

Instruction Manual



Treatment Optimiser

Variant: Asthma Optimiser | Version 1.0



UDI-DI: 4270001023551

Instruction for Use-version 1.1 / 2024-05

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Caution

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

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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.

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1 The Treatment Optimiser and the Asthma 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 **Asthma Optimiser is the first variant** of the medical device treatment optimizer.

2 Indications for Use

Indications: Diagnosed asthma.

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.

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 consequences
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., www.asthma-optimiser.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

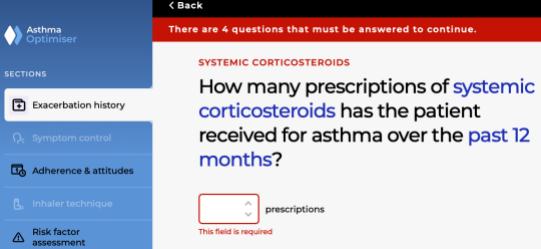
The product information (Unique Device Identifier (UDI), product and software version, manufacturer's contact etc.) and settings page (settings and profile details) are accessible after logging into the application.

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

1	1. Create a new patient session for patient Test1.	<h2>Hi Test</h2> <p>Asthma Optimiser provides sourced background information and best practice guidance based on the GINA 2023 Global Strategy for Asthma Management and Prevention.</p> <p>Please provide a unique patient reference (number or word). This will help identify your patient for your records later on, as required. This tool will not permanently save any identifiable patient data and any input you provide here is valid for the current session only.</p> <p>Patient reference Test1</p> <p>➤ Add additional patient details (optional)</p> <p>Start session</p> <p>Please note: This tool has been developed in collaboration with three asthma experts.</p>
2	1. In the 'Exacerbation history' section, click 'continue' without having entered any information.	
3	1. Enter the number of prescriptions of systemic corticosteroids for asthma over the past 12 months.	<p>SYSTEMIC CORTICOSTEROIDS</p> <p>How many prescriptions of systemic corticosteroids has the patient received for asthma over the past 12 months?</p> <p>0 prescriptions</p> <p>SYSTEMIC CORTICOSTEROIDS</p> <p>How many prescriptions of systemic corticosteroids has the patient received for asthma over the past 12 months?</p> <p>24 prescriptions</p> <p>SYSTEMIC CORTICOSTEROIDS</p> <p>How many prescriptions of systemic corticosteroids has the patient received for asthma over the past 12 months?</p> <p>25 prescriptions</p> <p>Please enter a number between 0 and 24</p>

4	<p>1. Select the number of emergency attendances, admissions or unscheduled visits due to asthma over the past 12 months.</p>	<div> <p>EMERGENCY VISITS</p> <p>How many times has the patient had an emergency attendance, admission or unscheduled visit due to asthma over the past 12 months?</p> <p><input checked="" type="radio"/> Never</p> <p><input type="radio"/> 1 time</p> <p><input type="radio"/> 2 times or more</p> </div> <div> <p>EMERGENCY VISITS</p> <p>How many times has the patient had an emergency attendance, admission or unscheduled visit due to asthma over the past 12 months?</p> <p><input type="radio"/> Never</p> <p><input checked="" type="radio"/> 1 time</p> <p><input type="radio"/> 2 times or more</p> </div> <div> <p>EMERGENCY VISITS</p> <p>How many times has the patient had an emergency attendance, admission or unscheduled visit due to asthma over the past 12 months?</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> 1 time</p> <p><input checked="" type="radio"/> 2 times or more</p> </div>
5	<p>1. Select whether or not the patient has been intubated or admitted to an ICU (intensive care unit) or a high dependency unit due to their asthma.</p>	<div> <p>INTENSIVE CARE</p> <p>Has the patient ever been intubated or admitted to an ICU (intensive care unit) or a high dependency unit due to their asthma?</p> <p><input checked="" type="button" value="Yes"/> <input type="button" value="No"/></p> </div> <div> <p>INTENSIVE CARE</p> <p>Has the patient ever been intubated or admitted to an ICU (intensive care unit) or a high dependency unit due to their asthma?</p> <p><input type="button" value="Yes"/> <input checked="" type="button" value="No"/></p> </div>

6	<p>1. Select whether the patient's asthma symptoms are worse when the patient is at work or not.</p>	<div> <p>ASTHMA AT WORK</p> <p>Are the patient's asthma symptoms worse when the patient is at work? (i.e. symptoms are better at home)</p> <p>Select no if the patient is not working, is retired or works from home.</p> <p> <input type="button" value="Yes"/> <input type="button" value="No"/> </p> </div> <div> <p>ASTHMA AT WORK</p> <p>Are the patient's asthma symptoms worse when the patient is at work? (i.e. symptoms are better at home)</p> <p>Select no if the patient is not working, is retired or works from home.</p> <p> <input type="button" value="Yes"/> <input type="button" value="No"/> </p> </div>
7	<p>1. Select/enter the current occupation.</p>	<div> <p>OCCUPATION</p> <p>Which of the following best describes the patient's current occupation?</p> <div> <input checked="" type="radio"/> Community and social service occupations <input type="radio"/> Personal care and service occupations </div> <div> <input type="radio"/> Protective service occupations <input type="radio"/> Life, physical, and social science occupations </div> <div> <input type="radio"/> Food preparation and serving related occupations <input type="radio"/> Architecture and engineering occupations </div> <div> <input type="radio"/> Office and administrative support occupations <input type="radio"/> Legal occupations </div> <div> <input type="radio"/> Education, training, and library occupations <input type="radio"/> Sales and related occupations </div> <div> <input type="radio"/> Management occupations <input type="radio"/> Production occupations </div> <div> <input type="radio"/> Construction and extraction occupations <input type="radio"/> Arts, design, entertainment, sports, and media occupations </div> <div> <input type="radio"/> Installation, maintenance, and repair occupations <input type="radio"/> Business and financial operations occupations </div> <div> <input type="radio"/> Healthcare practitioners and technical occupations <input type="radio"/> Healthcare support occupations </div> <div> <input type="radio"/> Farming, fishing, and forestry occupations <input type="radio"/> Computer and mathematical occupations </div> <div> <input type="radio"/> Building and grounds cleaning and maintenance occupations <input type="radio"/> Transportation and materials moving occupations </div> <div> <input type="radio"/> Other </div> </div>

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1. In the 'Symptom control' section, click 'continue' without having entered any information.

