Instructions for use "Psylaris Care"

About these Instructions for Use
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This document is intended for users of Psylaris Care. It provides all necessary instructions for safe and effective use, including preparation, installation, operation, maintenance, and decommissioning. Psylaris Care will be pre-installed on the VR headset provided to the user. Therefore, only the technical information relevant to the software will be included in these instructions for use. For technical specifications or further details regarding the use of the VR headset itself, please refer to the manufacturer's instructions for use.

Made by EMDR-VR B.V., located at Boschstraat 21, 6211 AS, Maastricht, the Netherlands

Manufacturer

Name	Psylaris (EMDR-VR B.V.)
Website	https://psylaris.com/
Contact details	info@psylaris.com +31 852 00 73 39
Address	Boschstraat 21, 6211 AS Maastricht, The Netherlands

Incident reporting

If a serious incident occurs in relation to this device, including but not limited to malfunctions, errors, failures, or unexpected adverse events that could result in a significant health risk, please report it without undue delay using the contact information provided above.

Discontinue the use of Psylaris Care if the incident poses immediate risks to the user's well-being, and make sure that the user receives appropriate care.

To assist in the investigation and resolution of the issue, please include the following details in your report:

1. **Device information.** Model name and software version.
2. **Incident details.** Date, location, and a clear description of what happened.
3. **Outcome.** Any impact on the patient, user, or third parties.
4. **Corrective actions taken.** Such as device removal, medical intervention, or software updates.

Our support team may request additional information when investigating the incident thoroughly and will take immediate action to address any issues.
For technical support or non-serious issues, please contact the support team (support@psylaris.com or +31 852 00 73 39).

Device

Label

Psylaris Care

Psylaris (EMDR-VR B.V.)
Boschstraat 21, 6211 AS Maastricht, The Netherlands
info@psylaris.com
+31 852 00 73 39
Psylaris Care is a medical device software designed to support healthcare professionals and clients with autonomous and therapist-guided session in therapeutic interventions for psychotherapy using virtual reality (VR) and other digital technologies
UDI (01)08720892417206(11)230324
This product is a medical device
Warnings: motion sickness, photosensitive epilepsy & psychological distress
Instructions for Use are provided in electronic form at the following website: https://psylaris.helpkit.so/
Refer to the manufacturer's instructions for use for details on any specific storage or handling requirements for the VR headset.
Consult the electronic instructions for use

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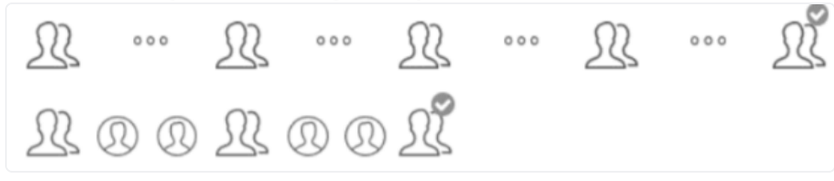
Intended use

Intended purpose	**Psylaris Care** is designed to support healthcare professionals and clients in therapeutic interventions using virtual-reality (VR) and other digital technologies. The platform is intended to increase treatment intensity and engagement for clients with various mental-health indications, while maintaining or improving clinical outcomes. All clinical claims stated herein are supported by evidence summarised in the Private (https://app.clickup.com/2476836/docs/2bjt4-21492/2bjt4-178612). **EMDR-VR, EMDR-plus and EMDR-remote** are used to reduce the impact of traumatic memories by targeting specific mental imagery. EMDR-VR provides autonomous VR

	sessions; EMDR-plus consists of therapist-guided VR sessions (on-site or remote); EMDR-remote offers therapist-guided computer sessions (on-site or remote). These modalities facilitate a more intensive EMDR treatment than conventional EMDR, as demonstrated by clinical evidence. **Exposure-VR** is used to reduce and ultimately eliminate anxiety responses by exposing users to anxiety-provoking situations in a controlled and safe virtual environment, helping users build confidence before real-life exposure. **Relaxation-VR** provides acute stress relief, reduces muscle tension, and supports pain management through breathing exercises, progressive relaxation, meditation techniques, and immersive 360° environments. The relaxation module also enhances the efficiency of ongoing therapies by improving relaxation and focus. **Medical Hypnosis-VR** supports the reduction of pain-medication use during medical or dental procedures by engaging patients in a comforting virtual environment. **CBT-VR** is used to educate clients about depression-related issues and coping strategies through interactive scenarios and mini-stories, promoting treatment focus and skill development. **Treatment efficiency:** By intensifying therapeutic processes and improving session structure, the platform may reduce the total number of required treatment sessions (up to approximately 30% for specific indications and protocols) when used within the defined user and patient environments.
Operating principles	Psylaris Care is a digital platform designed to integrate virtual reality (VR) and online technology with established therapeutic methods for treating trauma, anxiety, addiction, pain, stress and depression. The platform offers a range of tools and applications specifically designed to support both practitioners and clients in intensifying and enhancing therapeutic sessions. **1. Virtual reality integration:** Among other things, the platform uses VR technology to create immersive environments in which clients can be exposed to specific

