



Class I Medical Device - Intended Use Statement

The MyAsthma application (app) is for patients (or their carers) living with asthma.

The app is designed to help patients understand their asthma by providing environmental and lifestyle information that may be relevant to their condition, together with data indicating the status of their asthma.

Patients or their carers have the ability to check and track their asthma control by using the Asthma Control Test (ACT) or the Childhood Asthma Control Test (C-ACT) as appropriate within the app, and they can export information from the app to share with their healthcare professional if they choose to do so.

The app is not intended to diagnose asthma or provide advice on medicines as this is the responsibility of the patients' healthcare professionals.

About this document

This document is a technical overview for both users and developers. It contains information relating to the software application, MyAsthma, including an application summary with instructions on how to use it, clinical information relating to the adult and child asthma control tests, information regarding how MyAsthma runs its own software validation routine, a summary of all changes made to the app including versioning and a list of scientific references (where appropriate).

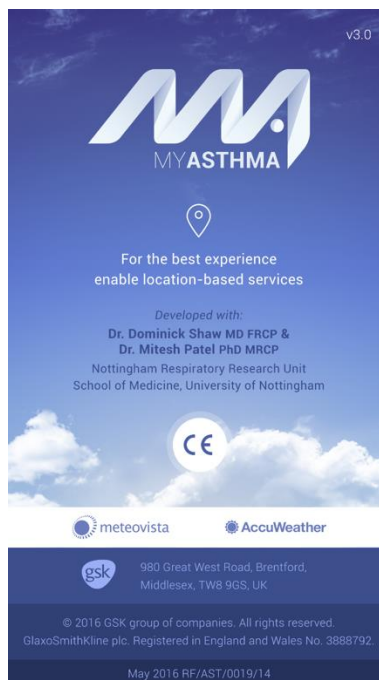
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MyAsthma Introduction

MyAsthma is a free application developed by GSK that has been designed to help asthma patients, and those caring for someone with asthma to manage their condition. The application has been designed specifically for iPhone and Android mobile devices. The purpose of this document is to describe how the app functions in detail. The screenshots used are those seen on an iOS device but the functionality remains the same on Android.

MyAsthma has been developed with healthcare professionals both at GSK and the Nottingham Respiratory Research Unit at the University of Nottingham to ensure quality and accuracy in the information it provides.



