KoKo® Px

Comprehensive Pulmonary Function Testing

ENSURE YOUR LAB IS AN ESSENTIAL PART OF ENHANCING RESPIRATORY PATIENT CARE

KoKo Px empowers you to enhance respiratory care by combining reliable, industry-leading PFT performance with seamless review, interpretation, and EMR interoperability to easily produce and distribute the highest quality, ATS-compliant test results in your modern, connected practice.

INCREASE EFFICIENCY

- Industry-proven reliability with an uptime guarantee and performance assurance over the life of the device
- Minimal setup and test time increases productivity
- Compact, ergonomic, touch-screen workstation
- Inbox worklist eliminates the need to search
- Real-time flow/volume and volume/time curves
- Real-time feedback and coaching of test procedure
- Securely share data across rooms or clinics
- Central standardization and configuration
- Lifetime flow sensor significantly lowers costs

ENHANCE PATIENT COMFORT & COMPLIANCE

- Shortest test times in the industry
- Ultra-low breathing resistance
- Real-time effort feedback to reduce number of efforts needed
- Filters and mouthpieces comfortable for adults and children
- Target-adjusted, photo-realistic incentive graphics

IMPROVE TEST QUALITY

- Highest accuracy (1% to scale) of any PFT system
- Verifiably accurate across a wide flow range and environmental conditions
- Automated quality checks and test grading
- Collect and consolidate virtually any data types with patient visit

STREAMLINE PHYSICIAN ACCESS

- Create trend graphs for longitudinal analysis
- Comprehensive, customizable reporting
- Automate transmission of test results to care providers via Iris™
- Remote and dedicated physician workstations
- EMR/HIS connectivity via Iris™ Connect

KoKo

INNOVATIVE TECHNOLOGY FROM THE PFT EXPERTS

ACCURATE, CONSISTENT RESULTS

KoKo Px's advanced iFlow™ flow sensor technology provides the highest accuracy (1% to scale) of any PFT system, surpassing the industry standard, enabling identification of smaller changes in lung function sooner. This dramatically enhances diagnostic precision, treatment planning, and monitoring value.

Test patients using the same clinically-proven, verifiably accurate flow sensor for the life of the system, ensuring more consistent, reliable results from test to test, requiring fewer efforts to get usable results.

Hook for hanging IVs

ALL-DIGITAL PLETHYSMOGRAPH

Enhance Patient Comfort & Compliance

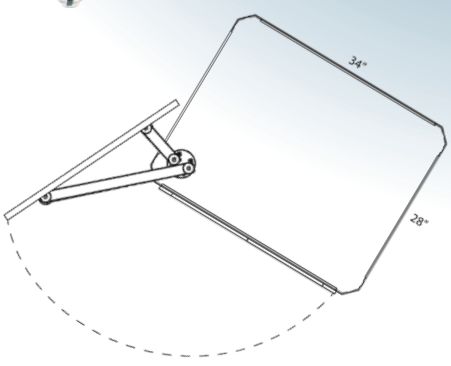
- Unobstructed tempered glass walls provide feeling of openness and allow patient to easily see technician
- Intercom with volume control inside the cabin allows patient to easily hear technician
- Chair height and back are adjustable. Patient valve height can be adjusted electronically by technician while outside the cabin
- Electromagnetic locking system automatically releases in emergencies. Patients can also easily open cabin with the push of a button
  - Much easier than mechanical solutions
  - Doesn't use gases to seal door for increased cost efficiency

Increase Efficiency

- No warm-up time
- Perform all tests with patient inside the cabin
- All areas of cabin can be easily cleaned while door is open
- Easily move patient valve outside the cabin to accommodate patients in wheelchairs without the need for more lab space

Improve Test Quality

- Sensors inside the cabin continuously sample and adjust for hotter, more humid air caused by patient exhalation
- Walls are made of tempered glass - more rigid and less susceptible to environmental noise than acrylic

