the information without editing it; • The user can choose a session; • The user can view the number of exercises; • The user can view the frequency of exercises; • The function for generating a report about a patient's progress.

Risk Assessment

Table 10 – Deactivate a clinic	
Action	The user (platform admin) opens the "Clinics" screen.
Reaction of the system	The "Clinics" screen is opened.
Use errors (PCA)	P. The user may select the wrong clinic; P. The user may not receive information about active patients and devices; C. The user may not know that there are active patients and devices in the clinic; A. The user can deactivate a clinic with active patients and devices by mistake.
Root cause	A lack of information in the modal window.
Hazardous situation	Deactivating the wrong clinic can cause the loss of rehabilitation progress and block further rehabilitation.
Risk control measures	• The user is asked to confirm the deactivation of a clinic (confirmation modal window); • The system displays the "Do you really want to deactivate the clinic <name>?" notification; • The information about deactivated clinics is stored in the archive; • All patients related to a deactivated clinic must be inactive; • The user can reactivate a clinic; • It is not possible to deactivate a clinic with active patients (patients who are still undergoing treatment); • It is not possible to deactivate a clinic with devices; • The system displays the "The clinic has successfully been deactivated" notification; • The system displays the "The clinic has not been deactivated. Please try again" notification in the case of technical issues; • The system displays the "The clinic cannot be deactivated because it has active patients or devices" notification.

Table 11 – Delete a physician's account	
Action	The user (physician or clinic admin) opens the "Physician accounts" screen.
Reaction of the system	The "Physician accounts" screen is opened.
Use errors (PCA)	P. The user (clinic admin) may select the wrong physician;
	P. The user may not receive information about the active patients of a selected physician;
	C. The user may not know that a selected physician has active patients;
	A. The user may delete a physician's account by mistake.
Root cause	A lack of information in the modal window.
Hazardous situation	Deleting the wrong physician's account can cause the loss of rehabilitation progress and block further rehabilitation.
Risk control measures	• The user needs to confirm the deletion of a physician's account (confirmation modal window);
	• The system displays the "Do you really want to delete <First name+Last name>'s account? It cannot be restored." notification;
	• The user can only delete a physician's account if they don't have any patients;
	• The system displays the "You cannot delete < First Name+ Last Name>'s account because <First Name+Last Name> has patients." notification;
	• A physician's account can only be deleted after their patients are assigned to other physicians.

Risk Assessment

Table 12 – Make a patient inactive	
Action	The user (physician) opens a patient's profile.
Reaction of the system	A patient's profile is opened.
Use errors (PCA)	P. The user may select the wrong patient; P. The user may not receive information about the patient's activity; C. The user may not understand that the patient is active (hasn't completed training sessions); A. The user may deactivate a patient who hasn't completed training sessions by mistake.
Root cause	A lack of information in the modal window.
Hazardous situation	Deactivating the wrong patient can cause the loss of their rehabilitation progress and block further rehabilitation.
Risk control measures	• The user needs to confirm the deactivation of the patient (confirmation modal window); • The system displays the "Do you want to make <First name+Last name> inactive?" notification; • The user can only deactivate a patient if this patient doesn't have any active training sessions; • The system displays the "You cannot deactivate < First Name+ Last Name> patient because <First Name+Last Name> has active training sessions." notification; • The patient needs to complete training sessions so that the user can deactivate them; • The system displays the "The patient has successfully been deactivated" notification; • The system displays the "The patient has not been deactivated. Please try again" notification.

