Koneksa Platform Spirometry Capability Overview

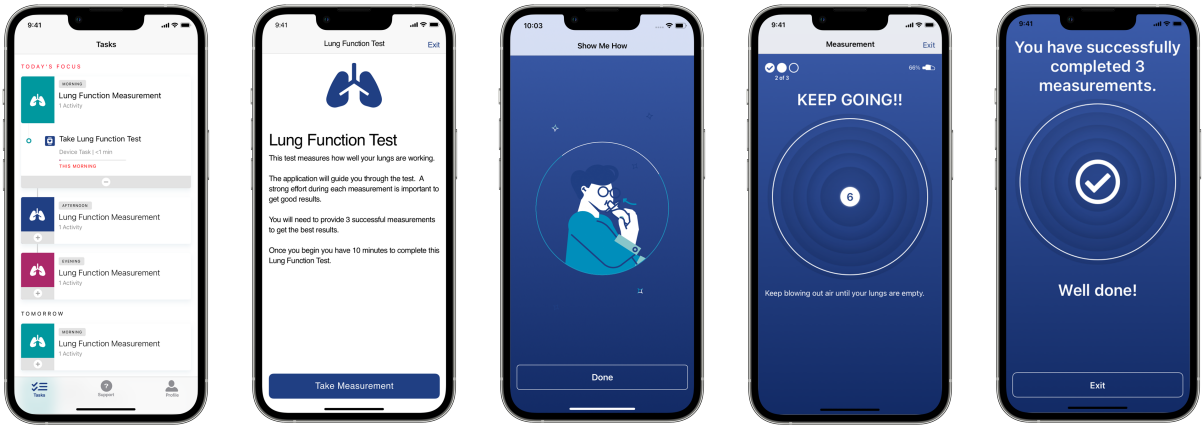
The Koneksa Platform is an end-to-end SaaS platform that can be configured to satisfy a variety of clinical study remote data collection requirements. When combined with Koneksa's study professional services and device/logistics services, a full lifecycle of a clinical study can be managed efficiently with high compliance.

Spirometry data collection, both in-clinic and remote, is offered as part of the platform's standard suite of devices and measures. Together with the Koneksa Mobile App, an ultrasonic spirometry device provides instant lung function measurements.

How does it work?

Koneksa implements an ultrasonic spirometer with Bluetooth technology. This device is capable of capturing both exhalation and inhalation data. When a study participant starts a lung function assessment via the Koneksa Mobile App, they are guided through a series of steps to connect and pair the device, given tips to ensure accurate measurements, and instructed to start blowing into the spirometer.

The spirometry assessment also allows for configurable questionnaires prior to performing the PFT to ensure participants complete the task at the correct time, or to gather other data points of interest. The device automatically captures the lung function measures, then transmits the configured endpoints via Bluetooth to the Koneksa Mobile App on the paired study iPhone. The data capture process takes a few seconds. Once the data is transmitted to the Koneksa Mobile App it is automatically uploaded onto and viewable in the Koneksa Platform web application.



The spirometer paired with the Koneksa Mobile App also provides real-time feedback to the study participant in cases where there are problems capturing the participant's measurements. For example, the Mobile App displays an error message to the participant if they did not blow into the device for a long enough period of time. All error prompts are based on the American Thoracic Society (ATS) and European Respiratory Society (ERS) guidelines.

Study Design

Koneksa evaluates each study protocol from clinical, scientific, technological, and usability perspectives to determine the optimal design for the study that meets your objectives. This includes supporting decisions on device selection, measures, and schedule of assessments to maximize participant compliance and the rate of data collection.

At home spirometry is often deployed during multiple 2-4 week monitoring periods throughout a study protocol. During each monitoring period, participants are asked to either do one or two spirometry measures a day (e.g. a measure in the morning or a measure in the morning and evening). Collecting data during specific monitoring periods allows the Sponsor to benefit from robust datasets via a repeated measurement paradigm, while also limiting participant burden.

