



User Manual

for MyorCare v4.0

I. Device Identification



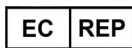
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<http://www.myorcare.com>
2023-09



This product is classified as Class I
according to Regulation 2017/745



IL-MF-000036036










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(01)7290019820000(8012)v4.0.0

Explanation of Symbols:

Symbol	Explanation
	Manufacturer
	Authorized Representative in the European Community / European Union
	CE Mark
	Unique Device Identifier
	Catalogue Number
	Medical device
	Consult instructions for use

II. Device Description

1. Intended Purpose

The MyorCare web-based software is intended to educate parents regarding factors that affect the risk of a child developing atopic dermatitis up to the age of three years and/or food allergies up to the age of four years.

The risk classification provided by the MyorCare software is based on the answers provided to a medical questionnaire concerning the health and medical history of the infant, the infants' parents, pregnancy and the infants' siblings, and other factors that may impact the infant's potential to develop atopic dermatitis and/or food allergies.

The device can be used from inception to 6-months of age for either singleton or multiple pregnancies. It is not intended for the diagnosis of atopic dermatitis and/or of food allergies and is not intended to inform clinical management with regards to any decision related to patient management, including any future diagnostic, follow-up, monitoring or preventive actions. The relevant professional guidelines with regards to the prevention of the development of food allergy in infants and young children and with regards to the treatment of atopic dermatitis in children should be followed regardless of the risk classification provided by the device.

Contraindications

- The device is limited for use from inception to 6-months of age.
- Baby must be born to his/her biological mother.
- The risk of developing atopic dermatitis cannot be assessed if the baby has already developed a food allergy.

Warnings

MyorCare is not intended for the diagnosis of atopic dermatitis and/or of food allergies and is not intended to inform clinical management with regards to any decision related to patient management, including any future diagnostic, follow-up, monitoring or preventive actions.

2. Allergies

What is an allergy?

An allergy is when one's immune system responds to a certain food or substance as if it is harmful to the body. If a person eats, touches or inhales that substance, they can have an allergic reaction. These substances - called allergens - can be found in dust, animal hair, medicines, various foods, and more.

There are several types of allergic reactions that vary by severity and body site. Allergic reactions can range from a mild unpleasant itch to a severe systemic reaction termed anaphylaxis.

What are the symptoms of a food allergy?

The symptoms of a food allergy are various and range from mild symptoms like raised and itchy skin rash, itchy or watery eyes, sneezing or runny nose, to more severe and dangerous systemic involvement like swelling of the throat, coughing or shortness of breath, vomiting, dizziness, loss of consciousness or in rare cases, death.

The symptoms may change or worsen with each exposure.

Symptoms can differ from person to person.

What is Atopic dermatitis or eczema?

Atopic dermatitis, or eczema, is a chronic inflammatory skin condition that is characterized by dry, itchy, and inflamed skin. It is a common condition, affecting up to 20% of children.

The exact cause of atopic dermatitis is not fully known, but is believed to be a combination of genetic and environmental factors such as exposure to allergens, irritants, stress, and changes in temperature or humidity.

Atopic dermatitis is a chronic condition. While there is no cure for atopic dermatitis, there are treatments available that can help to manage the symptoms and reduce the risk of flare-ups. These treatments may include over-the-counter emollients (moisturizers), and prescription medications including topical corticosteroids, calcineurin inhibitors, and oral antihistamines.

Most patients can be treated by their pediatrician or primary care provider. Children with severe atopic dermatitis may be referred to a dermatologist.

The link between atopic dermatitis and food allergies

Atopic dermatitis is considered a major risk factor for the development of food allergies. It is believed that small particles of allergenic substances can enter the body through dry and cracked eczematous skin and can cause sensitization to the food. Tolerance to allergens occurs through consistent oral exposure whereas allergic sensitization can occur through skin exposure.

What is the Atopic March?

Atopic dermatitis, allergic rhinitis, and asthma often affect the same patients and develop one after the other. This progression from atopic dermatitis in infancy to allergic rhinitis and asthma in childhood and young adulthood is referred to as the "allergic march" or "atopic march."

