

*The International Center for Research
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**Puritan - Bennett--the Renaissance™
Spirometry System
Listening to the Voice of the Customer**

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The following case study illustrates how Quality Function Deployment (QFD) was used to enhance sales and profit while satisfying customers and reducing the cycle time of new-product development. We hope that the reader will find the ideas generalizable to a wide variety of markets.

Puritan-Bennett's Boston Division, 1990-1991

Oscar Kaelin, Operations Manager of Puritan Bennett's Boston Division, and Jean Bartlett, Product Manager for Puritan Bennett's new Renaissance™ Spirometry System, had just returned from a very successful product introduction at the September 1991 Trade Show in Las Vegas, NV. At that show their new spirometry system was hailed as the hottest new piece of medical equipment at the show. At the show there were long lines and strong interest from distributors and at the home office the 800-line was ringing off the hook. Early forecasts projected a five-fold increase in sales over 1990 levels.

It had been an exciting, interesting year for Oscar and Jean. In early 1990, the future of Puritan Bennett's spirometry business was in doubt. Puritan Bennett (PB) had two spirometers on the market, each based on a different technology, but both priced at about \$4500. While sales had remained roughly constant, PB's market share had been slipping from 15% in 1988, to 11% in 1989, and 7% in 1990. A major competitor, Welch Allyn, had just introduced a new product, PneumoCheck, at the unheard of price of \$1995. Welch Allyn (WA) was a formidable competitor indeed. Although they were new to spirometry, they were well-known in the medical-equipment market, had a formidable distribution system, and had the projected staying power to make a commitment to the spirometry market. Furthermore, the WA price of \$1995 meant that WA would penetrate the fastest growing portion of the spirometry market, general practitioners (GPs), a portion of the market that PB had found difficult to attract. Indeed, WA's slogan of "You told us, 'Eliminate the extras.'" placed over a picture of bells and whistles suggested that WA provided a spirometer that fulfilled the basic spirometry functions in a low-cost product.

PB faced a real crisis. Without a growth in sales PB would be unlikely to sell enough spirometers to cover costs. However, because their sales reps were already calling on 80% of the hospitals and because PB had a well-established distribution system for physicians who did extensive spirometry testing, PB could not grow without penetrating the GP market. Oscar felt that a concerted effort by R&D could bring down the cost of the Boston Division's primary

product. However, Oscar had enough experience to know that the cost reductions that PB would be likely to achieve would just enable him to hold the line against inflation rather than achieve the 60% price reduction that would be needed to match WA. Emergency changes in product marketing, such as the 5-year warranty that was introduced in 1989, could maintain sales, but they were unlikely to reverse the decline in share nor were they likely to achieve the necessary growth in the market.

Furthermore, spirometry was extremely important to the success of PBs Boston Division. While the division did produce other products, none were as visible nor accounted for the sales impact as spirometers. Sales of other products, such as the Division's Operating Room monitor could not support the Boston Division. Oscar and Jean had to be successful in spirometry.

Spirometry

Spirometry is a simple medical test that requires a patient to inhale and then exhale as hard, as fast, and as long as possible in one long breath. The spirometer measures lung capacity -- the total volume of air in the lungs as well as the amount that can be exhaled in the first second. Some spirometers also measure inhaling ability. Measurements are compared to norms for age, height, sex, etc. and, in the case of prescribed treatment, measurements are compared before and after treatment ("pre/post" measurements).

Spirometry is an important diagnostic tool for a wide variety of illnesses. For example, spirometry is the only test that can detect Chronic Obstructive Pulmonary Disease (COPD) more than ten years before symptoms occur. (COPD is the third most frequent cause of disability and the fifth leading cause of death in the United States.) Spirometry is recommended by the National Institute of Health (NIH) as the test to diagnose and follow asthma. Hospitals routinely use spirometry before surgery so that surgeons and anesthesiologists are aware of any lung function impairment before a patient is operated upon.

Spirometry is growing in importance among GPs who have responsibilities for primary care. Not only has the NIH issued Asthma Awareness Guidelines which recommend spirometry for routine asthma screening, but physicians also use spirometers with pre/post capability to fine-tune treatments right in the office by adjusting the dosage of medication or changing it entirely. Some insurance companies now require spirometry screening -- a requirement that is a new source of revenue for many physicians.

Technology

The original spirometers use a technology of volume displacement. The patient exhales into a tube which is connected to the bottom of a container. The exhaled air fills the volume of the container (often displacing a cylinder). Lung capacity is observed directly as the amount

of volume that the exhaled air displaces. Volume-displacement spirometers are very accurate and are often cited as the "gold standard" of spirometry. But their large size and cost restricts their use to hospitals and large clinics. Another problem, recently made salient with the potential of antibiotic-resistant tuberculosis and other communicable diseases, is that the equipment becomes contaminated with the expired air and must be cleaned often.