Although turbine spirometers have a longer history of use, Koneksa recommends and has experience employing ultrasonic technology in clinical studies. Ultrasonic spirometers have the benefit of:

- Automatic calibration
- Increased sensitivity allowing for a bigger flow range
- Higher accuracy particularly in low or dynamically changing flows
- No disposable hardware beyond the filters
- Easy disinfection

Each of these advantages make ultrasonic spirometers better suited for clinical studies; in addition to higher quality data, the Koneksa spirometry offering guarantees a simple, in-clinic and remote participant experience. See our *Remote FEV1 monitoring in asthma patients: a pilot study* publication in the Koneksa Bibliography to learn more about the scientific basis for remote spirometry feasibility.

The Koneksa Mobile App and other supported Devices readily support additional measures such as questionnaires (i.e. ePROs), vital signs, and physical activity.

Devices

Devices deployed for Koneksa studies are provisioned and managed. Study participants do not have the ability to install or uninstall apps from the study iPhones, or to share their study data with organizations not commissioned by the study. A study that collects spirometry data is deployed with the following devices (see Device Specifications for more details):

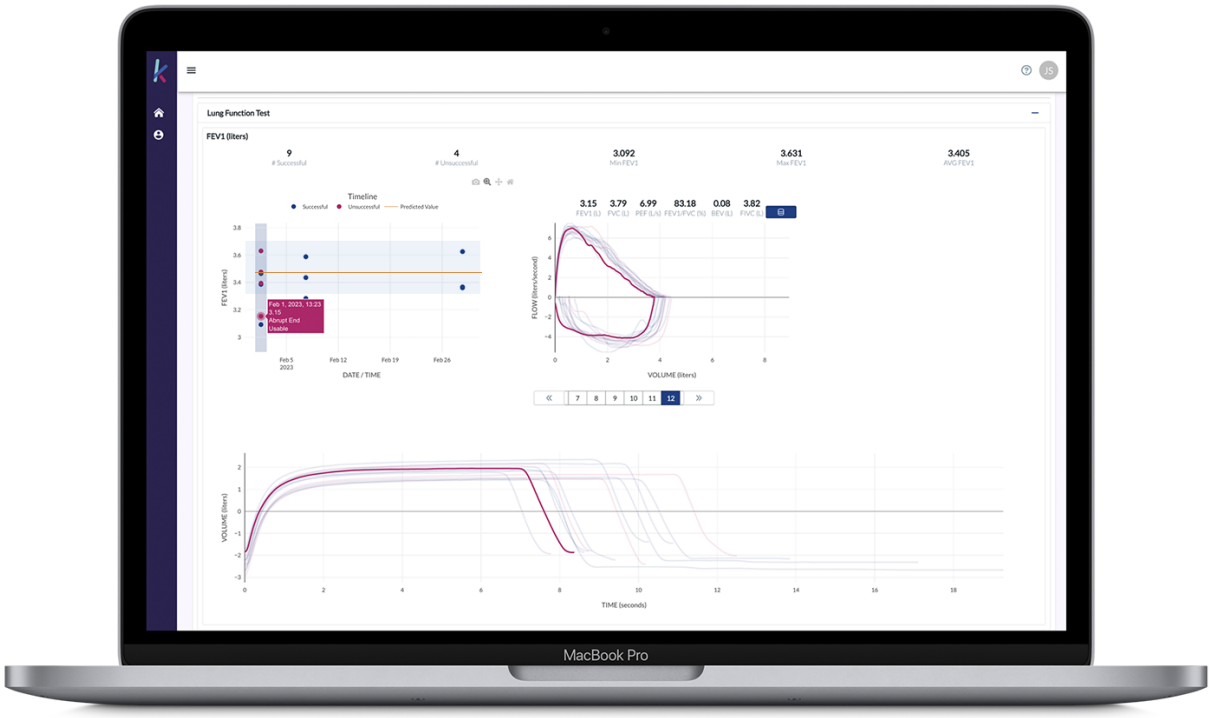
Device	Uscom SpiroSonic AIR	Apple iPhone XR/11/12
Image		
Certifications	CE Mark: link 510K: In Process	CE Mark: (XR) link, (11) link, (12) link 510K: No
Battery life	6 hours	25 hours
Storage	n/a	64 GB
Data Transfer	Via Bluetooth to Koneksa Mobile App installed on paired study iPhone	Via Koneksa Mobile App data upload to Koneksa Platform

