ENGLISH	**Instructions for Use regarding reading the ArtiQ.PFT 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.PFT-reports should be read.

Description / Intended Purpose

The intended purpose of ArtiQ.PFT is to provide automated interpretation of pulmonary function tests (PFTs) to assist physicians 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.PFT 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.PFT can be used for subjects aged 5-96 years, that have undergone pulmonary function testing. The disease probabilities are 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.PFT software is intended to be used by physicians, mainly pulmonologists.

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 highest disease probability) than the average individual pulmonologist (Topalovic 2019).

Warnings

Careful attention should be paid to the probabilities for disease presence. Different diseases may be present with similar PFT patterns.
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. ArtiQ.PFT reports are only reliable when the data is correctly submitted to the HTTP API. Verify the installation with tests before first use as instructed in the Installation Instructions.

Residual Risks

The report content might not represent clinical reality if data input is incorrect or of insufficient quality (see precautions).

Highest probability of disease presence might not correspond to correct and/or only diagnosis as different diseases may be present with similar PFT pattern.
Reports might not be produced when input data is not submitted correctly to the HTTP API.

READING INSTRUCTIONS

ArtiQ.PFT reports consist of 5 main sections (see figure 1 for an example):

1. **Interpretation of lung function tests**: a text description of the observed lung function pattern, based on calculations performed on submitted PFT parameters. ArtiQ.PFT calculates reference (predicted) values for each PFT parameter:
    - For the spirometric indices reference values are calculated 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.
    - For transfer factor for carbon monoxide Stanojevic GLI-2017 equations (Stanojevic 2017) inclusive of the GLI TLCO 2020 Correction (Stanojevic 2020) are used.
    - For static lung volume parameters GLI-2021 (Graham 2021) can be used (optional).

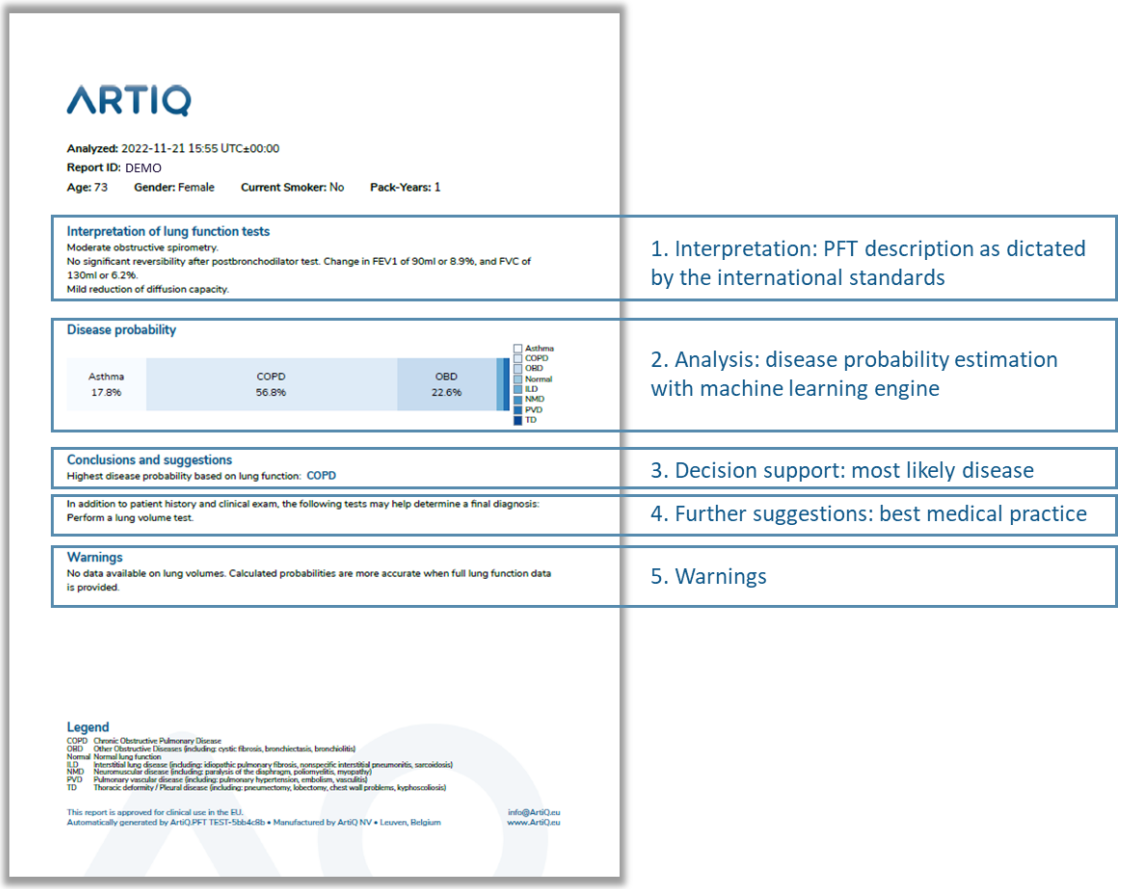
    In a second step, the test results are compared to predicted values. The resulting outcomes are reported according to the international guidelines (Pellegrino 2005 or Stanojevic 2021). The applied reference equations and interpretation guidelines are listed in the footer of the ArtiQ.PFT report.

2. **Analysis / Disease probabilities**: using PFT measurements and clinical information (such as age, BMI and smoking history) of the patient, the software describes an expected probability of disease: chosen among the 8 most common categories detectable with PFTs (Asthma, Chronic Obstructive Pulmonary Disease, Other Obstructive Diseases, Normal lung function, Interstitial lung disease, Neuromuscular disease, Pulmonary vascular disease, and Thoracic deformity). 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. Disease probabilities are 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 look 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 8 most common categories (7 diseases + healthy/normal lung function).

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

4. **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.

5. **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, No data available on diffusion, Probability of disease presence may not be accurate due to missing correct information of pack-years).



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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The IFU for ArtiQ.PFT 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:

LOT	ArtiQ.PFT 1.9.0	ArtiQ NV Boskouter 15 3010 Leuven Belgium	CE 1912
UDI	(01)05419980057600 (8012)ArtiQ.PFT1.9.0		
	www.artiq.eu/ instructions-for-use	2024-03	MD

⚠ ArtiQ.PFT reports are meant to supplement, and by no means substitute, any other available report and are not meant to replace the medical practitioner's interpretation.

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