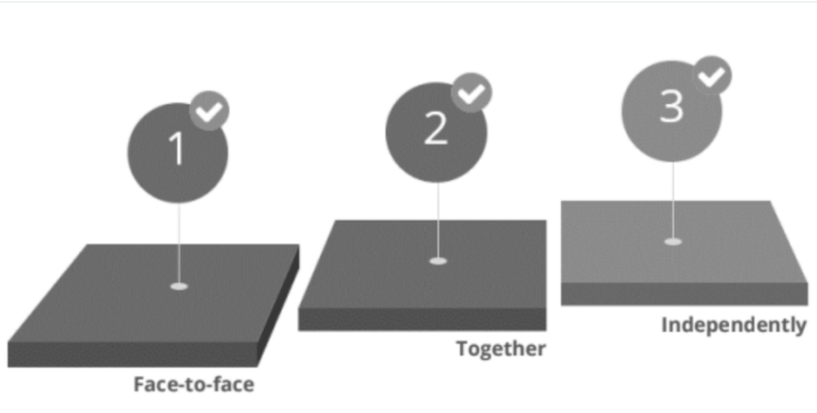
	scenarios, stimuli or relaxation environments, depending on therapeutic needs. **2. Clinician-driven interventions:** Through a user-friendly dashboard, healthcare providers can adjust the settings of the VR solutions, depending on the client's reactions and needs. **3. Client response feedback:** The system collects and analyses client responses and choices during VR sessions. This data is then presented to the practitioner to provide insight into the effects of the glasses **4. Data analysis and reporting:** The platform offers advanced data analysis features that allow healthcare providers to track clients' progress. This allows practitioners to make informed decisions about the next steps in treatment. **5. Modular design:** The various software modules, such as EMDR-VR, EMDR-plus, Exposure, and others, are designed to work seamlessly together within the platform. This allows practitioners to tailor therapies to each client's individual needs. **6. Autonomous interventions:** Through a user-friendly interface, patients can complete various treatments independently without the need for a practitioner to be present.
Intended users	- Qualified healthcare professionals who want to integrate technology into treatment. - The platform is intended exclusively for use by qualified healthcare professionals. Clients can only access and use certain solutions when guided or supervised by their healthcare provider: in the treatment room, remotely, or at home. - Psylaris Care is to be used by clients currently undergoing treatment under consultation of a healthcare professional (therapist). Its sessions do not completely replace sessions with a therapist, but they complement them: 

	Face-to-face therapy versus with the autonomous use of Psylaris Care in between sessions with the therapist
User qualifications and training requirements	Therapeutic content within Psylaris Care is designed for use by qualified healthcare professionals. Clients should not attempt to interpret or apply therapy content independently, as misinterpretation may lead to ineffective or harmful self-treatment. Optional training is available for each module. The software may only be used by qualified healthcare professionals working in mental health care. It is not intended for use by patients. The software is intended solely as an adjunct to the treatment provided by the healthcare professional.
Intended patient population	Clients aged 12 and above with one of the formulated indications.
Environment the medical device can be used	Psylaris care is designed to be used by clients under supervision of a healthcare professional, either in a clinical setting (such as hospitals or mental health clinics) or at home.
Patient selection criteria	Clients who - always under the guidance/supervision of their healthcare provider - together in the treatment room, remote or autonomously at home, want to use certain solutions on the platform. They should either be on a waiting list for treatment or actively receiving treatment.
Medical condition(s) and indications	Medical conditions: - Post-traumatic Stress Disorder (PTSD)/trauma - Generalized Anxiety Disorder (GAD) - Depression - Substance use disorders - Behavioral addictions Indications: - Depression - Stress - Pain - Anxiety - Phobias - Addiction - Trauma/PTSD
Contraindications, including any technical issues, limitations,	- Clients with severe VR-induced motion sickness or other VR-related health problems.