Asthma Optimiser

SECTIONS

- Exacerbation history
- Symptom control
- Adherence & attitudes
- Inhaler technique
- Risk factor assessment
- Lung function test

OUTPUT

- Summary

There are 6 questions that must be answered to continue.

ACQ6 QUESTIONNAIRE
Please select the relevant answers for the ACQ6 questions below:

Question 1 - On average, during the past week, how often was the patient woken by his/her asthma during the night?

0 1 2 3 4 5 6

Question 2 - On average, during the past week, how bad were the patient's asthma symptoms when he/she woke up in the morning?

0 1 2 3 4 5 6

Question 3 - In general, during the past week, how limited was the patient in his/her activities because of his/her asthma?

0 1 2 3 4 5 6

Question 4 - In general, during the past week, how much shortness of breath did the patient experience because of his/her asthma?

0 1 2 3 4 5 6

Question 5 - In general, during the past week, how much of the time did the patient wheeze?

0 1 2 3 4 5 6

Question 6 - On average, during the past week, how many puffs of short-acting bronchodilator has the patient used each day?

0 1 2 3 4 5 6

Support
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1. Select the answers to the questions of the ACQ6.

ACQ6 QUESTIONNAIRE

Please **select** the relevant **answers** for the **ACQ6** questions below:

Question 1 - On average, during the past week, how often was the patient woken by his/her asthma during the night?

0 1 2 3 4 5 6

Question 2 - On average, during the past week, how bad were the patient's asthma symptoms when he/she woke up in the morning?

0 1 2 3 4 5 6

Question 3 - In general, during the past week, how limited was the patient in his/her activities because of his/her asthma?

0 1 2 3 4 5 6

Question 4 - In general, during the past week, how much shortness of breath did the patient experience because of his/her asthma?

0 1 2 3 4 5 6

Question 5 - In general, during the past week, how much of the time did the patient wheeze?

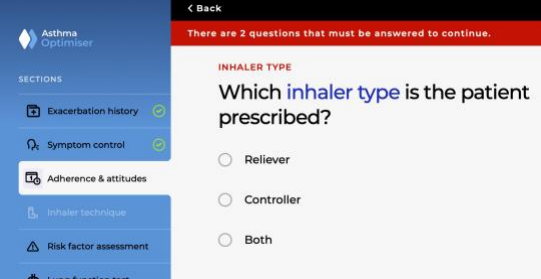
0 1 2 3 4 5 6




Question 6 - On average, during the past week, how many puffs of short-acting bronchodilator has the patient used each day?

0 1 2 3 4 5 6

ACQ Score: 0.7 (Controlled asthma)

	<p>ACQ6 QUESTIONNAIRE</p> <p>Please select the relevant answers for the ACQ6 questions below:</p> <p>Question 1 - On average, during the past week, how often was the patient woken by his/her asthma during the night?</p> <p>0 1 2 3 4 5 6</p> <p>Question 2 - On average, during the past week, how bad were the patient's asthma symptoms when he/she woke up in the morning?</p> <p>0 1 2 3 4 5 6</p> <p>Question 3 - In general, during the past week, how limited was the patient in his/her activities because of his/her asthma?</p> <p>0 1 2 3 4 5 6</p> <p>Question 4 - In general, during the past week, how much shortness of breath did the patient experience because of his/her asthma?</p> <p>0 1 2 3 4 5 6</p> <p>Question 5 - In general, during the past week, how much of the time did the patient wheeze?</p> <p>0 1 2 3 4 5 6</p> <p>Question 6 - On average, during the past week, how many puffs of short-acting bronchodilator has the patient used each day?</p> <p>0 1 2 3 4 5 6</p> <p>ACQ Score: 0.8 (Uncontrolled asthma)</p>
<p>10</p> <p>1. Select whether a patient's treatment has been optimised since their last exacerbation.</p>	<p>OPTIMISED CARE</p> <p>Has the patient's treatment been optimised since their last exacerbation?</p> <p>Yes No</p> <p>OPTIMISED CARE</p> <p>Has the patient's treatment been optimised since their last exacerbation?</p> <p>Yes No</p>

11	1. In the 'Adherence & attitudes' section, click 'continue' without having entered any information.	
12	1. Select the inhaler type.	<p>INHALER TYPE</p> <p>Which inhaler type is the patient prescribed?</p> <p><input checked="" type="radio"/> Reliever</p> <p><input type="radio"/> Controller</p> <p><input type="radio"/> Both</p> <p>INHALER TYPE</p> <p>Which inhaler type is the patient prescribed?</p> <p><input type="radio"/> Reliever</p> <p><input checked="" type="radio"/> Controller</p> <p><input type="radio"/> Both</p> <p>INHALER TYPE</p> <p>Which inhaler type is the patient prescribed?</p> <p><input type="radio"/> Reliever</p> <p><input type="radio"/> Controller</p> <p><input checked="" type="radio"/> Both</p>
13	1. Select the additional medications.	<p>ADDITIONAL MEDICATION</p> <p>Does the patient use one of the following medications?</p> <p><input checked="" type="checkbox"/> Long-acting muscarinic antagonist (LAMA) <input checked="" type="checkbox"/> Maintenance oral corticosteroids (OCS)</p> <p><input checked="" type="checkbox"/> Biological treatment <input type="checkbox"/> Leukotriene receptor antagonist (LTRA)</p> <p><input type="checkbox"/> None</p>