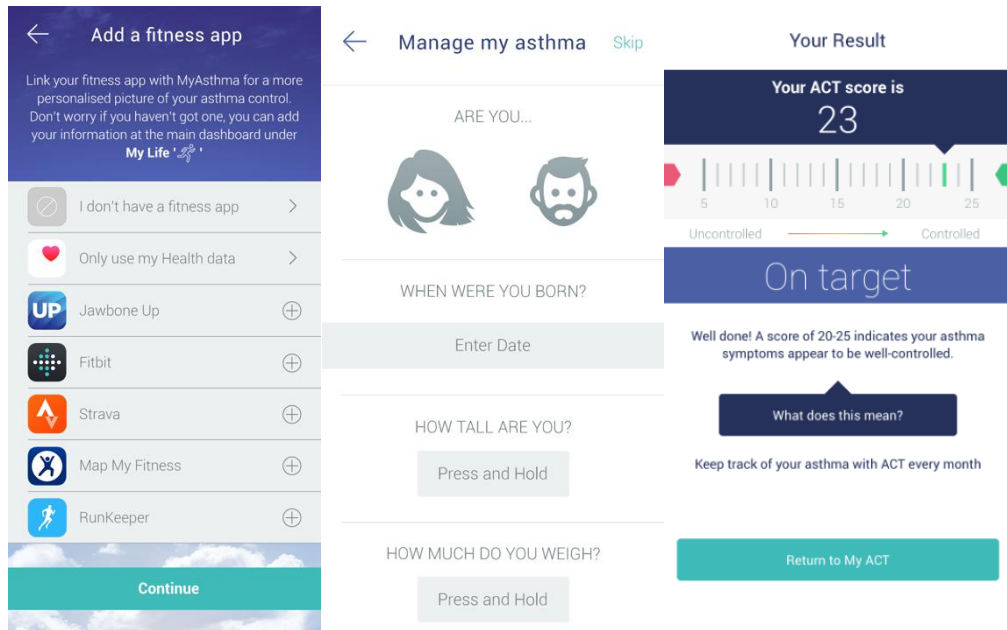
MyAsthma Application Overview

Registration

If the user has not used MyAsthma before they will need to complete a registration process. This process asks whether the user is monitoring their asthma or someone else's, as well as setting up their username and password. If the user is using 'Health' on iOS or an associated fitness application for both iOS and Android, the app will ask the user whether they would like to use one of these apps to link to. Doing this speeds up the registration process and collects information about the users everyday life, giving them a more personalised picture of their asthma. If the user does not use an associated fitness app they can manually input information (see MyLife).

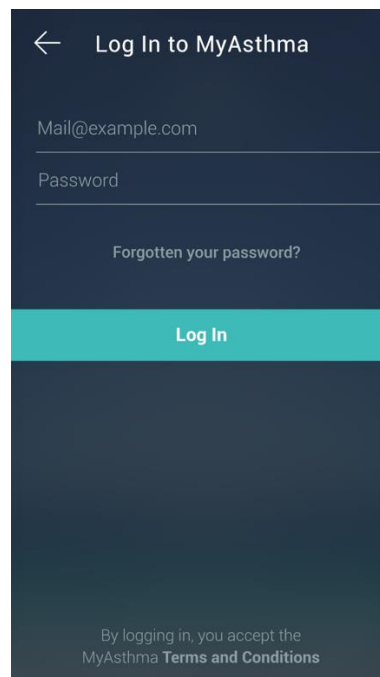
On the next screen the user will then define their sex, date of birth, height and weight (needed for the BMI calculation on the appointment plan), what type of medication they use for prevention, and what medication they use for their asthma reliever. The user will then also be asked to select what triggers they believe exacerbate their asthma; this configures what the user will see in the MyAsthma section of the app.

Users or their carers will then complete an Asthma Control Test (ACT) or Childhood Asthma Control Test (C-ACT) depending on their age. This ACT or C-ACT test enables the app to establish a baseline score to best help the patient from the beginning, as well as providing some up front information to the patient on what their ACT or C-ACT score means, and how to improve/sustain it.



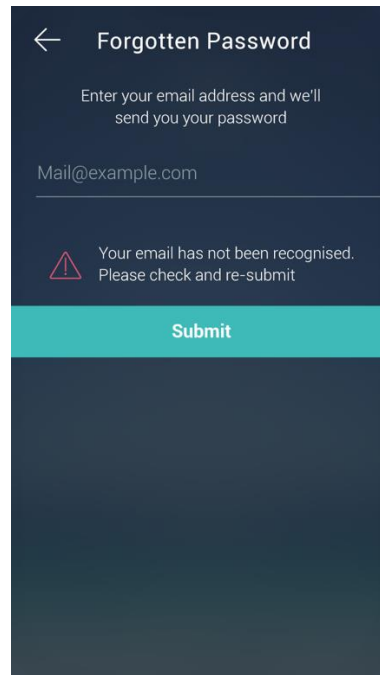
Login

When the application (app) launches for the first time the user is shown a splash screen before seeing the log in and registration screen. The Login screen will ask the user their username, which will be the patients' email specified upon registration, and the password previously defined by the patient.



