Instructions for use (EU)

LiverPRO IVD medical software

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1 Instructions for use (EU)

1.1 Introduction

This is the Instruction for use for the LiverPRO in vitro diagnostic medical device software. LiverPRO is a clinical decision support tool with the purpose of identifying individuals at risk of steatotic liver disease.

1.2 Product Description

The LiverPRO product consists of:

- An In Vitro Diagnostic (IVD) software as medical device (SaMD), called LiverPRO
- Instructions for Use (this document)
- Product label (accessed at “www.evido.health/eIFU”)

1.3 Intended purpose

LiverPRO is intended to assess the likelihood of having liver fibrosis among adult individuals at risk of steatotic liver disease.

1.4 Intended users

LiverPRO is intended for use by healthcare professionals only.

Specifically:

- Medical doctors at hospitals (secondary care sector) regardless of specialization.
- General Practitioners (GPs) (primary care sector).

1.5 Patient population

The target patient population for LiverPRO are individuals at risk of steatotic liver disease, categorized into the following:

1. Alcohol-related liver disease (ALD): individuals with alcohol overuse.

- Alcohol overuse is defined based on the healthcare professional’s discretion.

2. Metabolic dysfunction-associated steatotic liver disease (MASLD): encompasses patients who have hepatic steatosis and have at least one of five cardiometabolic risk factors:

- BMI ≥ 25 kg/m² OR waist circumference (WC): ≥ 94 cm (M), 80 cm (F)
- Fasting serum glucose ≥ 5.6 mmol/L (100 mg/dL) OR serum glucose ≥ 11.1 mmol/L (200 mg/dL) OR 2-hour post-glucose ≥ 7.8 mmol/L (140 mg/dL) OR HbA1c ≥ 5.7% (39 mmol/mol).
- Blood pressure ≥ 130/85 mmHg OR specific antihypertensive drug use.
- Plasma triglycerides ≥ 1.7 mmol/L (150 mg/dL) OR lipid-lowering treatment.
- Plasma HDL cholesterol < 1.0 mmol/L (40 mg/dL) (M) OR < 1.3 mmol/L (50 mg/dL) (F) OR lipid-lowering treatment.

3. MASLD and increased alcohol intake (MetALD):

- MetALD: Represents an overlap of MASLD and ALD, based on alcohol consumption thresholds.
- Weekly alcohol intake (grams):

a) MASLD predominant: 140/210 (female/male)

b) Overlap: 210–280 (female), 280–350 (male)

c) ALD predominant: 350/420 (female/male)

LiverPRO can be calculated in individuals regardless of the numbers of risk factors, meaning patients can have both alcohol overuse, and non-alcoholic risk factors (obesity, type-2 diabetes, and/or metabolic syndrome).

1.6 Application

LiverPRO software is used by healthcare professionals both in the primary and secondary care sector. It is not intended to be used by lay users.

There are no restrictions on the frequency of use i.e. it can be used whenever there is a suspected risk of having steatotic liver disease.

1.7 Environment guidance

Ambient temperature and humidity do not affect the performance of the device.

1.8 Use Scenario

1.8.1 Patient journey

1. You, as a healthcare professional, are in a consultation with a patient
2. You realise that the patient has risk factors for having steatotic liver disease
3. You order a blood sample through the regular biochemical ordering system
4. You decide to include a LiverPRO result as part of the order to aid your evaluation of the patient
5. The patient has the required blood samples drawn
6. You receive the LiverPRO result together with the other the blood sample results
7. You make final clinical judgement based on all clinical insights.

1.8.2 Ordering of blood samples for LiverPRO result

LiverPRO requires age and at least three of the parameters listed in the below table to be available for calculation. Using fewer than the full set of listed biomarkers may result in reduced diagnostic performance, as described in Analytical Performance Characteristics section.

