Instruction Manual

MD

Treatment Optimiser

Variant: COPD Optimiser | Version 1.1

CE 0123

UDI-DI: 4270001023551

Instruction for Use-version 1.1 / 2024-09

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Contact / Manufacturer

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Caution

Federal law restricts this device to sale by or on the order of a physician.

Note

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Names of persons appearing in examples of the operating instructions are fictitious. Any resemblance to living or deceased persons is therefore purely coincidental and not intended.

This document is available electronically at: https://www.lothar-medtec.de/instructions-for-use/

In case you want to receive a paper-based version please send your request to the manufacturer as indicated above. The paper-based version will be transmitted to you within 7 working days.

Release date: May 2024

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1 The Treatment Optimiser - the COPD Optimiser

The Treatment Optimiser is a medical device (software as a medical device; class IIa) consisting of a cloud-based software. It is a tool intended to quickly identify patients with a diagnosed respiratory disease who may benefit from a specialist review. The product provides a set of forms to collect information about a patient's current health status related to a respiratory disease. This information is analyzed according to recognized guidelines (e.g., GINA) and aggregated.

The **COPD Optimiser is a variant** of the medical device treatment optimizer.

2 Indications for Use

Indications: Diagnosed COPD,

Contraindications: There are no contraindications.

3 Intended Purpose

Intended Purpose

The Treatment Optimiser is used to collect information about a patient's current health status related to a pre-diagnosed respiratory disease. The product then uses this information to provide decision support for general practitioners and their staff whether a patient would benefit from a specialist review. The Treatment Optimiser is used by general practitioners and their staff in the doctor's office. The Treatment Optimiser decision support is based on recognized guidelines for respiratory disease management.

Intended user group

General practitioner and their staff

Intended patient population

The system is suitable for patients age 12 and older. For the **COPD Optimiser**, only data for patients of age 18 and above can be entered due to the prevalence of COPD.

4 Pictograms and Safety Instructions in the Instruction Manual

Following the **ANSI** (American National Standards Institute) recommendations for safety instructions, the following pictograms have been used in this instruction manual:

Danger level	Definition
Danger	**DANGER** indicates an imminently hazardous situation which, if not avoided, could result in extremely serious injury or death. This signal word is reserved for extreme situations.
Warning	**WARNING** indicates a potentially hazardous situation which, if not avoided, could result in extremely serious injury or death.
Caution	**CAUTION** indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. Also used to indicate unsafe procedures.

Additional pictograms shown in the instruction manual and/or in the user interface:

	Observe the instruction manual and accompanying documents.
	Medical device symbol
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed,or that the current situation needs operator awareness or operator action in order to avoid undesirable conse- quences
Attention	Important operating instructions and useful information. No information that warns of a dangerous or critical situation.
Note	Tips, info, and operating instructions.

Attention: Please also observe the safety and operating instructions in section 16.

5 Reporting of incidents and serious incident

- Incident shall be reported to the manufacturer as outlined at the very end of this Instruction for Use
- Serious incident shall be reported to the manufacturer and the competent authority

6 Data protection

For data protection please refer to the Data Privacy Policy available on the landing page of the Treatment Optimiser (e.g., app.copdoptimiser.com)

7 Security information

	Do not share your password with others in order to reduce risk of unauthorized access
Note	To ensure that the software is not used in areas not listed the access is restricted and automatically detected e.g. in case a VPN tool is used the access may be jeopardized.

8 Declaration of Conformity

LOTHAR MEDTEC declares that the product described herein has been designed and manufactured in accordance with the following specifications and standards: Medical Device Regulation 2017/745.

This device, which complies with class IIa for continuous operation according to Annex IX of the Regulation is realized under a Quality Management System complying with the requirements according to EN ISO 13485:2016. medical devices - quality management systems - requirements for regulatory purposes.

9 Practical Hints

Before initial operation, you should make yourself familiar with safe handling of the medical application and with the examination procedure.

10 Residual Risks

Modifications to the product endanger product safety and lead to the loss of the operating license! LOTHAR MEDTEC assumes no liability for modifications made by the customer.

11 Minimum Requirements

To use the Treatment Optimiser, you need computer system with internet access and a current common browser software application. The internet connectivity requires availability and bandwidth typical for medical care.

Internet access to the URL of the Treatment Optimiser must not be blocked or otherwise restricted by the configuration of the local IT infrastructure.

12 Access to the Software

Access to the Treatment Optimiser is restricted, credentials can be received from an administrator.

13 Product Information and Settings

The product information (Unique Device Identifier (UDI), product and software version, manufacturer’s contact etc.) and settings page (settings and profile details) are accessible after logging into the application.

