



# User Manual

for MyorCare v6.0

# I. MyorCare v6.0 Device Identification



MyOr Diagnostics Ltd.  
Bareket 29  
Zichron Yaakov, 3093674 Israel  
<http://www.myorcare.com>  
2024-02





Sponsor: Family Nutrition Services Australia Pty Ltd  
4643 The Parkway Hope Island QLD 4209



MY-0600



## Explanation of Symbols:

Symbol	Explanation
	Manufacturer
	Catalogue Number
	Medical device
	Consult instructions for use

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Release Date: February 2024

## Device Description

### 1. Intended Purpose

The MyorCare web-based software is intended to aid clinicians such as pediatricians and dietitians by providing recommendations about the screening of infants with regards to the risk of developing atopic dermatitis and/or food allergies.

These recommendations are provided based on the presence or absence of a combination of demographic, environmental, medical, nutritional and familial factors reported in the scientific literature which could make the specific infant at an increased risk (relative to the general population) of developing atopic dermatitis up to the age of three years and/or food allergies up to the age of four years.

The software can be used from inception to 6-months of age for either singleton or multiple pregnancies.

The MyorCare software is not intended for the diagnosis of atopic dermatitis and/or of food allergies. Other factors which could affect the risk of developing atopic dermatitis and/or food allergies, such as any existing genetic risk factors, should also be taken into account. The relevant professional guidelines with regards to the prevention of the development of food allergies and of atopic dermatitis should be followed regardless of the recommendations 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.

## 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

Myor Diagnostics Ltd. provides clinicians with a web-based questionnaire format that can be used to gather data regarding the demographic, environmental, medical, nutritional and familial factors relating to a particular fetus/newborn, his/her family and environment. You may employ this questionnaire when assessing the risk that an infant will develop atopic dermatitis and/or food allergies. You can either enter the data yourself (e.g. during a consultation with the infant's parents) or you may ask the parents to fill in this data prior to the consultation.

You may use the gathered data to assess the risk of the fetus/newborn developing atopic dermatitis and/or food allergies without use of the MyorCare software, while also taking into account other relevant data such as known genetic risk factors, if available. Alternatively, you may decide to enter the data gathered through the questionnaire to the MyorCare software version 6.0, in order to receive a classification recommendation.

The MyorCare software version 6.0 employs a risk assessment algorithm for each condition which recommends a risk classification for each condition separately. Risk factors and a risk recommendation are presented to a specialized dietitian who determines whether to invite the parents and child for a prevention consultation. Healthcare practitioner 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 Australasian Society of Clinical Immunology and Allergy (ASCIA) guidelines published in 2020 ([link](#)).

The device uses as its input 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 assist a clinician in assessing the risk of atopic dermatitis and food allergies in children. It consists of proprietary algorithms, and a clinician-facing results portal.

The device utilizes proprietary machine learning algorithms to process the data uploaded to the questionnaire. These algorithms analyze the input information and generate a risk classification recommendation for both atopic dermatitis and food allergies, which is then reviewed by a specialized dietitian. The specialized dietitian may decide to invite the child and parents to a prevention consultation. The purpose of the consultation is to help parents understand the potential risk their child may have for developing these conditions and to help guide them with up-to-date prevention strategies.

Healthcare practitioners can view the recommended risk levels for atopic dermatitis and food allergy by entering the unique code generated upon completion of the questionnaire in the results portal. The results screen also provides a risk report and educational content related to the risk classification and prevention, which can be sent to the parent's registered email address. It serves as a valuable resource for parents to gain insights into their child's potential risk and to help guide them with up-to-date prevention strategies.

Regardless of the risk classification recommendation provided by the specialist dietitian, 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 combination of environmental, medical, nutritional and familial factors is present which could make a fetus or infant at-risk of developing food allergies and/or atopic dermatitis.

The algorithms powering the MyorCareplatform 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 100,000infants and their associated risk factors and outcome measures.