The atopic march typically begins in infancy with the development of atopic dermatitis. As the child gets older, they may develop other allergic diseases, such as food allergies, allergic rhinitis (hay fever), and asthma.

3. How the Service Works

The device consists of a parent-facing digital questionnaire which collects information regarding the newborn, his/her family and environment. The information is fed into a risk assessment algorithm for each condition which immediately generates a risk score for each condition separately. The risk score is interpreted into a risk category (low and high) and presented to the user.

Registered users can access a detailed risk report in the results portal, which provides an in-depth presentation of the conditions and the current standard of care practices to mitigate the conditions. The current standard of care practices are taken from the European Academy of Allergy and Clinical Immunology (EAACI) guidelines published in 2020 ([link](#)) and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) guidelines published in 2017 ([link](#)).

The device collects data on a set of independent variables, including demography (e.g., sex, season of birth, etc.), family medical history (e.g. history of atopic dermatitis, food allergies, allergic rhinitis and asthma in first-degree relatives, medications used etc.), infant medical history and measurement (e.g. gestational age at birth, medical diagnoses, clinical visits, weight, medications etc.), and dietary history (e.g. breastfeeding, etc.).

4. Overview of MyorCare Device

The MyorCare device is a stand-alone web application designed to educate parents about the risk factors associated with atopic dermatitis and food allergies in children up to the age of four years. It consists of several components: a parent-facing questionnaire, proprietary algorithms, and a results portal. The purpose of the device is to provide parents with valuable information, but it does not diagnose these conditions or offer clinical management guidance.

The parent-facing questionnaire is a user-friendly tool that collects essential data from parents or guardians. It covers various aspects such as demographic information, family medical history, infant medical history and measurements, dietary history of the infant, and family history factors. To access the questionnaire, users can visit the following link: <https://myorcare.com>.

The device utilizes proprietary machine learning algorithms to process the data provided by the users. These algorithms analyze the inputted information and generate a risk score for both atopic dermatitis and food allergies. The risk score helps parents understand the potential risk their child may have for developing these conditions.

Upon completing the questionnaire, users receive a code and a general risk assessment. By entering the code into the results portal, registered users can view the risk levels for atopic dermatitis and food allergy. The results screen also provides a risk report and educational content related to the risk classification and prevention. It serves as a valuable resource for parents to gain insights into their child's potential risk.

It is important to note that the MyorCare device is intended for educational purposes only and should not be used for diagnosing atopic dermatitis or food allergies. Additionally, it does not provide clinical management guidance.

Regardless of the risk classification provided by the device, it is crucial to follow professional guidelines for the prevention and treatment of atopic dermatitis and food allergies in children.

5. Clinical Benefit, Device Performance and Accuracy of Results

The MyorCare platform indicates whether a fetus or infant is at-risk of developing food allergies or atopic dermatitis. The algorithms powering the MyorCare platform showed improved stratification between low and high risk infants when compared to the current standard-of-care risk stratification methodology reliant entirely on family history of atopic conditions or a previous diagnosis of atopy.

The sensitivity and specificity of MyorCare were validated on a database of over 100,000 infants and their associated risk factors and outcome measures.

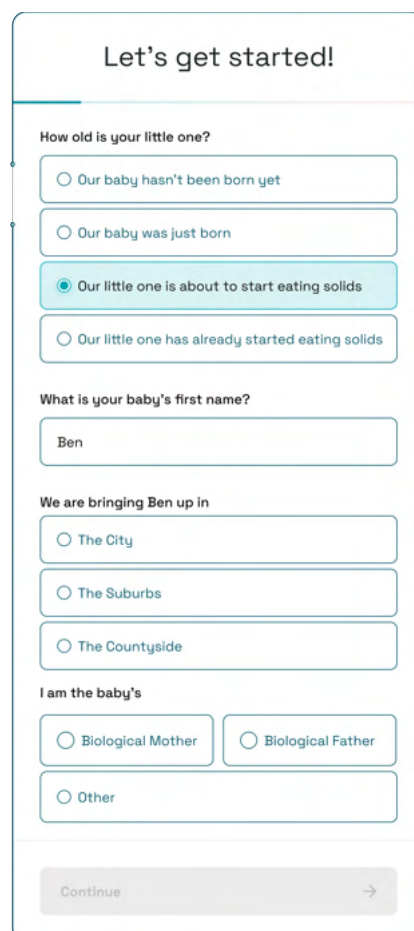
The MyorCare predictive algorithm's sensitivity for atopic dermatitis is 68% whereas its specificity is 76%. This greatly improves upon the currently available measure of risk, history of familial atopy, whose specificity and sensitivity do not exceed that of random guessing.