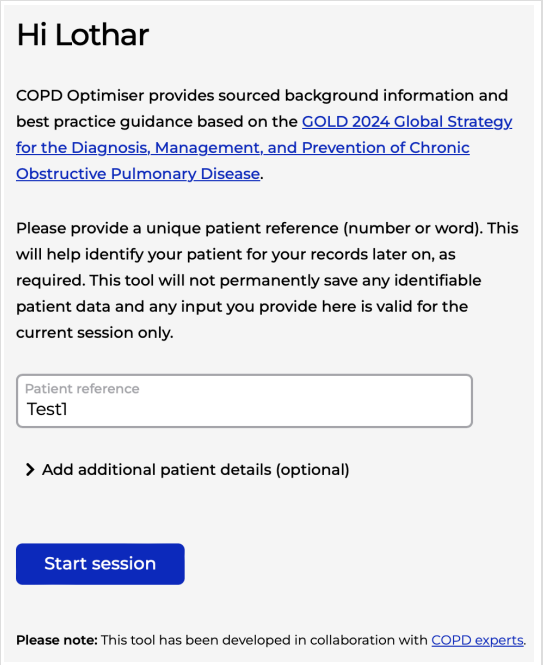
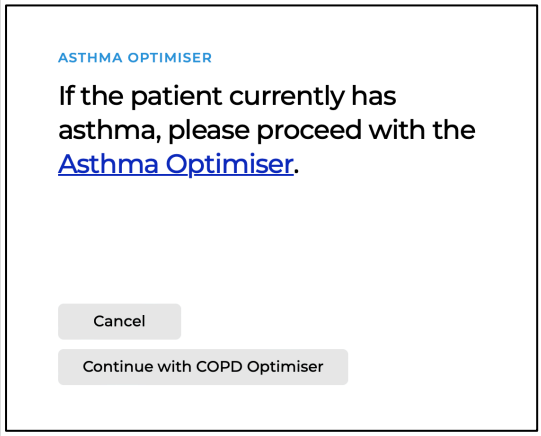
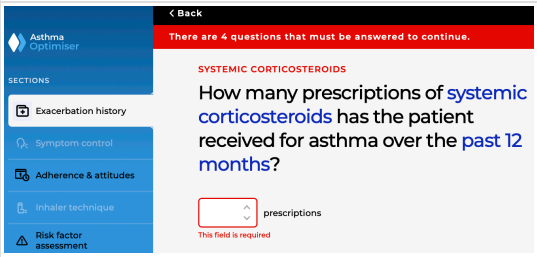
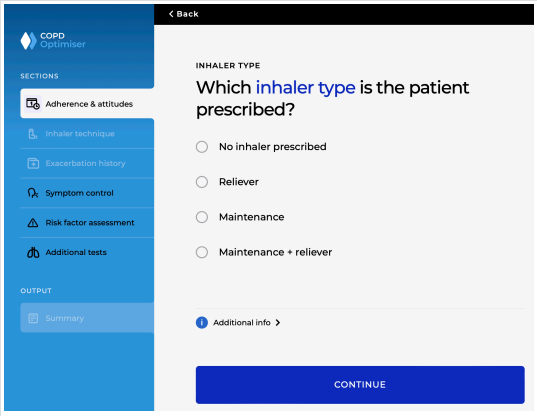
14 Operating Instructions

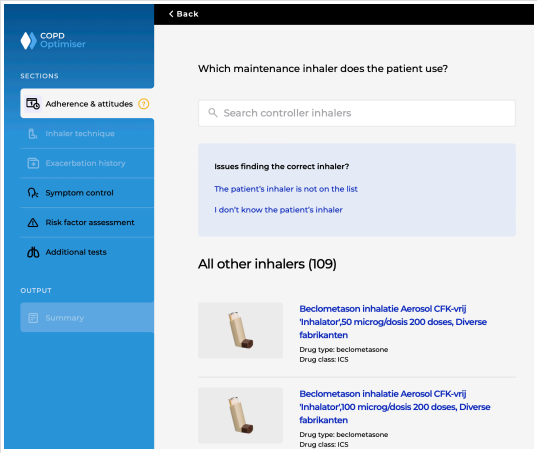
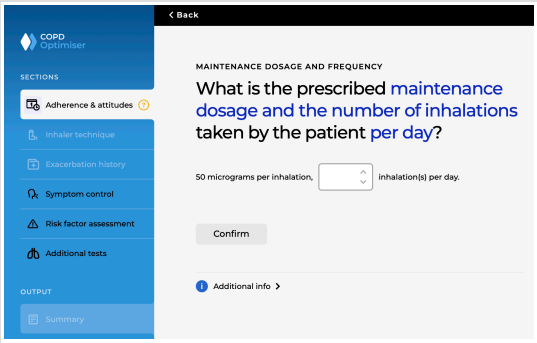
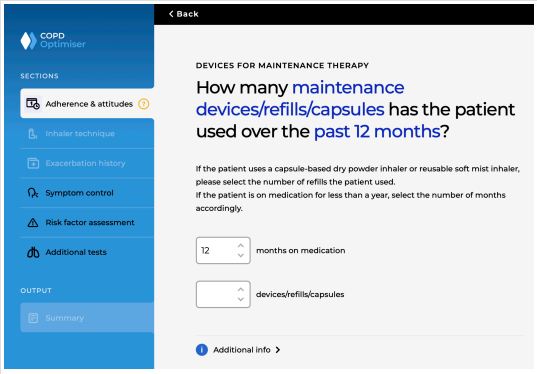
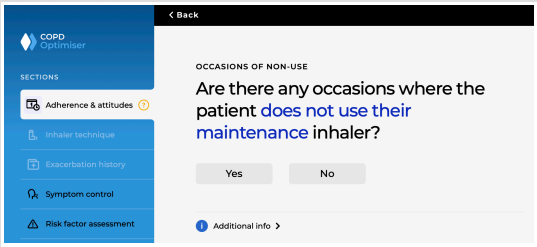
Login