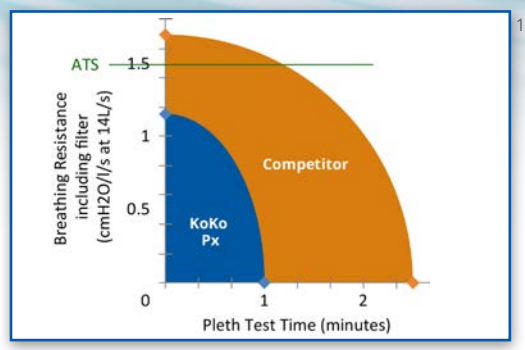


One of the smallest footprints & largest volume in the industry

PROVEN EASIER TO MEET MIN TESTING STANDARDS FOR REPEATABILITY

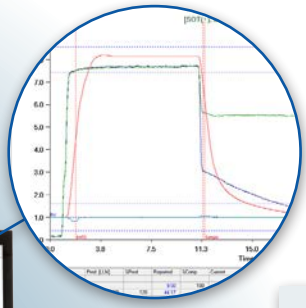
KoKo Px's industry leading accuracy and precision, carefully engineered testing sequences, and minimal breathing circuit resistance enhance patient comfort while minimizing the patient's effort required to meet repeatability criteria. This ensures reliable test results faster for every exam, and compliance with even the most challenging subjects.

Enhance Patient Comfort



[1]

Patient comfort is determined by breathing resistance and test time. KoKo Px enhances patient comfort by minimizing both.



INSTANT, PRECISION GAS ANALYSIS COMES STANDARD

Rapid-response MicroGas analyzer is clinically proven at twice the industry standard in precision and provides instant analysis, providing more accurate results. No need to adjust sample and washout values.

VERIFIABLY ACCURATE

Approx. 25% of labs perform DLCO tests using devices that cannot pass QC[2] and some labs don't know if their device is really accurate. A first of its kind, KoKo LLC provides an objective measure of the accuracy of the actual parameters collected during testing, ensuring system operation to specifications, improving diagnostic confidence.

COMPACT, ERGONOMIC WORKSTATION

Increase Efficiency

- High resolution, all-in-one, touch-screen computer
- Height of patient valve, work surface, and monitor are all adjustable to accommodate sitting or standing positions for adults and children
- Ample space on the work surface
- Small footprint and durable wheels for portability and bedside use

Modular design allows configuration to your needs

LOWEST LIFECYCLE COST

Lifetime flow sensors reduce replacement and recalibration costs, inexpensive anti-bacterial filters reduce the cost of operation, and bundled services with software updates and upgrades lead to the lowest cost per test over the life of the device.

Various filter kits available

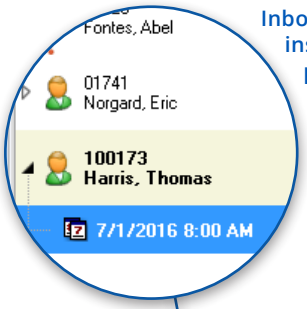
As the "gold-standard" for PFT accuracy, reliability, patient comfort, and cost per test, KoKo Px provides all the tools you need to run an ATS/ERS compliant lab while maximizing time and cost efficiencies.