Parameter	SI units
Aspartate transaminase (AST)	U/L
Alkaline phosphatase (ALP)	U/L
Gamma-glutamyl transferase (GGT)	U/L
International normalized ratio (INR)	-
Albumin	g/L
Bilirubin	μmol/L
Platelets	10^9/L
Sodium	mmol/L
Cholesterol	mmol/L

1.8.3 LiverPRO result

When the calculation is performed by LiverPRO, the healthcare professional will be given the result through/or in the Laboratory Information System (LIS), as a percentage risk prediction for the given patient's risk of having the configured level of liver fibrosis (e.g. Significant fibrosis (F2), Advanced fibrosis (F3) or Cirrhosis (F4)).

LiverPRO is not involved in handling any types of specimens and does not measure or detect any specific analytes so we cannot say that the terms "qualitative, semi-quantitative and quantitative" are applicable per se. However, the LiverPRO score itself represents a numerical value which correlates to a certain risk of having liver fibrosis displayed in percentages which could classify it as quantitative.

The LiverPRO result only provides guidance and the healthcare professional determines the appropriate actions for the patient.

1.8.3.1 Elements of the result

- LiverPRO score (integer between 0 and 100 which represents a percentage risk of liver fibrosis)

The model cannot produce values of 0 or 100, as we can never guarantee the complete absence of risk or absolute certainty of risk.

- A risk class: Low (L), Moderate (M), and High (H) dependent on the LiverPRO score and the cut offs described in the Clinical Performance Characteristics section.
- A clinical interpretation of the risk class and recommendation for next clinical actions.
- Device name and software version used.

1.8.3.2 Result shown in the LIS system Example of LiverPRO results using significant fibrosis (>=F2) as the target outcome:

1. Here is an example of a patient with low risk of significant fibrosis (>=F2)

A) 18

B) Low risk

This patient has a low risk of having significant fibrosis in the liver.

D) LiverPRO, version 1.1.1

2. Here is an example of a patient with moderate risk of significant fibrosis (>=F2)

A) 37

B) Moderate risk

C) Intervene on lifestyle and repeat tests.

This patient has a moderate risk of having significant fibrosis in the liver. Based on the standard liver function tests, this patient had a LiverPRO calculation performed to assess the risk of having severe liver disease, corresponding to significant liver fibrosis. As long as the patient does not show obvious signs of cirrhosis or other severe liver disease, we suggest that the test is repeated in 6-12 months, and that lifestyle interventions towards obesity, type 2 diabetes, and excessive alcohol consumption are initiated.

D) LiverPRO, version 1.1.1

3. Here is an example of a patient with high risk of significant fibrosis (>=F2)

A) 71

B) High risk

C) Consider referring the patient for specialist evaluation.

Based on the standard liver function tests, this patient had a LiverPRO calculation performed to assess the risk of having severe liver disease, corresponding to significant liver fibrosis. The result indicates that the patient has a high risk of having significant liver fibrosis. You should consider referring the patient for further examinations at the relevant Gastroenterology or Hepatology Department.

D) LiverPRO, version 1.1.1

An illustrative example of how the LiverPRO result can be displayed in an LIS system is found below:

Figure 1: mockup

1.9 Warnings

The LiverPRO software cannot be used for other purposes than described in this Instruction for Use.

LiverPRO is NOT intended for a final diagnosis and should not be used as a stand alone indication to perform a liver biopsy. The need to perform a liver biopsy will always be assessed by a physician.

Note to EU-based users: in case any serious incident occurs in relation to LiverPRO, report it to the manufacturer or the competent authority of the Member State you are established in.

The incidents can be reported to Evido by phone or email at:

Phone: +45 28 83 87 54

Email: support@evido.health

1.10 Limitations and Contraindications

There are no direct contraindications, but LiverPRO is not indicated in the following diseases:

- Viral hepatitis
- Autoimmune liver diseases: Autoimmune hepatitis, primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC)
- Inherited diseases: Wilson disease, alfa-1-antitrypsin deficiency, and hemochromatosis.
- Budd-Chiari syndrome and portal vein thrombosis.

- Non-primary liver cancer.
- Decompensated liver cirrhosis (liver fibrosis is evident at this stage)

1.10.1 Renal impairment

LiverPRO has not been specifically validated in patients with renal impairment, hepatorenal syndrome, or dialysis-dependent kidney disease.