The MyorCare predictive algorithm's sensitivity for food allergies is 62% whereas its specificity is 84%.

III. Operating Instructions

The MyorCare device can be used according to the following steps:

1. Insert baby's age and name



The screenshot shows a mobile app onboarding screen titled "Let's get started!". It contains several sections with radio button options and a text input field. The first section asks "How old is your little one?" with four options: "Our baby hasn't been born yet", "Our baby was just born", "Our little one is about to start eating solids" (which is selected), and "Our little one has already started eating solids". The second section asks "What is your baby's first name?" with a text input field containing "Ben". The third section asks "We are bringing Ben up in" with three options: "The City", "The Suburbs", and "The Countyside". The fourth section asks "I am the baby's" with three options: "Biological Mother", "Biological Father", and "Other". At the bottom is a "Continue" button with a right arrow.

Let's get started!

How old is your little one?

☐ Our baby hasn't been born yet

☐ Our baby was just born

☒ Our little one is about to start eating solids

☐ Our little one has already started eating solids

What is your baby's first name?

Ben

We are bringing Ben up in

☐ The City

☐ The Suburbs

☐ The Countyside

I am the baby's

☐ Biological Mother

☐ Biological Father

☐ Other

Continue →

2. Insert parent's information, and accept User Agreement and Privacy Policy

Let's get started!

First name

Last name

Phone number

Email

☒ I have read and agree to
[MYOR's User Agreement & Privacy Policy](#)

Continue →

3. Complete the survey

Keep it up!

Perfect! Now, when is your baby's expected due date?

MM DD YYYY

Do you know your baby's gender?

☐ Yes, it's a boy
 ☐ Yes, it's a girl

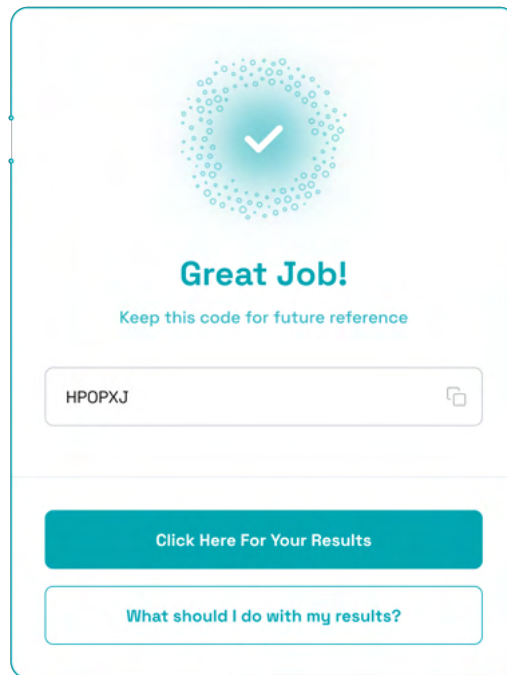
☐ We are waiting to be surprised!