Risk Assessment

3.2 Hazards, Hazardous Situations, and Hazard-Related Use Scenarios

Risk ID	U01	U02	U03
Function	Sign up	Sign up	Sign up
Hazard-related use scenario	The user may not understand how to find the Sign-up screen	The user may not understand what to enter	The user may forget the password rules
Hazardous situation	The inability to get access to HA can cause a delay in rehabilitation.		
Harm severity (value)	S1	S1	S1
Harm occurrence probability (value)	P3	P1	P2
Risk value acceptability	R2	R1	R1
Are risk control measures required?	Yes	No	No
Risk mitigation action	The system sends the link to the Sign-up screen with instructions	N/A	N/A
Traceability links	US-1.1 Sign up	N/A	N/A
Harm severity (value)	S1	N/A	N/A
Harm occurrence probability (value)	P2	N/A	N/A
Risk value after mitigation actions	R1	N/A	N/A
Is summative evaluation required?	No	N/A	N/A

Risk Assessment

Risk ID	U04	U05	U06
Function	Sign up	Sign up	Sign up
Hazard-related use scenario	The user may forget to push Sign-up	The user may forget to read the Privacy Policy	The user may forget to read the Terms and Conditions
Hazardous situation	The inability to get access to HA can cause a delay in rehabilitation.		
Harm severity (value)	S1	S1	S1
Harm occurrence probability (value)	P1	P2	P2
Risk value acceptability	R1	R1	R1
Are risk control measures required?	No	No	No
Risk mitigation action	N/A	N/A	N/A
Traceability links	N/A	N/A	N/A
Harm severity (value)	N/A	N/A	N/A
Harm occurrence probability (value)	N/A	N/A	N/A
Risk value after mitigation actions	N/A	N/A	N/A
Is summative evaluation required?	N/A	N/A	N/A

Risk Assessment

Risk ID	U07	U08	U09
Function	Log in	Log in	Log in
Hazard-related use scenario	The user may not understand how to find the screen	The user may not understand what to enter	The user may forget their password
Hazardous situation	Inability to get access to the application can cause the delay of rehabilitation		
Harm severity (value)	S1	S1	S1
Harm occurrence probability (value)	P2	P2	P3
Risk value acceptability	R1	R1	R2
Are risk control measures required?	No	No	Yes
Risk mitigation action	N/A	N/A	1. Fields contain hints for login and passwords (gray font); 2. The user can reset their password using the link to the password reset feature ("Forgot Password?") on the Log-in screen.
Traceability links	N/A	N/A	US-1.2 Log in
Harm severity (value)	N/A	N/A	S1
Harm occurrence probability (value)	N/A	N/A	P2
Risk value after mitigation actions	N/A	N/A	R1
Is summative evaluation required?	N/A	N/A	No

Risk Assessment

Risk ID	U10	U11	U12
Function	Log in	Add a new patient	Add a new patient
Hazard-related use scenario	The user may enter the wrong password	The user may not find the "Add a new patient" form	The user may not understand what to enter
Hazardous situation	Inability to get access to the application can cause the delay of rehabilitation	Incorrectly entered data can cause misdiagnosis, leading to incorrect rehabilitation	
Harm severity (value)	S1	S2	S2
Harm occurrence probability (value)	P3	P2	P3
Risk value acceptability	R2	R1	R2
Are risk control measures required?	Yes	No	Yes
Risk mitigation action	1. Fields contain hints for login and passwords (gray font); 2. The user can reset their password using the link to the password reset feature ("Forgot Password?") on the Log in screen; 3. The system issues a notification when an incorrect login or password is entered.	N/A	The system shows hints under fields where necessary
Traceability links	US-1.2 Log in	N/A	US-3.6 Add a new patient
Harm severity (value)	S1	N/A	S2
Harm occurrence probability (value)	P2	N/A	P2
Risk value after mitigation actions	R1	N/A	R1
Is summative evaluation required?	No	N/A	No

Risk Assessment

Risk ID	U13	U14	U15
Function	Add a new patient	Add a new patient	Add a new patient
Hazard-related use scenario	The user may forget to enter their diagnosis or clinical summary	The user may specify the wrong rehabilitation type	The user may forget to save the form
Hazardous situation	Incorrectly entered data can cause misdiagnosis, leading to incorrect rehabilitation		
Harm severity (value)	S2	S2	S2
Harm occurrence probability (value)	P3	P1	P2
Risk value acceptability	R2	R1	R1
Are risk control measures required?	Yes	No	No
Risk mitigation action	1.The system refuses to save the form if it has empty required fields; 2. The system displays a notification about whether the action is completed successfully or not.	N/A	N/A
Traceability links	US-3.6 Add a new patient	N/A	N/A
Harm severity (value)	S2	N/A	N/A
Harm occurrence probability (value)	P2	N/A	N/A
Risk value after mitigation actions	R1	N/A	N/A
Is summative evaluation required?	No	N/A	N/A

