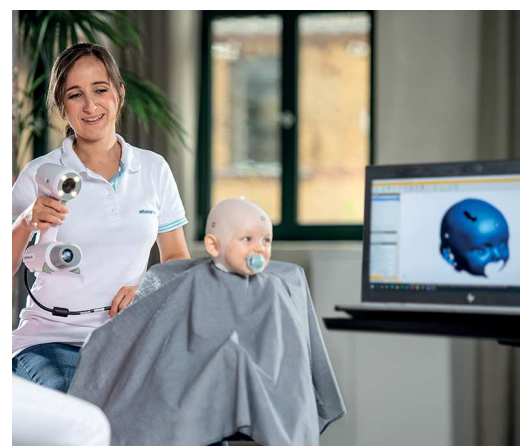


# MyCRO Band Cranial Orthosis

Scanning and ordering

Technical information 5.6.3.1



# 1 Introduction

## INFORMATION

Last update: 2021-10-25

This technical information supports you in conducting the scan for a MyCRO Band cranial orthosis and guides you through the order process.

The Ottobock MyCRO Band is a non-sterile temporary orthosis to aid in the correction of head shape caused by positioning. The orthosis uses contact and growth zones to guide the growth of the head. The contact zones define gentle limits for growth, while the growth zones leave space in areas required for forming the natural head shape. An adaptable closure allows for adjustability as the child grows. The orthosis is made of thermoplastic material with a soft, washable lining on the interior.

This document is directed to trained O&P professionals. It is a prerequisite that the qualified personnel are trained in the handling of the various materials, machines and tools.

This technical information does not claim to be exhaustive. Reading this technical information does not substitute reading the instructions for use for all required products.

## 2 Indications for use and Contraindications

### 2.1 Indications for use

Intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic shaped heads by applying mild pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. These devices are also indicated for adjunctive use for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have moderate-to-severe cranial deformities including plagio cephalic-, brachycephalic -, and scaphocephalic-shaped heads.

The orthosis must be used in accordance with the indications.

### 2.2 Contraindications

Not for use on infants with pre-surgical craniosynostosis or hydrocephalus.

## 3 Scanning

### 3.1 Scanner selection

Ottobock has qualified the following scanners for use when ordering a MyCRO Band:

Manufacturer	Ottobock	Creaform	Artec
Product name	iFab EasyScan	OMEGA Scanner 3D M4DScan Bodyscan Peel 1/Peel 3D HCP	Eva Eva Lite

When a scanner is purchased, the appropriate software must be installed on a client computer by the end-user. It is expected that end-users adhere to the manufacturer's recommendations for best practice guidelines. Instructions for use are available with scanners and the associated software by the scanner manufacturer. All hardware and software specifications are published by the scanner manufacturer, and are available to the scanner end-users.

### 3.2 Scanning landmarks

Ensure that the following anatomical features are visible when scanning the infant:

- Both ears (fully visible and not covered with stockinette)
- Tragus
- Nose tip
- Glabella
- Occiput
- Neck
- Eyes

**INFORMATION**

The scanner may not capture clearly defined ears in the scan. The purpose of leaving the ears uncovered is to clearly define the margins of the ear and prevent stockinet tenting, rather than capturing details of the ears themselves.

**3.3 Tips for cranial scanning**

Best practices for scanning vary by the scanner used, and manufacturer recommended guidelines should always be followed. Below are some general recommendations for cranial scanning. Refer to manufacturer guidelines for detailed information on scanning distance, scan path, and lighting conditions, as these can vary by scanner.

- Arrange an appointment for the scanning after nap or meal time so the child is not too restless.
- Remove infant's shirt to avoid obscuring the neck.
- Have an infant seat with a low backrest that allows the infant to sit securely such as a Bumbo seat. Ensure that you follow the safety guidelines of each model. Alternatively, the infant may sit in the caregiver's lap.
- Ensure that the room has adequate space to walk around the infant at an appropriate scanning distance.



- Prepare a stockinette by cutting out holes for the infant's face and ears. Ideally, a relatively opaque stockinette with a tight weave should be used (i.e. 99B25).



- Put a stockinette on the infant's head so that the infant's head shape is clearly visible, and the face is fully uncovered. Ensure that any seams in the stockinette are facing inwards.



- Smooth out any wrinkles in the stockinette.



- Scanner positioning targets may be used to help with scanner tracking.



- Ask the caregiver to distract the infant by using a phone or to orient the infant's head straight forward.
- If necessary leave the pacifier with the infant. Ensure that the final scan has adequate neck data, no holes in the cranium, and captures data across the entire face.

## 4 Place order

After successfully scanning the infant, please log in to the Ottobock iFab Customer Center (iCC) and follow the guided ordering process for the MyCRO Band. It is important to submit the scan as soon as possible, as the device must be fit within 14 days of scanning the infant.

### Using the iCC Web Portal

- 1) Open the iCC web portal (<https://www.ifab-customer-center.com/>).
- 2) Log-in using your customer login information and password.
- 3) Select the appropriate body segment (HEAD for MyCRO Band).
- 4) Select Cranial Helmet to start ordering process.
- 5) Customer Data tab:
  - Enter/review facility and practitioner information or edit if needed.
  - Select Delivery address from drop-down menu or add in new address.
  - Add any individual labeling and unique patient ID.
  - Select desired delivery date (ensure device is fit within 14 days of scan).
  - Click NEXT to go to Files tab.
- 6) Files tab:
  - Drag and drop the scan file (.STL or .OBJ) into the box or press 'browse' button to select file from computer.
  - Once added click NEXT to go to patient tab.
- 7) Patient tab:
  - Select Order type - Report or Cranial Helmet.
  - Enter Date of Birth, Gender, and Condition.
  - If premature, enter number of weeks premature.
  - Select or enter Scanner used and date of scan.
  - Enter a physical circumference measurement.
  - Click NEXT to save data and go to Product tab.
- 8) Product tab:

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- Choose emblem and color of inner lining.
  - Optional: Choose quantity of additional inner linings or elastic bands.
  - Click NEXT to go to Comment tab.
- 9) Comment tab:
- Optional: Enter any additional comments related to the order.
  - Click NEXT to go to Summary tab.
- 10) Summary tab:
- Review order details.
  - Select "Save entry as order Template" to store these as default order settings.
  - Check box to Agree with the Terms and Conditions.
  - Select SAVE AS DRAFT for later use or click SUBMIT ORDER.

Once order is submitted an order received e-mail will be sent.

Once order is complete an e-mail will be sent confirming completion.

Order status can be checked in the iCC customer center portal.





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