

Information for use FIB-4 Index		
Document ID: 10277-DOC-21	rev: 1.0	
Status: Effective		

1. REVISION HISTORY

ECO #	Version	Name	Change Description	Change Date
N/A	1.0	Thijs Pasman	Initial version	29-APR-2024

2. PURPOSE

This document details where the information for the use of the FIB-4 Index is described.

3. REFERENCED FILES

Ref	Doc ID	Document title
[R1]	REC-110	R.G. Pleijhuis Curriculum Vitea in English
[R2]	10277-DOC-43	User manual SaMD – FIB-4 Index

4. INFORMATION FOR USE

On the SaMD page, much information is given to the user during the use of the SaMD. The information is given as (SaMD) details, study characteristics, supporting publications, intended use, electronic label, and the declaration of conformity.

To ensure the user gets enough information related to the SaMD the user manual is made available with the model. In the user manual of the model among others, the intended purpose, patient population, and intended users are described.

5. LANGUAGES

This chapter describes that the information in the respective language is accurate and clinically correct. This is the version with UDI-DI number 08720938015113.

Table 1. Approved languages

Language	Documents reviewed and approved (and version number)/ rationale why not reviewed	Reviewed and approved by	Sufficient experience:
English	Model version with UDI-DI number 08720938015113 10277-DOC-43 User manual FIB-4 Index rev1.0 10277-DOC-A5 Declaration of Conformity rev1.0	R.G. Pleijhuis	REC-110