Renal dysfunction may alter the concentration of certain biochemical parameters included in the LiverPRO algorithm due to reduced clearance, altered protein binding, fluid shifts, or chronic systemic inflammation. For example, bilirubin and inflammatory markers may be affected independently of liver fibrosis severity.

As a result, LiverPRO scores in patients with significant renal impairment may not reflect liver status with the same performance characteristics as observed in the validated population.

Results in patients with eGFR <60 mL/min/1.73 m^2 should therefore be interpreted in conjunction with renal function and the overall clinical context.

1.10.2 Vitamin K antagonists

LiverPRO should be used with caution in patients treated with vitamin K antagonists, as these agents are associated with a clinically relevant elevation of INR that may result in a falsely elevated LiverPRO score. Vitamin K antagonists include, but are not limited to:

- Warfarin
- Phenprocoumon
- Acenocoumarol

Use of LiverPRO in patients receiving vitamin K antagonists should be interpreted in the clinical context, taking the expected effect on INR into account. To mitigate this risk, LiverPRO includes an automated input validation rule and rejects any request containing an INR value greater than 2.0; in such cases, no LiverPRO calculation is performed.

1.10.3 Direct oral anticoagulants (DOACs)

Direct oral anticoagulants are not considered contraindications for the use of LiverPRO, as they do not directly interfere with the vitamin K–dependent coagulation pathway and typically result in only minimal or variable effects on INR. These include:

- Dabigatran (direct thrombin inhibitor)
- Rivaroxaban (factor Xa inhibitor)
- Apixaban (factor Xa inhibitor)
- Edoxaban (factor Xa inhibitor)

The effect of these agents on INR is generally limited and substantially lower than that observed with vitamin K antagonists.

1.11 Analytical performance characteristics

LiverPRO has the following ROC AUC performance in the following intervals. The presented ROC AUC performance intervals are split based on disease progress stage (F2, F3 and F4) and the number of input variables.

1.11.1 AUC-intervals for Significant Fibrosis (F2)

- Age + 3 input biomarkers: AUC 0.56 – 0.81
- Age + 4 input biomarkers: AUC 0.57 – 0.81
- Age + 5 input biomarkers: AUC 0.59 – 0.81
- Age + 6 input biomarkers: AUC 0.62 – 0.81
- Age + 7 input biomarkers: AUC 0.66 – 0.81
- Age + 8 input biomarkers: AUC 0.74 – 0.81
- Age + 9 input biomarkers: AUC 0.81(only one algorithm)

1.11.2 AUC-intervals for Advanced Fibrosis (F3)

- Age + 3 input biomarkers: AUC 0.61 – 0.86
- Age + 4 input biomarkers: AUC 0.68 – 0.86
- Age + 5 input biomarkers: AUC 0.71 – 0.86
- Age + 6 input biomarkers: AUC 0.73 – 0.86
- Age + 7 input biomarkers: AUC 0.75 – 0.86
- Age + 8 input biomarkers: AUC 0.80 – 0.86
- Age + 9 input biomarkers: AUC 0.86(only one algorithm)

1.11.3 AUC-intervals for Cirrhosis (F4)

- Age + 3 input biomarkers: AUC 0.64 – 0.89
- Age + 4 input biomarkers: AUC 0.72 – 0.89
- Age + 5 input biomarkers: AUC 0.75 – 0.89
- Age + 6 input biomarkers: AUC 0.76 – 0.89
- Age + 7 input biomarkers: AUC 0.79 – 0.89
- Age + 8 input biomarkers: AUC 0.84 – 0.89
- Age + 9 input biomarkers: AUC 0.89(only one algorithm)

1.12 Clinical performance characteristics

LiverPRO has the following clinical performance in the different disease stages targeted.

1.12.1 Performance targeting Significant Fibrosis (F2)

LiverPRO demonstrates the following clinical performance for identification of significant liver fibrosis (F2 or higher).

Performance targeting significant fibrosis (F2) - corresponding to a Liver Stiffness Measurement (LSM) < 8kPa.

The below performance measures are based on a LiverPRO combination using 4 input parameters.

