AC Instructions for use

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ID	Internal References	Space key

2.2. Citation table

ID	Cited By	Space key

3. Symbols and glossary

3.1. Symbols

Manufacturer	
Date of Manufacture	
Medical Device	
Electronic Instructions for Use	

Table 1: Symbols

3.2. Glossary

.NET: .NET is a free and open-source application platform supported by Microsoft.

NuGet: NuGet is the package manager for .NET.

NuGet package: a single ZIP file with the .nupkg extension that contains compiled Asthma Calculator library code (DLLs), other files related to that code, and a descriptive manifest that includes information like the package's version number

DLL: A dynamic-link library (DLL) is a shared library in the Microsoft Windows or OS/2 operating system

Client System: The system that integrates and uses the Asthma Calculator.

4. Warnings

If you have any questions about the warnings and cautions in this section, please contact Orla DTx technical support using the contact information at the end of this document.

WARNING: Security and privacy protection must be taken care of by the Client System, in a manner appropriate for the intended use of the Client System. In particular:

1. The operating system access rights of the Client System (process permissions) must be limited to the minimum possible, in order to limit the effects of a possible compromise.
2. Appropriate protections must be implemented to ensure the confidentiality, integrity and availability of data. In particular, data should be encrypted in-transit and at-rest using strong encryption protocols and backed up regularly.
3. Appropriate authentication, access control and auditing measures must be implemented to protect data against unauthorized access and record the authorized accesses.
4. Regulatory security and privacy requirements for healthcare information systems must be fulfilled as appropriate. In Finland, refer to Order 5/2024 on essential requirements for healthcare information systems (in Finnish) from Finnish Institute for Health and Welfare.

WARNING: While every effort has been made to ensure the accuracy of calculation results, the possibility of software error cannot be completely ruled out. Data should not be used as a sole means for determining the patient diagnosis.

WARNING: If the Asthma Calculator reports an error that you are not able to correct, or fails to provide results, please contact Orla DTx technical support using the contact information at the end of this document.

WARNING: Use of the results provided by the Asthma Calculator is not recommended for diagnosing patients below 12 years of age.

WARNING: PEF EU reference value calculation is not suitable for patients below 15 years of age, or above 85 years of age.

CAUTION: Care must be taken to ensure that maintenance operations do not change the used .NET implementation to one that is not compatible with .NET standard 2.0.

CAUTION: To ensure safe operation, you should install new updates without undue delay.

CAUTION: Ensure that you notify Orla DTx if your contact information changes. Orla DTx contact information is available at the end of this document.

5. Preface

This document is a user manual for Asthma Calculator version 1.1.0. Read this manual carefully, before using device. Save this manual for later use.

5.1. Intended use

The Asthma Calculator is intended to be used for calculation of analytical results relevant for asthma diagnosis and treatment, based on PEF measurement results.

The intended users of the software are medical professionals (nurses, doctors and assistants).

5.2. Target patients and operators

5.2.1. Target patient operators

Intended users are medical professionals (nurses, doctors and assistants). There are no restrictions concerning age or sex. Users are expected to have knowledge and skills of the healthcare facility's official language.

There are two user groups:

Nurses and Doctors: People who interpret the results provided by the Asthma Calculator. Minimum education level is a nurse.

Assistants: People who use the Asthma Calculator but do not interpret the results, e.g. download a report and deliver it to a doctor or a nurse. These users can be anyone with sufficient skills to use Client System.

5.2.2. Target engineering operators

Software engineers: People responsible for installing, integrating and maintaining the Asthma Calculator. In addition to the software engineering skills required for these tasks (C#, .NET, and NuGet package management skills), these users are expected to have knowledge and skills of English.

5.2.3. Target patient population

The PEF EU reference value calculation is suitable for adults and children between 15 and 85 years of age. The calculations related to PEF diurnal variation and bronchodilation response are suitable for adults and children above 12 years of age undergoing PEF monitoring. Other PEF calculations are suitable for all patients for whom PEF monitoring is suitable.

There are no restrictions concerning patient's sex, weight, ethnicity, or any impairments.

5.3. Environment of use

Asthma Calculator is a medical calculator used in a healthcare facility in a normal office space.

5.4. Lifetime of the Device

The lifetime of the device, during normal conditions of use and when properly maintained in accordance with the manufacturer's instructions, is five (5) years. The lifetime is counted from the installation of the last software update, or the original installation if no updates have been installed.

5.5. Contraindications

PEF diurnal variation and bronchodilation response calculations are contraindicated for children under 12 years.

PEF EU reference value calculation is restricted to adults and children between 15 and 85 years of age, because the reference values have not been defined for other patient age groups.