Risk Assessment

Risk ID	U16	U17	U18
Function	Add a new patient	Add a new patient	Reassign patients
Hazard-related use scenario	The user may create a duplicate patient	The user may enter an incorrect diagnosis or clinical summary	The user may forget to save the form
Hazardous situation	Incorrectly entered data can cause misdiagnosis, leading to incorrect rehabilitation		Wrong patient assignment can cause the absence or delay of rehabilitation
Harm severity (value)	S2	S2	S1
Harm occurrence probability (value)	P3	P3	P2
Risk value acceptability	R2	R2	R1
Are risk control measures required?	Yes	Yes	No
Risk mitigation action	1. A combination of Name+DOB+Gender+Identification number is required to avoid duplicates; 2. The system displays a notification that the created patient already exists in the system.	1. The format of diagnoses is the following: Latin letters, German umlauts, special characters, numbers (1 symbol min, 250 symbols max); 2. A drop-down list of diagnoses	N/A
Traceability links	US-3.6 Add a new patient	US-3.6 Add a new patient	N/A
Harm severity (value)	S2	S2	N/A
Harm occurrence probability (value)	P1	P2	N/A
Risk value after mitigation actions	R1	R1	N/A
Is summative evaluation required?	No	No	N/A

Risk Assessment

Risk ID	U19	U20	U21
Function	Reassign patients	Reassign patients	Reassign patients
Hazard-related use scenario	The user may not understand how to reassign the patient	The user may reassign the wrong patient	The user may reassign a patient to the wrong physician (without an account)
Hazardous situation	Wrong patient assignment can cause the absence or delay of rehabilitation		
Harm severity (value)	S1	S1	S1
Harm occurrence probability (value)	P2	P2	P2
Risk value acceptability	R1	R1	R1
Are risk control measures required?	No	No	No
Risk mitigation action	N/A	N/A	N/A
Traceability links	N/A	N/A	N/A
Harm severity (value)	N/A	N/A	N/A
Harm occurrence probability (value)	N/A	N/A	N/A
Risk value after mitigation actions	N/A	N/A	N/A
Is summative evaluation required?	N/A	N/A	N/A

Risk Assessment

Risk ID	U22	U23	U24
Function	View a patie nt's details		
Hazard-related use scenario	The user may not find the needed patient	The user may open the wrong patient profile	The user may not recognize the rehabilitation type
Hazardous situation	An unclear diagnosis can lead to incorrect rehabilitation		
Harm severity (value)	S2	S2	S2
Harm occurrence probability (value)	P2	P2	P2
Risk value acceptability	R1	R1	R1
Are risk control measures required?	No	No	No
Risk mitigation action	N/A	N/A	N/A
Traceability links	N/A	N/A	N/A
Harm severity (value)	N/A	N/A	N/A
Harm occurrence probability (value)	N/A	N/A	N/A
Risk value after mitigation actions	N/A	N/A	N/A
Is summative evaluation required?	N/A	N/A	N/A

Risk Assessment

Risk ID	U25	U26
Function	View a patie nt's details	
Hazard-related use scenario	The user may not recognize the diagnosis or clinical summary	The user may not understand what device has been added
Hazardous situation	An unclear diagnosis can lead to incorrect rehabilitation	
Harm severity (value)	S2	S2
Harm occurrence probability (value)	P3	P3
Risk value acceptability	R2	R2
Are risk control measures required?	Yes	Yes
Risk mitigation action	1.The format of diagnoses is the following: Latin letters, German umlauts, special characters, numbers (1 symbol min, 250 symbols max); 2. A user can update information about diagnoses (either delete or add a new diagnosis)); 3. A user can edit a clinical summary. After editing, the user needs to confirm the saving of changes); 4. A drop-down list of diagnoses.	The user can see the device that has been added to a patient (only for AFTERCARE patients)
Traceability links	US-3.2 View patient's details	N/A
Harm severity (value)	S2	S2
Harm occurrence probability (value)	P3	P1
Risk value after mitigation actions	R1	R1
Is summative evaluation required?	No	No