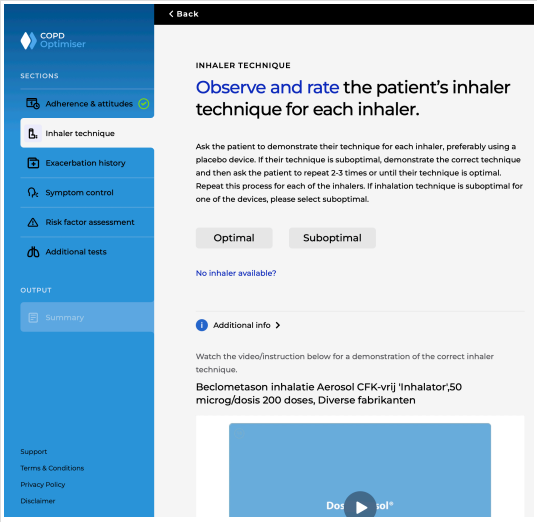
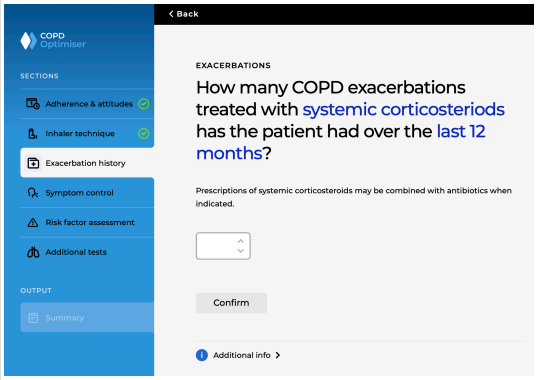
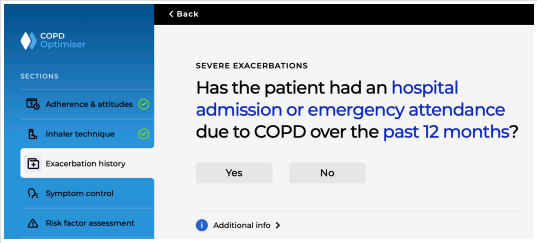
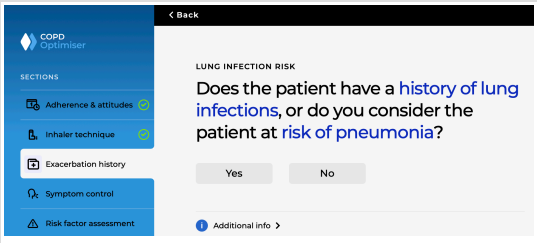
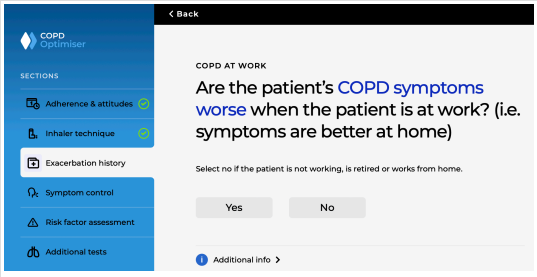
After logging into the Treatment Optimiser, in a "Quick Tour" the main functions of the software are explained. The “Quick Tour” is also accessible from the settings page. To use the software, follow the explanations in the “Quick Tour” and the instructions on screen.