disclaimer to the use of the software	- Clients with severe psychotic disorders or currently experiencing a severe crisis unless specifically recommended and supervised by a qualified health professional. - Clients with a history of severe photosensitive epileptic seizures. - Clients with current suicidal tendencies. - Psylaris Care may have limited accessibility for clients with visual, auditory, motor, or cognitive impairments. Therapists should assess suitability before use. Alternative therapeutic methods should be considered if accessibility limitations prevent safe or effective use. - Clients with a history of severe or recurrent dissociation or depersonalization should not use Psylaris Care unless specifically recommended and closely supervised by a qualified healthcare professional.
Residual risks and side-effects	As a client, do NOT use Psylaris Care when: - You are not currently seeing a therapist or when it was not directly agreed upon with your therapist. - You are subject to any form of seizures or epilepsy. - You are getting nauseous from being in virtual reality (see “Warnings and precautions”). - You are – or recently were – having suicidal feelings. As a therapist, do NOT let a client use Psylaris Care when: - The user is getting nauseous from being in virtual reality (see “Warnings and precautions”). - You are not confident you have an overview of the client’s history and current (home) situation.
Warnings and notices for safety and/or security	- Motion sickness or discomfort: if VR content involves rapid movements, it can induce motion sickness. Symptoms can be reduced by taking breaks and focusing on stationary objects. If you experience nausea during the first sessions, cease use of the virtual reality headset and finish the session with treatment as usual from your therapist. - Photosensitive epilepsy: VR may trigger adverse reactions, so suitability and potential risks should be assessed by a healthcare professional beforehand. - Physical harm: do not use Psylaris Care in an unsafe situation due to environmental hazards (such as open fire or water) or relational stress. - Battery: do not use Psylaris Care when the battery of the headset and controller(s) are not charged. - Connectivity: an internet connection is required for the therapist to send tasks and/or media to the VR-headset.

	- Updates: application updates are not downloaded when there is no internet connection. Psychological distress: - Addressing challenging or traumatic experiences may evoke strong emotional responses. Users should consult with a healthcare professional before using Psylaris Care and communicate any distress they experience during sessions. - Some clients may experience dissociation or depersonalization during or after sessions (e.g., feeling detached from their body or surroundings). If such symptoms occur, discontinue the session immediately and consult the supervising therapist. Clients with a history of dissociation require additional monitoring. Autonomous use: - Do not skip the recommended onboarding process. Each client should first use Psylaris Care in a therapist-led session, then in supervised sessions, before moving to autonomous use. Skipping these steps increases the risk of overwhelming emotional responses or misuse. - Psylaris Care is an adjunct to therapy and not a substitute. Over-reliance on the software without ongoing therapeutic contact may negatively affect treatment outcomes. - Do not exceed the frequency or duration of sessions agreed with the therapist. Excessive or prolonged use may cause fatigue, stress, or reduced therapeutic benefit.
Intended conditions of use	- Psylaris Care is used to treat mental health conditions like those mentioned in "Medical condition(s) and indications". - Sessions are tailored to the client's treatment plan. - Psylaris Care is often integrated with traditional therapeutic methods like cognitive-behavioral therapy. - Clients should adhere to the agreed treatment plan and scheduled Psylaris Care sessions. Lack of adherence may reduce treatment effectiveness and requires therapist follow-up. - It is the health professional who decides if and when Psylaris Care is suitable for the client's therapy plan. In most cases, a stepwise approach is recommended where: 1. The client and therapist have a face-to-face session and follow the standard protocol. 2. The client uses Psylaris Care with the therapist present.

3. The client uses Psylaris Care autonomously, without the therapist present, e.g. at home or in a different room.
After each step, the client and therapist will re-evaluate whether Psylaris Care suits the personal needs.



A stepwise approach in starting with Psylaris Care

Expected clinical benefits

Clinical benefits	Relevant clinical outcome measures	Justification	Applicable in specific contexts or certain demographic groups
EMDR			
Shorter therapy duration compared to traditional therapy.	Less total (face-to-face) treatment minutes.	White paper from Mental Care Group: "Zelfstandige behandelinterventies in de GGZ: De toekomst of nu al "Virtuele Realiteit"?". This highlights the higher efficiency of autonomous therapy. In 2026, the feasibility study of GGz Drenthe will be published on applying VR EMDR as an add-on to regular trauma focused treatment in veterans with PTSD.	Demonstrated in a Dutch mental healthcare setting using autonomous VR interventions (Mental Care Group whitepaper). Feasibility study announced for use as an add-on to trauma-focused therapy in veterans with PTSD (GGZ Drenthe).
Greater treatment adherence	**- Session Attendance Rate:** Proportion of scheduled sessions attended.	White paper from Mental Care Group: "Zelfstandige behandelinterventies in de GGZ: De toekomst of nu al "Virtuele Realiteit"?". This	Reported in a Dutch mental healthcare setting (Mental Care Group whitepaper) showing comparable