EMPOWER YOUR LAB WITH INTUITIVE, STREAMLINED SOFTWARE

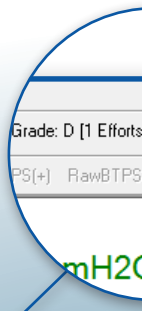
Increase Efficiency

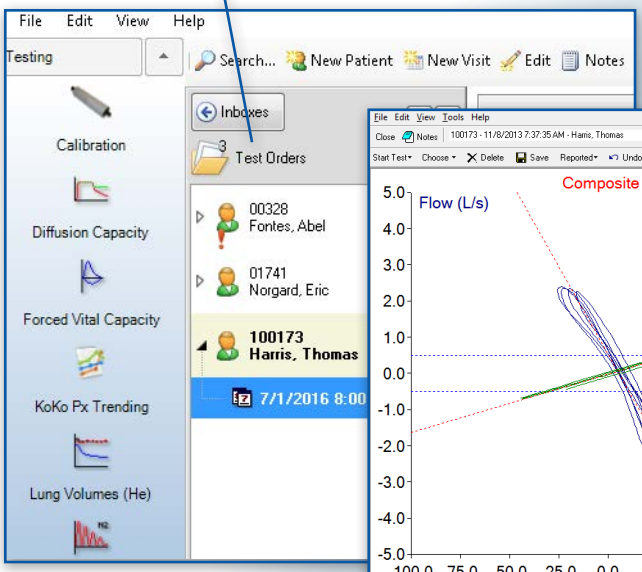
- Unique inbox workflow routes patient/visit data so it is accessible to various healthcare providers when and where they need it
- Search, create new, or edit existing patients, if needed
- Create new order or visit, if needed
- Shortest test times in the industry with immediate test starts, real-time sensors, fast gas sampling, and combined maneuvers, improving patient comfort and test results
- Real-time display and exclusive retrospective analysis of raw high definition test data reduces the need for repeat exams, shortens test times, and improves overall test accuracy
- Technician and routing notes provide contextual information based on the visit experience, adding clinical value that only technicians can provide
- Auto-text for common phrases can be pre-configured

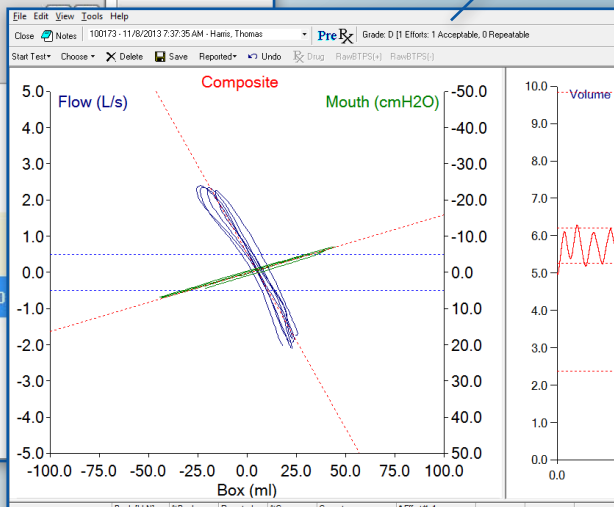
Inbox worklist provides instant access to patient visits without the need to filter or search

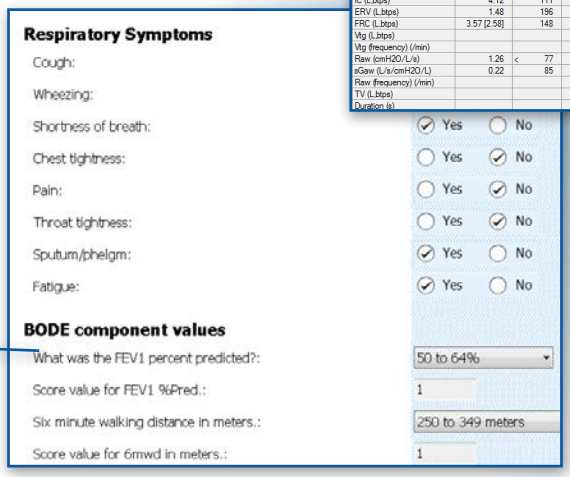


Tests are graded regarding acceptability and reproducibility eliminating guess work

