

Instructions for Use

LiverPRO IVD medical software

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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.

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")

2.1. Intended purpose

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

3. Intended users

LiverPRO is intended for use by healthcare professionals only.

Specifically, for the initial ordering and interpretation of LiverPRO results:

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

Specifically, LiverPRO is used in the laboratory and operated by:

- Laboratory professionals

Neither of the intended users interact directly with the LiverPRO software because it is integrated with the laboratory system.

4. Patient population

The target patient population for LiverPRO are adult individuals (aged 18 years or older) 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 medical doctor'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 $\geq 5.7\%$ (39 mmol/mol).
 - Blood pressure $\geq 130/85$ 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):
 - MASLD predominant: 140/210 (female/male)
 - MetALD: 140–350 (female), 210–420 (male)
 - 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).

5. Application

LiverPRO software is used both in the primary and secondary care sector.

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.

6. Environment guidance

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

7. Use scenario

7.1. Patient journey (Example)

- 1) You, as a medical doctor, are in a consultation with a patient
- 2) You assess 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) The LiverPRO result is automatically calculated at the laboratory using blood sample results that are overseen by a laboratory professional
- 7) You receive the LiverPRO result together with the blood sample results
- 8) You make final clinical judgement based on all clinical insights.

7.2. 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	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
Platelet Count	10 ⁹ /L
Sodium	mmol/L
Cholesterol	mmol/L

7.3. LiverPRO result

When the calculation is performed by LiverPRO, the result will be provided through/or in the Laboratory Information System (LIS), as a percentage risk prediction for the given patient's risk of having the predefined 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 to you, as a medical doctor, when determining the appropriate actions for your patient.

7.3.1. Elements of the result

#	Element	Description
a)	Risk class	Low, moderate or high, determined by the score relative to two cut-offs specific to the installed fibrosis stage ($\geq F2$, $\geq F3$ or $F4$), applied across every enabled configuration.
b)	Considerations	[Short Text] The information necessary to interpret the score and category, presented with the result [Long Text] The common clinical considerations
c)	LiverPRO score	An integer from 1 to 99, reported without units.
d)	Device ID	Device name and software version including unique device identification (UDI)

7.3.2. Result shown in the LIS system

Example of LiverPRO results using significant fibrosis ($\geq F2$) as the target outcome:

1. Example of a patient with low risk of significant fibrosis ($\geq F2$)

- a) Low Risk
- b) This patient has a low risk of having $\geq$ significant liver fibrosis.
This patient has a low risk of having $\geq$ significant liver fibrosis. Consider repeating tests in 2-3 years if lifestyle risk factors persist.
- c) 18
- d) LiverPRO, version: 1.2.0., UDI: (01)05700002258601(8012)10200

2. Example of a patient with moderate risk of significant fibrosis ($\geq$ F2)

a) Moderate Risk

b) Intervene on lifestyle and repeat tests

This patient has a moderate risk of having $\geq$ significant liver fibrosis. 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 $\geq$ 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.

c) 37

d) LiverPRO, version: 1.2.0., UDI: (01)05700002258601(8012)10200

3. Example of a patient with high risk of significant fibrosis ($\geq$ F2)

a) High Risk

b) 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 $\geq$ significant liver fibrosis. The result indicates that the patient has a high risk of having $\geq$ significant liver fibrosis. You should consider referring the patient for further examinations at the relevant Gastroenterology or Hepatology Department.

c) 71

d) LiverPRO, version: 1.2.0., UDI: (01)05700002258601(8012)10200

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

Electronic health record system - illustrative example

Home Chart Lab sheet Dr. Michelle Carter Hepatologist

John Johnson ID: 260432-XXXX - Male - 45y

Patient chart Lab sheet

Analysis	Reference area	Result	Date
LiverPRO score	0 - 25	71	12.08.2026
LiverPRO consideration	txt	high risk	
Aspartate transaminase	15-45	50	
Alkaline phosphatase	35-105	80	
Gama-glutamyl transferase	15-115	91	
International normalised ratio	0.9-1.2	1.1	
Albumin	3.5-5.0	3.1	12.08.2026
Bilirubin	0.29-1.46	1.76	12.08.2026

High risk - 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 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.

LiverPRO, version 1.2.0., UDI: (01)05700002258601(8012)10200

short text

long text

8. 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

9. 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)

9.1. 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 $\text{eGFR} < 60 \text{ mL/min/1.73 m}^2$ should therefore be interpreted in conjunction with renal function and the overall clinical context.

9.2. 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.

9.3. 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.

10. 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 parameters.

10.1. AUC-intervals for Significant Fibrosis (F2)

- Age + 3 input biomarkers: AUC 0.54 – 0.82
- Age + 4 input biomarkers: AUC 0.55 – 0.82
- Age + 5 input biomarkers: AUC 0.55 – 0.82
- Age + 6 input biomarkers: AUC 0.57 – 0.80
- Age + 7 input biomarkers: AUC 0.64 – 0.80
- Age + 8 input biomarkers: AUC 0.69 – 0.79
- Age + 9 input biomarkers: AUC 0.76

10.2. AUC-intervals for Advanced Fibrosis (F3)

- Age + 3 input biomarkers: AUC 0.65 – 0.87
- Age + 4 input biomarkers: AUC 0.68 – 0.87
- Age + 5 input biomarkers: AUC 0.72 – 0.87
- Age + 6 input biomarkers: AUC 0.74 – 0.87
- Age + 7 input biomarkers: AUC 0.76 – 0.87
- Age + 8 input biomarkers: AUC 0.77 – 0.86
- Age + 9 input biomarkers: AUC 0.80