	- Treatment Dropout Rate: Percentage of participants who discontinue before planned end. **- Visual Analogue Scales (VAS) or Session Feedback Forms:** Patient-rated perceived benefit or symptom relief after each session.	highlights a similar dropout rate compared to treatment as usual.	dropout rates to treatment as usual. No specific demographic group identified.
Reduction in overall PTSD symptom severity	**- CAPS-5 (Clinician-Administered PTSD Scale for DSM-5):** Gold standard for assessing PTSD symptom severity; sensitive to treatment changes. **- PCL-5 (PTSD Checklist for DSM-5):** Self-report measure for PTSD symptom severity; good for tracking over shorter intervals.	Study using Psylaris Care: Bragt-de Jong, H. J., Dejonckheere, E., Smeets, T., Lodder, P., & Karreman, A. (2025). Combining virtual reality-based positive mental imagery and dual tasking increases children's willingness to exposure. *Cognition and Emotion*, 1-15. White paper from Mental Care Group: "Zelfstandige behandelinterventies in de GGZ: De toekomst of nu al "Virtuele Realiteit"?". In 2026, the feasibility study of GGz Drenthe will be published on applying VR EMDR as an add-on to regular trauma focused treatment in veterans with PTSD. In 2026, the qualitative case study of 1 patient using EMDR-VR with the UMC hospital will be published in the internal journal of the hospital for psychiatrists.	Feasibility study announced for use of VR EMDR as an add-on in veterans with PTSD (GGZ Drenthe). Single qualitative case study in a psychiatric hospital patient (UMC) using EMDR-VR.
Reduced emotional intensity of trauma-related memories	PCL-5 subscale improvement in **negative mood** and **hyperarousal**	Study using Psylaris Care: IJdema, T., Laceulle, O. M., Dibbets, P., & Korrelboom, K.	Adult population: VR eye movements were found non-

	items suggests reduced emotional reactivity to trauma reminders. These results where also found in a non-clinical population, where participants self-reported significantly lower emotionality on 0-100 Visual Analogue Scales (VAS).	(2023). Virtual reality eye movements are not inferior to computerized eye movements and exposure in ameliorating aversive memories. *Computers in Human Behavior Reports*, *11*, 100311. White paper from Mental Care Group: "Zelfstandige behandelinterventies in de GGZ: De toekomst of nu al "Virtuele Realiteit"?". In 2026, the feasibility study of GGz Drenthe will be published on applying VR EMDR as an add-on to regular trauma focused treatment in veterans with PTSD. In 2026, the qualitative case study of 1 patient using EMDR-VR with the UMC hospital will be published in the internal journal of the hospital for psychiatrists.	inferior to computerized eye movements and exposure for reducing emotionality of aversive memories (Ijdema et al., 2023). Also observed in a non-clinical adult sample.
Reduced vividness and sensory intrusiveness of aversive memories	PCL-5: Decreased **Intrusion subscale** scores, particularly items related to **flashbacks** and **intrusive thoughts**, reflecting lower sensory impact of memories. These results where also found in a non-clinical population, where participants self-reported significantly lower vividness on 0-100 Visual Analogue Scales (VAS).	Study using Psylaris Care: IJdema, T., Laceulle, O. M., Dibbets, P., & Korrelboom, K. (2023). Virtual reality eye movements are not inferior to computerized eye movements and exposure in ameliorating aversive memories. *Computers in Human Behavior Reports*, *11*, 100311. White paper from Mental Care Group: "Zelfstandige behandelinterventies in de GGZ: De toekomst of nu al "Virtuele Realiteit"?".	Adult population: VR eye movements were found non-inferior to computerized eye movements for reducing vividness and sensory intrusion of aversive memories (Ijdema et al., 2023). Also observed in a non-clinical adult sample.

		In 2026, the feasibility study of GGz Drenthe will be published on applying VR EMDR as an add-on to regular trauma focused treatment in veterans with PTSD. In 2026, the qualitative case study of 1 patient using EMDR-VR with the UMC hospital will be published in the internal journal of the hospital for psychiatrists.	
Decreased frequency of intrusive thoughts and recollections	Statistically significant reduction in the frequency of **intrusive recollections** of traumatic events as indicated by **Intrusion subscale** of the PCL-5.	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5 subscale scores were not reported in the publications.	No subgroup or demographic-specific effects reported in publications.
Reduced avoidance behaviors	Marked improvements in **Avoidance subscale** scores, including avoidance of trauma-related thoughts, conversations, and people.	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5 subscale scores were not reported in the publications.	No subgroup or demographic-specific effects reported in publications.
Improved cognitive and emotional regulation	Decrease in **arousal** and **negative mood** symptoms (PCL-5), indicating enhanced **emotional regulation** and decreased irritability.	Study using Psylaris Care: Bragt-de Jong, H. J., Dejonckheere, E., Smeets, T., Lodder, P., & Karreman, A. (2025). Combining virtual reality-based positive mental imagery and dual tasking increases children's willingness to exposure. *Cognition and Emotion*, 1-15.	No subgroup or demographic-specific effects reported in publications.
Improved ability to engage with trauma-related content and	Reduction in **avoidance** and **negative mood** on the PCL-5, facilitating more effective engagement in trauma-	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5	No subgroup or demographic-specific effects reported in publications.