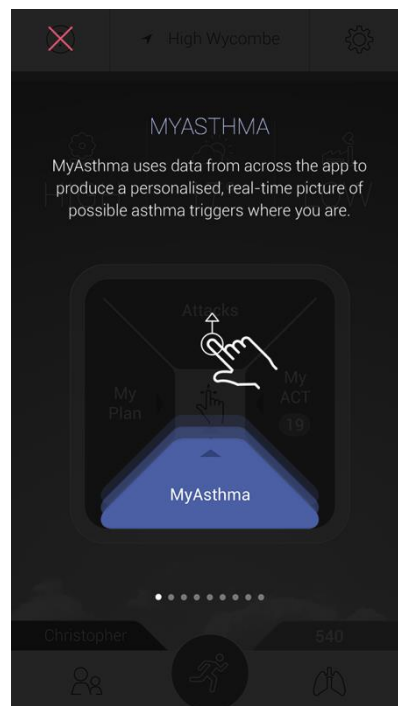
Forgotten Password

If the patient has forgotten their password, they will be asked to fill in their username and an email will be sent to the associated email inbox. Following the link in the email the user will be presented with an app screen prompting them to enter, and re-enter a new password for MyAsthma.



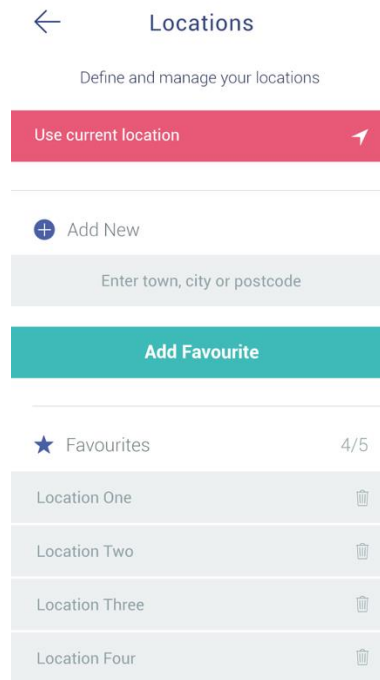
Help Screen

The first screen the user will see upon entry into the app itself (for the first time) is the help screen. This is intended to help the user to understand what is included in the app and how to navigate through. After the first entry into the app, the information will be accessible from the 'i' button top left in the app.



Locations

The app will ask the user to enable location services therefore allowing GPS positioning in order to provide up to date weather and pollen information relating to where the user is. The user also has a function to save their favourite locations so they can get a view on locations they, or the person whose asthma they are managing, visit frequently.



Attacks

The 'Attacks' section allows the user to track their asthma attacks, possible triggers and medication use. MyAsthma uses this data to identify and alert the user to possible new triggers, which should be discussed with the patients' healthcare professional.



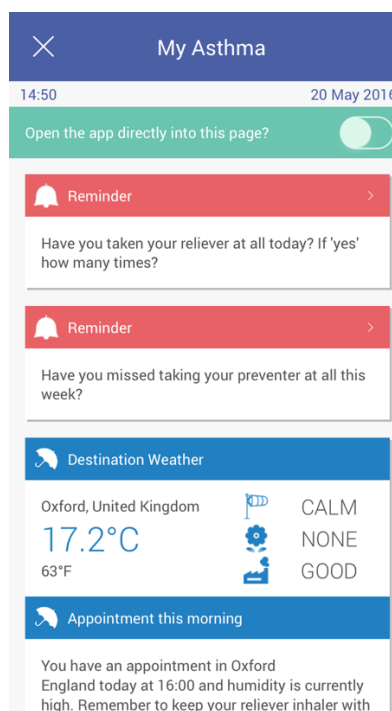
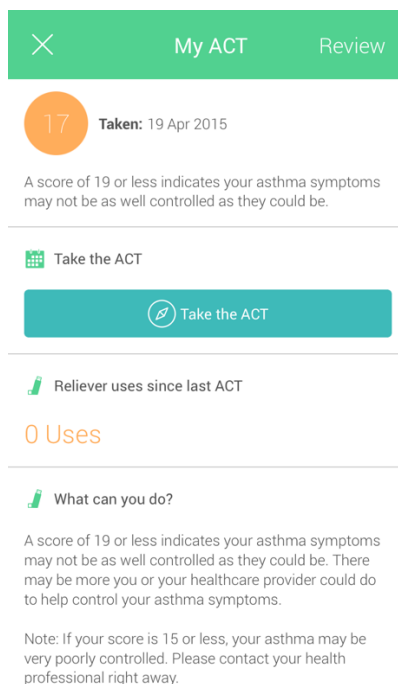
ACT

The Asthma Control Test (ACT) is a clinically validated questionnaire, designed by medical experts and referred to by [Global Institute for Asthma \(GINA\)](#), in the [Global Strategy for Asthma Management and Prevention 2016](#).

