

FO-8007 Tuning Validation Record

This document is a record sheet intended for use by clinicians when validating a turning profile as providing the intended benefit to a patient.

Instructions:

1. Follow the instructions provided in **EDU-8013 (Sheet #0)** for Parts 1-6 and **EDU-8020 (Sheet #7)** for Parts 7-8.
2. Additional pages may be attached for any reason (obtain consent and omit identifiable data).



Validation of the tuning profile is mandatory to ensure safe, effective use of Keeogo. Do not release Keeogo for use until tuning has been validated and this sheet has been completed.



Part 1: Observe functional mobility of user and summarize deficits

Summary of User Deficits: *(based on initial assessment)*

Part 2: Set clinical goal(s) for use of Keeogo



Tip: For best results, pick goals that you know Keeogo can help the patient achieve.

Clinical Goal(s) based on user needs: *(may be vague or precise)*

Part 3: Select an analysis method for detecting deficits related to clinical goals

Analysis method(s) chosen:

Examples: written instruments (e.g., MAS, BBS, Fugl-Meyer, etc.), questionnaires, gait observation checklists, gait mats/walkways, timed functional testing, motion-capture, or direct clinical observations.



Part 4: Collect baseline data using chosen method(s)

Baseline data from chosen method(s) attached?

☐ Yes ☐ No

Deficits linked to Clinical Goal(s) listed in [Part 2](#) present in baseline data?

☐ Yes ☐ No

Part 5: Review and prioritize baseline data



Prioritize and list the deficits in order of planned intervention with Keeogo

Prioritized Deficits

1. _____
2. _____
3. _____
4. _____
5. _____

Part 6: Fit Keeogo w/ checklist *IFU-001*

Fine tune for deficit(s) w/ **Sheet #1-6**

↓ Fill in Part 8 ↓

Deficit Resolved?

Yes	Partial	No	Notes
☐	☐	☐	_____
☐	☐	☐	_____
☐	☐	☐	_____
☐	☐	☐	_____
☐	☐	☐	_____

Part 7: Collect Keeogo data using chosen method(s)

Is the data collected for user wearing Keeogo with final tuning profile attached?

☐ Yes ☐ No

Part 8: Confirm benefit

Has the clinical goal been met? (Fill in "Deficit Resolved?" checkboxes) ☐ Yes ☐ No

Is fine tuning complete? (i.e. no benefit from additional fine tuning) ☐ Yes ☐ No

If both questions at the end of Part 8 are 'Yes' → Tuning profile is validated. Sign off below and continue to final release criteria listed on Device Release Record (**FO-8014**).

Else → reiterate through relevant parts of Part 6 – 8 until clinical goals are satisfied.

Fine tuning completed and validated by:

Clinician name (Print)

☐ ☐ ☐ ☐ / ☐ ☐ / ☐ ☐
Date (YYYY/MM/DD)

Signature

Name of validated profile