processing thereof in therapy	focused therapies (e.g., prolonged exposure).	subscale scores were not reported in the publications.	
Reduced hypervigilance and startle response	Significant reductions in **hyperarousal** symptoms, including **exaggerated startle response** and **hypervigilance** as reflected in PCL-5 scores.	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5 subscale scores were not reported in the publications.	No subgroup or demographic-specific effects reported in publications.
Increased readiness for or engagement in additional therapeutic interventions	Improved PCL-5 subscale scores on **avoidance** and **negative mood** suggest increased **engagement in therapy** and readiness for further interventions.	Study using Psylaris Care: Bragt-de Jong, H. J., Dejonckheere, E., Smeets, T., Lodder, P., & Karreman, A. (2025). Combining virtual reality-based positive mental imagery and dual tasking increases children's willingness to exposure. *Cognition and Emotion*, 1-15.	No subgroup or demographic-specific effects reported in publications.
Reduced emotional numbness and detachment	Improvements in **negative mood** and **dissociation** items, including a reduction in feelings of detachment from others and the world.	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5 subscale scores were not reported in the publications.	No subgroup or demographic-specific effects reported in publications.
Improved concentration and mental clarity	PCL-5 scores show reduced **cognitive impairment** (e.g., difficulty concentrating) commonly seen in PTSD, suggesting improved mental clarity.	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5 subscale scores were not reported in the publications.	No subgroup or demographic-specific effects reported in publications.
Reduced self-blame and negative self-perceptions	Decrease in **negative alterations in cognition** subscale, particularly self-blame, guilt, and negative self-image, as measured by PCL-5.	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5 subscale scores were not reported in the publications.	No subgroup or demographic-specific effects reported in publications.
[indirect] Improved sleep quality	Decreased **sleep disturbances** related to trauma, as evidenced by improvements in	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5	No subgroup or demographic-specific effects

	arousal/reactivity and **intrusion** symptoms on PCL-5.	subscale scores were not reported in the publications.	reported in publications.
[indirect] Improved day-to-day functioning and coping capacity	Improved PCL-5 scores correlate with increased **functional capacity** in social, occupational, and personal domains, leading to better **coping strategies**.	Various studies using Psylaris Care included PCL-5 as an outcome measure; however, results for individual PCL-5 subscale scores were not reported in the publications.	No subgroup or demographic-specific effects reported in publications.
Relaxation			
Reduced anxiety	Reported significant decrease in reported anxiety. **GAD-7 (Generalized Anxiety Disorder-7):** A brief, validated self-report measure widely used for screening and monitoring anxiety symptoms. Sensitive to change and appropriate across populations.	Study using Psylaris Care: Bernaerts, S., Bonroy, B., Daems, J., Sels, R., Struyf, D., Gies, I., & van de Veerdonk, W. (2022). Virtual reality for distraction and relaxation in a pediatric hospital setting: an interventional study with a mixed-methods design. *Frontiers in digital health*, *4*, 866119.	Paediatric hospital setting: VR distraction and relaxation used to reduce anxiety, pain, and stress in children during hospitalisation (Bernaerts et al., 2022).
Reduced pain	**Visual Analogue Scale (VAS)** for pain.	Study using Psylaris Care: Bernaerts, S., Bonroy, B., Daems, J., Sels, R., Struyf, D., Gies, I., & van de Veerdonk, W. (2022). Virtual reality for distraction and relaxation in a pediatric hospital setting: an interventional study with a mixed-methods design. *Frontiers in digital health*, *4*, 866119. At the end of 2025, a study in collaboration with the Albert Schweitzer Ziekenhuis hospital and Tilburg University will analyze the use of VR relaxation in a pre-operative setting to reduce anxiety and pain.	Paediatric hospital setting: VR distraction and relaxation used to reduce anxiety, pain, and stress in children during hospitalisation (Bernaerts et al., 2022).

Reduced stress/tensions levels	**- Subjective Units of Distress Scale (SUDS):** Real-time rating (0–100) of perceived tension or distress. **- Visual Analogue Scale (VAS)** for stress/tension. **- Heart Rate Variability (HRV):** Objective physiological indicator of stress. Useful when exploring biological correlates of subjective stress reduction.	Study using Psylaris Care: Bernaerts, S., Bonroy, B., Daems, J., Sels, R., Struyf, D., Gies, I., & van de Veerdonk, W. (2022). Virtual reality for distraction and relaxation in a pediatric hospital setting: an interventional study with a mixed-methods design. *Frontiers in digital health*, *4*, 866119. Blogpost about analysis of Psylaris' internal database: https://psylaris.com/en/blog/blog-how-different-settings-may-impact-sud-reduction/ In 2026, a study on active versus passive relaxation in VR versus non-VR groups will be published in collaboration with Tilburg University. Both psychological and physiological measures will be assessed. In 2026, a study on using a VR headset at home for stress reduction in students will be published in collaboration with the University of Twente. At the end of 2025, a study in collaboration with the Albert Schweitzer Ziekenhuis hospital and Tilburg University will analyze the use of VR relaxation in a pre-operative setting to reduce anxiety and pain.	Paediatric hospital setting: VR distraction and relaxation used to reduce anxiety, pain, and stress in children during hospitalisation (Bernaerts et al., 2022).
Decreased anger and irritability	**PCL-5 Item-Level Analysis:** Specific items on irritability and anger	Source: Use Case - Thomas More (2024), Virtual reality ontspanning voor zorgverleners.	Healthcare professionals: VR relaxation used for stress management