Clinical purpose	LiverPRO cut-off	Target fibrosis stage	Corresponding LSM	Primary metrics	Clinical interpretation
RULE OUT significant fibrosis	< 25%	>= F2	< 8 kPa	Sensitivity: 82%, NPV:98%	A result below the low cut-off indicates a low likelihood of significant fibrosis
RULE IN significant fibrosis	>65%	>= F2	>= 8 kPa	Specificity: 91%. PPV:26%	A result above the high cut-off indicates a high likelihood of significant fibrosis

1.12.1.1 Clinical recommendations Low risk (<25%):

Short: This patient has a low risk of having significant fibrosis in the liver.

Long: This patient has a low risk of having significant fibrosis in the liver. Consider repeating tests in 2-3 years if life style risk factors persists.

Moderate risk (25-65%):
Short: Intervene on lifestyle and repeat tests.

Long: This patient has a moderate risk of having significant fibrosis in the liver. Based on the standard liver function tests, this patient had a LiverPRO calculation performed to assess the risk of having severe liver disease, corresponding to significant liver fibrosis. As long as the patient does not show obvious signs of cirrhosis or other severe liver disease, we suggest that the test is repeated in 6-12 months, and that lifestyle interventions towards obesity, type 2 diabetes, and excessive alcohol consumption are initiated.

High risk (>=65%):
Short:Consider referring the patient for specialist evaluation.

Long: Based on the standard liver function tests, this patient had a LiverPRO calculation performed to assess the risk of having severe liver disease, corresponding to significant liver fibrosis. The result indicates that the patient has a high risk of having significant liver fibrosis. You should consider referring the patient for further examinations at the relevant Gastroenterology or Hepatology Department.

1.12.2 Performance targeting Advanced Fibrosis (F3)

LiverPRO demonstrates the following clinical performance for identification of advanced liver fibrosis (F3 or higher).

Performance targeting advanced fibrosis (F3) - corresponding to a Liver Stiffness Measurement (LSM) < 12kPa.

The below performance measures are based on a LiverPRO combination using 4 input parameters.

Clinical purpose	LiverPRO cut-off	Target fibrosis stage	Corresponding LSM	Primary metrics	Clinical interpretation
RULE OUT advanced fibrosis	<5%	>= F3	< 12 kPa	Sensitivity: 81%, NPV:99%	A result below the low cut-off indicates a low likelihood of advanced fibrosis
RULE IN advanced fibrosis	>15%	>= F3	>= 12 kPa	Specificity: 91%. PPV:13%	A result above the high cut-off indicates a high likelihood of advanced fibrosis

1.12.2.1 Clinical recommendations Low risk (<5%):

Short: This patient has a low risk of having advanced fibrosis in the liver.

Long: This patient has a low risk of having advanced fibrosis in the liver. Consider repeating tests in 2-3 years if life style risk factors persists.

Moderate risk (5-15%):
Short: Intervene on lifestyle and repeat tests.

Long: This patient has a moderate risk of having advanced fibrosis in the liver. Based on the standard liver function tests, this patient had a LiverPRO calculation performed to assess the risk of having severe liver disease, corresponding to advanced liver fibrosis. As long as the patient does not show obvious signs of cirrhosis or other severe liver disease, we suggest that the test is repeated in 6-12 months, and that lifestyle interventions towards obesity, type 2 diabetes, and excessive alcohol consumption are initiated.

High risk (>=15%):
Short: Consider referring the patient for specialist evaluation.

Long: Based on the standard liver function tests, this patient had a LiverPRO calculation performed to assess the risk of having severe liver disease, corresponding to advanced liver fibrosis. The result indicates that the patient has a high risk of having advanced liver fibrosis. You should consider referring the patient for further examinations at the relevant Gastroenterology or Hepatology Department.

1.12.3 Performance targeting Cirrhosis (F4)

LiverPRO demonstrates the following clinical performance for identification of cirrhosis (F4).

Performance targeting cirrhosis (F4) - corresponding to a Liver Stiffness Measurement (LSM) < 15kPa. The below performance measures are based on a LiverPRO combination using 4 input parameters.