The MyorCare predictive algorithm's sensitivity for atopic dermatitis is 68%, whereas its specificity is 76%.<sup>1</sup> 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 65%, whereas its specificity is 84%.<sup>2</sup>

## II. Operating Instructions

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

- 1. Risk factors and recommendations will be reviewed by a registered specialized MyorCare dietitian.**
- 2. The specialist dietitians' personalized risk recommendation will be sent to the parent's registered email address. Depending on the outcome, the specialized dietitian may recommend scheduling a consultation with one of our experienced healthcare practitioners.**

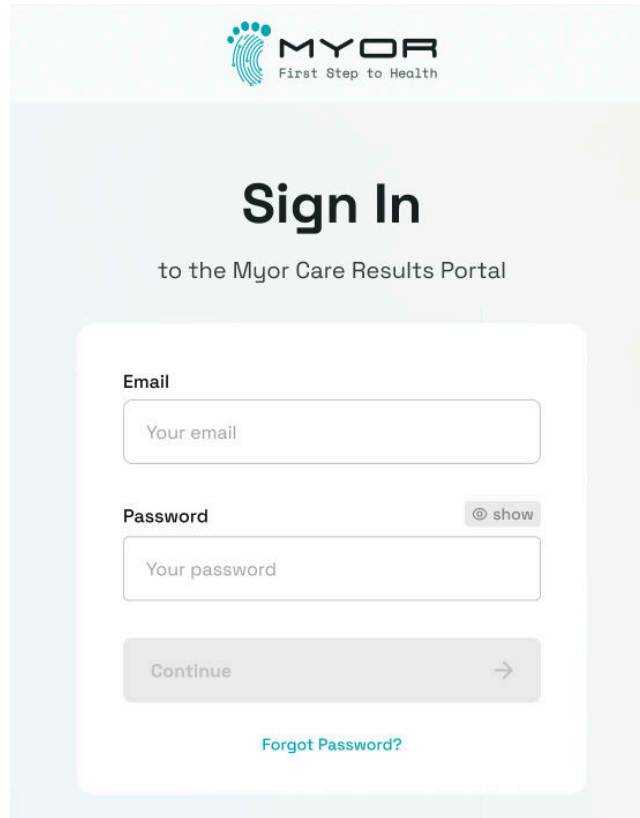
<sup>1</sup> Brandwein, Michael, Michal Ashkenazi, and Kirill Pevzner. "Stratifying Risk for Early Onset Atopic Dermatitis from Birth: An Ai-empowered Clinical Decision Support Tool." Pediatrics 149.1 Meeting Abstracts February 2022 (2022): 42-42.

<sup>2</sup> Landau, Tamar, et al. "A machine learning approach for stratifying risk for food allergies utilizing electronic medical record data." Allergy 79.2 (2024): 499-502.



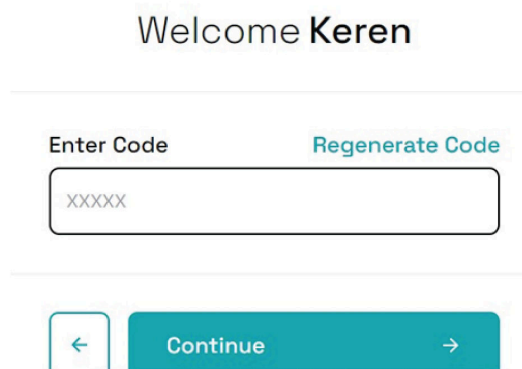
### 3. Access the Results Portal

#### a) Sign in



The screenshot shows the 'Sign In' page for the Myor Care Results Portal. At the top is the MYOR logo with the tagline 'First Step to Health'. Below the logo, the text 'Sign In' is prominently displayed, followed by 'to the Myor Care Results Portal'. The main content area contains a white card 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. Below the fields is a 'Continue' button with a right arrow. At the bottom of the card is a link for 'Forgot Password?'.