	outbursts can be tracked over time.		in care providers (Thomas More, 2024).
Reduced tiredness	The **Borg Rating of Perceived Exertion (RPE) scale**, is a tool for measuring an individual's effort and exertion, breathlessness and fatigue.	Source: External study that did not use Psylaris Care - Rodrigues, I. M., Lima, A. G., Santos, A. E. D., Santos, A. C. A., Nascimento, L. S. D., Serra, M. V. C. L., ... & Zanona, A. D. F. (2022). A single session of virtual reality improved tiredness, shortness of breath, anxiety, depression and well-being in hospitalized individuals with COVID-19: a randomized clinical trial. *Journal of Personalized Medicine*, *12*(5), 829.	Hospitalised adult COVID-19 patients: Single VR session improved perceived tiredness, breathlessness, anxiety, depression, and wellbeing (Rodrigues et al., 2022).
Decrease in physiological arousal associated with negative affect	**- Heart Rate Variability (HRV):** Higher HRV is associated with greater parasympathetic (calming) activity and emotional regulation. Decreased arousal is typically marked by increased HRV, especially during or after relaxation or emotion-regulation interventions. **- Heart Rate (HR):** Reliable measure of arousal. A decrease in resting or reactive HR indicates lowered physiological activation in response to negative affect. **- Skin Conductance Level (SCL):** Measures sweat gland activity tied to sympathetic arousal. Reductions in SCL indicate reduced physiological arousal, especially in	Source: various use cases using Psylaris Care by Thomas More. - Thomas More (2024), Virtual reality ontspanning voor zorgverleners. - Thomas More (2024), Virtual reality ontspanning voor patiënten op een PAAZ. - Thomas More (2024), Virtual reality ontspanning voor ouders op de afdeling neonatale intensieve zorgen. In 2026, a study on active versus passive relaxation in VR versus non-VR groups will be published in collaboration with Tilburg University. Both psychological and physiological measures will be assessed.	Documented in use cases with healthcare professionals, psychiatric ward patients (PAAZ), and parents in neonatal intensive care settings (Thomas More, 2024).

	response to stress, anxiety, or fear stimuli. **- Cortisol (Salivary):** Cortisol is a key stress hormone. Reduced baseline or reactivity levels (especially in saliva) reflect lowered physiological stress, often tied to improvements in mood and affect regulation. **- Respiration Rate (RR):** Elevated breathing rate is linked to anxiety and stress. A reduction in RR suggests a shift to a calmer physiological state.		
Increased happiness	**- Visual Analogue Scale (VAS) for Happiness:** The VAS is a simple, flexible tool that allows individuals to rate their current level of happiness on a continuum. **- Positive and Negative Affect Schedule – Positive Affect Subscale (PANAS-PA):** Separates positive from negative emotional states. The Positive Affect subscale specifically tracks feelings such as enthusiasm, alertness, and joy—key indicators of increased happiness.	Study using Psylaris Care: Bernaerts, S., Bonroy, B., Daems, J., Sels, R., Struyf, D., Gies, I., & van de Veerdonk, W. (2022). Virtual reality for distraction and relaxation in a pediatric hospital setting: an interventional study with a mixed-methods design. *Frontiers in digital health*, *4*, 866119.	Paediatric hospital setting: VR distraction and relaxation used to reduce anxiety, pain, and stress in children during hospitalisation (Bernaerts et al., 2022).
Exposure			
Desensitization to trauma-related stimuli (e.g. decreased feelings of fear, distress,	**- Subjective Units of Distress Scale (SUDS):** A session-by-session or in-session self-report measure (0–100) that	Study using Psylaris Care: Bragt-de Jong, H. J., Dejonckheere, E., Smeets, T., Lodder, P., & Karreman, A. (2025). Combining virtual	Observed in a paediatric/youth population: VR-based positive mental imagery and

