ENGLISH	**Instructions for Use regarding reading the ArtiQ.Spiro output report** ALL OF THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINICAL USE	ENGLISH

This document is intended to give general guidance on how ArtiQ.Spiro reports should be read.

Description / Intended Purpose

The intended purpose of ArtiQ.Spiro is to provide automated interpretation of pulmonary function tests (PFTs) to assist clinicians in the diagnosis and follow-up of respiratory diseases. It is a software as medical device with no graphical user interface that can be used through an application programming interface (API) for the generation of ArtiQ.Spiro reports. These reports are meant to supplement, and by no means substitute, any initial report(s) generated by PFT devices, and are not meant to be used as a replacement of the medical practitioner's interpretation.

Indications for Use, Contra-Indications and Patient Target Group

ArtiQ.Spiro can be used for subjects aged 5-96 years, that have undergone pulmonary function testing. The AI-supported interpretation is only calculated and can only be used for adults that did not have a lung transplant or were not diagnosed with Covid-19 in the past 2 weeks.

Intended users

The ArtiQ.Spiro software is intended to be used by clinicians.

Performance Characteristics

The software has a more accurate and faster pattern recognition according to the international guidelines than the average individual pulmonologist (Topalovic 2019).
The software has higher diagnostic suggestion accuracy (based on the highest disease probability) than the average individual pulmonologist: the software accuracy range is 64-75% against the mean accuracy of 44.6% of the individual pulmonologist (Topalovic 2019).

Warnings

Careful attention should be paid to the AI-supported interpretation. Different diseases may be present with similar spirometry patterns.
The output of the report should always be considered in combination with patient history and clinical examination. The output is intended to support, not replace, clinical decision-making.
These reports are meant to supplement, and by no means substitute, any other available report (automated or manual).

PRECAUTIONS

The input data should be of sufficient quality according to international guidelines (Graham 2019). It is recommended to verify the installation and perform a test run before the first use to confirm the data is correctly submitted.

RESIDUAL RISKS

The report content might not represent clinical reality if data input is incorrect or of insufficient quality (see precautions).
AI-supported interpretation might not correspond to correct and/or only diagnosis as different diseases may be present with similar PFT patterns.
Reports might not be produced when input data is not submitted correctly to the HTTP API.

READING INSTRUCTIONS

ArtiQ.Spiro reports consist of 6 main sections (see figure 1 for an example):

1. **Quality of lung function tests (optional)**: The FEV1 and/or FVC session quality grades are shown when available. An interpretation of the meaning of these quality grades is provided based on MacIntyre et al., 2025. When the quality grade is lower than C, no AI-supported interpretation is provided. When the quality grade is F, no physiological interpretation is provided either.

2. **Physiological interpretation of lung function tests**: a text description of the observed lung function pattern, based on calculations performed on submitted spirometry parameters.
   ArtiQ.Spiro calculates reference (predicted) values per the Quanjer GLI-2012 equations (Quanjer 2012). Alternatively, the GLI Global (2022) reference equations can be used for the spirometric indices calculation (Bowerman 2022). Where no GLI Global (2022) spirometry reference equations are available, “Other/Mixed” is used as ethnicity. The spirometric prediction equations for the 5–96-age range include appropriate age-dependent lower limits of normal. For parameters not described in the above publications, equations published by Quanjer in 1993 are used. In a second step, the test results are compared to predicted values. The resulting outcomes are reported according to the international guidelines (Pellegrino 2005 or Stanojevic 2021). The applied reference equations and interpretation guidelines are listed in the footer of the ArtiQ.Spiro report.

3. **AI-supported interpretation:** using spirometry measurements and clinical information (such as age, BMI, and smoking history) of the patient, the software describes an expected probability of disease chosen among Asthma, Chronic Obstructive Pulmonary Disease, Normal lung function, Interstitial Lung Disease (including idiopathic pulmonary fibrosis, nonspecific interstitial pneumonitis, sarcoidosis) or Unidentified (including other obstructive diseases (= cystic fibrosis, bronchiectasis, bronchiolitis), neuromuscular disease, pulmonary vascular disease, thoracic deformity, pleural disease). This feature is to be taken as a suggestion, as in daily clinical practice, doctors still need to further examine patients before giving and validating a final diagnosis.

The AI-supported interpretation is calculated using a predictive model that was trained using a machine learning algorithm (Topalovic 2019). That means that from a database with clinically validated known diseases, the software has learned how each disease looks like and how to detect it. Once new data comes in, the algorithm checks how well the new data matches with different diseases (like fingerprint mapping). The output is the similarity with each of the 5 categories.

4. **Decision support**: based on the analysis, the disease with the highest predicted probability is highlighted.

5. **Further suggestions:** the software proposes a set of further clinical tests necessary for exploration and further validation of the suggested diagnosis provided by the analysis function.

6. **Warnings:** the software gives an indication if there are certain factors that could influence the analysis/disease probabilities (e.g. Lung function may be influenced by obesity, Probability of disease presence may not be accurate due to missing correct information of pack-years).