#### b) Enter the infant's unique code

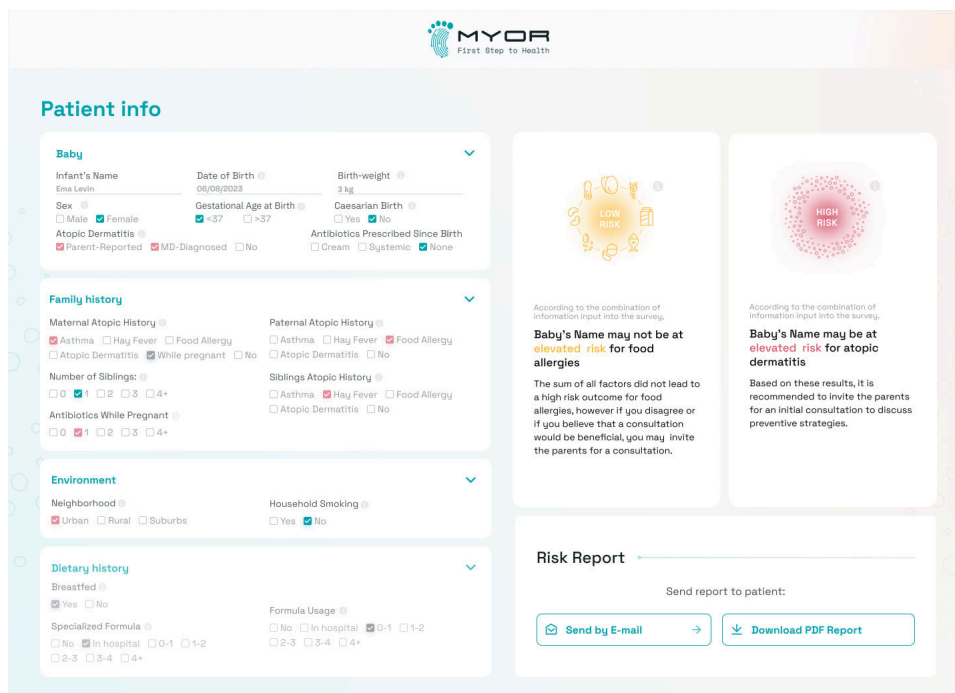


The screenshot shows the 'Enter Code' screen. At the top, it says 'Welcome Keren'. Below this is a horizontal line. Under the line, there is an 'Enter Code' label and a 'Regenerate Code' link. A text input field contains 'XXXXX'. At the bottom, there is a navigation bar with a left arrow, a 'Continue' button, and a right arrow.

### c) Access infant's results

Access infant's results: Additional information from the scientific literature explaining why the provided answer has been regarded as either a risk or a protective factor can be reviewed by hovering over the "i" next to the field title and references can be viewed by clicking on the "Learn More" link. Each factor is presented as follows:

- Green=associated with protection
- Red=associated with risk
- Grey=not associated with protection or risk.



The screenshot displays the MYOR Patient info form. The form is divided into several sections: Patient info, Family history, Environment, and Dietary history. The Patient info section includes fields for Infant's Name, Date of Birth, Birth-weight, Sex, Gestational Age at Birth, Caesarian Birth, Atopic Dermatitis, and Antibiotics Prescribed Since Birth. The Family history section includes Maternal Atopic History, Paternal Atopic History, Number of Siblings, and Antibiotics While Pregnant. The Environment section includes Neighborhood and Household Smoking. The Dietary history section includes Breastfed, Specialized Formula, and Formula Usage. To the right of the form, there are two risk assessment cards: one for Food Allergies (Low Risk) and one for Atopic Dermatitis (High Risk). Each card provides a brief explanation of the risk level and a recommendation to consult a healthcare provider. At the bottom right, there is a Risk Report section with buttons for 'Send by E-mail' and 'Download PDF Report'.

## III. 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 Australasian Society of Clinical Immunology and Allergy (ASCI) guidelines published in 2020 can be downloaded from the results portal. The risk report is password protected and can be accessed with the unique code generated upon survey completion.

## IV. Instructions for proper use

### 1. Privacy Notice

The platform's 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](mailto: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](mailto: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](mailto: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.

## V. 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.

## VI. Problems/Troubleshooting

If you cannot access MyorCare, the platform is malfunctioning, or if you suspect something is wrong with the platform, please contact our service desk via [support@myorcare.com](mailto:support@myorcare.com) and our trained support agents will assist you.