vividness, and anxiety)	captures real-time emotional distress during exposure to trauma-related stimuli. Useful for tracking fear reduction across exposure tasks. **- PTSD Checklist for DSM-5 (PCL-5) – Item-Level Analysis:** Specific items (e.g., distress when exposed to trauma reminders) can track symptom-level change tied to desensitization. **- Difficulties in emotion regulation scale – parent-report (DERS-P):** measures the parental perception of the child's difficulties in emotion regulation.	reality-based positive mental imagery and dual tasking increases children's willingness to exposure. *Cognition and Emotion*, 1-15. In 2026, the study of using VR for exposure in youth will be published. This was executed by FamilySupporters and Tilburg University.	dual-tasking increased willingness to exposure (Bragt-de Jong et al., 2025). Additional youth exposure study announced (FamilySupporters & Tilburg University).
Decrease physiological arousal associated with trauma-related stimuli	Expected: - Heart Rate Variability (HRV) - Heart Rate (HR) - Skin Conductance Level (SCL) - Cortisol (Salivary) - Respiration Rate (RR)	Not yet substantiated by clinical data. Decrease of physical arousal has only been monitored in the context of the Relaxation module.	No population- or context-specific applicability can be stated based on current evidence.
Reduced need for in vivo exposure	Expected: In-vivo requirement index**:** proportion of exposure hierarchy items completed in VR vs real-world.	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.
Reduced threshold for engaging in in vivo exposure	Willingness to Approach Trauma-Related Cues (custom VAS or Likert scale).	Study using Psylaris Care: Bragt-de Jong, H. J., Dejonckheere, E., Smeets, T., Lodder, P., & Karreman, A. (2025). Combining virtual reality-based positive mental imagery and dual tasking increases children's willingness to	Paediatric/youth population: VR-based interventions increased willingness to approach trauma-related cues (Bragt-de Jong et al., 2025).

		exposure. *Cognition and Emotion*, 1-15. Blogpost regarding internal database analysis: https://psylaris.com/en/blog/onderzoek-inzicht-in-vr-kijkgedrag-bij-360-graden-scenarios/	
CBT			
Reduction in maladaptive coping strategies	**Brief COPE Inventory:** Assesses a broad range of coping responses, including maladaptive strategies such as denial, self-blame, behavioral disengagement, and substance use. Allows tracking of change in specific coping styles over time.	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.
Development of adaptive coping and problem-solving skills	**Coping Strategies Inventory (CSI):** Differentiates adaptive vs. maladaptive coping across problem- and emotion-focused domains. Useful for identifying growth in constructive coping.	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.
Increased self-efficacy and perceived control	**Coping Self-Efficacy Scale (CSES)*:*** Specifically assesses confidence in one's ability to use coping skills in stressful situations. Highly relevant for trauma and anxiety-focused interventions.	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.
Enhanced recognition and labeling of emotional states	**Difficulties in Emotion Regulation Scale (DERS)** – *Awareness* and *Clarity* subscales: Measures increased emotional	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.

	insight, which CBT promotes via cognitive restructuring and emotion tracking.		
Reduction in depressive symptoms	**- PHQ-9 (Patient Health Questionnaire-9):** A brief, validated self-report scale aligned with DSM-5 criteria for major depression. Frequently used in CBT to monitor symptom change session-by-session and assess treatment response. Highly sensitive to behavioral and cognitive shifts targeted in CBT. **- HAM-D (Hamilton Rating Scale for Depression):** A clinician-administered scale that evaluates somatic, cognitive, and affective symptoms of depression. Useful in CBT settings to provide an objective assessment alongside self-report. Particularly valuable in research or when clinical validation of improvement is needed.	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.
Support of habit change and goal setting	**Behavioral Activation for Depression Scale (BADS)** – *Activation* and *Work/School Impairment* subscales: Tracks engagement in positive routines and reduced avoidance.	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.
Help break patterns of avoidance and isolation	**Social Avoidance and Distress Scale (SADS):** CBT often includes graded exposure or social skills training for clients	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.

	with isolation/social anxiety.		
Increases motivation and engagement in activities	**Behavioral Activation for Depression Scale (BADS)** – *Activation* Subscale**:** Assesses motivation and engagement in value-driven tasks, a core mechanism in behavioral activation.	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.
Restoration of positive affect and emotional engagement	Contributes to the restoration of emotional range and positive affect, enabling patients to experience and enjoy pleasurable emotions and activities. Measured through increases in PANAS-Positive Affect scores and clinical reports of reduced anhedonia, this benefit is particularly relevant in the treatment of major depressive disorder and PTSD-related emotional numbing.	Not yet substantiated by clinical data.	No population- or context-specific applicability can be stated based on current evidence.