We are planning on bringing up our child in

☐ The Countryside
 ☐ The City
 ☐ The Suburbs

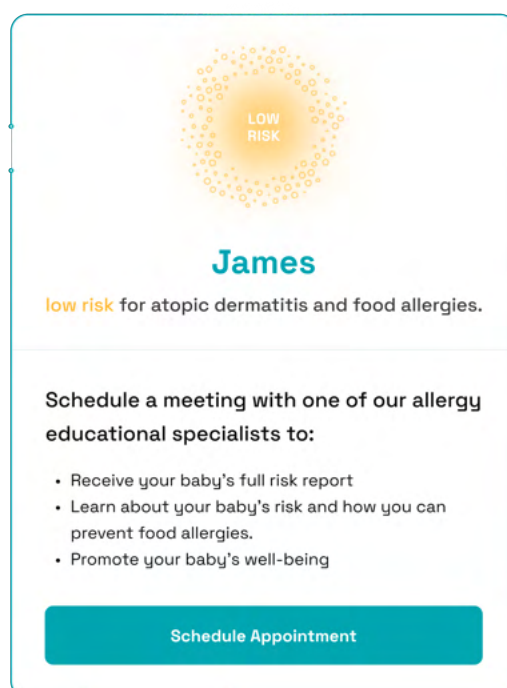
Continue →

4. After completing the survey, a unique code will be provided on screen and by text message which can be used to access your results. Click on the button "Click Here For Your Results" to view your results.



A screenshot of a mobile app screen with a light blue background. At the top, there is a circular graphic with a white checkmark inside, surrounded by small blue dots. Below this, the text "Great Job!" is displayed in a bold, dark blue font. Underneath, in a smaller, lighter blue font, it says "Keep this code for future reference". A white rectangular box contains the code "HPOPXJ" in black, with a small copy icon to its right. Below the code box, there are two buttons: a solid blue button with the text "Click Here For Your Results" and a white button with a blue border and the text "What should I do with my results?".

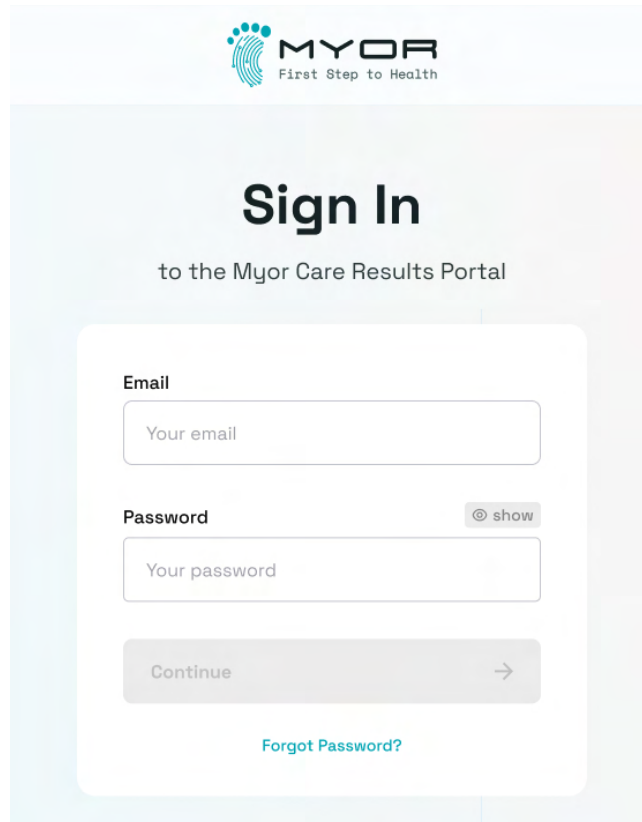
5. You will obtain a General Risk Assessment



A screenshot of a mobile app screen with a light blue background. At the top, there is a circular graphic with a yellow-to-orange gradient, containing the text "LOW RISK" in white. Below this, the name "James" is displayed in a bold, dark blue font. Underneath, in a smaller, orange font, it says "low risk for atopic dermatitis and food allergies." Below this, the text "Schedule a meeting with one of our allergy educational specialists to:" is displayed in a bold, dark blue font. Underneath, there is a list of three bullet points: "• Receive your baby's full risk report", "• Learn about your baby's risk and how you can prevent food allergies.", and "• Promote your baby's well-being". At the bottom, there is a solid blue button with the text "Schedule Appointment" in white.