5.6. General Description

Asthma Calculator is a medical calculator, which operates within a Client software system. Asthma Calculator does not have a user interface of its own. Calculator usage is controlled by the client software system user interface.

5.7. Reporting of Serious Incidents

Any serious incident that occurs in relation to the Asthma Calculator should be reported to the Orla DTx (contact information is provided at the end of this document) and to the competent authority of your country (Fimea in Finland).

5.8. Obtaining Instructions for Use in paper form

You may obtain these Instructions for Use in paper form at no additional cost by contacting Orla DTx Oy using the contact information at the end of this document. The Instructions for User in paper form will be provided within 7 calendar days of receiving your request.

5.9. Obtaining Instructions for Use online

This document is also available online at https://orladtx.com/ifu/.

6. Getting started

6.1. Installation

The Asthma Calculator library is published as a NuGet package on GitHub Packages in the Asthma Calculator repository. Access to the Orla GitHub repository (https://github.com/orladtx/asthma-calculator) and the Orla NuGet repository

(https://nuget.pkg.github.com/orladtx/index.json) has been provided to you as part of the software delivery. To consume this package, add a NuGet source with authentication and add the AsthmaCalculator package to your project.

To install and use the library, client system must support .NET standard 2.0. See Table 2 below for .NET implementation version compatibility. Microsoft NET Standard overwiew 11152023.pdf

CAUTION: Care must be taken to ensure that maintenance operations do not change the used .NET implementation to one that is not compatible with .NET standard 2.0.

.NET implementation	Version support
.NET and .NET Core	2.0, 2.1, 2.2, 3.0, 3.1, 5.0, 6.0, 7.0, 8.0
.NET Framework [1]	4.6.1 [2], 4.6.2, 4.7, 4.7.1, 4.7.2, 4.8, 4.8.1
Mono	5.4, 6.4
Xamarin.iOS	10.14, 12.16
Xamarin.Mac	3.8, 5.16
Xamarin.Android	8.0, 10.0
Universal Windows Platform	10.0.16299, TBD
Unity	2018.1

Table 2: .NET implementation version compatibility

7. Integration

API documentation of the Asthma Calculator described in Figure 1 below. Asthma Calculator requires Monitoring Program data as input, and produces Results.

Based on Monitoring Program Type, the Results are either Daily Monitoring Program Results or Work-related Monitoring Program Results.

Each Monitoring Program data contains:

- Patient Data
  - age, sex, and height
- Monitoring Program Type
  - daily, or work-related
- Monitoring Program Configuration (see section 10)
- Collection of Measurement data, each datapoint composed of:

- sequence of blows
- additional, program-type-specific data

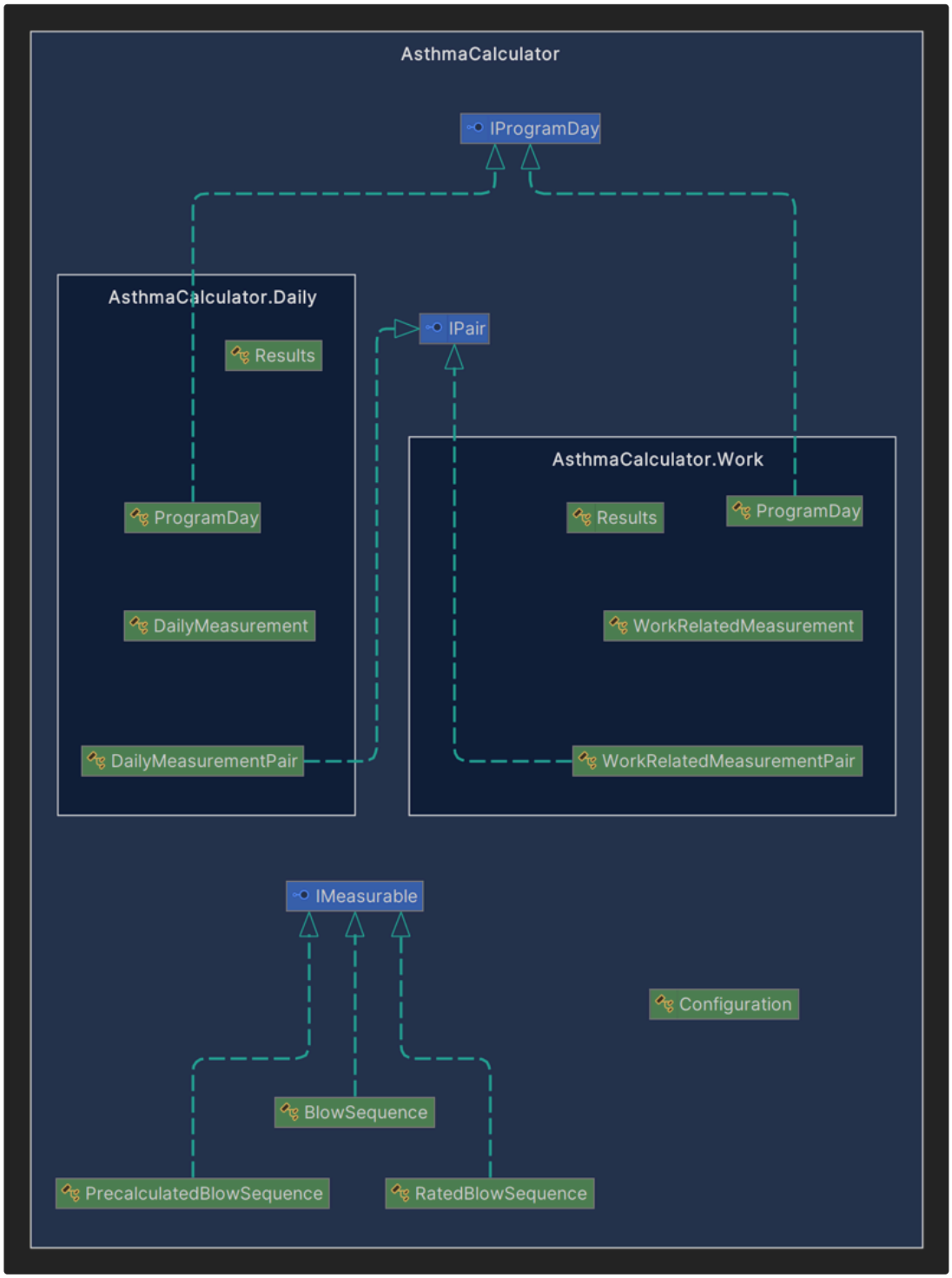

Figure 1: API of the Asthma Calculator

The following labeling information is available via NuGet package properties:

UDI: (01)06429811352001(8012)<version number, e.g. “1.0.4”>

Manufacturer: Orla DTx Oy, Agricolantie 21, 07930 Pernaja, Finland

Manufacturing date: <manufacturing date, e.g. “2024-07-22”>

Name: Asthma Calculator

7.1. Integration Training

Orla DTx provides a mandatory training for integration of the Asthma Control library, which provides the knowledge and skills necessary for safe integration of the library to another system. The arrangements for training will be made when access to the library is provided.

7.2. Integration Verification

The following manual checks must be performed after integration to verify that the integration is safe. A signed declaration that all requirements are fulfilled must be sent to the manufacturer (see contact information at the end of the document), including the required evidence, and the integrated Asthma Calculator may not be taken into use before the manufacturer has received the declaration and given written permission to continue.

7.2.1. Requirement 1

When patient’s age is below 12, the system must display a message alongside the results which states that use of the results for diagnosis is not recommended based on patient’s age.

Evidence: Screenshot of patient information showing patient age, and screenshot of the results and the message

7.2.2. Requirement 2

When such information is reasonably available, the system must display the source of input data (such as type or identity of the measurement device used) for each measurement. The purpose of showing this information is to allow the user to determine the reliability of the input data (for example, manually recorded input data is less reliable than automatically recorded). If the entire monitoring program of a patient has a single source of input data, displaying the source for the program is sufficient. When information is not reasonably available, justification must be provided.

Evidence: Screenshot of measurement data with source of input data being displayed (or a written statement justifying why the information is not reasonably available)

7.2.3. Requirement 3

When the number of significant diurnal variations or bronchodilations is displayed, the threshold values used to determine significance must be displayed alongside the result.

Evidence: Screenshot of threshold values displayed alongside the results (or a written statement that significant diurnal variations or bronchodilations are not displayed)

7.2.4. Requirement 4

When measurements are grouped for work-related monitoring, both the grouping and the actual measurement date and time must be shown for each measurement, so that the user can verify grouping correctness.

Evidence: Screenshot of how measurements are shown (or a written statement that work-related monitoring is not used)

7.2.5. Requirement 5

If use of precalculated measurements (the user of the Client System checks repeatability manually and enters only the highest measurement for the entire series of blows, in order to reduce data entry effort) is supported by the Client System, it must be tested after integration that precalculated measurements are shown as repeatable.