Performance characteristics

Characteristic	Description	Reference
Intended functions	Virtual reality environment providing EMDR, exposure, and relaxation modules. Supports intensive stimuli (visual and auditory) for trauma processing, exposure therapy, and stress relief. Designed as an adjunct to therapy.	User manual

Key performance parameters	Plug-and-play readiness upon unboxing; always up-to-date via automatic updates; autonomous session initiation as soon as headset is powered on. Shortens treatment duration by up to 30%.	Software performance testing
Accuracy & precision	EMDR-Plus allows higher working memory load with configurable stimuli (videos, images, exposure tasks), enabling precise timing and intensity of distraction stimuli.	Clinical evaluation report
Expected outcomes	Augmentation of therapy by enabling more intensive and autonomous sessions, increasing client engagement and reducing treatment duration. Strong therapist and client satisfaction reported.	Intended use, Clinical claims & Expected clinical benefits
Performance limitations	Dependent on stable Wi-Fi and battery power; performance may vary in poor connectivity or lighting. Not explicitly specified by Psylaris, but typical for VR systems.	Software Validation Reports

Preparation, installation or handling

Installation instructions	Psylaris Care will be pre-installed on the VR-headset of the therapist's or patient's choice from the list of compatible devices. In order for the software to work optimaly it needs to be connected to the wifi. Please refer to the manufacturer's instructions for use for details on any specific storage or handling requirements for the VR headset. An internet connection is required for the therapist to send tasks and/or media to the VR-headset.

System requirements and hardware platforms intended to execute the software	Psylaris Care requires 120 MB of available storage on the VR-headset.
Operational security options to be set at installation time	Psylaris Care will be pre-installed on the VR-headset. No operational security options needs to be set at installation time by the user.
IT networks characteristics	Refer to the manufacturer's instructions for use for details on IT networks characteristics for the VR-headset.
Critical dependencies on other applications	An internet connection is required for the therapist to send tasks and/or media to the VR-headset.
Configuration requirements	In order for the software to work the VR-headset needs to be connected to wifi. Refer to the manufacturer's instructions for use for further information on wifi configuration for the VR-headset.
System interface requirements	The software is pre-installed on the VR headsets by Psylaris and verified for correct installation and safety. No further system interface requirements needs to be required by the user.
Details of the supported software platforms	n.a.
Compatible devices, accessories and general-purpose equipment	Psylaris Care is compatible with the VR-headsets “Oculus Go” and “Pico G3 4K” and "Pico 4 Enterprise"
Accessory selection guidance	n.a.
Verification checks and suitability verification	The software is pre-installed on the VR headsets by Psylaris and verified for correct installation and safety. No further checks are required from the user.
Ongoing maintenance, servicing and handling	The software is updated automatically when the headset is powered on, sufficiently charged, and connected to the internet. The update process may take 10–20 minutes depending on the Wi-Fi speed. The headset will restart once the update is complete. No user action is required.
Reference materials	Please refer to the manufacturer's instructions for use provided with the VR headset for details on any

	specific storage or handling requirements for the VR headset.

Start-up and shutdown

Start-up procedure	The software will automatically start when turning on the VR headset.
Shutdown procedure	The software will be turned off when turning off the VR-headset.

Operating procedures & troubleshooting

- Before starting a session with Psylaris Care, please make sure the battery of headset and controller(s) are charged. If the headset does not have sufficient charge to last an average session length, the application will notify you about this.
- If the Psylaris application does not start automatically, navigate through your VR headset's menus to manually start the Psylaris application. In most cases, these menus will be called "Library" or "Applications". When in doubt, please refer to your headset's manufacturer manual.
- If the web browser stays empty after loading EMDR-remote, please ensure you are using a (current) version of the supported web browsers.
- In case Psylaris Care is not pre-installed or for other technical assistance, please contact support: support@psylaris.com.
- For other questions and troubleshooting, please be referred to https://psylaris.helpkit.so/.

Messages & errors
If the application cannot connect to Wi-Fi or fails to start, a notification will be displayed.

End of use

- When treatment is done the patient will turn in the VR headset and accessories at their healthcare provider.
- Data collected during the session is transferred to the healthcare provider's cloud environment after the session ends. Once the transfer is completed, the data is automatically deleted from the headset. Only the healthcare provider has access to the cloud environment.

Data protection

Psylaris Care processes and stores (personal) data in accordance with applicable data protection regulations, including the GDPR. For detailed information about how and where data is hosted, how personal and health-related data is stored and secured, and what technical and organisational measures are in place to protect this data, please refer to our privacy statement.

- The Psylaris Care software is hosted on a standalone VR headset, PC or laptop.
- During sessions, the user interactions, psychological responses (if applicable), and progress through exercises will be collected for real-time interpretation of user inputs and appropriate responses in the virtual environment.

- Session data will be encrypted and temporarily stored on the device. After the data is transmitted to Psylaris' server, the data will be erased from the local storage. The storage infrastructure ensures data integrity and security where data can't be linked to individual users.