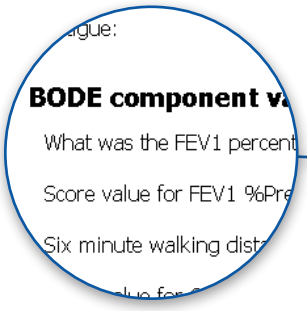


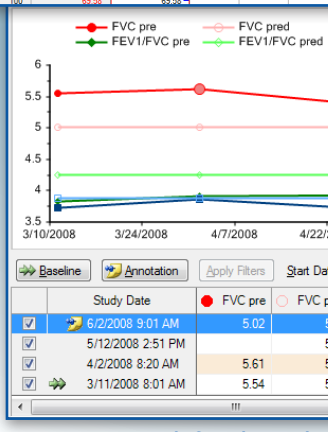






eForms are clinically designed based on disease state





Accurate, user-defined trendin trends for QA during testing and

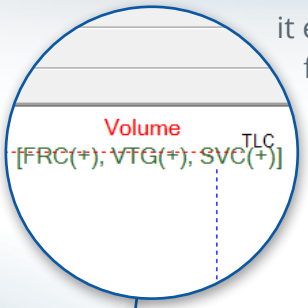
COLLECT & CONSOLIDATE ALL RELEVANT DATA

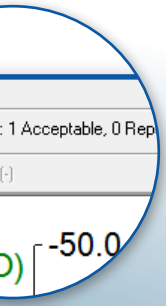
Quickly collect other data types including 6 Minute Walk, High Altitude Simulation Test, SHUNT, and patient reported data / eForms (symptom scores, quality of life information, electronic questionnaires) and associate test results from other respiratory devices (vendor neutral) with the patient visit so they can be reviewed, interpreted, and sent to the EMR using a single interface. These files are attached to your patient's test data throughout the visit workflow, providing more relevant data during test interpretation and for ongoing disease management.

WITHIN-TEST FEEDBACK VALIDATED TO MEET ATS GUIDELINES

Automated test quality checks provide immediate test-specific feedback making it easy to obtain acceptable and repeatable results. This within-test quality feedback has been validated to meet ATS guidelines so you know the data is representative of the patient's best efforts and highly comparable to the conditions with which the predicted values were derived.

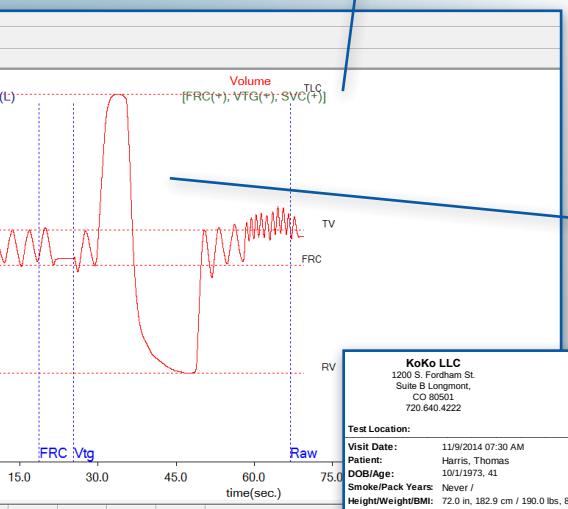
ATS/ERS quality checks provide feedback regarding test-specific acceptiblity criteria