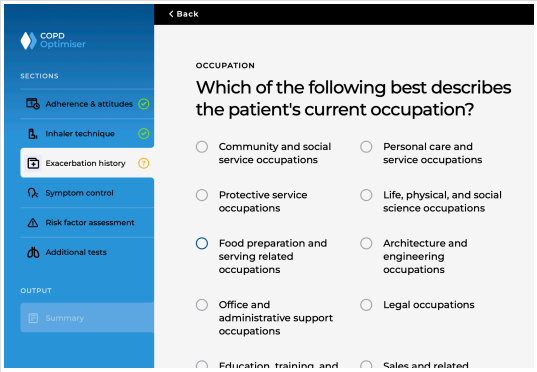
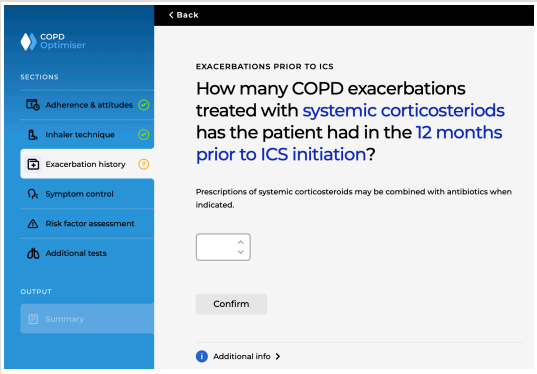
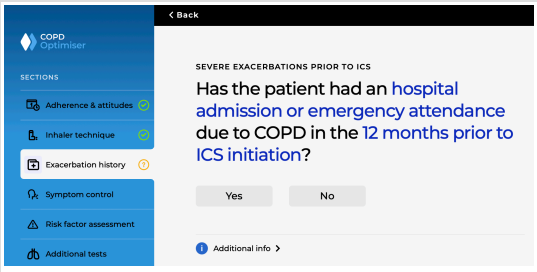
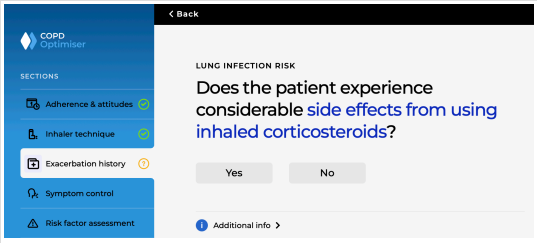
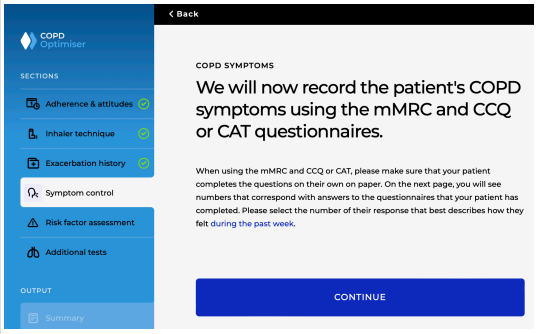
Operating the software with all use cases

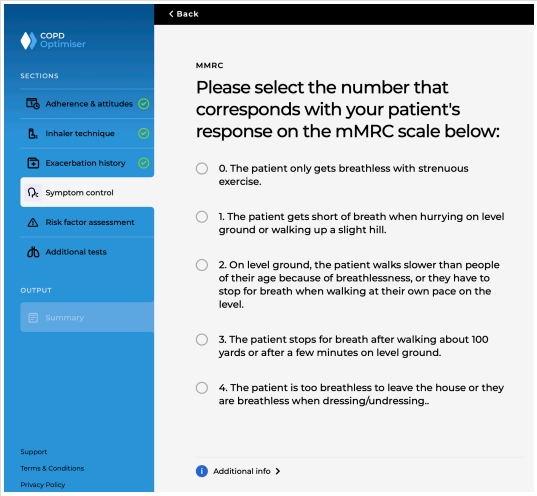
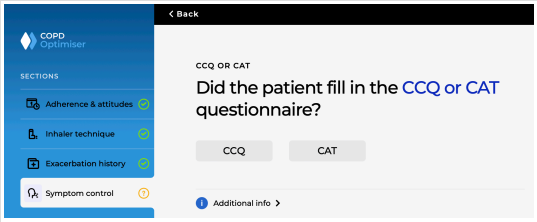
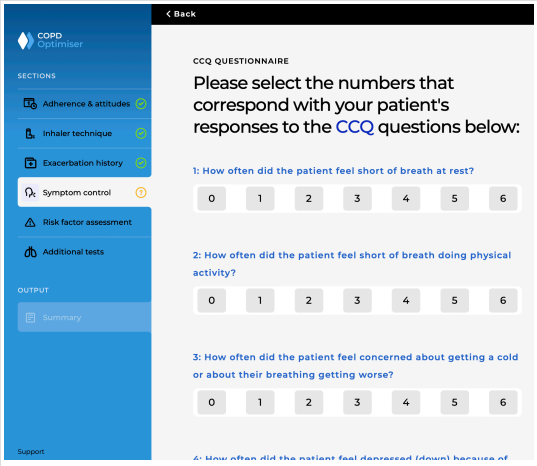
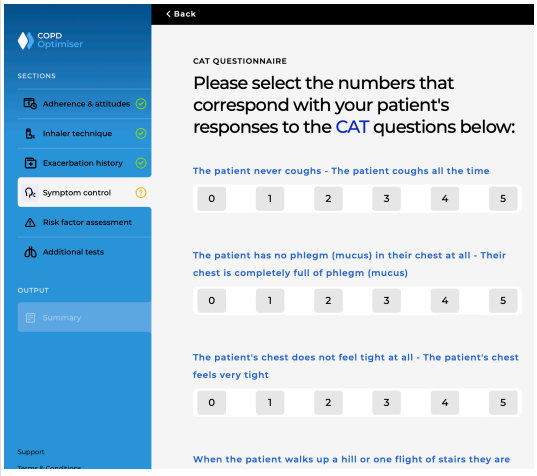
Please note, some of the options below may not be provided depending on your previous entries for a patient.

