



## **Instruction for Use CHES.Flag 1.0.0 - English**

Evaluation Software Development (ESD)


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<b>Document</b>	Instruction for Use CHES.Flag 1.0.0 - English
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<b>Version</b>	35

<b>Signee Name Title</b>	<b>Meaning</b>	<b>Date &amp; Time</b>	<b>Content Version</b>	<b>Verified</b>
Yvonne Rauner Yvonne Rauner	Author	Jun 10, 2024 12:33 PM Europe/Berlin	v. 34	<b>VERIFIED</b>
Florian Santner	Reviewed	Jun 10, 2024 12:41 PM Europe/Vienna	v. 35	<b>VERIFIED</b>
Gerhard Rumpold CEO	Approved	10 Jun 2024 11:34 GMT	v. 35	<b>VERIFIED</b>

 **All Signatures Verified**

The integrity of all signatures and content was verified on Jun 10, 2024 8:19 AM America/New\_York. The Confluence content and attachments have not been modified since signing commenced.

**Version History**

<b>Version</b>	<b>Date</b>	<b>Comment</b>
<b>Current Version (v. 35)</b>	<b>Jun 10, 2024 10:32</b>	<b>Yvonne Rauner</b>

v. 34	Jun 07, 2024 13:43	Yvonne Rauner
v. 33	Jun 07, 2024 13:21	Yvonne Rauner
v. 32	Jun 07, 2024 08:56	Yvonne Rauner
v. 31	Jun 06, 2024 11:10	Florian Santner
v. 30	Jun 06, 2024 09:25	Laura Vetter
v. 29	Jun 06, 2024 09:16	Laura Vetter
v. 28	Jun 06, 2024 09:10	Laura Vetter
v. 27	May 29, 2024 14:46	Laura Vetter
v. 26	May 29, 2024 14:24	Laura Vetter
v. 25	May 29, 2024 14:22	Laura Vetter
v. 24	May 29, 2024 14:22	Laura Vetter
v. 23	May 29, 2024 13:43	Laura Vetter
v. 22	May 29, 2024 13:07	Florian Santner
v. 21	May 29, 2024 12:23	Laura Vetter
v. 20	May 29, 2024 09:00	Laura Vetter
v. 19	May 29, 2024 08:11	Laura Vetter
v. 18	May 28, 2024 09:56	Laura Vetter
v. 17	May 27, 2024 15:22	Laura Vetter
v. 16	May 25, 2024 04:52	Gerhard Rumpold
v. 15	May 25, 2024 04:51	Gerhard Rumpold
v. 14	May 25, 2024 04:44	Gerhard Rumpold
v. 13	Apr 19, 2024 08:37	Yvonne Rauner
v. 12	Mar 31, 2024 10:53	Yvonne Rauner
v. 11	Mar 27, 2024 08:00	Niclas Hubel
v. 10	Mar 26, 2024 19:03	Yvonne Rauner
v. 9	Mar 26, 2024 18:28	Yvonne Rauner
v. 8	Mar 26, 2024 18:26	Yvonne Rauner

v. 7	Mar 26, 2024 17:37	Yvonne Rauner
v. 6	Mar 26, 2024 17:19	Yvonne Rauner
v. 5	Mar 25, 2024 12:15	Yvonne Rauner
v. 4	Mar 25, 2024 12:05	Yvonne Rauner
v. 3	Mar 25, 2024 10:53	Yvonne Rauner
v. 2	Mar 24, 2024 17:41	Yvonne Rauner
v. 1	Mar 24, 2024 17:03	Yvonne Rauner

## Glossary

**CHES:** The word CHES is an acronym of Evaluation Software Development GmbH and stands for **C**omputer-based **H**ealth **E**valuation **S**oftware.

**CHES.Flag:** A software module in CHES which provides a sophisticated system to facilitate the interpretation of patient-related outcomes (PROs) recorded in CHES. The use of CHES.Flag is only possible as an integration in CHES.

**CHES.Main:** Centerpiece of CHES which provides means for patient administration, visualization of questionnaire results and studies as well as export of data for healthcare professionals.