Evidence: Screenshot of a measurement with a single blow, where it can be seen that the measurement is considered to be repeatable

8. Error conditions

Asthma Calculator library gives error information for the Client System from below topics. When error information is returned, the Client System must show a corresponding error message to the end-user in the language currently used by the Client System. Error messages shown to end-users based on these errors must be approved by Orla DTx in writing prior to production use of the Asthma Calculator.

8.1. Terminology

Blow: One blow into the PEF measurement device, producing one PEF value

Measurement: A sequence of blows performed consecutively. Multiple blows are done to confirm consistent blow technique (repeatability).

Repeatable measurement: A measurement is repeatable if it contains at least 3 approved blows (blows may also be rejected by the PEF measurement device) of which the two largest ones are within the repeatability threshold of each other.

Program day type: A program day in a work-related measurement program may be a leisure day or a work day.

Group processing: Grouping measurements to program days according the method specified by the Finnish Institute of Occupational Health.

Baseline measurement: In order to measure bronchodilation response, a pair of measurements is performed, one before using the bronchodilator and one after. The baseline measurement is the one before using the bronchodilator.

Delay: The valid time range (minimum and maximum) between the measurements in a measurement pair (measurement taken before using the bronchodilator and measurement taken after using the bronchodilator). If the time range is not valid, the measurement pair cannot be used for determining bronchodilation response.

Bronchodilation response threshold: The threshold for considering a bronchodilation response significant.

Diurnal variation threshold: The threshold for considering a diurnal variation significant.

8.2. Errors

Measurements:

- Blows were set in multiple times
- No blows were set
- No repeatable measurements
- Measurements are empty
- Unknown program day type
- Group processing failed

Blow sequences:

- Not enough blows
- Invalid blow value
- No blows

Bronchodilation response:

- Baseline measurement is missing
- No bronchodilation response results found

Diurnal variation:

- No repeatable measurements in a day

Configuration:

- Configuration not available
- Repeat threshold out of range
- Bronchodilation response threshold out of range
- Diurnal variation threshold out of range
- Delay range out of range
- Invalid delay range

Patient information:

- Age out of range
- Height out of range
- Unknown sex

9. Service and maintenance

9.1. Cleaning the device

Asthma Calculator is a MDSW so cleaning is not required.

9.2. Storage

Asthma Calculator is a MDSW so it is not physically stored.

9.3. Periodical Maintenance

Maintenance of the Asthma Calculator is done by software updates to Client System. Orla DTx will contact you when a new version of the Asthma Calculator library is available. Orla DTx uses the contact information stored in Orla DTx Asthma Calculator customer registry for contacting you, please ensure your contact information is up to date by contacting Orla DTx using the contact information at the end of this document. Integration verification checks must be redone after the update (including sending the signed declaration to Orla together with screenshots and getting approval from Orla to proceed, as described in section 7.2), using the instructions accompanying the updated version.

You must keep records of the Asthma Calculator version currently in use in your system.

CAUTION: To ensure safe operation, you should install new updates without undue delay.

CAUTION: Ensure that you notify Orla DTx if your contact information changes. Orla DTx contact information is available at the end of this document.

9.4. Safe disposal of device

Asthma Calculator is a MDSW so disposal of the device is to uninstall / delete software from the Client System.

10. Technical specifications

This software library is a CE-marked medical device of Class IIa (EU MDR 2017/745 Rule 11).

This software library supports the following calculations related to PEF monitoring:

- Repeatability
- Bronchodilation and number of significant bronchodilations
- Diurnal variation and number of significant diurnal variations
- EU reference value
- Measurement grouping used in work-related PEF monitoring as used by the Finnish Institute of Occupational Health (as of 2024-07-16)

The following values are configurable by setting the appropriate function parameters in the Asthma Calculator library API. The default values are set according to Finnish Current Care guidelines:

- Minimum and maximum time (in minutes) between a measurement pair (see **Delay** in section 8.1)
- Diurnal variation significance thresholds
- Bronchodilation significance thresholds
- Maximum difference between two highest measurements when determining repeatability (repeatability threshold)
  - This value is recommended to be set to either 20 l/min (Finnish Current Care Guidelines) or 40 l/min (British recommendation, especially if PEF values are large).

The software library uses calculation formulas and default configuration values from Finnish Current Care guidelines: https://www.kaypahoito.fi/nix01892 (as of 2024-07-16)

11. Warranty

As the manufacturer of a CE-marked medical device, Orla DTx Oy is committed to ensuring continuous safe use of the library. Defects will be reported and fixed in accordance with the requirements of EU MDR 2017/745, and customers in Orla DTx Asthma Calculator customer registry will be notified when new versions of the library become available. No additional

warranty beyond the requirements of EU MDR 2017/745 and other applicable legislation is provided by Orla DTx Oy.

12. Contact

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