To find out how well the user or the person whose asthma is being controlled, the test asks asthma related questions based upon their last 4 weeks. The app uses two tests of control – one for use with people over the age of 12 (ACT) and one for use with people under 12 (C-ACT). The ACT and C-ACT are explained in more detail in [the clinical overview](#) section.

MyAsthma

MyAsthma uses data from across the app e.g. personal input information combined with environmental data, producing a personalised view of possible asthma triggers in the user's vicinity (provided they have location based services enabled or have provided a location). Users can decide to set this as their homepage if they wish, or navigate to it from the dashboard.



Appointment planner

The appointment planner helps the user to keep track of asthma appointments and add questions they can take to their doctor/nurse. Users can also create, view and/or email an asthma summary ready to take to the appointment. This document will provide the user with a summary of all of the user-inputs into the application; from attacks and associated triggers, to ACT/C-ACT, peak flow readings and spirometry ratios.

My life

To get the most from MyAsthma, users are able to use the MyLife section, allowing them to manually input data about their sleep, exercise, movement and mood patterns.

If the user has added a wearable fitness device, this information is automatically added when they synchronise.

← Build Your Plan

📌 Your last ACT score

16 Taken: 20 May 2016

A score of 19 or less indicates your asthma symptoms may not be as well controlled as they could be.

📌 Peak Flow

Your peak flow records don't seem to be up to date, do you want to do this now?

Add New

📌 Spirometer

Do you want to update your spirometry records?

Add New

⚡ Asthma Attacks

Other attacks since your last recorded on:

← My Life

⊕ When are you adding details for?

Today

Enter Date

🚴 Exercise

Cardio

Strength

ℹ Intensity

Light Moderate Vigorous

🕒 Duration

Enter time

zzz Sleep

Lung Function

A user may want to measure and record their peak flow and/or spirometry readings (spirometry readings are typically taken during asthma clinic visits). Users can input the readings in the lung function section to keep track of the results. The spirometry input will calculate the spirometry ratio based upon the FVC and FEV1 inputs by the user. See the [clinical overview](#) for more information on the calculations.

The screenshot shows the 'Lung Function' screen. At the top, there is a back arrow and the title 'Lung Function' with a lung icon. Below the title is a section titled 'Enter a spirometer reading'. It contains two input fields: 'FEV1 (litres)' with a value of 4.25 and 'FVC (litres)' with a value of 5.80. Below these fields is a question 'When did you take this reading?' with a plus icon. There are three buttons: a red 'Today' button, a grey 'Enter date' button, and a teal 'Save' button.

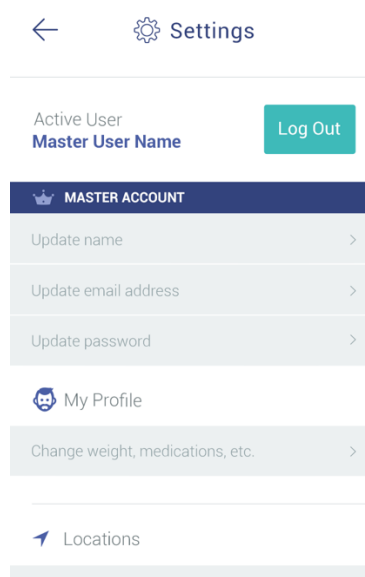
User List

If the MyAsthma application owner is managing more than their own asthma e.g. a child's, the user can move between patients using this function. Users can view or edit the various patients' information and see how well their asthma is being controlled.