Risk Assessment

Risk ID	U27	U28	U29
Function	View a patie nt's details	Configure a plan for stationary patients	
Hazard-related use scenario	The user may forget to assign a training plan	The user may not understand how to select an activated device	The user can forget to create a training plan
Hazardous situation	An unclear diagnosis can lead to incorrect rehabilitation	The inability to create a training plan can lead to the absence of rehabilitation	
Harm severity (value)	S2	S1	S1
Harm occurrence probability (value)	P2	P2	P2
Risk value acceptability	R1	R1	R1
Are risk control measures required?	No	No	No
Risk mitigation action	N/A	N/A	N/A
Traceability links	N/A	N/A	N/A
Harm severity (value)	N/A	N/A	N/A
Harm occurrence probability (value)	N/A	N/A	N/A
Risk value after mitigation actions	N/A	N/A	N/A
Is summative evaluation required?	N/A	N/A	N/A

Risk Assessment

Risk ID	U30	U31	U32
Function	Configure a plan for stationary patients	Configure a plan for aftercare patients	
Hazard-related use scenario	The user can forget to create a training plan	The user may not understand how to configure an aftercare plan	The user may not receive patient progress results
Hazardous situation	The inability to create a training plan can lead to the absence of rehabilitation	The wrong aftercare plan can cause injury or lead to incorrect rehabilitation	
Harm severity (value)	S1	S2	S2
Harm occurrence probability (value)	P2	P2	P2
Risk value acceptability	R1	R1	R1
Are risk control measures required?	No	No	No
Risk mitigation action	N/A	N/A	N/A
Traceability links	N/A	N/A	N/A
Harm severity (value)	N/A	N/A	N/A
Harm occurrence probability (value)	N/A	N/A	N/A
Risk value after mitigation actions	N/A	N/A	N/A
Is summative evaluation required?	N/A	N/A	N/A

Risk Assessment

Risk ID	U33	U34
Function	Configure a plan for aftercare patients	
Hazard-related use scenario	The user may not understand that the patient is not ready for aftercare (the patient hasn't finished their stationary training program)	The user may prescribe aftercare to a patient by mistake
Hazardous situation	The wrong aftercare plan can cause injury or lead to incorrect rehabilitation	
Harm severity (value)	S2	S2
Harm occurrence probability (value)	P3	P3
Risk value acceptability	R2	R2
Are risk control measures required?	Yes	Yes
Risk mitigation action	1.A user can download a report about a patient's progress in the CSV format; 2. The function to view patient progress/activity.	1. The user can't prescribe the patient aftercare if the patient has an active stationary training plan; 2. The "The patient has an active stationary training plan" notification; 3. A dashboard displays the latest stationary sessions of patients.
Traceability links	https://livingb rain.atlassian. net/wiki/spac es/AN/pages/1052672001/US-10.1+Get+a+report+about+patient+s+progress US-3.3 View patient's plan	US-3.13 Configure a plan for aftercare patients US-8.1 View available sections
Harm severity (value)	S2	S2
Harm occurrence probability (value)	P2	P1
Risk value after mitigation actions	R1	R1
Is summative evaluation required?	No	No