**CHES.Monitor:** Questionnaire application, allowing patients to answer questionnaires directly on any device (most commonly a tablet PC).

**CHES.Portal:** Where patients can fill in questionnaires from home.

**MD:** Abbreviation for the term **M**edical **D**evice.

**SaMD:** Abbreviation for the term **S**oftware **a**s a **M**edical **D**evice.

**MDR:** Abbreviation for the term **M**edical **D**evice **R**egulation.

**MDR Class 2a:** Classification of CHES.Flag based on the Medical Device Regulation.

# 1 Product Information

<b>Name</b>	CHES.Flag	<b>Version Number</b>	1.0.0
<b>UDI-DI (if available)</b>	(01)9120130600039	<b>Basic-UDI-DI</b>	912013060CHES.FlagN 7

<b>Date of manufacture</b>	<b>May 2024</b>
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## 2 About the Instructions for Use

This instruction manual provides comprehensive guidance on the proper usage, maintenance, and troubleshooting of CHES.Flag. It is essential for users to thoroughly read and understand these instructions to ensure safe and effective operation. This document includes information on the product, its intended use and instructions and how it is embedded in CHES.



## 3 What is CHES.Flag and how is it integrated in CHES?

### 3.1 CHES.Flag

CHES.Flag is a software module, used within the [Computer-based Health Evaluation System \(CHES\)](#) (see page 8). CHES.Flag offers a sophisticated system to facilitate the interpretation of patient-reported outcomes (PROs), collected in CHES, in order to support decisions for diagnostic or therapeutic purposes. As a medical device, it therefore falls under MDR Class IIa. CHES.Flag can be configured for the specific needs of researchers, healthcare professionals and patients.

### 3.2 CHES

CHES is a web-based software solution for electronic data collection (including electronic questionnaires and electronic case report forms), storage and data analysis, that is based on a modular architecture. It is intended for the documentation of subjective patient data and/or the documentation of other medical information, in case such information is not recorded in the on-site clinical information system (CIS). For this purpose, the products of Evaluation Software Development (ESD) are not considered medical devices according to the following regulations:

- COICR Contribution
- EU: Manual on Borderline and Classification
- UK Medicines and Healthcare Products Regulatory Agency
- International Medical Device Regulator Forum (IMDRF)

CHES includes different applications:

1. CHES.Main: the main application is the centerpiece for physicians and provides means for patient administration, visualization of questionnaire results and studies as well as export of data.
2. CHES.Portal: using the portal, patients are enabled to retrieve specific information for their treatment and to fill in questionnaires from home. Depending on your installation, CHES.Portal may also be available as a native app (iOS and Android).
3. CHES.Main-Admin: the administration panel for configuring CHES. Additional references values can also be configured using this application.
4. CHES.Portal-Admin: the administration panel for configuring the content of the patient portal.

A description of the functions of CHES.Main, CHES.Portal, CHES.Main-Admin as well as CHES.Portal-Admin can be found in the CHES User Manual.

## 4 Target group & users

The main target group for the use of CHES.Flag are patients, healthcare professionals and research staff.

CHES.Flag can support patients to communicate relevant aspects about their health status in a standardised way which can be used for diagnostic and therapeutic decisions in treating their illness.

CHES.Flag can support diagnostic and therapeutic decision-making process of healthcare professionals by the categorisation of individual patient values in a clinical reference framework.

CHES.Flag can support further research to improve patient care.

## 5 Usage of CHES.Flag

Questionnaires can be completed using a smartphone or browser on a computer, smartphone or tablet. Depending on the installation, an iOS or Android app may be available in the respective app store. Information on the access to the respective application is provided by the treatment or research team.

The typical workflow is as follows:

1. CHES is used to generate the PROs using standardized questionnaires. These PROs serve as input for the CHES.Flag module.
2. CHES.Flag uses the PROs, collected by CHES, as input, calculates a score for them and, based on reference values from literature or previously collected data, allows for the quick identification of patients with clinically relevant problems, using cut-off scores or score distributions.
3. The output of CHES.Flag is used within CHES for the graphical presentation of results as colored graphs in real-time and after checking the results with the patient, the treatment team uses the information for taking further treatment steps.