		<p>ADDITIONAL MEDICATION</p> <p>Does the patient use one of the following medications?</p> <div> <input type="checkbox"/> Long-acting muscarinic antagonist (LAMA) <input type="checkbox"/> Maintenance oral corticosteroids (OCS) </div> <div> <input type="checkbox"/> Biological treatment <input type="checkbox"/> Leukotriene receptor antagonist (LTRA) </div> <input checked="" type="checkbox"/> None
14	1. Select/enter the controller inhaler.	<div> <input type="text" value="Search controller inhalers"/> </div> <div> <p>All other inhalers (63)</p> <div>  <p>Beclometason inhalatie Aerosol CFK-vrij 'Inhalator',50 microg/dosis 200 doses, Diverse fabrikanten Drug type: beclometasone Drug class: ICS</p> </div> <div>  <p>Beclometason inhalatie Aerosol CFK-vrij 'Inhalator',100 microg/dosis 200 doses, Diverse fabrikanten Drug type: beclometasone Drug class: ICS</p> </div> </div> <div>  <p>Your selection Beclometason inhalatie Aerosol CFK-vrij 'Inhalator',50 microg/dosis 200 ...</p> <p>CONTINUE</p> </div> <div> <p>DRUG CLASS</p> <p>Select the controller inhaler drug class:</p> <div> <input type="radio"/> ICS <input type="radio"/> ICS-LABA <input type="radio"/> Other controller </div> </div> <div> <p>ACTIVE DRUG</p> <p>Which ICS is the patient prescribed?</p> <div> <input type="radio"/> Beclometasone <input type="radio"/> Budesonide <input type="radio"/> Ciclesonide <input type="radio"/> Mometasone <input type="radio"/> Triamcinolone <input type="radio"/> Fluticasone furoate <input type="radio"/> Fluticasone propionate <input type="radio"/> Other </div> </div> <div> <p>DRUG FORMAT</p> <p>Select the controller inhaler drug format:</p> <div> <input type="radio"/> (p)MDI <input type="radio"/> DPI <input type="radio"/> Other </div> </div>

		<p>CONTROLLER DOSAGE</p> <p>What is the dosage provided by the controller inhaler?</p> <p>200 <input type="button" value="up"/> <input type="button" value="down"/> micrograms per inhalation</p> <p>Leave this question unanswered if you don't have the information.</p> <p>CONTROLLER DOSAGE</p> <p>How many inhalations per inhaler are provided within the controller inhaler?</p> <p>200 <input type="button" value="up"/> <input type="button" value="down"/> inhalations per inhaler</p> <p>Common inhalers contain 30, 50, 60, 120 or 200 inhalations. Leave this question unanswered if you don't have the information.</p> <p>Issues finding the correct inhaler?</p> <p>The patient's inhaler is not on the list</p> <p>I don't know the patient's inhaler</p>
15	1. Enter the number of inhalations per day.	<p>CONTROLLER DOSAGE</p> <p>What is the controller dosage and inhalations taken by the patient per day?</p> <p>50 micrograms per inhalation, 1 <input type="button" value="up"/> <input type="button" value="down"/> inhalation(s) per day.</p> <p>CONTROLLER DOSAGE</p> <p>What is the controller dosage and inhalations taken by the patient per day?</p> <p>50 micrograms per inhalation, 8 <input type="button" value="up"/> <input type="button" value="down"/> inhalation(s) per day.</p> <p>CONTROLLER DOSAGE</p> <p>What is the controller dosage and inhalations taken by the patient per day?</p> <p>50 micrograms per inhalation, 0 <input type="button" value="up"/> <input type="button" value="down"/> inhalation(s) per day.</p> <p>Please enter a number between 1 and 8</p> <p>CONTROLLER DOSAGE</p> <p>What is the controller dosage and inhalations taken by the patient per day?</p> <p>50 micrograms per inhalation, 9 <input type="button" value="up"/> <input type="button" value="down"/> inhalation(s) per day.</p> <p>Please enter a number between 1 and 8</p>

16	1. Enter the number of months on medication and controller prescriptions.	<p>CONTROLLER DEVICES</p> <p>How many controller devices has the patient had over the past 12 months?</p> <p>If the patient is on medication for less than a year, select the number of months accordingly.</p> <div> <input type="text" value="0"/> months on medication </div> <div> <input type="text" value="0"/> devices </div> <p>CONTROLLER DEVICES</p> <p>How many controller devices has the patient had over the past 12 months?</p> <p>If the patient is on medication for less than a year, select the number of months accordingly.</p> <div> <input type="text" value="12"/> months on medication </div> <div> <input type="text" value="24"/> devices </div> <p>CONTROLLER DEVICES</p> <p>How many controller devices has the patient had over the past 12 months?</p> <p>If the patient is on medication for less than a year, select the number of months accordingly.</p> <div> <input type="text" value="13"/> months on medication <small>Please enter a number between 0 and 12</small> </div> <div> <input type="text" value="25"/> devices <small>Please enter a number between 0 and 24</small> </div>
17	1. Select the reliever inhaler type.	<p>DRUG CLASS</p> <p>Select the reliever inhaler drug class:</p> <div> <input checked="" type="button" value="SABA"/> <input type="button" value="Low dose ICS-formoterol"/> </div> <p>DRUG CLASS</p> <p>Select the reliever inhaler drug class:</p> <div> <input type="button" value="SABA"/> <input checked="" type="button" value="Low dose ICS-formoterol"/> </div>
18	1. Enter the number of months on medication and SABA reliever prescriptions.	<p>SABA RELIEVER PRESCRIPTIONS</p> <p>How many SABA inhalers has the patient used over the past 12 months?</p> <p>If the patient is on medication for less than a year, select the number of months accordingly.</p> <div> <input type="text" value="0"/> months on medication </div> <div> <input type="text" value="0"/> inhalers </div>

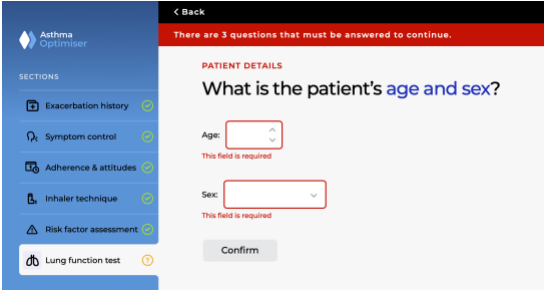
		<p>SABA RELIEVER PRESCRIPTIONS</p> <p>How many SABA inhalers has the patient used over the past 12 months?</p> <p>If the patient is on medication for less than a year, select the number of months accordingly.</p> <div> <input type="text" value="12"/> months on medication </div> <div> <input type="text" value="100"/> inhalers </div> <p>SABA RELIEVER PRESCRIPTIONS</p> <p>How many SABA inhalers has the patient used over the past 12 months?</p> <p>If the patient is on medication for less than a year, select the number of months accordingly.</p> <div> <input type="text" value="13"/> months on medication <small>Please enter a number between 0 and 12</small> </div> <div> <input type="text" value="101"/> inhalers <small>Please enter a number between 0 and 100</small> </div>
19	<p>1. Select whether there are occasions where a patient doesn't use their inhaler or not.</p>	<p>INHALER ATTITUDE</p> <p>Are there any occasions where the patient does not use their controller inhaler?</p> <div> <input checked="" type="button" value="Yes"/> <input type="button" value="No"/> </div> <p>INHALER ATTITUDE</p> <p>Are there any occasions where the patient does not use their controller inhaler?</p> <div> <input type="button" value="Yes"/> <input checked="" type="button" value="No"/> </div>
20	<p>1. Select/enter the reasons, why the patient doesn't use their inhaler.</p>	<p>INHALER USAGE</p> <p>Select the reasons why your patient may not use their controller inhaler.</p> <div> <input checked="" type="checkbox"/> Forgets to use it <input type="checkbox"/> Unaware of need for regular usage </div> <div> <input type="checkbox"/> Worries about side-effects <input checked="" type="checkbox"/> Worries about becoming too dependent on it </div> <div> <input checked="" type="checkbox"/> Tends to rely on the reliever inhaler for immediate relief <input type="checkbox"/> Other reasons </div>