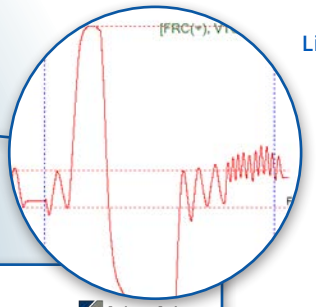




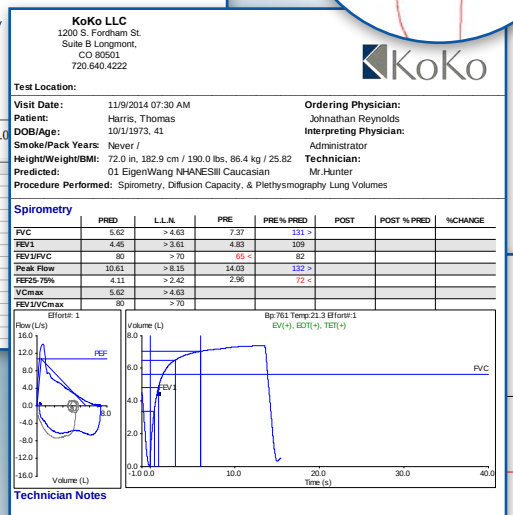
CALIBRATION OPTIMIZATION

KoKo Px software automatically identifies variability with calibration reference standards, such as syringes, helping you avoid common issues such as a heated syringe, that build undetectable biases into your result data. With KoKo Px you can be confident that the results the system displays represent the actual physiology of the patient.



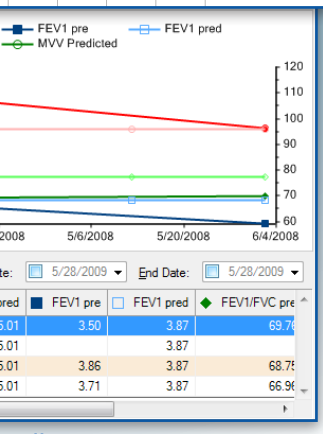


Linked maneuvers shorten overall test time, improving compliance and test results



Enhance Patient Compliance

Incentive graphic automatically adjusts target values based on patient ability, increasing test performance.



g allows you to create viewing
d a different trend for reporting

PROVIDE BETTER REPORTS

Reporting is the most visible output of the PFT lab. KoKo Px features a wide variety of comprehensive, configurable reporting, predicted equation, and automated interpretation options, packaging the complete data in a way that physicians prefer, increasing lab value.

Full PFT Report

KoKo Px software increases lab efficiency with it's easy-to-use interface making the quality of your tests more visible and empowering your lab to produce better, more valuable results helping physicians improve patient care.