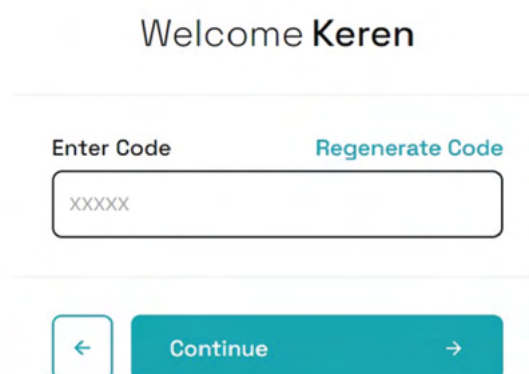
6. Access the Results Portal (for registered users only)

a) Sign in



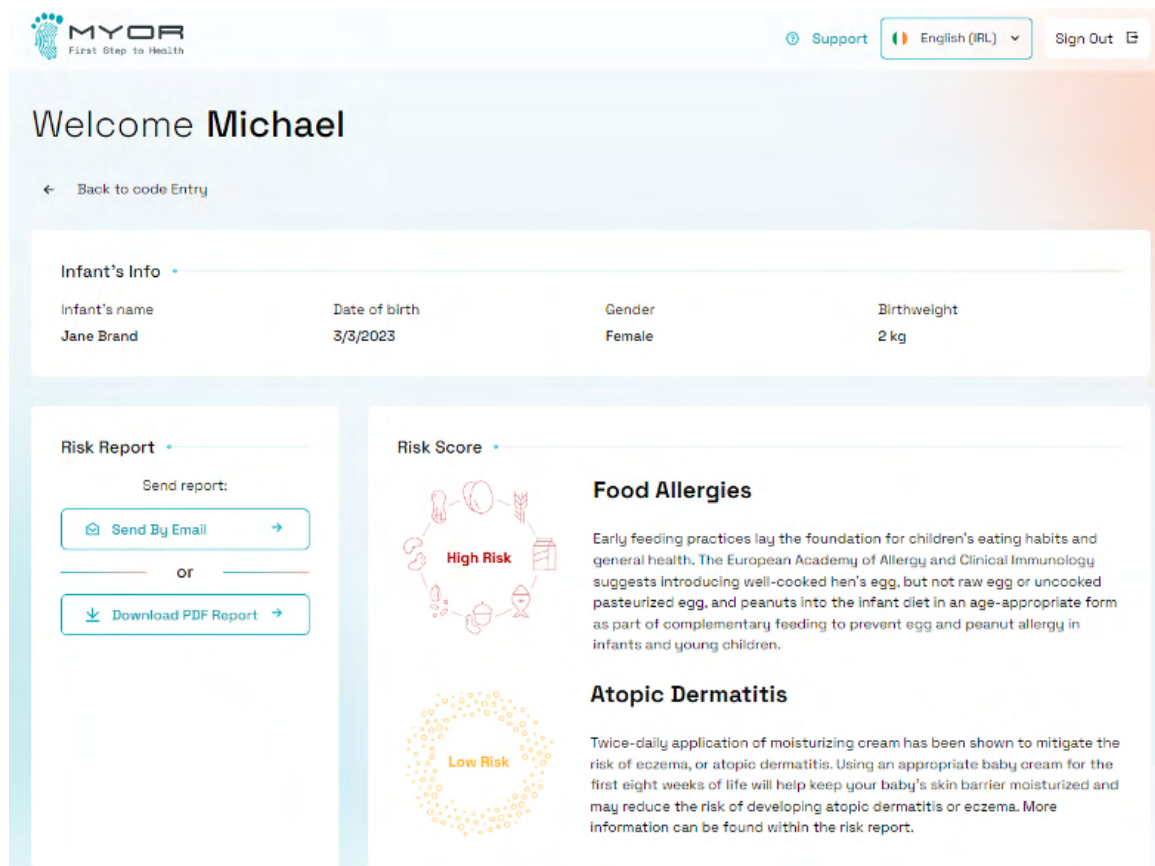
The sign-in page features the MYOR logo at the top. The main heading is "Sign In" followed by "to the Myor Care Results Portal". Below this is a form with two input fields: "Email" with a placeholder "Your email" and "Password" with a placeholder "Your password". A "show" button is next to the password field. A "Continue" button with a right arrow is at the bottom of the form. A link "Forgot Password?" is located below the "Continue" button.