10.3. AUC-intervals for Cirrhosis (F4)

- Age + 3 input biomarkers: AUC 0.66 – 0.91
- Age + 4 input biomarkers: AUC 0.67 – 0.91
- Age + 5 input biomarkers: AUC 0.67 – 0.91
- Age + 6 input biomarkers: AUC 0.67 – 0.91
- Age + 7 input biomarkers: AUC 0.76 – 0.88
- Age + 8 input biomarkers: AUC 0.79 – 0.88
- Age + 9 input biomarkers: AUC 0.80

LiverPRO is designed to achieve the highest possible performance from the available number of input parameters. If an input parameter is missing or outside LiverPRO's accepted technical range, LiverPRO does not include this parameter in the calculation. Instead, the result is calculated using an alternative combination of the remaining available input parameters.

11. Clinical performance characteristics

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

11.1. Performance targeting Significant Fibrosis (F2)

LiverPRO demonstrates the following clinical performance for identification of $\geq$ significant liver fibrosis (F2 or higher). Performance targeting $\geq$ significant fibrosis (F2) - corresponding to a Liver Stiffness Measurement (LSM) > 8 kPa.

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 $\geq$ significant fibrosis	$< 25\%$	$\geq F2$	< 8 kPa	Sensitivity: 82%, NPV: 98%	A result below the low cut-off indicates a low likelihood of $\geq$ significant fibrosis
RULE IN $\geq$ significant fibrosis	$\geq 65\%$	$\geq F2$	≥ 8 kPa	Specificity: 91%, PPV: 26%	A result above the high cut-off indicates a high likelihood of $\geq$ significant fibrosis

11.1.1. Clinical recommendations

Low risk ($< 25\%$):

Short: This patient has a low risk of having $\geq$ significant liver fibrosis.

Long: This patient has a low risk of having $\geq$ significant liver fibrosis. Consider repeating tests in 2-3 years if lifestyle risk factors persist.

Moderate risk (25 to $< 65\%$):

Short: Intervene on lifestyle and repeat tests.

Long: This patient has a moderate risk of having $\geq$ significant liver fibrosis. 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 $\geq$ 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 ($\geq 65\%$):

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 $\geq$ significant liver fibrosis. The result indicates that the patient has a high risk of having $\geq$ significant liver fibrosis. You should consider referring the patient for further examinations at the relevant Gastroenterology or Hepatology Department.

11.2. Performance targeting Advanced Fibrosis (F3)

LiverPRO demonstrates the following clinical performance for identification of $\geq$ advanced liver fibrosis (F3 or higher). Performance targeting $\geq$ advanced fibrosis (F3) - corresponding to a Liver Stiffness Measurement (LSM) > 12 kPa.

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 $\geq$ advanced fibrosis	$< 5\%$	$\geq F3$	< 12 kPa	Sensitivity: 81%, NPV: 99%	A result below the low cut-off indicates a low likelihood of $\geq$ advanced fibrosis
RULE IN $\geq$ advanced fibrosis	$\geq 15\%$	$\geq F3$	≥ 12 kPa	Specificity: 91%, PPV: 13%	A result above the high cut-off indicates a high likelihood of $\geq$ advanced fibrosis

11.2.1. Clinical recommendations

Low risk ($< 5\%$):

Short: This patient has a low risk of having $\geq$ advanced liver fibrosis.

Long: This patient has a low risk of having $\geq$ advanced liver fibrosis. Consider repeating tests in 2-3 years if lifestyle risk factors persist.

Moderate risk (5 to $< 15\%$):

Short: Intervene on lifestyle and repeat tests.

Long: This patient has a moderate risk of having $\geq$ advanced liver fibrosis. 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 $\geq$ 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 ($\geq 15\%$):

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 $\geq$ advanced liver fibrosis. The result indicates that the patient has a high risk of having $\geq$ advanced liver fibrosis. You should consider referring the patient for further examinations at the relevant Gastroenterology or Hepatology Department.

11.3. 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) $> 15\text{kPa}$.

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	$< 15\text{ kPa}$	Sensitivity: 82%, NPV: 99%	A result below the low cut-off indicates a low likelihood of cirrhosis
RULE IN cirrhosis	$> 15\%$	F4	$\geq 15\text{ kPa}$	Specificity: 91%, PPV: 9%	A result above the high cut-off indicates a high likelihood of cirrhosis

11.3.1. Clinical recommendations**Low risk ($< 5\%$):**

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

Long: This patient has a low risk of having cirrhosis. Consider repeating tests in 2-3 years if lifestyle risk factors persist.

Moderate risk (5 to $< 15\%$):

Short: Intervene on lifestyle and repeat tests.

Long: This patient has a moderate risk of having cirrhosis. 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 ($\geq 15\%$):

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.

12. Symbols



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.



Title/Meaning: CE-mark of conformity according to the In Vitro Diagnostic Regulation 2017/746.

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.



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.



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



Title/Meaning: Company logo



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.

13. Rules 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
- 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

14. 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:

Main Site:

Evido ApS

Gasværksvej 15D, 1. sal

1656 København V, Danmark

Telefon: +45 28 83 87 54

E-mail: support@evido.health

Web: www.evido.health

Modifications compared to latest date of issue for the Instructions for Use:

No modifications have been introduced to this Instruction for Use, version 1.0 with date of issue: 07-09-2026.