The screenshot shows the 'Registered Users' screen. At the top, there is a close 'X' icon and the title 'Registered Users'. Below the title is a message: 'You can manage multiple users within MyAsthma. Each user can have their own settings, data and measurements. Switch between or manage your users here'. Below the message are two sections: 'Master User' with a crown icon and a red bar containing the name 'Kai', and 'Managed Users' with a person icon and a list containing 'Child' with a trash icon. At the bottom is a teal 'Add User' button.

Settings

'Settings' allows users to view and edit details about the users account, including the user name, password and email address. Users can also edit the fitness apps and devices linked to MyAsthma.



Clinical Overview

The following parameters table details the ranges used within the MyAsthma content algorithm

MyAsthma Parameters Table

Perceived trigger	Minimum Range	Maximum Range	Information Provider
Hot weather	25°C	Above 25°C	AccuWeather
Normal weather	10°C	25°C	AccuWeather
Cold weather	Below 10°C	10°C	AccuWeather
Wind chill	N/A	10°C	AccuWeather
Wind speed	30mph		AccuWeather
Thunderstorms	N/A	N/A	AccuWeather
Air pollution	101	N/A	AccuWeather
Low humidity	< 15%	N/A	AccuWeather
High humidity	50%	N/A	AccuWeather
Pollen Low	Low	N/A	Meteovista
Pollen Medium	MEDIUM	N/A	Meteovista
Pollen High	HIGH	N/A	Meteovista

C-ACT Calculations Users <12 years of age

What is the Childhood Asthma Control Test (C-ACT)?

The C-ACT is the Asthma Control test for children aged 4-11. It is a 7 question tool that is self-administered by the patient and their parent/guardian to help them understand their asthma control

How to use the C-ACT with children <12

Step 1 Let the child respond to the first four questions (1 to 4 in blue). If the child needs help reading or understanding the question, an adult may help, but let the child select the response. The responsible adult is then to complete the remaining three questions (5 to 7 illustrated in red below) on their own and without letting the child's response influence their answers. There are no right or wrong answers.

Step 2 The total is calculated as a sum of the carer and child's inputs. By matching the total to the scoring parameters below, the user will have an indication of the child's level of asthma control

See below for the <12 C-ACT question table and scores.

Question	ACT Score	Score
How is your asthma today?		
Very bad	0	
Bad	1	
Good	2	
Very Good	3	
How much of a problem is your asthma when you run, exercise or play sports?		
It's a big problem, I can't do what I want to do	0	
It's a problem and I don't like it	1	
It's a little problem but it's okay	2	
It's not a problem	3	
Do you cough because of your asthma?		
Yes, all of the time	0	
Yes, most of the time	1	
Yes, some of the time	2	
No, none of the time	3	
Do you wake up during the night because of your asthma?		
Yes, all of the time	0	
Yes, most of the time	1	
Yes, some of the time	2	
No, none of the time	3	
During the last 4 weeks, on average, how many days per month did your child have any daytime asthma symptoms?		
Not at all	5	
1-3 days/mo	4	
4-10 days/mo	3	
11-18 days/mo	2	

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19-24 days/mo	1	
Everyday	0	
During the last 4 weeks, on average, how many days per month did your child wheeze during the day because of asthma?		
Not at all	5	
1-3 days/mo	4	
4-10 days/mo	3	
11-18 days/mo	2	
19-24 days/mo	1	
Everyday	0	
During the last 4 weeks, on average, how many days per month did your child wake up during the night because of asthma?		
Not at all	5	
1-3 days/mo	4	
4-10 days/mo	3	
11-18 days/mo	2	
19-24 days/mo	1	
Everyday	0	
Total:		0