## 6 Purpose & expected benefits

Our goal at ESD is to *'give patients a voice'*. We aim to make healthcare and clinical research focused on patients by providing software solutions to help integrate patients' perspectives on their own health into clinical treatment and research. The software module CHES.Flag helps do this by supporting the systematic and standardized assessment of questionnaires (often also referred to as patient-reported outcome measures) and offering ways to integrate the analysis questionnaire scores into clinical practice and research. Moreover, CHES, that embeds CHES.Flag, has additional features that support interaction between patients and the clinical team and help support patients, for example, during treatment. These features may include video consultations, graphical display of patients' own results for them to review, providing a patient portal as a platform for medical information and communication with patients, extensive documentation of medical data, interfaces to other clinical software, or other features. All of these features aim to enrich clinical practice or research. The clinical benefit of CHES and its integrated module CHES.Flag can vary depending on the indication and usage behaviour, but it enables detailed information about the patient's health status to be obtained through continuous, standardised collection of PROs, which allows clinical care to be adapted.

## 7 Contraindications, Warnings and Precautions

### 7.1 Contraindications

While CHES.Flag serves as a valuable tool for enhancing clinical insights, there are specific contraindications and exclusions to consider:

**Visually or cognitively impaired persons:** The use of CHES.Flag by visually or cognitively impaired persons is subject to the discretionary judgement of the attending physician.

**Limited Clinical Data:** In cases where comprehensive clinical data, including Patient-Reported Outcomes (PROs) and other relevant medical information, is unavailable or incomplete, the efficacy of CHES.Flag may be compromised. The module's effectiveness is contingent on the availability of a diverse dataset to provide meaningful insights.

**Lack of Patient Collaboration:** CHES.Flag impact is most pronounced in scenarios where there is active collaboration and engagement between healthcare professionals and patients. If patients are unwilling or unable to participate in providing accurate PROs, the module's benefits may be diminished.

**Non-validated sources:** CHES.Flag may only utilize Patient-Reported Outcome (PRO) data derived from validated questionnaires. Input from non-validated data sources, lacking rigorous validation and reliability testing, should not be integrated as input for CHES.Flag. Ensuring the use of validated data sources is critical for maintaining the accuracy and reliability of the module's graphical representations and clinical insights.

### 7.2 Warnings and Precautions

- **Security Risks:** CHES.Flag, as a module in CHES, may indirectly be vulnerable also to cyber-attacks which could result in the unauthorized access, manipulation, or theft of patient data. The potential harm includes the exposure of sensitive patient information, which could lead to identity theft or other types of fraud. To investigate this matter further a separate cybersecurity assessment was conducted. The residual threats, namely outdated software, the exploitation of bugs in the software and unauthorized admin-access were identified and are managed by the manufacturer.
- **Technical Malfunctions:** CHES.Flag may experience technical malfunctions, such as software glitches or hardware failures, which could lead to the loss or corruption of patient data, inaccurate assessment, or delayed diagnosis.
- **Misinterpretation of Data:** CHES.Flag may generate incorrect or misleading results due to errors in patient input or faulty algorithms, leading to an incorrect diagnosis, inappropriate treatment, or delay in treatment.
- **Inadequate Training:** Inadequate training of healthcare professionals or patients on how to use CHES or CHES.Flag may lead to user errors, misinterpretation of data, or delays in assessment.

## 8 Installation of CHES.Flag

CHES.Flag is always used as a module of CHES and is installed by ESD along with CHES. It is not possible to install CHES.Flag as a standalone software.

### 8.1 Hardware requirements

CHES.Flag is always installed as a module within CHES. CHES can be run on both hardware machines or virtual machines, as CHES does not pose any restrictions on the low-level system.

For a detailed information about the hardware requirements of CHES please see the corresponding manual of your CHES installation.