Risk Assessment

Risk ID	U35	U36
Function	Configure a plan for aftercare patients	View a patient's plan
Hazard-related use scenario	The user may assign the wrong training plan	The user may open the wrong patient profile
Hazardous situation	The wrong aftercare plan can cause injury or lead to incorrect rehabilitation	The wrong training plan can lead to incorrect rehabilitation
Harm severity (value)	S2	S2
Harm occurrence probability (value)	P3	P2
Risk value acceptability	R2	R1
Are risk control measures required?	Yes	No
Risk mitigation action	1. The user can see all scenarios that can be used by patients; 2. The user can specify the number of sessions for the patient; 3. The user can see the list of available scenarios/exercises for the patient; 4. The user cannot select a completely empty plan; 5. The system asks the user to create a training plan.	N/A
Traceability links	US-3.13 Configure a plan for aftercare patients	N/A
Harm severity (value)	S2	N/A
Harm occurrence probability (value)	P3	N/A
Risk value after mitigation actions	R1	N/A
Is summative evaluation required?	No	N/A

Risk Assessment

Risk ID	U37	U38	U39
Function	View a patient's plan		
Hazard-related use scenario	The user may not receive patient progress results	The user may not know that exercises are included in each scenario	The user may not know that exercises were assigned to the patient
Hazardous situation	The wrong training plan can lead to incorrect rehabilitation		
Harm severity (value)	S2	S2	S2
Harm occurrence probability (value)	P2	P3	P3
Risk value acceptability	R1	R2	R2
Are risk control measures required?	No	Yes	Yes
Risk mitigation action	N/A	A drop-down list of exercises (from a scenario)	The user can view selected scenarios (exercise availability switch)
Traceability links	US-3.3 View patient's plan		
Harm severity (value)	N/A	S2	S2
Harm occurrence probability (value)	N/A	P1	P1
Risk value after mitigation actions	N/A	R1	R1
Is summative evaluation required?	N/A	No	No

Risk Assessment

Risk ID	U40	U41	U42
Function	View a patient's plan		
Hazard-related use scenario	The user may not know that cognitive functions are trained with each exercise	The user may assign wrong scenarios	The user may forget to save changes
Hazardous situation	The wrong training plan can lead to incorrect rehabilitation		
Harm severity (value)	S2	S2	S2
Harm occurrence probability (value)	P3	P2	P2
Risk value acceptability	R2	R1	R1
Are risk control measures required?	Yes	No	No
Risk mitigation action	The user can view what each cognitive exercise focuses on	N/A	N/A
Traceability links	US-3.3 View patient's plan	N/A	N/A
Harm severity (value)	S2	N/A	N/A
Harm occurrence probability (value)	P1	N/A	N/A
Risk value after mitigation actions	R1	N/A	N/A
Is summative evaluation required?	No	N/A	N/A

Risk Assessment

Risk ID	U43	U44	U45	U46
Function	View a patient's progress and a patient's sessions			
Hazard-related use scenario	The user may open the wrong patient profile	The user may not receive/find the patient's general progress	The user may not receive/find the patient's daily progress (detailed results)	The user may not receive/fi nd what sessions were completed
Hazardous situation	Unawareness of patient progress can lead to a lack of or excessive rehabilitation			
Harm severity (value)	S2	S2	S2	S2
Harm occurrence probability (value)	P2	P2	P2	P2
Risk value acceptability	R1	R1	R1	R1
Are risk control measures required?	No	No	No	No
Risk mitigation action	N/A	N/A	N/A	N/A
Traceability links	N/A	N/A	N/A	N/A
Harm severity (value)	N/A	N/A	N/A	N/A
Harm occurrence probability (value)	N/A	N/A	N/A	N/A
Risk value after mitigation actions	N/A	N/A	N/A	N/A
Is summative evaluation required?	N/A	N/A	N/A	N/A