SCALABLE & EXTENSIBLE SOLUTIONS FOR COLLABORATIVE CARE

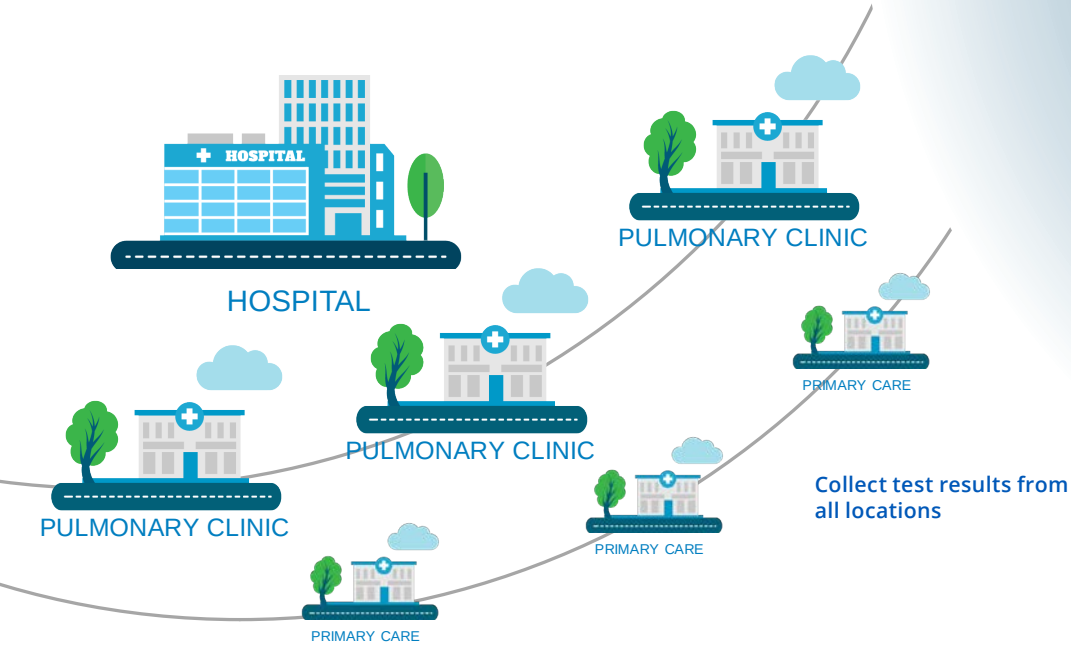
MULTI-SOURCE DATA IN ONE LOCATION

The Iris™ Integrated Respiratory Information System brings relevant respiratory data together in one place, empowering physicians to efficiently analyze and optimally diagnose, stage, and manage respiratory disease. Iris lets you quickly and easily share real-time information and updates with key members of a patient's care team, enabling the most informed clinical decisions, leading to enhanced outcomes and lower costs.

CENTRAL STANDARDIZATION & CONFIGURATION

Increase Efficiency & Reduce Costs

- Modern, Secure, Scalable, Standards-based Architecture
- Enterprise-wide IT security management and central configuration makes standardization across your entire enterprise easier and less time consuming
- Sites, locations, user permissions, reports, inbox workflow, questionnaires, and predicteds are centrally configured. A specific user's settings will follow them no matter where they log in
- Standardization protocols can be seamlessly deployed enterprise-wide and managed from one central location