Data Collection & Visualization

On the Participant Dashboard in the Koneksa Platform, **FEV1** and **FVC** measures are visualized in near real-time as the participant completes their measurements. For each measure, site coordinators may view timeline and **full flow-volume loop** graphs, as well as the **FEV1**, **FVC**, **PEF**, **FEV1/FVC**, **BEV**, and **FIVC** averages for a single maneuver.

Based on ATS guidelines, each FEV1 and FVC measurement for a single maneuver is:

- Classified as successful or unsuccessful
- Classified as usable or acceptable
- Given the reason for failure when applicable.



If desired, it is also possible to enter demographic information in order to calculate predicted values and upper and lower bounds for FEV1 and FVC measures using the Global Lung Function Initiative (GLI) formula. This allows site coordinators to better understand how well the participant is performing.

Additional measures are collected during the spirometry assessment which may be available for SDTM export. See **Appendix A** for the complete list of measures.

Next Generation Spirometry

Data Capture/Training (Q3'2023)
○ Video training to guide participants through the maneuver ○ Define thresholds to trigger alerts - Let Site Coordinators know if a participant's FVC drops a certain percentage from baseline ○ Repeatability grades

Compliance Monitoring

- Configurable notifications available to remind participants to perform study tasks
- Participants' task completion metrics are provided on various dashboards on the Koneksa Platform web application for study site coordinator users.
- Key metric reports available to view and download for further understanding of compliance and study progress.

Experience Highlights

- All data is anonymized.
- Configurable platform brings a tailored study Mobile App experience to participants: study schedule of assessments and study assessment reminders are all configurable.
- The following measures can also be enabled on the Mobile App on the same study iPhone for additional data collection:
    - Vital Signs data from a variety of devices
    - Questionnaires (i.e. ePROs)
    - Various Neuroscience assessments
- Participants experience the Mobile App in their native language; for a complete list of supported languages, see Language Support.
- Standard SDTM exports available

Appendix A - Spirometry Measures

Measure	Units
AEX	liters^2/second
BEV	liters
EOTV0.5	liters
EOTV1	liters
FEF 25%	liters/second
FEF 50%	liters/second
FEF 50%/FIF 50 %	%
FEF 50%/FIF 50%	ratio
FEF 75%	liters/second
FET	seconds
FEV0.5	liters
FEV0.5/FVC	%
FEV0.75	liters
FEV0.75/FVC	%
FEV1	liters
FEV1 Acceptability	N/A
*FEV1 Percent Predicted	%
*FEV1 Predicted	liters
FEV1/FEV6	%
FEV1/FIVC	%
FEV1/FVC	%
FEV1/FVC	ratio
FEV3	liters
FEV3/FVC	%
FEV6	liters
FIF 25%	liters/second
FIF 50 %	liters/second
FIF 75 %	liters/second
FIT	seconds
FIV1	liters
FIV1/FIVC	%
FIVC	liters
FVC	liters
FVC Acceptability	N/A
*FVC Percent Predicted	%
*FVC Predicted	liters
Max MEF 25-50%	liters/second
Max MEF 25-75%	liters/second
Max MEF 50-75%	liters/second
PEF	liters/second
PEF time	seconds
PIF	liters/second
TR	seconds
VPEF	liters

**Measures included for participants who electively provide their personal demographic information.*

The Koneksa Platform is also capable of ingesting overreading data calculated from ArtiQ. Reach out for more information if you are interested in this additional integration.