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Scoring	Level of Control	Colour in the appointment planner	Copy to be shown	“What you can do” copy
CHILDREN'S ACT SCORE 20 AND ABOVE	Well Controlled	Green	Name of child]'s C-ACT score is X. On target. Well done! A score of 20-27 indicates your child's asthma symptoms appear to be well-controlled.	A score of 20-27 indicates your child's asthma symptoms appear to be well-controlled. Even so, asthma control can change over time so it's important to retest your child regularly. Continue to talk to their healthcare provider about their asthma control.
CHILDREN'S ACT SCORE 19 AND BELOW	Not Controlled	Red	[Name of child]'s C-ACT score is X. Off-target. A score of 19 or less indicates your child's asthma symptoms may not be as well controlled as they could be.	A score of 19 or less indicates your child's asthma symptoms may not be as well controlled as they could be. There may be more you or your child's healthcare provider could do to help control their symptoms. Note: If your child's score is 12 or less their asthma may be very poorly controlled. Please contact your child's healthcare provider right away. [only to appear on second ACT test result] Remember, you can go to the appointment planner to review/print information like Christopher's reliever use and peak flow to share with the doctor during his appointment.

ACT Calculations Users >=12 years of age

What is the Asthma Control Test (ACT)?

The ACT is a 5 question tool that is self-administered by the patient to help them understand their asthma control

How to use the ACT

Step 1 Let the asthma patient respond to the questions. There are no right or wrong answers.

Step 2 The total is calculated as a sum of the asthma patients inputs. By matching the total to the scoring parameters below, the user will have an indication of the level of asthma control

See below for the >=12 ACT question table and scores.

Question	ACT Score	Score
During the past 4 weeks, how often did your asthma prevent you from getting as much done at work, school		
All of the time	1	
Most of the time	2	
Some of the time	3	
A little of the time	4	
None of the time	5	
During the past 4 weeks, how often have you had shortness of breath?		
More than once a day	1	
Once a day	2	
3-6 times a week	3	
1-2 times a week	4	
Not at all	5	
During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, chest tightness, shortness of breath) wake you up at night or earlier than usual in the morning?		
4 or more times a week	1	
2-3 nights a week	2	
Once a week	3	
Once or twice	4	
Not at all	5	
During the past 4 weeks, how often have you used your reliever inhaler (usually blue)?		
3 or more times a day	1	
1-2 times a day	2	
2-3 times a week	3	
Once a week or less	4	
Not at all	5	
How would you rate your asthma control during the past 4 weeks?		
Not Controlled	1	
Poorly Controlled	2	
Somewhat Controlled	3	
Well Controlled	4	

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Completely Controlled	5	
Total:		0

Scoring	Level of Control	Colour in the appointment planner	Copy to be shown	“What you can do” copy
ADULT ACT SCORE 20 AND ABOVE	Well Controlled	Green	Your ACT score is X. On target. Well done! A score of 20-25 indicates your asthma symptoms appear to be well-controlled.	A score of 20-25 indicates your asthma symptoms appear to be well-controlled. Even so, asthma control can change over time so it's important to retest yourself regularly. Continue to talk to your healthcare provider about your asthma control.
ADULT ACT SCORE 19 TO 16	Poorly Controlled	Yellow	Your ACT score is X. Off target. A score of 19 or less indicates your asthma symptoms may not be as well controlled as they could be.	A score of 19 or less indicates your asthma symptoms may not be as well controlled as they could be. There may be more you or your healthcare provider could do to help control your asthma symptoms. Note: If your score is 15 or less, your asthma may be very poorly controlled. Please contact your healthcare provider right away. [only to appear on second ACT test result] Remember, you can go to the appointment planner to review and email information like your reliever use, peak flow, exercise and sleep patterns to share with your doctor or pharmacist during your appointment which may help them see how you are getting on more clearly, and what they can do to help.