21	<p>1. Select how often the patient doesn't use their inhaler.</p>	<div> <p>SKIPPING INHALER USE</p> <p>How often does the patient not take their controller, because of forgetfulness or intentionally not taking it?</p> <p><input checked="" type="radio"/> Once per week</p> <p><input type="radio"/> 2-4 times/week</p> <p><input type="radio"/> >4 times/week</p> </div> <div> <p>SKIPPING INHALER USE</p> <p>How often does the patient not take their controller, because of forgetfulness or intentionally not taking it?</p> <p><input type="radio"/> Once per week</p> <p><input checked="" type="radio"/> 2-4 times/week</p> <p><input type="radio"/> >4 times/week</p> </div> <div> <p>SKIPPING INHALER USE</p> <p>How often does the patient not take their controller, because of forgetfulness or intentionally not taking it?</p> <p><input type="radio"/> Once per week</p> <p><input type="radio"/> 2-4 times/week</p> <p><input checked="" type="radio"/> >4 times/week</p> </div>
22	<p>1. Select whether the inhaler technique is optimal or not.</p>	<div> <p>OBSERVE INHALER TECHNIQUE</p> <p>Observe and rate the patient's inhaler technique.</p> <p><input checked="" type="button" value="Optimal"/> <input type="button" value="Suboptimal"/></p> </div> <div> <p>OBSERVE INHALER TECHNIQUE</p> <p>Observe and rate the patient's inhaler technique.</p> <p><input type="button" value="Optimal"/> <input checked="" type="button" value="Suboptimal"/></p> </div>

23	1. Start the inhaler technique demonstration video.	<div>Beclometason inhalatie Aerosol CFK-vrij 'Inhalator', 50 microg/dosis 200 doses, Diverse fabrikanten</div> <div><p>Adem langzaam en volledig uit (niet in de dosisaerosol).</p><p>Video provided by zorgatlasweb.nl</p></div>
24	1. In the 'Risk factor assessment' section, click 'continue' without having entered any information.	<div><div><div><div>Asthma Optimiser</div><div>SECTIONS</div><div><div>Exacerbation history</div><div>Symptom control</div><div>Adherence & attitudes</div><div>Inhaler technique</div><div>Risk factor assessment</div><div>Lung function test</div></div></div></div><div><div>< Back</div><div>There are 4 questions that must be answered to continue.</div><div>ASTHMA TRIGGERS</div><div>Do any of these triggers make the patient's asthma worse?</div><div><div><input type="checkbox"/> Air pollution (noxious chemicals, cleaning products)</div><div><input type="checkbox"/> Anti-inflammatory drugs (e.g. aspirin)</div><div><input type="checkbox"/> Respiratory viruses</div><div><input type="checkbox"/> Allergies (pollen / hay fever / pets / dust / moulds / others)</div><div><input type="checkbox"/> Passive smoking / vaping</div><div><input type="checkbox"/> Perfume</div></div></div></div>
25	1. Select/enter the asthma triggers.	<div><div>ASTHMA TRIGGERS</div><div>Do any of these triggers make the patient's asthma worse?</div><div><div><input checked="" type="checkbox"/> Air pollution (noxious chemicals, cleaning products)</div><div><input type="checkbox"/> Anti-inflammatory drugs (e.g. aspirin)</div><div><input type="checkbox"/> Respiratory viruses</div><div><input checked="" type="checkbox"/> Allergies (pollen / hay fever / pets / dust / moulds / others)</div><div><input checked="" type="checkbox"/> Passive smoking / vaping</div><div><input checked="" type="checkbox"/> Perfume</div><div><input type="checkbox"/> Other</div><div><input type="checkbox"/> None</div></div></div> <div><div>ASTHMA TRIGGERS</div><div>Do any of these triggers make the patient's asthma worse?</div><div><div><input type="checkbox"/> Air pollution (noxious chemicals, cleaning products)</div><div><input type="checkbox"/> Anti-inflammatory drugs (e.g. aspirin)</div><div><input type="checkbox"/> Respiratory viruses</div><div><input type="checkbox"/> Allergies (pollen / hay fever / pets / dust / moulds / others)</div><div><input type="checkbox"/> Passive smoking / vaping</div><div><input type="checkbox"/> Perfume</div><div><input type="checkbox"/> Other</div><div><input checked="" type="checkbox"/> None</div></div></div>

26	1. Select whether the patient smokes, has smoked in the past, or has never smoked.	<div> SMOKING Is the patient smoking or did the patient smoke in the past? </div> <div> <input checked="" type="radio"/> Current smoker <input type="radio"/> Former smoker <input type="radio"/> Never smoker </div> <div> SMOKING Is the patient smoking or did the patient smoke in the past? </div> <div> <input type="radio"/> Current smoker <input checked="" type="radio"/> Former smoker <input type="radio"/> Never smoker </div> <div> SMOKING Is the patient smoking or did the patient smoke in the past? </div> <div> <input type="radio"/> Current smoker <input type="radio"/> Former smoker <input checked="" type="radio"/> Never smoker </div>
27	1. Select/enter the comorbidities.	<div> COMORBIDITIES Does the patient have any of these comorbidities that may contribute to their symptoms, impaired quality of life, and poor asthma control? </div> <div> <input type="checkbox"/> Anxiety or depression <input checked="" type="checkbox"/> Deconditioning <input checked="" type="checkbox"/> Obesity <input type="checkbox"/> Chronic rhinosinusitis or nasal polyps <input checked="" type="checkbox"/> Gastroesophageal reflux disease <input type="checkbox"/> None </div> <div> <input type="checkbox"/> Obstructive sleep apnoea <input type="checkbox"/> Bronchiectasis <input type="checkbox"/> Cardiac disease <input type="checkbox"/> Chronic obstructive pulmonary disease <input checked="" type="checkbox"/> Other <input type="text"/> </div>