Risk Assessment

Risk ID	U47	U48
Function	View a patient's progress and a patient's sessions	
Hazard-related use scenario	The user may not understand the results of rehabilitation	The user may not understand that rehabilitation is completed
Hazardous situation	Unawareness of patient progress can lead to a lack of or excessive rehabilitation	
Harm severity (value)	S2	S2
Harm occurrence probability (value)	P2	P3
Risk value acceptability	R1	R2
Are risk control measures required?	No	Yes
Risk mitigation action	N/A	1. The user can view the detailed progress of a patient; 2. The user can view the progress in three formats: calendar, table, diagram (general progress) 3. The user can select a day in the calendar to view more details about treatment; 4. The user can choose a session; 5. The user can view the number of exercises; 6. The user can view the frequency of exercises; 7. The function for generating a report about a patient's progress.
Traceability links	N/A	US-3.4 View a patient's progress US-3.5 View a patient's sessions US-10.1 Get a report about a patient's progress
Harm severity (value)	N/A	S2
Harm occurrence probability (value)	N/A	P1
Risk value after mitigation actions	N/A	R1
Is summative evaluation required?	N/A	No

Risk ID	U49	U50	U51
Function	View a patient's progress and a patient's sessions		View a patient's progress and a patient's sessions
Hazard-related use scenario	The user may assign additional sessions	The user may stop the rehabilitation too early	The user may select the wrong clinic
Hazardous situation	Unawareness of patient progress can lead to a lack of or excessive rehabilitation		Deactivating the wrong clinic can cause the loss of rehabilitation progress and block further rehabilitation
Harm severity (value)	S2	S2	S1
Harm occurrence probability (value)	P2	P3	P2
Risk value acceptability	R1	R2	R1
Are risk control measures required?	Yes	Yes	No
Risk mitigation action	N/A	1. The user can only deactivate a patient if this patient doesn't have any active training sessions; 2. The system displays the "You cannot deactivate <FirstName+ Last Name> because <First Name+Last Name> has active training sessions." notification.	N/A
Traceability links	N/A	US-3.14 Make a patient inactive	N/A
Harm severity (value)	N/A	S2	N/A
Harm occurrence probability (value)	N/A	P1	N/A
Risk value after mitigation actions	N/A	R1	N/A
Is summative evaluation required?	N/A	N/A	N/A

Risk Assessment

Risk ID	U52	U53	U54
Function	View a patient's progress and a patient's sessions		
Hazard-related use scenario	The user may not receive information about active patients and devices	The user may not know that there are active patients and devices in the clinic	The user can deactivate a clinic with active patients and devices by mistake
Hazardous situation	Deactivating the wrong clinic can cause the loss of rehabilitation progress and block further rehabilitation		
Harm severity (value)	S1	S1	S1
Harm occurrence probability (value)	P2	P3	P3
Risk value acceptability	R1	R2	R2
Are risk control measures required?	No	Yes	Yes
Risk mitigation action	N/A	1. All patients related to a deactivated clinic must be inactive; 2. It is not possible to deactivate a clinic with active patients (patients who are still undergoing treatment);	1. It is not possible to deactivate a clinic with active patients (patients who still undergo treatment); 2. It is not possible to deactivate the clinic with devices; 3. The system displays the "The clinic cannot be deactivated because it has active patients or devices" notification.
Traceability links	N/A	US-5.3 Deactivate a clinic	US-5.3 Deactivate a clinic
Harm severity (value)	N/A	S1	S1
Harm occurrence probability (value)	N/A	P1	P1
Risk value after mitigation actions	N/A	R1	R1
Is summative evaluation required?	N/A	No	No

Risk ID	U55	U56	U57
Function	Delete a physician's account		
Hazard-related use scenario	The user (clinic admin) may select the wrong physician	The user may not receive information about active patients of a selected physician	The user may not know that a selected physician has active patients
Hazardous situation	Deleting the wrong physician's account can cause the loss of rehabilitation progress and block further rehabilitation		
Harm severity (value)	S1	S1	S1
Harm occurrence probability (value)	P2	P2	P3
Risk value acceptability	R1	R1	R2
Are risk control measures required?	No	No	Yes
Risk mitigation action	N/A	N/A	A physician's account can only be deleted after their patients are assigned to other physicians.
Traceability links	N/A	N/A	US-6.3 Delete a physician's account
Harm severity (value)	N/A	N/A	S1
Harm occurrence probability (value)	N/A	N/A	P1
Risk value after mitigation actions	N/A	N/A	R1
Is summative evaluation required?	N/A	N/A	No