Clinical purpose	LiverPRO cut-off	Target fibrosis stage	Corresponding LSM	Primary metrics	Clinical interpretation
RULE OUT cirrhosis	<5%	F4	< 15 kPa	Sensitivity: 82%, NPV:99%	A result below the low cut-off indicates a low likelihood of cirrhosis

Clinical purpose	LiverPRO cut-off	Target fibrosis stage	Corresponding LSM	Primary metrics	Clinical interpretation
RULE IN cirrhosis	>15%	F4	>= 15 kPa	Specificity: 91%. PPV:9%	A result above the high cut-off indicates a high likelihood of cirrhosis

1.12.3.1 Clinical recommendations Low risk (<5%):

Short: This patient has a low risk of having cirrhosis in the liver.

Long: This patient has a low risk of having cirrhosis in the liver. Consider repeating tests in 2-3 years if life style risk factors persists.

Moderate risk (5-15%):
Short: Intervene on lifestyle and repeat tests.

Long: This patient has a moderate risk of having cirrhosis in the liver. Based on the standard liver function tests, this patient had a LiverPRO calculation performed to assess the risk of having severe liver disease, corresponding to cirrhosis. As long as the patient does not show obvious signs of cirrhosis or other severe liver disease, we suggest that the test is repeated in 6-12 months, and that lifestyle interventions towards obesity, type 2 diabetes, and excessive alcohol consumption are initiated.

High risk (>=15%):
Short: Consider referring the patient for specialist evaluation.

Long: Based on the standard liver function tests, this patient had a LiverPRO calculation performed to assess the risk of having severe liver disease, corresponding to cirrhosis. The result indicates that the patient has a high risk of having cirrhosis. You should consider referring the patient for further examinations at the relevant Gastroenterology or Hepatology Department.

1.13 Symbols

1.13.1 Consult instructions for use

Figure 2: IFU

1.13.1.1 Meaning Title/meaning: Consult instructions for use or consult electronic instructions for use.

Function/description: To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.

1.13.2 Mark of conformity according to the In Vitro Diagnostic Regulation 2017/746

CE
2797

Figure 3: CE mark

1.13.2.1 Meaning Title/Meaning: CE mark.

Function/description: To indicate that the device has successfully passed a conformity assessment by a notified body and is therefore compliant with the Regulation (EU) 2017/746 - IVDR.

1.13.3 In Vitro Diagnostic Medical device

Figure 4: IVD

1.13.3.1 Meaning Title/Meaning: In Vitro Diagnostic Medical device.

Function/description: To indicate that the software is an in vitro diagnostic medical device according to the European In Vitro Diagnostic Regulation 2017/746.

1.13.4 Unique device identifier

Figure 5: UDI

1.13.4.1 Meaning Title/Meaning: Unique Device Identifier.

Function/description: To indicate a carrier that contains unique device identifier information according to the European In Vitro Diagnostic Regulation 2017/746.

1.13.5 Company logo

Figure 6: Logo

1.13.5.1 Meaning Title/Meaning: Company logo.

1.13.6 Manufacturer

1.13.6.1 Meaning Title/Meaning: Manufacturer.

Function/description: To identify the manufacturer of a product. It shall be used filled in all applications to differentiate it from ISO 7000-2497.

1.14 Regulations and standards

Medical software LiverPRO is classified according to IVDR (EU) 2017/746, Annex VIII: Class B, Rule 6. LiverPRO is classified as Class A according to IEC 62304:2006/A1:2015 - Medical device software — Software lifecycle processes. The device complies with the following product standards:

- IEC 62304:2006/A1:2015 - Medical device software – Software lifecycle processes
- EN ISO 13485:2016/A11:2021 - Medical devices - Quality management systems - Requirements for regulatory purposes
- IEC 82304-1:2016 - Health Software - Part 1: General requirements for product safety
- In Vitro Diagnostic Regulation IVDR (EU) 2017/746

Figure 7: Manufacturer

- EN ISO 14971:2019/A11:2021 - Medical devices – Application of risk management to medical devices
- IEC 62366-1:2015/AMD1:2020 - Medical devices - Part 1: Application of usability engineering to medical devices