		<p>COMORBIDITIES</p> <p>Does the patient have any of these comorbidities that may contribute to their symptoms, impaired quality of life, and poor asthma control?</p> <div> <input type="checkbox"/> Anxiety or depression <input type="checkbox"/> Obstructive sleep apnoea </div> <div> <input type="checkbox"/> Deconditioning <input type="checkbox"/> Bronchiectasis </div> <div> <input type="checkbox"/> Obesity <input type="checkbox"/> Cardiac disease </div> <div> <input type="checkbox"/> Chronic rhinosinusitis or nasal polyps <input type="checkbox"/> Chronic obstructive pulmonary disease </div> <div> <input type="checkbox"/> Gastroesophageal reflux disease <input type="checkbox"/> Other </div> <div> <input checked="" type="checkbox"/> None </div>
28	1. Select/enter the socioeconomic factors.	<p>SOCIOECONOMIC FACTORS</p> <p>Is the patient exposed to any of these socioeconomic status (SES) triggers that may contribute to their symptoms, impaired quality of life, and poor asthma control?</p> <div> <input checked="" type="checkbox"/> Financial status <input checked="" type="checkbox"/> Living conditions (mould, dust, other) </div> <div> <input type="checkbox"/> Educational attainment <input checked="" type="checkbox"/> Occupational </div> <div> <input type="checkbox"/> Other <input type="checkbox"/> No SES detected </div> <p>SOCIOECONOMIC FACTORS</p> <p>Is the patient exposed to any of these socioeconomic status (SES) triggers that may contribute to their symptoms, impaired quality of life, and poor asthma control?</p> <div> <input type="checkbox"/> Financial status <input type="checkbox"/> Living conditions (mould, dust, other) </div> <div> <input type="checkbox"/> Educational attainment <input type="checkbox"/> Occupational </div> <div> <input type="checkbox"/> Other <input checked="" type="checkbox"/> No SES detected </div>
29	1. Enter required data about the patient's smoking habits.	<p>YEARS OF SMOKING</p> <p>How many years has the patient been smoking?</p> <div> <input type="text" value="10"/> years </div> <p>CIGARETTES PER DAY</p> <p>How many cigarettes per day does the patient smoke?</p> <div> <input type="text" value="20"/> cigarettes per day </div>

		<p>MOTIVATION QUIT SMOKING</p> <p>Is the patient planning to quit smoking?</p> <p>Yes No</p>
30	1. In the 'Lung function test' section, click 'continue' without having entered any information.	
31	1. Enter the required patient data. 2. Enter the spirometry readings.	<p>PATIENT DETAILS</p> <p>What is the patient's age and sex?</p> <p>Age: 38</p> <p>Sex: Female</p> <p>Confirm</p> <p>PATIENT MEASUREMENTS</p> <p>What is the patient's height and weight?</p> <p>Height: 165 cm</p> <p>Weight: 67 kg</p> <p>PATIENT RACE</p> <p>Please specify the patient's race:</p> <p><input checked="" type="radio"/> Caucasian <input type="radio"/> African American</p> <p><input type="radio"/> Northeast Asian <input type="radio"/> Southeast Asian</p> <p><input type="radio"/> Other</p>

32 1. Select whether the patient is currently under the care of an asthma specialist or not.

Treatment Optimiser – Asthma Optimiser

1. Open the summary report

HCP: Test User
Reference ID: Test1


! Consider review by a specialist


- **Exacerbation history:** 3 reported
- **Occupational asthma:** Symptoms are worse at work
- **Care optimised :** No

Please refer to the details in the summary report for further information.

Guidance is offered based on the [GINA 2023 report](#) and expert opinion.

Important: The results do not provide professional or medical advice. Healthcare practitioners who use this tool should exercise their own clinical judgement and take into account local and national guidelines when making treatment decisions for their patients.

 Download Summary Report

 Create Referral Letter

Summary report

Patient details:

- Age: 38
- Sex: Female
- Height: 165 cm
- Weight: 67 kg

Exacerbation history:

- 1 course of systemic corticosteroids for asthma over the past 12 months
- 2 or more emergency attendances, admissions or unscheduled visits due to asthma over the past 12 months
- No history of intubation or admission to an intensive care unit or high dependency unit due to their asthma
- Symptoms are worse at work (Occupation: Community and social service occupations)

Indications that the patient may benefit from a review by a specialist include:

- Severely uncontrolled asthma or frequent exacerbations, including frequent asthma-related healthcare utilisation (e.g. emergency hospital attendances).
- Any risk factor for asthma-related death, including intensive care unit admission
- Evidence of, or risk of, significant treatment side effects, including frequent courses of oral corticosteroids (e.g. two or more courses a year)
- Suspected occupational asthma

Symptoms (ACQ6): Controlled

- Night waking due to asthma: (0) Never
- Asthma symptoms in the morning: (0) No symptoms
- Activity limitations: (0) Not limited at all
- Shortness of breath: (0) None
- Wheezing: (0) Not at all
- Inhalations of short-acting bronchodilator: (0) None
- ACQ Score: 0.00 (Controlled)

The patient's asthma symptoms are well controlled.

GINA 2023 recommendation: Consider stepping down gradually once good asthma control has been achieved and maintained for 2-3 months, to find the patient's lowest treatment that controls both symptoms and exacerbations.

Optimised care: No

- Treatment has not been optimised since the patient's last exacerbation.

Treatment: Step 2

- Current controller therapy (Step 2):
Beclometason inhalatie Aerosol CFK-vrij 'Inhalator', 50 microg/dosis 200 doses,
Diverse fabrikanten,
3 inhalation(s) a day
- Current reliever therapy:
SABA, 2 canisters in the last 12 months

GINA 2023 recommends that all adults and adolescents with asthma should receive ICS-containing controller treatment to reduce their risk of serious exacerbations and control symptoms.

