

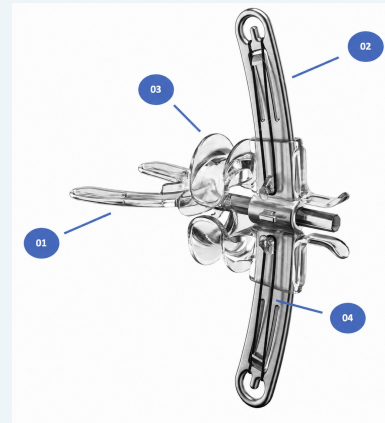


## CLINICAL & PROFESSIONAL RESOURCES

# Clinical Overview

A concise orientation to the ISO Metrik platform, provider-directed care pathway, supported exercise modes, professional roles, and current evidence and regulatory boundaries.

Designed for  
Physical therapists, speech-language pathologists, referring  
clinicians, rehabilitation leaders, and institutional reviewers.



### Regulatory status

FDA 510(k) pending. ISO Metrik has not received FDA clearance for the proposed clinical uses described in this resource. This document is for professional education and pathway planning; it is not authorization to market, ship, prescribe, bill, or use an investigational device.

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# What the pathway is designed to organize

ISO Metrik is presented as a provider-directed facial and perioral resistance-training platform. The public pathway connects clinical evaluation, device configuration, supervised treatment, structured home practice when appropriate, reassessment, and care-team communication.

|                                                                                                                                                                                                |                                                                                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Clinical evaluation</b><br><br>A qualified PT or SLP reviews diagnosis, function, tissue and dental status, precautions, goals, movement quality, and the need for medical or dental input. | <b>Provider configuration</b><br><br>The trained clinician selects the working axis, fit, orientation, mode, resistance, dosage, cueing, rest, and reassessment plan.                  |
| <b>Supervised instruction</b><br><br>The provider teaches placement, movement quality, symptom monitoring, stopping rules, cleaning, storage, and any approved home-program parameters.        | <b>Measured follow-up</b><br><br>Comparable impairment, functional, participation, tolerance, and adherence measures inform progression, regression, continuation, or discontinuation. |

## Potential clinical contexts

The treating clinician determines whether an evaluation is appropriate and whether use falls within professional scope, current labeling, training, facility policy, regulatory status, and the individual plan of care.

- Facial weakness, reduced excursion, selective motor-control difficulty, or asymmetry affecting meaningful function.
- Labial seal, saliva containment, articulation, oral transit, or related oral-motor concerns within the clinician's scope.
- A transition from acute, specialist, surgical, or inpatient care to a defined rehabilitation pathway.
- A need for supervised teaching and a repeatable provider-directed program between visits.

|                                 |                                                                                                                                                                                                                                                       |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Not a candidacy decision</b> | Device capability and a public clinical overview do not establish suitability for an individual. Urgent medical issues, airway safety, swallowing assessment, healing status, tissue integrity, dental concerns, and other precautions take priority. |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

# Platform architecture and supported exercise modes

The platform is organized around a stable, inspectable device, interchangeable resistance elements, four working axes, and provider-selected exercise parameters. Exact use must follow current authorized instructions and training.

|                                                                                                                                                            |                                                                                                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Four working axes</b><br><br>Horizontal, vertical, and two diagonal orientations support direction-specific and combined movement patterns.             | <b>Adjustable demand</b><br><br>Resistance selection and dosage are individualized; progression is based on movement quality, response, functional goals, and provider judgment. |
| <b>Inspectable components</b><br><br>Before use, the provider checks cleanliness, integrity, fit, alignment, bands, connectors, and any stop-use criteria. | <b>Documented parameters</b><br><br>Position, direction, mode, resistance, repetitions, hold time, rest, tempo, assistance, symptoms, and response are recorded.                 |

## Three public-facing mode descriptions

|                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01                                                                                                                                                                                                                                                            | <b>Isometric Therapy</b><br><br>The patient develops force against resistance while the intended position is held without purposeful movement through range.                                                         |
| 02                                                                                                                                                                                                                                                            | <b>Isotonic Therapy</b><br><br>The patient moves through a provider-selected range against resistance, with concentric and eccentric control addressed as appropriate.                                               |
| 03                                                                                                                                                                                                                                                            | <b>Isokinetic-Style Cadence Training</b><br><br>The clinician prescribes and externally monitors a movement cadence while the patient regulates motion. The device does not mechanically maintain constant velocity. |
| <b>Terminology boundary</b><br><br>Isokinetic-Style Cadence Training is a cadence-based training description. The clinician prescribes and monitors timing while the patient regulates movement; the device does not mechanically maintain constant velocity. |                                                                                                                                                                                                                      |