1.15 Contact information

If you have any questions or concerns about the use of LiverPRO, or if you experience any technical issues while using LiverPRO please contact Evido customer support at:

Site	Address
Main site	Evido ApS Gasværksvej 15D 1st floor 1656 København V Denmark Phone: +45 28 83 87 54 Email (Support): support@evido.health Email (General): hello@evido.health Website: www.evido.health

1.16 About this document

1.16.1 Terms and abbreviations

Term	Definition
Analytical performance	The ability of a device to correctly detect or measure a particular analyte
Clinical performance	The ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user
Incident	Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device
Serious incident	Any incident that directly or indirectly led, might have led or might lead to any of the following:(a) the death of a patient, user or other person(b) the temporary or permanent serious deterioriation of a patient's, user's or other person's state of health(c) a serious public health threat

Abbreviation	Definition
UDI	Unique Device Identifier
AUC-ROC	Area Under the (Receiver Operating) Curve
PPV	Positive Predictive Value
NPV	Negative Predictive Value
LIS	Laboratory Information System
IVD	In Vitro Diagnostic
ALD	Alcohol-Related Liver Disease
MASLD	Metabolic dysfunction-associated steatotic liver disease
MetALD	Metabolic Dysfunction-Associated and Alcohol-Associated Liver Disease

Abbreviation	Definition
LSM	Liver Stiffness Measurement
IFU	Instructions For Use
SaMD	Software as Medical Device
GP	General Practitioner
WC	Waist Circumference
BMI	Body Mass Index
HbA1c	Glycated Hemoglobin
HDL	High-density Lipoprotein
AST	Aspartate Transaminase
ALP	Alkaline phosphatase
GGT	Gamma-glutamyl transferase
INR	International normalized ratio
PBC	Primary Biliary Cholangitis
PSC	Primary Sclerosing Cholangitis
DOAC	Direct Oral Anticoagulant

1.16.2 Revision history

Revision	Date	Author	Changes	Scope
8.0	2023-07-03	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Initial markdown version	Minor
9.0	2024-04-21	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Clean up formatting	Cosmetic
10.0	2024-04-25	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Update Evidos phone number	Minor
11.0	2024-05-09	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Update company address	Minor
12.0	2024-05-09	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Update company address	Minor
13.0	2024-05-10	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Fix incorrect address include reference	Minor
14.0	2024-08-05	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Update terms and abbreviations	Minor
15.0	2024-08-07	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Updated hard- & software requirements	Minor
16.0	2025-01-09	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Updated ROC AUC values	Minor
17.0	2025-01-14	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Updated cut-off values and derived quality metrics	Minor
18.0	2025-02-26	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Make this IFU EU only. Only title change, no content updates.	Cosmetic
19.0	2025-02-27	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Patient population terminology updated,post-market obligations section added	Minor

Revision	Date	Author	Changes	Scope
20.0	2025-07-28	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Reformatting, no content change	Cosmetic
21.0	2025-09-29	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Updated performance of f4 model includes revision	Minor
22.0	2025-10-03	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Updates according to comments from Roche	Minor
23.0	2025-12-15	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Company address updated	Minor
24.0	2025-12-24	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Author list updated with Katrine as the new PRRC and Søren not affiliated with Evido anymore	Minor
25.0	2026-01-19	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Software installation requirements updated. Removed customerdata (licensing module) information since this functionality has been removed from the LiverPRO product. Changed icon sizes.	Minor
26.0	2026-01-20	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Sites information updated.	Minor
27.0	2026-01-21	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Phone information updated.	Minor
28.0	2026-02-06	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Input from external collaborator.	Major
29.0	2026-02-24	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Elements of the result section slightly rephrased, new mockup image of the result inserted, section on renal impairment added	Minor
30.0	2026-03-04	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Updated for release 1.1.0.	Minor
31.0	2026-04-10	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Updated for release 1.1.1.	Minor

1.16.3 Storage location

The original of this document is stored in GitHub.

Any print-out of this document or a document stored in different location is considered an “Uncontrolled Copy”.