	<p>Adherence: Good (91%)</p> <ul style="list-style-type: none"> Controller (Good: 91%): Beclometason inhalatie Aerosol CFK-vrij 'Inhalator', 50 microg/dosis 200 doses, Diverse fabrikanten: 5.5 required controller device(s) according to treatment, 5 controller device(s) in the last 12 months <p>Inhaler attitude: Inconsistent usage</p> <ul style="list-style-type: none"> The patient does not use inhaler once per week. The patient forgets to use the inhaler. The patient worries about becoming too dependent on it. The patient tends to rely on reliever inhaler for immediate relief. <p>A discussion with the patient on the highlighted concerns may be appropriate. Poor adherence and incorrect inhaler technique may underlie poor symptom control and are potentially modifiable risk factors for future exacerbations, even in patients with few symptoms.</p> <p>GINA 2023 recommendation: depending on the clinical context, identify and treat modifiable risk factors before considering a review by a specialist. Evidence of, or risk of, significant treatment side-effects is an indication that the patient may benefit from a review by a specialist.</p> <p>If the patient forgets to use their inhaler, suggest associating the daily adherence with another routine activity like brushing their teeth.</p> <p>Lung function test: Pre FEV1(L) Ratio: 100%, Post FEV1(L) Ratio: 100%</p> <ul style="list-style-type: none"> Pre FEV1(L) Ratio = 100% (Z-score: -0.01) Pre FEV1/FVC(%) = 82% (Z-score: -0.07) Post FEV1(L) Ratio = 100% (Z-score: -0.01) Post FEV1/FVC(%) = 82% (Z-score: -0.07) Age = 38 Height = 165 cm Weight = 67 kg Sex = Female Race = Caucasian BMI = 24.61 <p>Measure lung function at start of treatment. After 3-6 months of controller treatment record personal best lung function, and take periodic measurements for ongoing risk assessment.</p> <p>Low FEV1, especially <60% predicted, is a potentially modifiable risk factor for future exacerbations, even in patients with few symptoms. Low initial FEV1 is a risk factor for developing persistent airflow limitation.</p> <p>A reduced FEV1/FVC ratio, is indicative of obstructive lung disease. A z score of -1.64 or less indicates that 95% of people with these characteristics record a higher FEV1 value.</p> <p>Low lung function despite correct inhaler technique, good adherence with step 4 treatment (moderate dose ICS-LABA) and identification and treatment of modifiable risk factors and comorbidities, is an indication that the patient may benefit from a review by a specialist.</p> <p>Inhaler technique: Optimal</p> <ul style="list-style-type: none"> The patient's technique is optimal. <p>Risk factors: Present</p> <ul style="list-style-type: none"> Triggers: <ul style="list-style-type: none"> Air pollution (noxious chemicals, cleaning products), Allergies (pollen / hay fever / pets / dust / moulds / others), Passive smoking / vaping, Perfume Smoking: <ul style="list-style-type: none"> Current smoker (10 pack-years, motivated to quit) Comorbidities: <ul style="list-style-type: none"> Other (), Deconditioning, Obesity, Gastroesophageal reflux disease Socio economic factors: <ul style="list-style-type: none"> Financial status, Living conditions (mould, dust, other), Occupational <p>Having risk factors may increase the patient's risk of exacerbations even if they have few asthma symptoms.</p> <p>GINA 2023 recommendation: depending on the clinical context, identify and treat modifiable risk factors and comorbidities before considering a review by a specialist. Suspected occupational asthma is an indication that the patient may benefit from a review by a specialist.</p>
<p>34</p> <p>1. Select the symptom control test to be used in the settings.</p>	<p>Asthma symptom control</p> <p>Please select which asthma symptom control test you prefer to use:</p> <p><input checked="" type="radio"/> GINA: The Global Initiative for Asthma is an International organisation that releases evidence-based strategy documents for asthma management – 4 questions to assess level of asthma control.</p> <p><input type="radio"/> RCP3Q: Royal College of Physicians – 3 questions to assess level of asthma control in the UK.</p> <p><input type="radio"/> ACQ6: Asthma Control Questionnaire – 6 questions to assess level of asthma control.</p>

		<p>Asthma symptom control</p> <p>Please select which asthma symptom control test you prefer to use:</p> <p><input type="radio"/> GINA: The Global Initiative for Asthma is an International organisation that releases evidence-based strategy documents for asthma management – 4 questions to assess level of asthma control.</p> <p><input checked="" type="radio"/> RCP3Q: Royal College of Physicians – 3 questions to assess level of asthma control in the UK.</p> <p><input type="radio"/> ACQ6: Asthma Control Questionnaire – 6 questions to assess level of asthma control.</p> <p>Asthma symptom control</p> <p>Please select which asthma symptom control test you prefer to use:</p> <p><input type="radio"/> GINA: The Global Initiative for Asthma is an International organisation that releases evidence-based strategy documents for asthma management – 4 questions to assess level of asthma control.</p> <p><input type="radio"/> RCP3Q: Royal College of Physicians – 3 questions to assess level of asthma control in the UK.</p> <p><input checked="" type="radio"/> ACQ6: Asthma Control Questionnaire – 6 questions to assess level of asthma control.</p>
35	<ol style="list-style-type: none"> 1. Select the GINA questionnaire in the settings. 2. Start a new session. 3. Enter data on the exacerbation history. 4. Select the answers to the GINA questions. 	<p>GINA - DAYTIME SYMPTOMS</p> <p>Has the patient had daytime asthma symptoms more than twice a week, in the last 4 weeks?</p> <p><input checked="" type="button" value="Yes"/> <input type="button" value="No"/></p> <p>GINA - NIGHT WAKING</p> <p>Has the patient had any night waking due to asthma, in the last 4 weeks?</p> <p><input type="button" value="Yes"/> <input checked="" type="button" value="No"/></p> <p>GINA - RELIEVER USE</p> <p>Did the patient need their reliever for symptoms* more than twice a week, in the last 4 weeks?</p> <p><input checked="" type="button" value="Yes"/> <input type="button" value="No"/></p> <p>GINA - ACTIVITY LIMITATION</p> <p>Has the patient had any activity limitation due to asthma, in the last 4 weeks?</p> <p><input type="button" value="Yes"/> <input checked="" type="button" value="No"/></p>
36	<ol style="list-style-type: none"> 1. Select the RCP3Q questionnaire in the settings. 2. Start a new session. 3. Enter data on the exacerbation history. 4. Select the answers to the RCP3Q questions. 	<p>RCP3Q - DIFFICULTY SLEEPING</p> <p>Has the patient had difficulty sleeping due to asthma symptoms (including cough) in the last month?</p> <p><input type="radio"/> Not at all</p> <p><input checked="" type="radio"/> Once or twice per month</p> <p><input type="radio"/> Once or twice per week</p> <p><input type="radio"/> Daily symptoms</p>