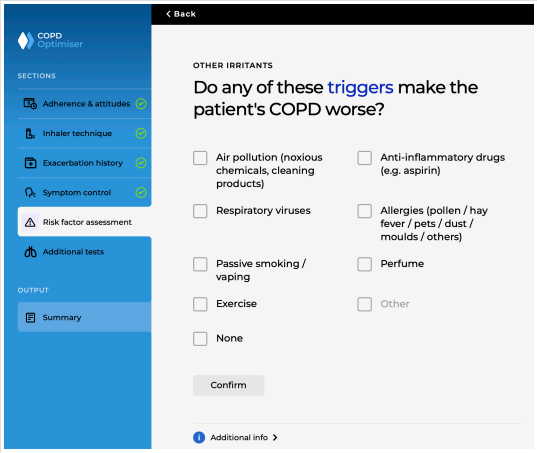
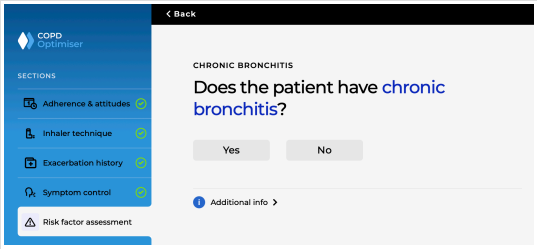
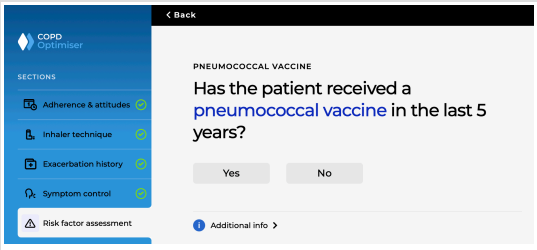
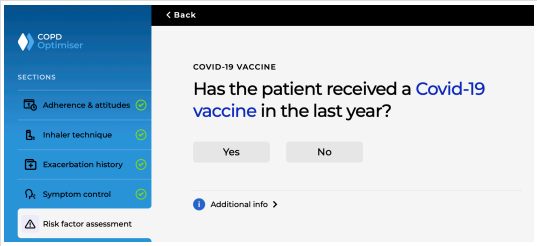
1	1. Create a new patient session for patient Test1.	
2	1. Select 'Continue with COPD Optimiser', if your patient is diagnosed with COPD.	
3	1. In the 'Adherence & attitudes' section, click 'continue' without having entered any information.	
4	1. Select the patient's prescribed inhaler type.	