### 8.2 Software Requirements

As being part of CHES, CHES.Flag requires the same software requirements as CHES. We support CHES installations on Ubuntu 22.04 as the operation system. We aim to support installations on future Ubuntu LTS version after a suitable grace period when they get released. Other operating systems might be possible to use upon request. To access CHES an up-to-date browser is required. All major browsers, like Safari, Google Chrome, Microsoft Edge and Mozilla Firefox are supported. Additionally, depending on your installation an Android or iOS App might be available.

For a detailed information about the software requirements of CHES please see the corresponding manual of your CHES installation.

### 8.3 Network Requirements

CHES.Flag is accessed through CHES, which is a web-based solution, clients will access CHES through their browser. Likewise, the servers must be reachable from the devices (e.g., computer, tablet) on which CHES is intended to be used (port 80 for HTTP redirect to HTTPS; port 443 for HTTPS).

For a detailed information about the network requirements of CHES please see the corresponding manual of your CHES installation.

## 9 Maintenance

Planned maintenance may only be carried out by qualified and authorized Customer Support technicians. ESD supports a full planned maintenance and repair customer support on both a call and a contract basis. Full details are available from ESD.

# 10 Troubleshooting

## 10.1 Problems and Solutions

If any issues are encountered during the use of CHES, please refer to the table below for common problems and their solutions. If the problem persists, please contact technical support.

Problem	Possible Cause	Solution
<b>Software is not starting</b>	<ul style="list-style-type: none"> <li>System requirements not met</li> </ul>	<ul style="list-style-type: none"> <li>Ensure your browser meets the minimum requirements listed in the user manual</li> </ul>
<b>Unable to log in</b>	<ul style="list-style-type: none"> <li>Incorrect username or password</li> <li>Server issues</li> </ul>	<ul style="list-style-type: none"> <li>Verify that you are using the correct login credentials.</li> <li>Check if there are any server maintenance notifications.</li> <li>Reset your password if necessary.</li> </ul>
<b>Slow performance</b>	<ul style="list-style-type: none"> <li>High CPU or memory usage</li> <li>Network issues</li> </ul>	<ul style="list-style-type: none"> <li>Close unnecessary applications running on your computer.</li> <li>Check your internet connection and ensure it's stable.</li> </ul>
<b>Unexpected software crash</b>	<ul style="list-style-type: none"> <li>Software bug</li> <li>Incompatible third-party browser-plugins</li> </ul>	<ul style="list-style-type: none"> <li>Restart the browser.</li> <li>Check for browser updates and install the latest version.</li> <li>Identify and uninstall any incompatible third-party browser-plugins.</li> </ul>
<b>Incorrect data displayed</b>	<ul style="list-style-type: none"> <li>Data entry error</li> </ul>	<ul style="list-style-type: none"> <li>Verify the accuracy of the data entered.</li> </ul>

## 10.2 Technical Support

If your issue is not listed above or if the suggested solutions do not resolve your problem, please contact the support ([support@ches.pro](mailto:support@ches.pro)).



Please provide the following information when contacting support:

- Your software version
- Description of the issue
- Steps taken to resolve the issue
- Any error messages received

## 11 Privacy regulations

Data provided and entered via the CHES system (including CHES.Flag) is securely transferred via an encrypted connection (HTTPS) and is securely stored in a central server. Modern web browsers allow the storage of usernames and passwords in their password managers. We highly recommend that you do not store usernames and passwords to any application of CHES on devices that might be handed to patients, e.g. a tablet used for completing a questionnaire.

## 12 Customer Feedback

We would like to continue to improve. We would be delighted if you let us know your suggestions for improvement and wishes with regard to the CHES.Flag product. You can contact us via [support@ches.pro](mailto:support@ches.pro)<sup>1</sup>. Of course, we also accept feedback sent to the following address:

**Evaluation Software Development GmbH**

**Customer Feedback**

**Valiergasse 62**

**Austria - 6020 Innsbruck**

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<sup>1</sup> <mailto:support@ches.pro>