		<p>RCP3Q - DAYTIME SYMPTOMS</p> <p>Has the patient had asthma symptoms during the day (e.g. cough, wheeze, chest tightness or breathlessness) in the last month?</p> <p> <input type="radio"/> Not at all <input type="radio"/> Once or twice per month <input checked="" type="radio"/> Once or twice per week <input type="radio"/> Daily symptoms </p> <p>RCP3Q - ACTIVITY LIMITATION</p> <p>Has asthma interfered with their day-to-day activities (e.g. housework, work, school) in the last month?</p> <p> <input checked="" type="radio"/> Not at all <input type="radio"/> Once or twice per month <input type="radio"/> Once or twice per week <input type="radio"/> Daily symptoms </p>
37	<ol style="list-style-type: none"> 1. Select the lung function test to be used in the settings. 	<p>Lung function</p> <p>Please select which lung function test you prefer to use: However, if you do not wish to perform a lung function test, you will be able to skip this during your sessions.</p> <p> <input checked="" type="radio"/> Peak expiratory flow: Measures the maximum speed with which a person can exhale. <input type="radio"/> Spirometry: Measures the amount and/or speed of air that can be inhaled and exhaled. </p> <p>Lung function</p> <p>Please select which lung function test you prefer to use: However, if you do not wish to perform a lung function test, you will be able to skip this during your sessions.</p> <p> <input type="radio"/> Peak expiratory flow: Measures the maximum speed with which a person can exhale. <input checked="" type="radio"/> Spirometry: Measures the amount and/or speed of air that can be inhaled and exhaled. </p>
38	<ol style="list-style-type: none"> 1. Select 'Peak expiratory flow' in the settings. 2. Start a new session. 3. Go to the section 'Lung function test'. 4. Enter the required patient data. 5. Enter the peak flow readings. 	<p>PATIENT DETAILS</p> <p>What is the patient's age and sex?</p> <p>Age: <input type="text" value="38"/></p> <p>Sex: <input type="text" value="Female"/></p> <p><input type="button" value="Confirm"/></p>

	<div>PATIENT MEASUREMENTS</div> <p>What is the patient's height and weight?</p> <p>Height: <input type="text" value="165"/> cm</p> <p>Weight: <input type="text" value="67"/> kg</p> <div>PEAK FLOW READING</div> <p>Please enter the patient's peak flow reading below:</p> <p>Peak flow: <input type="text" value="409,5"/> litres/minute</p> <p>Predicted normal value is estimated to be 409.5 litres/minute</p>
<p>39</p> <ol style="list-style-type: none"> 1. Start a new session. 2. Go to the section 'Adherence and attitudes'. 3. Select 'Controller' for the inhaler type and 'None' for the additional medication and continue. 4. Select the option 'I don't know the patient's inhaler'. 5. Select whether the patient is adherent to their treatment. 6. Select the current GINA treatment step. 	<div>ADHERENCE</div> <p>Do you consider the patient to be adherent to their treatment?</p> <p><input checked="" type="button" value="Yes"/> <input type="button" value="No"/></p> <div>ADHERENCE</div> <p>Do you consider the patient to be adherent to their treatment?</p> <p><input type="button" value="Yes"/> <input checked="" type="button" value="No"/></p> <div>TREATMENT STEP</div> <p>Please select the patient's current GINA 2023 treatment step.</p> <p>To identify and fully understand the patient's current GINA 2023 treatment step, please refer to page 65 of the GINA 2023 report. As a supporting reference for each of the treatment steps given below, some general information on commonly used medications is given alongside each treatment step.</p> <p>If the patient is on treatment step 5, for the purposes of this session, please select the option 'Step 4 treatment'.</p> <p><input checked="" type="radio"/> Step 1 treatment: As-needed low dose ICS-formoterol or as-needed SABA</p> <p><input type="radio"/> Step 2 treatment: Daily low dose ICS</p> <p><input type="radio"/> Step 3 treatment: Low dose ICS-LABA</p> <p><input type="radio"/> Step 4 treatment: Medium dose ICS-LABA</p>

TREATMENT STEP

Please select the patient's **current**
GINA 2023 treatment step.

To identify and fully understand the patient's current GINA 2023 treatment step, please refer to page 65 of the [GINA 2023 report](#). As a supporting reference for each of the treatment steps given below, some general information on commonly used medications is given alongside each treatment step.

If the patient is on treatment step 5, for the purposes of this session, please select the option 'Step 4 treatment'.

- ☐ **Step 1 treatment:** As-needed low dose ICS-formoterol or as-needed SABA
- ☒ **Step 2 treatment:** Daily low dose ICS
- ☐ **Step 3 treatment:** Low dose ICS-LABA
- ☐ **Step 4 treatment:** Medium dose ICS-LABA

TREATMENT STEP

Please select the patient's **current**
GINA 2023 treatment step.

To identify and fully understand the patient's current GINA 2023 treatment step, please refer to page 65 of the [GINA 2023 report](#). As a supporting reference for each of the treatment steps given below, some general information on commonly used medications is given alongside each treatment step.

If the patient is on treatment step 5, for the purposes of this session, please select the option 'Step 4 treatment'.

- ☐ **Step 1 treatment:** As-needed low dose ICS-formoterol or as-needed SABA
- ☐ **Step 2 treatment:** Daily low dose ICS
- ☒ **Step 3 treatment:** Low dose ICS-LABA
- ☐ **Step 4 treatment:** Medium dose ICS-LABA

TREATMENT STEP

Please select the patient's **current**
GINA 2023 treatment step.