Risk Assessment

Risk ID	U58	U59	U60
Function	Delete a physician's account	Make a patient inactive	
Hazard-related use scenario	The user may delete a physician's account by mistake	The user may select the wrong patient	The user may not receive information about the patient's activity
Hazardous situation	Deleting the wrong physician's account can cause the loss of rehabilitation progress and block further rehabilitation	Deactivating the wrong patient can cause the loss of their rehabilitation progress and block further rehabilitation	
Harm severity (value)	S1	S1	S1
Harm occurrence probability (value)	P3	P2	P2
Risk value acceptability	R2	R1	R1
Are risk control measures required?	Yes	No	No
Risk mitigation action	1. The user can only delete a physician's account if this physician does not have any assigned patients; 2. The system displays the "You cannot delete <First Name+Last Name>'s account because <First Name+Last Name> has patients." notification.	N/A	N/A
Traceability links	US-6.3 Delete a physician's account	N/A	N/A
Harm severity (value)	S1	N/A	N/A
Harm occurrence probability (value)	P1	N/A	N/A
Risk value after mitigation actions	R1	N/A	N/A
Is summative evaluation required?	No	N/A	N/A

Risk Assessment

Risk ID	U61	U62
Function	Make a patient inactive	
Hazard-related use scenario	The user may not understand that the patient is active (hasn't completed training sessions)	The user may deactivate a patient who hasn't completed training sessions by mistake
Hazardous situation	Deactivating the wrong patient can cause the loss of their rehabilitation progress and block further rehabilitation	
Harm severity (value)	S1	S2
Harm occurrence probability (value)	P3	P3
Risk value acceptability	R2	R2
Are risk control measures required?	Yes	Yes
Risk mitigation action	1. The user can view detailed progress of a patient; 2. The user can view the progress in three formats: calendar, table, diagram (general progress). 3. The user can select a day in a calendar to view more details about treatment; 4. The user can select a session; 5. The user can view the number of exercises; 6. The user can view the frequency of exercises; 7. The function for generating a report about a patient's progress.	1. The user can only deactivate a patient if this patient doesn't have any active training sessions; 2. The system displays the "You cannot deactivate < First Name+Last Name> patient because <First Name+Last Name> has active training sessions." notification.
Traceability links	US-3.4 View a patient's progress US-3.5 View a patient's sessions US-10.1 Get a report about a patient's progress	US-3.14 Make a patient inactive
Harm severity (value)	S1	S1
Harm occurrence probability (value)	P2	P2
Risk value after mitigation actions	R1	R1
Is summative evaluation required?	No	No

3.3 Hazard-Related Use Scenarios for Summative Evaluation

All hazard-related use scenarios are mitigated in the HA functionality (see Sec 3.2). Formative evaluation will be performed in the frame of manual testing according to AS.HP.PP.04 Validation Plan. Summative evaluation is not required since all hazard-related use scenarios are mitigated.

Migration Actions and User Interface Specification

Mitigation actions are defined as risk control measures and listed in tables 1-12 and section 3.2 (see above). The user interface of HA is described in AS.HP.PD.06 Software Design Document.

Formative Evaluation

Formative evaluation has been performed in the frame of manual testing according to AS.LB.PP.04 Validation Plan. Test results are described in AS.HP.PR.05 Test Result Report and AS.HP.PR.02 Validation Report.

Summative Evaluation

N/A

Conclusion

All hazard-related use scenarios are mitigated in the HA functionality (see Sec 3.2). Formative evaluation will be performed in the frame of manual testing according to AS.HP.PP.04 Validation Plan. Test results are described in AS.HP.PR.05 Test Result Report and AS.HP.PR.02 Validation Report. Summative evaluation is not required since all hazard-related use scenarios are mitigated in the HA functionality. No user errors are expected. The HA is considered safe for intended use.