



Caution: profile validation is mandatory for ensuring safe, effective use of the device.

Do not release Keeogo for use until tuning has been validated and the tuning validation record is complete (FO-8007).

- 1

Review clinical goals and prioritized list of deficits

Steps 1-5 of validation record in *FO-8007*


- 2

Collect data for Keeogo with new tuning profile

Use identical method as baseline testing to collect matched data with Keeogo
- 3

Compare Keeogo data to baseline data

Baseline and Keeogo data should be stapled to *FO-8007*


- 4

Confirm benefit of Keeogo with new tuning

Use checkboxes in table of deficits on record sheet to mark whether new tuning profile improves or resolves each deficit listed

IF:

Tuning profile allows user to reach their clinical goal and no further improvement is practical

Sign Validation Record (*FO-8007*)

Else:

Return to Sheets # 1-6 and continue familiarization and fine tuning process


- Observe functional mobility

Set clinical goal(s)

Collect baseline

Prioritize deficits

Deficit(s) detected?

Yes

No

F&FT w/ Keeogo Sheets #1-6

Collect w/ Keeogo

Compare Keeogo to baseline

Clinical goal(s) met?

Yes

No

More F&FT improvement possible?

Tuning Validated

Tip for finalizing tuning profiles:

When in doubt, double check with Keeogo user if additional fine tuning changes to parameter(s) would help them in specific tasks.
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Blue Star Training Module 3 Instruction Sheet # 7	EDU-8020 Blue Star Module 3.7- Tuning Validation & Release				Setting:	Rehab and clinical	Doc #:	EDU-8020
					Supervision:	Certified clinical professional	Version:	1,2
	Population:	General use (per indications)	Section:	Clinical Tools	Operation:	Validation of tuning profile		

Revision History			
DATE	REV	Change description	Owner
2019-07-05	1,0	Original Version. Modified from IN-8000 Series (M. Brookshaw and A. Mai)	B-Temia Inc.
2019-12-16	1,1	Updated language to match version 1.1 of the IN-8000 Series (M. Brookshaw and A. Mai)	
2020-05-01	1,2	Updated cross-reference to documents (A.Mai)	
This document SHALL be print on both side to show the revision history on the back side			