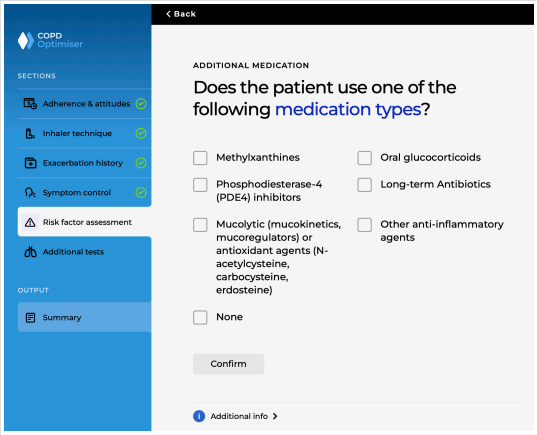
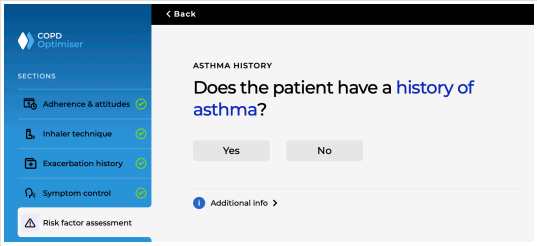
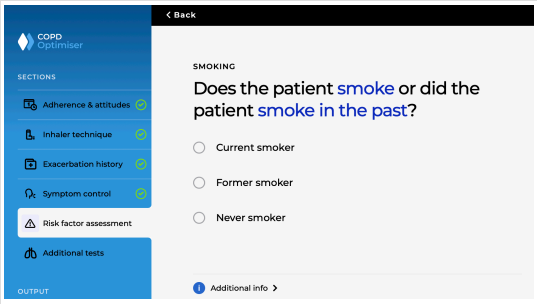
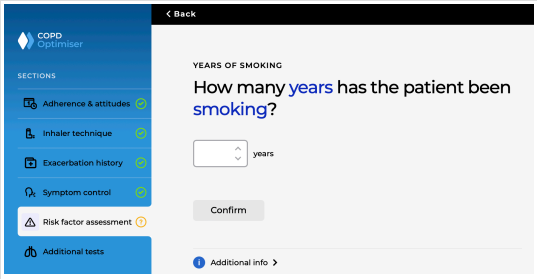
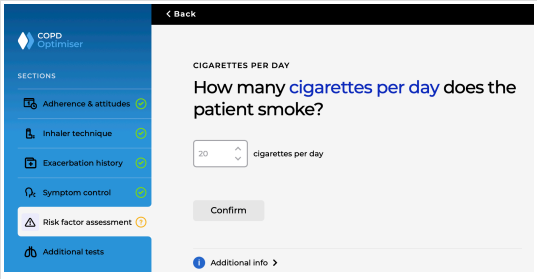
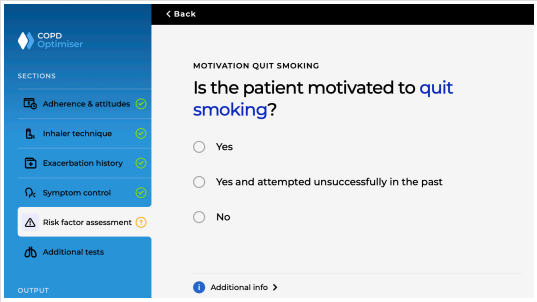
5	1. Select which maintenance inhaler the patient uses.	
6	1. Select the prescribed maintenance dosage and the number of inhalations taken by the patient per day.	
7	1. Enter how many maintenance devices/refills/capsules the patient has used over the past 12 months.	
8	1. Document whether there are any occasions where the patient does not use their maintenance inhaler.	

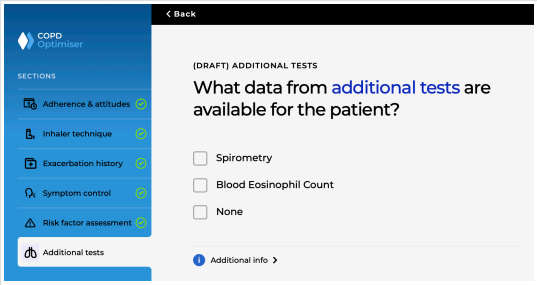
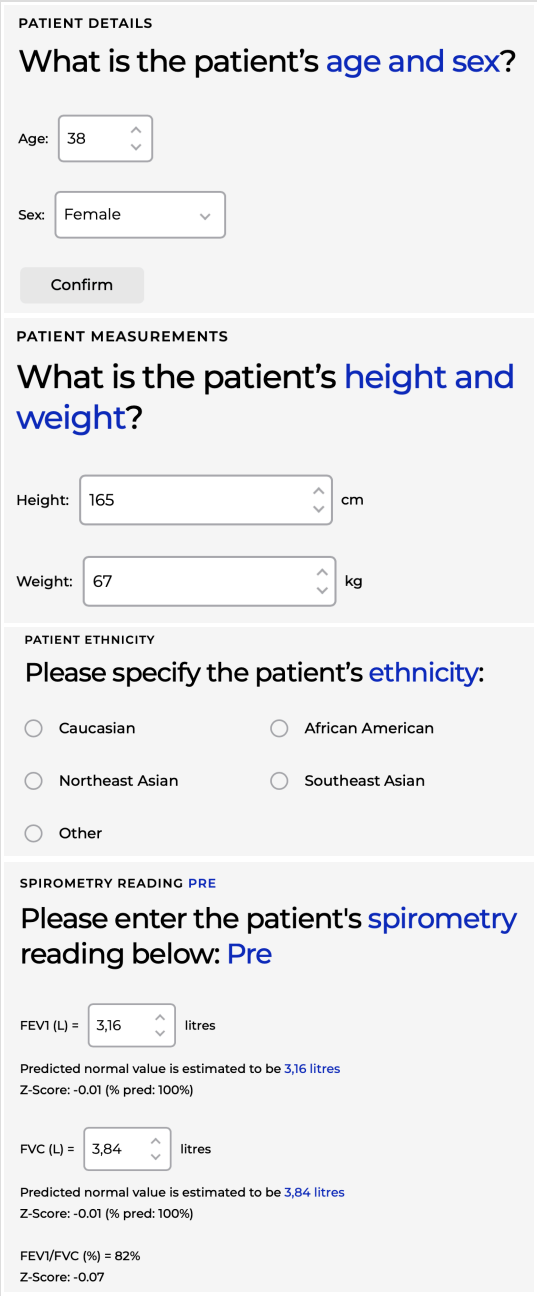
9	1. Observe and rate the patient's inhaler technique for each inhaler. If the inhaler technique is optimal for all inhalers, select 'Optimal' in the 'Inhaler Technique' section. 2. If the patient's inhaler technique is suboptimal for one or multiple inhalers, show the corresponding inhaler specific video(s) to the patient to demonstrate the correct use of the corresponding inhaler. 3. Reassess the patient's inhaler technique.	
10	1. In the 'Exacerbations History' section, enter how many COPD exacerbations treated with systemic corticosteroids the patient had over the last 12 months.	
11	1. Select whether the patient had an hospital admission or emergency attendance due to COPD over the past 12 months.	
12	1. Select whether the patient has a history of lung infections, or do you consider the patient at risk of pneumonia.	
13	1. Select whether the patient's COPD symptoms are worse when the patient is at work.	