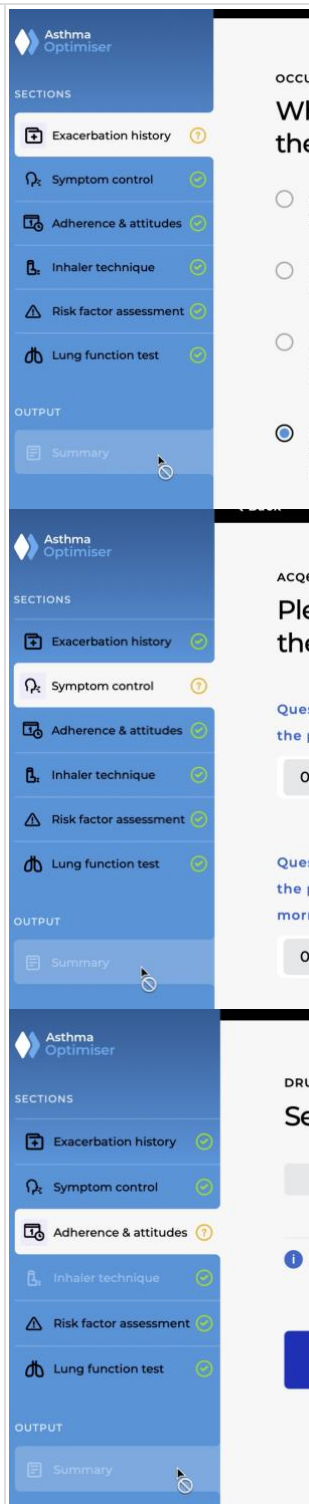
To identify and fully understand the patient's current GINA 2023 treatment step, please refer to page 65 of the [GINA 2023 report](#). As a supporting reference for each of the treatment steps given below, some general information on commonly used medications is given alongside each treatment step.

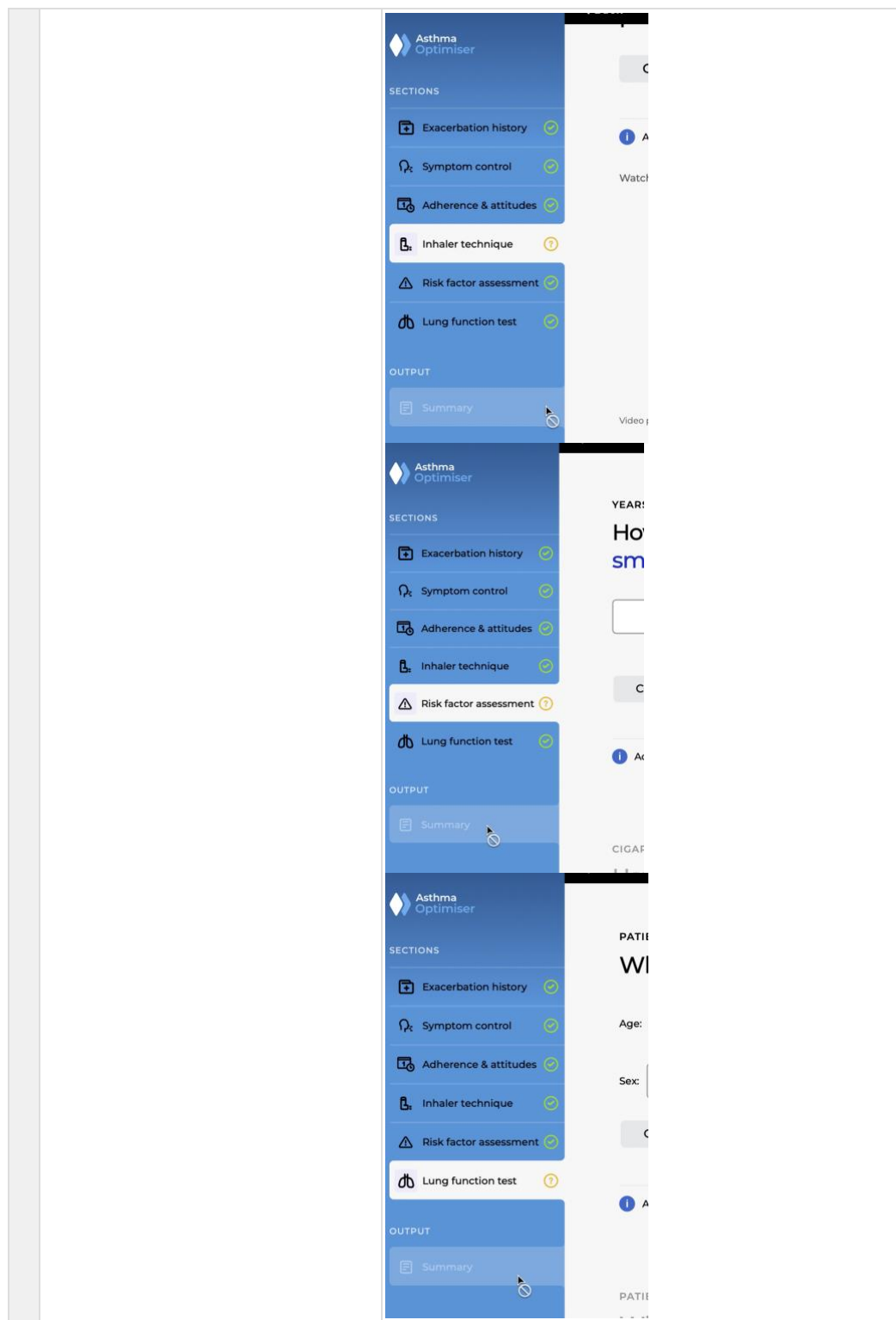
If the patient is on treatment step 5, for the purposes of this session, please select the option 'Step 4 treatment'.

- ☐ **Step 1 treatment:** As-needed low dose ICS-formoterol or as-needed SABA
- ☐ **Step 2 treatment:** Daily low dose ICS
- ☐ **Step 3 treatment:** Low dose ICS-LABA
- ☒ **Step 4 treatment:** Medium dose ICS-LABA

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1. Start a new session.
2. Go through the AO sections entering information.
3. Click on 'Summary' with a section being started but incomplete.





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 Asthma. Global Strategy for Asthma Management and Prevention, 2023.

Available from www.ginasthma.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.

22 Contact

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