

Introduction to the Renaissance II Spirometry System

Figure 3. A green LED indicator will light on the front panel of the Renaissance II spirometer and on the AC adapter when properly connected to an electrical outlet.

WARNING



- To avoid risk of electrical shock, this unit should only be used in dry locations.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.



CAUTION:

The Renaissance II Spirometry System and Base Station are designed for use only with the Puritan Bennett AC adapter (P-495208-00). Do not connect AC Adapter (P-495208-00) to an original Renaissance system (PB100/PB110) or damage will result. Conversely, do not connect a PB100/PB110 AC adapter (P-062521-00) to the Renaissance II Spirometry System.

Battery Operation

The Renaissance II spirometer includes a pre-installed rechargeable custom NiCad battery pack. As an option, the user can install 4 AA alkaline batteries or 4 standard AA NiCad cells. (Refer to *Battery Installation* on page 49 for installation instructions.) If NiCad cells are used, an external charger is required.

NOTES:

- The custom battery pack must be charged at least 24 hours before portable use.
- The Renaissance II Spirometry System is designed to recharge only the custom battery pack supplied with the system, and will not recharge batteries from other manufacturers.

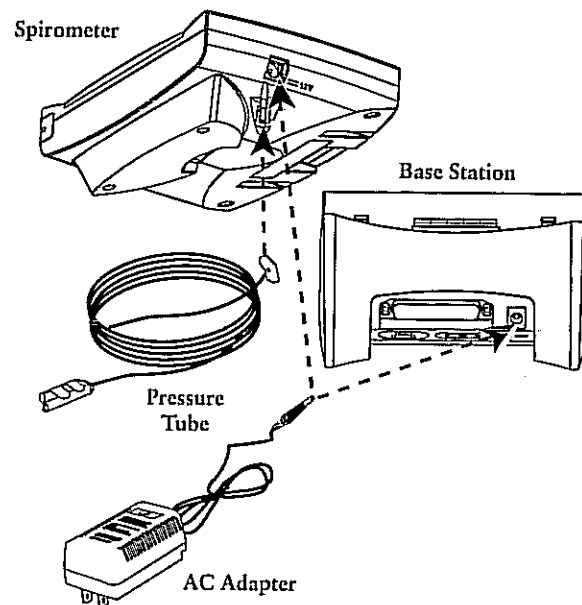


Figure 3: Setting up the System

Technical References

Technical References

Table 9: Product Specifications Renaissance II Spirometer

Dimensions:	5.75" (H) x 7.5" (W) x 2.25" (D)
Weight:	18 ounces
Accuracy: *	Validated to comply with American Thoracic Society Standards for Spirometry (1994) ⁽¹¹⁾
Volume:	±3% of reading or 50 ml, whichever is greater; FEV1, FEV3 and FEV6 measured by back extrapolation
PEF:	±10% of reading or 0.40 L/sec, whichever is greater
FEF25-75% or MMEF:	±5% of reading or 0.20 L/sec, whichever is greater
Volume Range:	0-12 Liters BTPS
Flow Range:	±16 Liters/sec
Resistance:	Less than 1.5 cm H ₂ O /Liters/sec from 0-12 Liters/sec
Test Time:	SVC/FVC/FVL: 30 seconds; MVV: 15 seconds
Display:	3.1" x 2.4" viewable area (78mm x 61mm), 320 x 240 dots
Parameters Measured:	FVC, FEV1, FEV3, FEV6, FEV1/FVC (FEV1%), FEF25-75, FEF25, FEF50, FEF75, PEF, FET, VC, FVC Variability, FEV1 Variability, PEF Variability, FIVC, PIF, FEF50/FIF50%, MVV Time, MVV Rate, FVL, SVC
Memory Capacity:	Stores up to 1,000 patient tests
Adult Predicted Normal Values:	Knudson 1983, Knudson 1976, Crapo, Morris, NHANES III
Pediatric Predicted Normal Values:	Hsu, Polgar, Dockery, NHANES III
Interpretation Criteria:	American Thoracic Society, 1991. Lung Function Testing: <i>Selection of Reference Values and Interpretative Strategies</i> . <i>Am. Rev. Respir. Dis.</i> 144:1202-1218, NHLEP

*Contact Puritan Bennett Technical Support at 1.800.255.6774 for information regarding validation testing.

Table 9: Product Specifications Renaissance II Spirometer (cont.)

Battery:	6V rechargeable (600mAh min. capacity) NiCad battery pack, also supports 4 AA Alkaline batteries or NiCad batteries Charge life: 10-12 hrs. with unit turned ON; approx. 8 days with unit turned OFF <i>NOTE: Do not mix brands or types of batteries. Only the custom battery pack can be recharged using the AC adapter.</i>
Adapter/charger:	Output: 12VDC, 400mA Adapter Input: 120VAC/60 Hz/82mA/9.85VA IEC 601-1 Medical Grade compliant
Operating Temperature:	+17° to +40°C
Operating Humidity:	15% to 95% non-condensing
Operating Altitude: *	Up to 15,000 feet
Storage Temperature:	-20° to +60° C
Storage Humidity:	15% to 95% non-condensing
Storage Pressure:	500hPa to 1060hPa
Equipment Classification	Enclosure Degree of Protection from liquid ingress: IPX1 Applied Parts: Type BF Mode of Operation: Short-time operation Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

* Accuracy specifications are specified for 0-10,000 feet operation.

Table 10: Product Specifications Renaissance II Base Station

Dimensions:	6.5" (H) x 4.75" (W) x 2.5" (D)
Weight:	8oz.
Interface:	Centronics-compatible IEEE 1284 parallel port for printer, custom RS-232 compatible connection for computer interface.
Printout:	8-1/2" X 11" or A4
Adapter/charger:	Output: 12VDC, 400mA Adapter Input: 120VAC/60Hz/52mA/9.55VA IEC 601-1 Medical Grade compliant

Table 10: Product Specifications Renaissance II Base Station (cont.)

Operating Temperature:	+17 to +40° C
Operating Humidity:	15% to 95% non-condensing
Operating Altitude:	Up to 15,000 feet
Storage Temperature:	-20° to +60° C
Storage Humidity:	15% to 95% non-condensing
Storage Pressure:	500hPa to 1060hPa
Equipment Classification	Applied Parts: Type BF Mode of Operation: Short-time operation Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

The FSII Single-Patient Use Flow Sensor

The Renaissance II Spirometry System uses Puritan Bennett's unique, individually calibrated, disposable FSII sensor. The single-patient use sensor eliminates the need to clean or sterilize any part of the spirometry system. The FSII sensor is designed for single-patient use only. This minimizes the effects of cross-contamination.

The FSII disposable sensor is used for all testing procedures. A 6-digit code is printed on the sensor in two forms:

- Numeric code
- Bar code

The code can be entered manually or by swiping the sensor through the bar code reader located on the spirometer. The sensor code contains information about the linearity characteristics of the sensor. The spirometer needs this information to accurately calculate the spirometric parameters. The numeric code is entered with each new patient, each time a calibration check is performed or anytime a new sensor is used. Your supply of sensors should be stored in a cool location. Each sensor should remain sealed in a plastic bag until ready for use.



CAUTION:

- *Use only the FSII flow sensor specifically designed for the Renaissance II Spirometry System.*
- *The FSII sensor is for single-patient use only. In the interest of environmental protection, dispose of all sensors and nose clips properly.*