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ADULT ACT SCORE 15 AND BELOW	Poorly Controlled	Red	Your ACT score is X. Off target. A score of 19 or less indicates your asthma symptoms may not be as well controlled as they could be.	<p>A score of 19 or less indicates your asthma symptoms may not be as well controlled as they could be. There may be more you or your healthcare provider could do to help control your asthma symptoms.</p> <p>Note: If your score is 15 or less, your asthma may be very poorly controlled. Please contact your healthcare provider right away.</p> <p>[only to appear on second ACT test result]</p> <p>Remember, you can go to the appointment planner to review and email information like your reliever use, peak flow, exercise and sleep patterns to share with your doctor or pharmacist during your appointment which may help them see how you are getting on more clearly, and what they can do to help.</p>
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Spirometry Calculation

Forced vital capacity (FVC)

Forced vital capacity (FVC) is the volume of air that can forcibly be blown out after full inspiration, measured in litres.

Forced expiratory volume in 1 second (FEV1)

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration also measured in litres.

FEV1/FVC ratio (FEV1%)

FEV1/FVC (FEV1%) is the ratio of FEV1 to FVC. In healthy adults this should be approximately 70–85% (declining with age).

The lung capacity parameters MyAsthma works within are as detailed below:

	Max	Min	Unit	Decimal places (0.X)
FVC	5	0	Litres	2
FEV1	5	0	Litres	2

The calculation for the spirometry ratio shown in MyAsthma is as follows:

$$(FEV1/FVC)*100 = FEV1/FVC \text{ Ratio\%}$$

How MyAsthma Verifies Itself

In order to ensure that device specifics and changes to the device operating system are not going to cause an inaccurate result being calculated, the application runs validation checks to ensure the accuracy of the device.

When the user starts up the MyAsthma application the app runs every possible calculation for the spirometry ratio calculator and ACT/C-ACT tests. If any of these validation checks fail, the application will prevent the user from operating the relevant section of the MyAsthma app (ACT/C-ACT or spirometry) until the problem has been resolved.

Change Log

No changes have occurred

References

Global Institute for Asthma. Global Strategy for Asthma Management and Prevention 2016. Available from: www.ginasthma.org. Accessed on 20th July 2016.

Release updates

Internal release code V3.0.1

Errors and issues addressed in this release: -

- MYAIOS-1762 – Fixed crash that could occur with MyLife when integrated with FitBit
- MYAIOS-1763 – Fixed the missing chevron icons missing in weather overlay.
- MYAIOS-1764 - ‘Bonfire Night’ contextual card displays fixed for UK
- MYAIOS-1765 – Destination weather card displays data for USA
- MYAIOS-1766 – Fixed crash on Attacks when trying to access ‘Edit Data Points’
- MYAIOS-1767 – All graphs displaying 1 month ahead
- MYAIOS-1768 – Fixed PDF that displayed wrong number of attacks
- MYAIOS-1769 – Fixed PDF that displayed an incorrect BMI
- MYAIOS-1770 – Fixed PDF that was displaying the wrong number of average uses per day for preventer
- MYAIOS-1771 – Fixed My Plan – Your Overview page displays attacks for reliever use entered without an attack
- MYAIOS-1772 – Fixed an issue that prevented Jawbone fitness data from importing into MyLife
- MYAIOS-1773 – Destination Location Environment parameter text not displayed in MyAsthma now section now resolved
- MYAIOS-1774 – Add encryption to locally stored database.
- MYAIOS-1775 – Wrong colour for ACT score in PDF export is now fixed
- MYAIOS-1776 – Fixed an issue with “My Profile” data that failed to be updated from data sources.
- MYAIOS-1777 – Fixed an incorrect app version number.
- MYAIOS-1778 – Fixed an issue where deleting a final attack causes could cause a crash
- MYAIOS-1779 – Fixed an issued where the app could crash on the dashboard at first launch
- MYAIOS-1780 – Changed to allow you to deselect days of the week on preventer screen

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- MYAIOS-1781 – Corrected MyLife Edit data points – Wrong date order originally displayed when connected with FitBit
- MYAIOS-1782 – Updated the export PDF with registered trademark
- MYAIOS-1783 – Update MyAsthma splash screen with registered trademark
- MYAIOS-1784 – Update logo on Welcome screen with registered trademark
- MYAIOS-1785 – Increased Meteovista pollen database to cover European countries