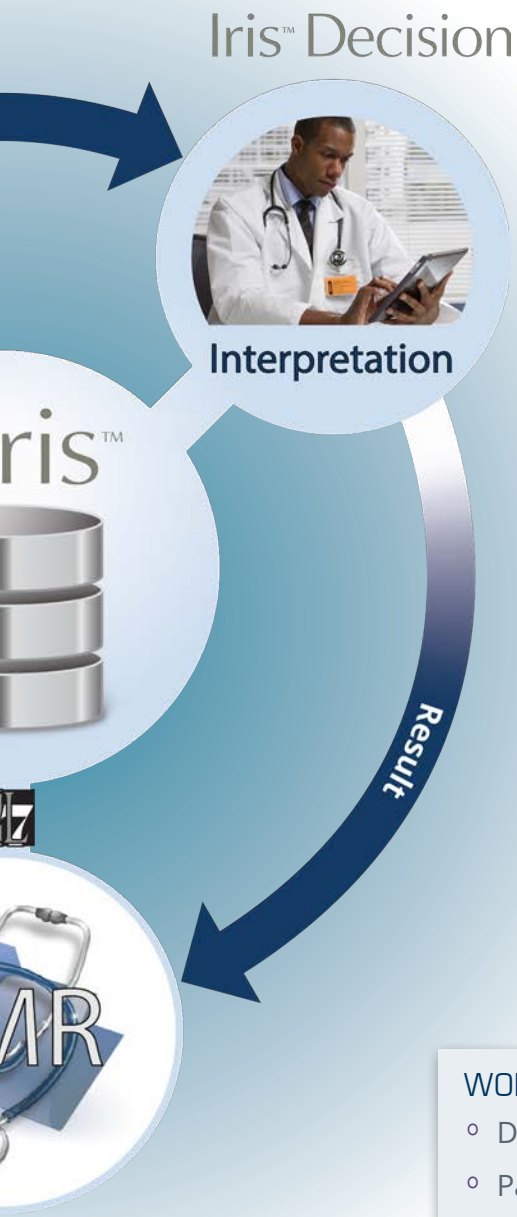


ACCESS TO FUTURE INNOVATION

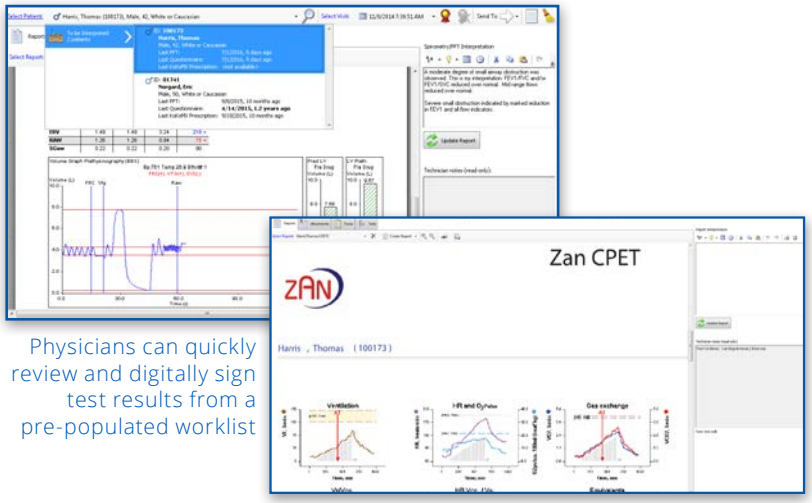
KoKo LLC extensible solution is designed to accommodate new features and capabilities over time and can be easily upgraded based on your facility's changing needs.

DEDICATED PHYSICIAN & PRACTICE MANAGEMENT WORKSTATIONS

Physicians can easily review and interpret patient test data based on the complete picture (including patient reported data and priors) and generate final reports authenticated with a true digital signature at a workstation designed specifically for physicians. Associating interpretations directly with the report before sending along to the EMR ensures your findings are viewed in context by other healthcare providers.



Streamline Physician Access



Physicians can quickly review and digitally sign test results from a pre-populated worklist

Interpretations of external reports are packaged in a single PDF file that can be digitally signed and locked.

SHARE & ACCESS DATA ANYWHERE

Automatically send PFT reports and relevant respiratory data (including eForms) to the next step in your workflow and securely share data with all healthcare providers, between clinics or across the room, from ER to Surgery to Primary Care, without the need for a common EMR or HIS system.

STREAMLINED EMR CONNECTIVITY

Based on a powerful standards-based HL7 interface engine, Iris Connect and Iris work together with any HL7 compliant EMR system to ensure seamless transmission of patient orders and test results without any third party licensing fees.

WORLD-CLASS SUPPORT

- Dedicated support teams ensure maximum KoKo system uptime
- Patented device quality control tools and methodologies provide a cost effective way to introduce a quality assurance program to your practice
- IRIS clinical and technical experts review your specific practice needs, provide custom-fit solutions, and optimize system integration and onboarding

Beyond patient testing, improving patient care requires streamlined data management and access for all healthcare providers that can easily be standardized throughout your entire hospital network

Tests Performed	KoKo Px 3000	KoKo Px 4000N
Forced Vital Capacity	✓	✓
Slow Vital Capacity	✓	✓
Maximal Voluntary Ventilation	✓	✓
Challenge – Chemical, Exercise (Dosimeter Optional)	✓	✓
Pre- & Post- Bronchodilator Evaluation	✓	✓
Diffusion Capacity – Single Breath & 3-EQ	✓	✓
Single Breath Methane Washout Lung Volumes	✓	✓
Maximum Inspiratory & Expiratory Pressures	Option	Option
Nitrogen Washout Lung Volumes – Multiple & Single Breath	✓	✓
Closing Volumes	✓	✓
Plethysmography Lung Volumes	-	✓
Airway Resistance & Specific Conductance	-	✓

KOKO PX TEST OUTPUT SPECIFICATIONS

Providing customers a verification method of output specifications for all testing indications (with limits of precision) are a FDA requirement for manufacturers of medical devices. (CFR 21, 820). Minimum suggestions for device performance are also referenced in the ATS/ ERS Standardization Guidelines for Spirometry, Diffusion Capacity & Lung Volumes. With the industry's best accuracy and precision specifications, KoKo Px, meets or exceeds all current recommendations with 95% levels of confidence. These specifications differ from calibration specifications for sensors, in that device output specifications are pulmonary function measurements; not sensor outputs. Output specifications (those based on the intended use of a PFT device) are now easily verified with 95% confidence using integrated patent pending KoKo Qx Calibration Reference Standards.