b) Enter the infant's unique code



The page displays "Welcome Keren". Below this is a section titled "Enter Code" with a "Regenerate Code" link. A text input field contains "XXXXX". At the bottom, there is a back arrow button, a "Continue" button with a right arrow, and a forward arrow button.

c) Access infant's results



MYOR First Step to Health

Support English (IRL) Sign Out

Welcome Michael

← Back to code Entry

Infant's Info

Infant's name	Date of birth	Gender	Birthweight
Jane Brand	3/3/2023	Female	2 kg

Risk Report

Send report:

Send By Email →

or

Download PDF Report →

Risk Score

High Risk

Food Allergies

Early feeding practices lay the foundation for children's eating habits and general health. The European Academy of Allergy and Clinical Immunology suggests introducing well-cooked hen's egg, but not raw egg or uncooked pasteurized egg, and peanuts into the infant diet in an age-appropriate form as part of complementary feeding to prevent egg and peanut allergy in infants and young children.

Low Risk

Atopic Dermatitis

Twice-daily application of moisturizing cream has been shown to mitigate the risk of eczema, or atopic dermatitis. Using an appropriate baby cream for the first eight weeks of life will help keep your baby's skin barrier moisturized and may reduce the risk of developing atopic dermatitis or eczema. More information can be found within the risk report.

IV. Results

You will be presented with a risk level (high/low) for atopic dermatitis and separately for food allergies. The risk levels are shown on the results portal along with a brief introduction to best practices for preventing these conditions. An in-depth and personalized risk report containing product recommendations, instructions and guidelines based on best practices for preventing these conditions as defined in the European Academy of Allergy and Clinical Immunology (EAACI) guidelines published in 2020 and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) guidelines published in 2017 can be downloaded from the results portal. The risk report is password protected for your safety and can be accessed with the unique code provided when you completed the survey.

V. Instructions for proper use

1. Privacy Notice

User must agree to the platform's privacy policy before filling out the questionnaire. The privacy policy can be accessed anytime at <https://myorcare.com/privacy-policy>

2. Permissions

Permission will be provided to registered users to access the results portal by the MyorCare team. To request access, contact us at support@myorcare.com.

3. Compatible devices

The following devices may be used to access the platform:

- A mobile phone running Android OS (version 7 or above) or iOS (version 14 or above), 250 kbps or faster internet.
- A computer or tablet with an Internet browser: Google Chrome, Apple Safari. 250 kbps or faster internet.

4. How to use the platform?

For operating instructions beyond those presented in the User Manual, contact the MyorCare team at support@myorcare.com

5. About

Press the About button on the "Let's get started!" screen of the survey for more information about the platform.

6. Security

MyOr maintains a high level of security and data privacy in our platform. The platform is monitored for security events and data breaches. If a security event or data breach should occur, the issue will be contained and resolved with urgency according to our established processes and you as a user will receive the information you need regarding your continued safe and secure use of the application.

In case you suspect a cyberattack or cybersecurity incident, please report them by contacting us at support@myorcare.com.

It is strongly recommended that you choose a strong password for the results platform to protect your account from unauthorized use. While not recommended, if you should choose to share your login with somebody, you do so at your own risk. Keep in mind that you can always revoke access by changing the password to your account and contacting support in order to close existing sessions.

Watch out for emails or messages asking you to provide your MyorCare login details. MyorCare will not usually send you emails asking for your password unless you have initiated this process yourself via support or a password reset.

In addition, we recommend you use the latest version of your browser.

VI. Installation

There is no need to install the software. The platform can be accessed using any mobile phone or computer that runs an internet browser and is connected to the internet.

VII. Problems/Troubleshooting

If you cannot access MyorCare, the platform is malfunctioning, or if you suspect something is wrong with the platform, please follow the steps below:

1. Please contact our service desk via support@myorcare.com and our trained support agents will assist you.
2. Serious incidents involving this device should be reported both to MyOr at support@myorcare.com and to the Competent Authority in your country. A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

- a. the death of a patient, user or other person,
- b. the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- c. a serious public health threat.