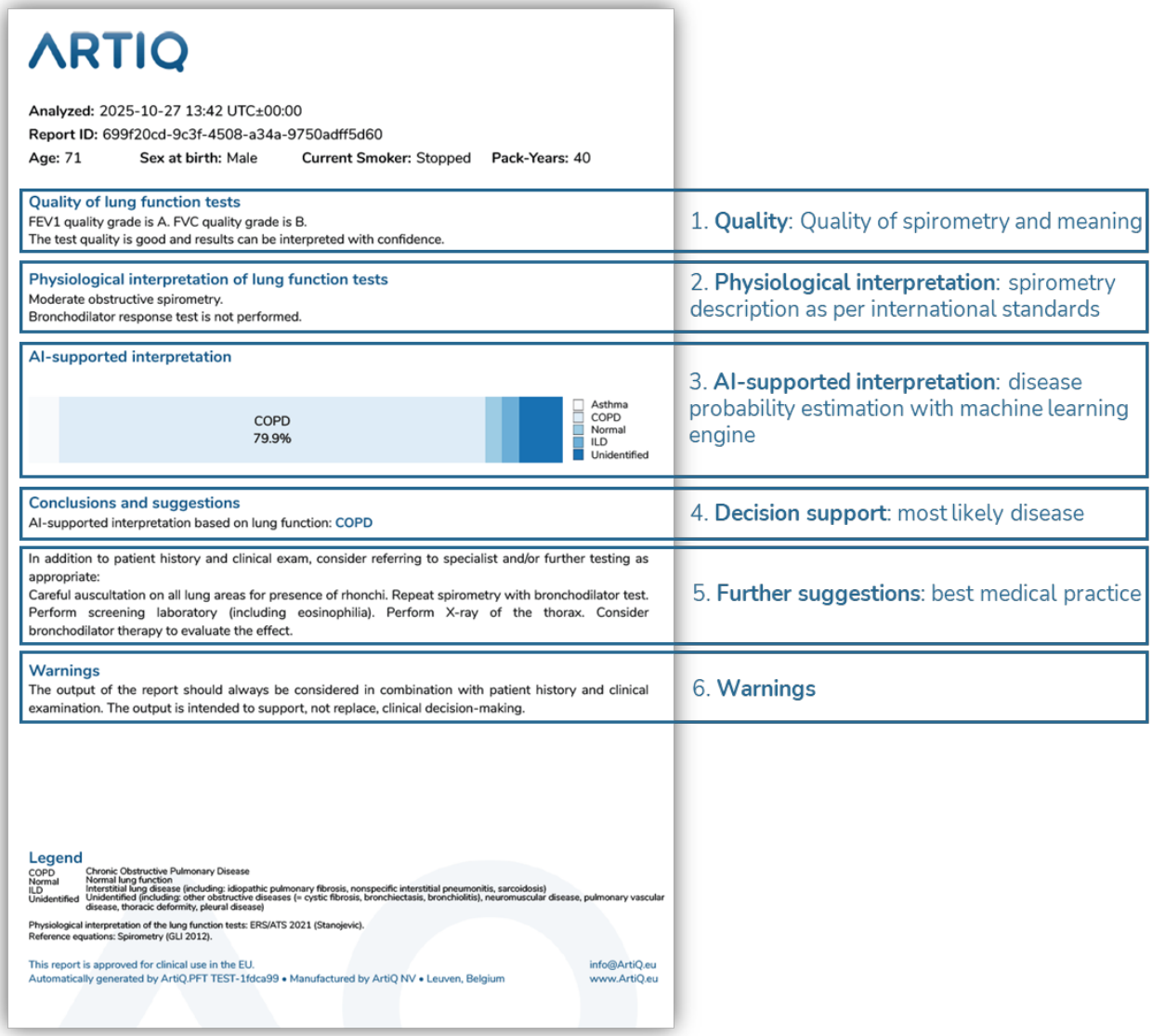

Figure 1: Example report

Installation

ArtiQ.Spiro can be triggered from compatible spirometers via software integration. ArtiQ.Spiro is integrated with MIR Spiro (MIR), SpiroConnect (MedChip) and Spirotrac (Vitalograph). A list of currently supported software versions is maintained by ArtiQ and available upon request.
To activate ArtiQ.Spiro, a license key and password are provided upon purchase of the software. Installation and activation instructions are available in the documentation provided by the integrator (e.g., the integrator's Instructions For Use) or can be obtained through the integrator's support team.

System and Network Requirements

There are no specific hardware or software requirements for the use of ArtiQ.Spiro.
For network connectivity, the following conditions apply:

- An outbound HTTPS connection (port 443) must be open.
- The domain api.artiq.eu should be whitelisted if firewall restrictions are in place.

ArtiQ.Spiro ensures data protection through encryption and access control mechanisms implemented within the Amazon Virtual Private Cloud (VPC) infrastructure. From the user side, no additional IT security measures are required beyond standard good practices (e.g., maintaining password protection and access control on local computers and networks, not sharing any ArtiQ.Spiro credentials).

Contact Details

For any questions or concerns, please contact your ArtiQ representative or ArtiQ directly.

In case you encounter any problem when using this product or want to provide any feedback, please contact ArtiQ:

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3000 Leuven
Belgium

E-mail: support@artiq.eu

The IFU for ArtiQ.Spiro is supplied in electronic form in PDF format on https://www.artiq.eu/instructions-for-use/. A paper version may be requested by emailing support@artiq.eu and will be provided within 7 calendar days at no additional cost.

Notice to the User

For a patient or user in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

LABELING INFORMATION:

ArtiQ.Spiro

REF ArtiQ.PFT 1.10.0

UDI (01)05419980057617
(8012)ArtiQ.PFT1.10.0

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instructions-for-use

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