TEST OUTPUT	KOKO PX SPEC	ATS 2017 SPEC*
FEV1/FVC	+/- 1%	+/- 2%
DLCO	+/- 2 ml/min/mmHg	+/- 3 ml/min/mmHg
Vi	+/- 2%	+/- 2%
Va	+/- 5%	+/- 5%
TLC-N2	+/- 5%	+/- 5%
Vtg-Pleth	+/- 4%	+/- 4%

*as interpreted by clinical application experts at KoKo LLC

PERFORMANCE SPECIFICATIONS

Physical Specifications

Cart
Size: 53.5-63.5 in H x 22 in W x 33-37 in D (125.7-152.4 x 55.9 x 83.8-94 cm) , 37-42 in D (94-106.7 cm) with printer tray option
Weight: 216.5 lbs (98.2 kg), 231.5 lbs (105 kg) with printer tray option
Mouthpiece Height Range: 37-60 in (94-152.4 cm), 42-65 in (107-165.1 cm) with extension
Mouthpiece Horizontal Reach: 22 in (55.9 cm) from cart, 34 in (86.4 cm) with extension

Cabin
Size: 72 in H x 34 in W x 28 in D (182.8 x 86.4 x 71.1 cm) , 31 in D (78.8 cm) with door handle
Weight: 358 lbs (162.4 kg)
Mouthpiece Height Range: 43.7 - 57.1in (111 - 145cm)
Internal Volume: 980 L
Patient Capacity: 330 lbs (150 kg)
Type: Compensated, Volume Constant
Materials: Aluminum & Safety Glass

Power Requirements
US: 115V, 6.0A
EU: 230V, 3.15A

Ambient Conditions
Temperature: 10° to 35° C (50° to 95° F)
Relative Humidity: 20% to 80%

Gas Requirements
DLCO Mix: 0.3% CO, 0.3% CH4, 21% O2, Bal N2, 43 psi
Nitrogen Washout: 100% Oxygen, 43 psi
Calibration Gas: 5% CO2, 15% O2, Bal N2, 43 psi

GemTach-HD™ Flow Sensor
Type: Screen Pneumotachometer
Resistance (at 14 L/sec): <0.5 cmH2O/L/sec
<1.04 cmH2O/L/sec with KoKo filter
Range: ±15 L/sec

MicroGas-HD™ Analyzer
Type: Electrochemical O2,
Infrared (NDIR) CO, CH4, CO2
Response: <100 msec

AutoFlow™ Gas Delivery
Type: Electromagnetic, Flow Controlled
Resistance: <0.25 cmH2O/L/Sec (1.5 cmH2O) at 6 L/sec

Computer (Provided)
Operating System: Windows 10 Professional, 64-bit
Network Interface: Wired and 802.11ac Wireless

Standards & Regulation Conformance
Industry Guidelines:
ATS/ERS 2005
Quality System Regulations:
FDA QSR, ISO 13485 (CMDCAS, MDD)
Product Testing Standards:
IEC/EN 60601-1, 60601-1-2, 60601-1-6, ISO 26782
European Directives:
MDD 93/42/EEC, RoHS 2011/65/EU

ABOUT KOKO LLC

KoKo LLC is a global respiratory information systems software developer and medical device manufacturing company. We are the exclusive provider and developer of Iris™, the world's first Integrated Respiratory Information System, and KoKo® pulmonary function, diagnostic spirometry, and respiratory home monitoring devices. Together, our expert scalable software solutions and sophisticated data collection products empower healthcare providers to advance respiratory diagnostic processes and improve patient outcomes, while meeting the demanding clinical and business objectives of thought leaders in respiratory care.

References
1. Series "ATS/ERS Task Force: Standardisation of Lung Function Testing", Standardisation of spirometry, Eur Respir J 2005; 26: 319-338
2. Quality control of DLCO instruments in global clinical trials, Eur Respir J 2009; 33: 828-834

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