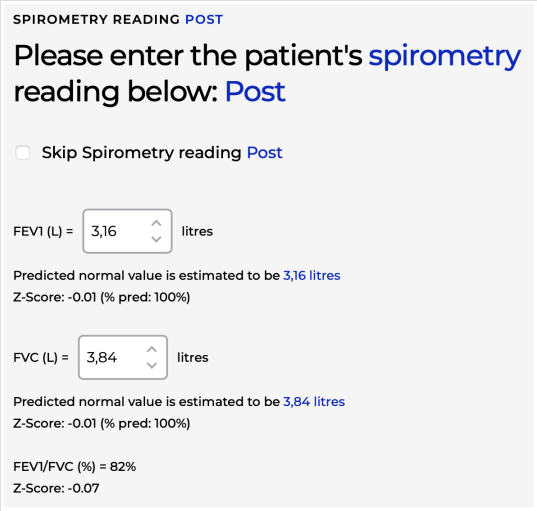
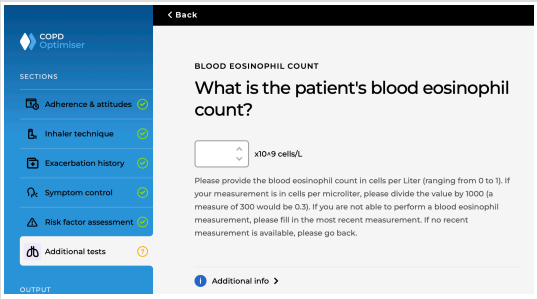
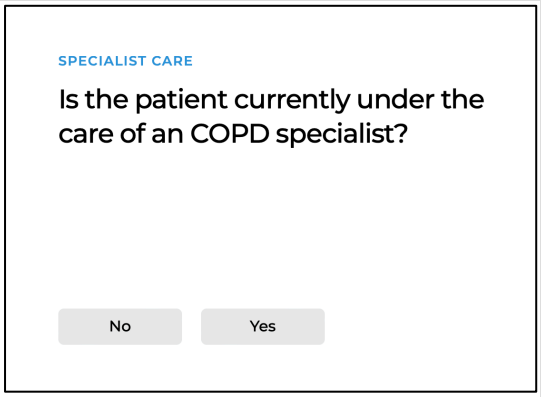
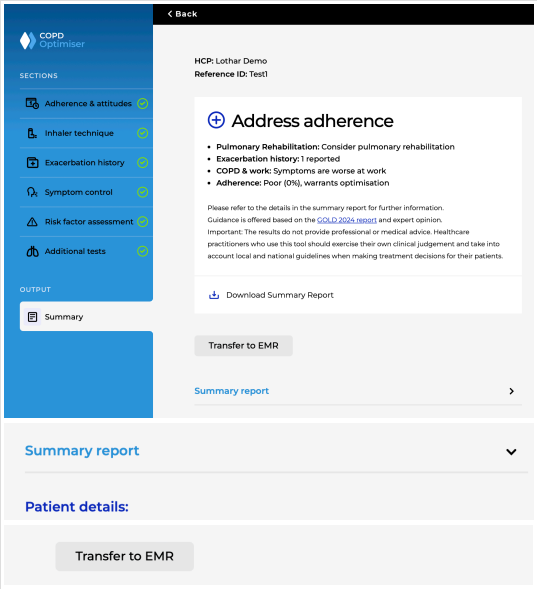
14	1. Select which of the options best describes the patient's current occupation.	
15	1. Enter how many COPD exacerbations treated with systemic corticosteriodshas the patient had in the 12 months prior to ICS initiation.	
16	1. Select Whether the patient had an hospital admission or emergency attendancedue to COPD in the 12 months prior to ICS initiation.	
17	1. Select whether the patient experiences considerable side effects from using inhaled corticosteroids.	
18	1. In the section ‘Symptoms Control’ the patient's COPD symptoms are recorded using the mMRC and CCQ or CAT questionnaires. The questionnaires shall be completed by the patient on paper an the results are now transferred to the COPD Optimiser.	