# Provider-directed clinical workflow

|    |                                                                                                                                                                                                               |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01 | <b>Establish medical and rehabilitation context</b><br>Confirm diagnosis, onset, relevant procedures, stability, precautions, restrictions, red flags, and the reason for rehabilitation.                     |
| 02 | <b>Evaluate candidacy and baseline</b><br>Assess movement, functional priorities, patient factors, tissue and dental status, symptoms, compensations, and any need for additional medical input.              |
| 03 | <b>Inspect, fit, and orient</b><br>Inspect all components, select the working axis, establish alignment and comfort, and use teach-back for placement and removal.                                            |
| 04 | <b>Configure and supervise</b><br>Select mode, resistance, repetitions, holds, rest, tempo, cueing, assistance, and stopping criteria. Observe movement quality and response.                                 |
| 05 | <b>Decide on home practice</b><br>Only assign home activity when the clinician determines it is appropriate and the patient can follow the approved setup, parameters, cleaning, storage, and stopping rules. |
| 06 | <b>Reassess and coordinate</b><br>Compare outcomes, review symptoms and adherence, adjust the plan, communicate with the care team, and document the rationale.                                               |

## Professional responsibilities

- Use remains within licensure, competence, state law, facility policy, current instructions, and the individual plan of care.
- Product training and certification do not create or expand a professional license.
- The treating provider owns patient-specific screening, prescription parameters, monitoring, documentation, and escalation.
- Patient information is exchanged only through an approved secure clinical channel; public inquiries contain professional contact details only.

# Evidence, regulatory, and access boundaries

|                                                                                                                                                                                                                                             |                                                                                                                                                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Evidence context</b><br><br>Broader rehabilitation science and facial rehabilitation studies may inform pathway design, but they do not establish ISO Metrik-specific safety or effectiveness.                                           | <b>Device-specific evidence</b><br><br>The public evidence page does not currently cite a peer-reviewed ISO Metrik-specific clinical outcome publication or a public study-registry identifier.        |
| <b>Regulatory status</b><br><br>FDA 510(k) pending means the proposed clinical uses described here have not received FDA clearance. Pending review is not marketing authorization.                                                          | <b>Clinical investigations</b><br><br>Any U.S. investigation must follow the applicable sponsor, FDA, IRB, informed-consent, labeling, monitoring, reporting, privacy, and institutional requirements. |
| <b>DME and coverage</b><br><br>No Medicare DME benefit-category status, dedicated HCPCS Level II code, payer coverage, or payment has been established on the public site.                                                                  | <b>Protected clinical tools</b><br><br>Detailed fitting, treatment, home-program, quality, and incident tools remain in the authenticated provider portal for authorized trained users.                |
| <b>Read next</b><br><br>Review the <a href="#">Evidence &amp; Publication Reference Guide</a> and the live <a href="#">Clinical Evidence page</a> for evidence classifications, citations, PubMed links, DOI links, and stated limitations. |                                                                                                                                                                                                        |

# Connect with ISO Metrik

Use the public inquiry pathway for professional contact and program questions. Do not send patient names, dates of birth, records, images, or other protected health information through public forms, general email, or the website AI assistant.

## Professional contact

ISO Metrik Solutions, Inc.  
5505 Peachtree Dunwoody Road, Suite 640  
Atlanta, GA 30342

Phone: (678) 632-3735  
Email: [info@isometrik.com](mailto:info@isometrik.com)  
Web: [isometriktherapy.com](https://isometriktherapy.com)

## Public pathway links

- [Clinical Evidence](#)
- [Training & Certification](#)
- [Refer or Prescribe](#)
- [DME & Coverage](#)
- [Clinical Pilot](#)
- [Provider & Clinic Sign In](#)

## Use boundary

This resource does not replace current product labeling, instructions for use, professional training, licensure, medical judgment, payer policy, supplier requirements, institutional review, or applicable law. Individual clinical and reimbursement decisions belong to the responsible provider, institution, supplier, and payer.