19	1. Transfer the result for the mMRC to the COPD Optimiser.	
20	1. Select whether the patient has completed the CCQ or the CAT questionnaire.	
21	1. If the patient has completed the CCQ, transfer the results to the COPD Optimiser.	
22	1. If the patient has completed the CAT, transfer the results to the COPD Optimiser.	

23	1. In the section 'Risk factors assessment' the patient's risk factors are recorded. This section starts with reording triggers which make the patient's COPD worse.	
24	1. Select whether the patient has chronic bronchitis.	
25	1. Select whether the patient received a pneumococcal vaccine in the last 5 years.	
26	1. Select whether the patient received a Covid-19 vaccine in the last year.	
27	1. Select whether the patient received received an influenza vaccine in the last year.	

28	1. Select whether the patient use one of the listed medication types.	
29	1. Select whether the patient has a history of asthma.	
30	1. Select whether the patient did smoke in the past.	
31	1. Enter how many years has the patient been smoking.	
32	1. Enter **h**ow many cigarettes per day did/does the patient smoke.	
33	1. Select whether the patient is motivated to quit smoking.	

34	1. In the section 'Additional tests', data from additional tests available for the patient are recorded.	
35	If spirometry results are recorded: 1. Enter the required patient data. 2. Enter the spirometry readings. Recording the post readings can be skipped if only pre readings are available.	

		
36	If blood eosinophil count is recorded, enter the cell count.	
37	1. Select whether the patient is currently under the care of an asthma specialist or not.	
38	1. Open the summary report. The summary report provides you with a selection of important outcomes. In addition, you can open the full summary report listing all outcomes and GOLD-based recommendations. If available for your country, results can be transferred to the patient's electronic medical record (EMR).	

15 Possible Sources of Error and Remedies

	Error	Error source	Remedy
1	User interface cannot be loaded or refreshed	No adequate internet connection available	Make sure the computer system you are using is connected to the internet. Restart the browser software.

16 Safety and Operating Instructions

This instruction manual describes the currently valid status of the product considering the requirements of MDR 2017/745. Strict adherence to the operating instructions is a prerequisite for the intended use of the Treatment Optimiser. Please follow the manufacturer's specifications (technical data, explanation and compliance with the pictograms and other information).

17 Deviation from the Intended Purpose

Any non-compliance of the procedures described in this instruction manual will result in a deviation from the intended purpose. In this case, the operator/user must provide proof of compliance with all applicable essential requirements. This is possible with the implementation of a corresponding conformity assessment procedure within the scope of in-house-manufacture (compare § 12, section 1, last sentence, Medical Product Law). The operator/user is responsible for the proper performance of the conformity assessment, and he also assumes the complete product liability - not only the liability for the application/use of the medical device changed by him.

LOTHAR MEDTEC guarantees the safety, reliability, and function only if the product is used in compliance with the instruction manual.

This instruction manual is considered part of the product and must be always kept accessible.

If any potentially serious harm to a patient occurs during use of the product, such an occurrence must be reported immediately to the manufacturer and to the appropriate national competent authorities.

18 Medical Responsibility

The Treatment Optimiser is not intended to give professional or medical advice. General practitioners and their staff who use this tool should exercise their own clinical judgement and take into account applicable guidelines when making treatment decisions for their patients.

19 CE notice

The CE 0123 symbol indicates that the Treatment Optimiser complies with the provisions of the Medical Device Regulation 2017/745 of the European Commission. It also indicates that the Treatment Optimiser meets or exceeds the requirements of the applicable technical standards.

20 Maintenance

In the event of malfunctions, LOTHAR MEDTEC support team will be happy to advise you and to take care for remedy.

21 Literature

The Treatment Optimiser implements applicable parts of the following published recognized guidelines:

Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease, 2024.

Available from www.goldcopd.org.

The Treatment Optimiser implements the following published reference models for calculation of patient-specific reference values:

Spirometry

Philip H. Quanjer, Sanja Stanojevic, Tim J. Cole, Xaver Baur, Graham L. Hall, Bruce H. Culver, Paul L. Enright, John L. Hankinson, Mary S.M. Ip, Jinping Zheng, Janet Stocks and the ERS Global Lung Function Initiative, Multi-ethnic reference values for spirometry for the 3–95-yr age range: the global lung function 2012 equations, Eur Respir J, 2012; 40.

Peak flow

Sterk PJ, Fabbri LM, Quanjer PH, Cockcroft DW, O'Byrne PM, Anderson SD, Juniper EF, Malo JL., Airway responsiveness. Standardized challenge testing with pharmacological, physical and sensitizing stimuli in adults. Report Working Party Standardization of Lung Function Tests, European Community for Steel and Coal. Official Statement of the European Respiratory Society. Eur Respir J Suppl. 1993; 16.

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