In 1974 flow spirometers were introduced. In a flow spirometer the patient blows into a tube, called a pneumotach. At the end of the tube is a membrane that measures the pressure and, hence, the rate of flow of the exhaled air. By integrating the flow rates over the time of the test, a computer or microprocessor can compute the volume of air that was exhaled. Flow spirometers are smaller in size and easier to clean and, in recent years, have proven to be as accurate as their larger volume-displacement cousins. Some flow spirometers measure inhaling capability by monitoring the pressure on the membrane in the reverse direction as well as the forward direction. The majority of flow spirometers use permanent pneumotachs but cap them with a disposable mouthpiece for sanitation. Flow spirometers made their inroads into the market during 1985-1987 and by 1988 most clinics and physicians (who had spirometers) had adopted flow devices. (Many hospitals had the space to retain the volume-displacement spirometers.)

In 1979 Puritan Bennett acquired a company that introduced the first disposable pneumotach, a device which provided an improved level of infection control. In 1989 PB added inhale-measurement capability with the PB900A diagnostic spirometer. (Disposable pneumotachs cost about \$2 for exhale-only measurement and about \$4 for inhale-and-exhale measurement.) In 1982 PB expanded their line to include a volume-displacement device, the PS600 Processing Spirometer.

Products Available in 1990

The PB900A (Exhibit I) was a 14-lb., 4" x 12" x 16", white instrument that is "the ideal instrument for simple, but complete, screening spirometry. It included a keypad to enter data and select functions. Output was produced by a silent thermal printer on 4¼-inch tape. It included a microprocessor for pre/post comparisons and, with the BD250 pneumotach, could record both expiratory and inspiratory lung capacity. PB also sold a PB950 spirometer which provided all the features of the PB900A plus data management.

The PS600 (Exhibit II), a volume-displacement device, is a 16-lb., 9" x 12" x 15", white instrument "designed to meet the challenge of today's demanding medical market." While more bulky than the PB900A, it provided many features including the ability to provide a complete output of patient data and statistical analysis. It was sold to high-volume customers who wanted a low cost per test. (The low cost per test was achieved because the PS600 did not use disposable pneumotachs. In 1991 PB planned to phase out the PS600 to focus on the benefits of disposable pneumotachs.)

The Welch Allyn PneumoCheck (Exhibit III) is a 6 lb., 8" x 7" x 10", black, two-part instrument that "provides a lot more of the information you want for a lot less than you would expect." The reusable pneumotach detaches for easy patient use. It calculates "best effort" and displays the results on an LCD screen. The pneumotach is attached to the base unit for thermal printing and recharging. However, the PneumoCheck did not provide pre/post comparisons nor bi-directional testing capabilities.

Other competitors include Spirometrics (SM) Flowmate (\$3,650), a 9-lb., 6" x 13" x 13" flow spirometer with pre/post capability, visual display, hard-copy output, and serial output to computers and external printers. Tamarac Systems Corporation makes the Presto Standalone Spirometry System (\$2,495), a 5-lb., 9" x 9" x 3" two-part instrument with integrated thermal printer. Both units have disposable mouthpieces, but the flow meters must be sterilized between uses.

Research and Development at Puritan Bennett

Prior to 1990, PB had used a traditional phase-review product development process in which the engineering group draws upon their knowledge of the market, supplemented by inputs from marketing and sales. They had been successful at enhancing spirometers with new technologies such as the disposable pneumotach, but had also experienced cost, time, and quality delays in bringing products to market. The PB engineers had a deep understanding of spirometry, perhaps the best in the market. But it was clear to Oscar and Jean that technology alone would not meet the Welch-Allyn competitive threat. Furthermore, both Oscar and Jean believed that it was important to meet the WA threat quickly. They could not afford delays in the new-product development process.

Quality Function Deployment

On the recommendation of Moe Blais, a General Manager at Puritan-Bennett, Oscar called Mel Klein of Applied Marketing Sciences, Inc. (AMS) to learn more about a product-development technique known as Quality Function Deployment (QFD). QFD had been developed by the Japanese and had been brought to the United States in 1986. Japanese experience suggested that QFD leads to new products that are focused on the voice of the customer and thus more likely to succeed. In addition, there was some indication that QFD could reduce design costs by 60% and design time by 40%. Even if these claims were exaggerated, QFD seemed to be worth investigating.

Mel assured Oscar that QFD was worth exploring. The basic idea was to begin by identifying and structuring customer needs, that is, descriptions in the customers own words of what benefits they want (need) related to spirometry. Once these customer needs are identified and prioritized, Puritan Bennett would then identify the means to fulfill these needs. A formal "House of Quality" would provide a framework to match design goals to customer needs and

solutions to design goals, but even without the formality, a good knowledge of customer needs would provide direction for the R&D effort at Puritan Bennett. (See exhibit IV for a short introduction to QFD and the House of Quality.) Mel indicated that AMS was in the business of providing help with the implementation of QFD and that, through their Vocalyst™ service, they could help PB develop the voice of the customer into a form that R&D could use. Oscar was intrigued.

An Interfunctional Product-Development Team

An important part of the QFD philosophy is that, once identified, the voice of the customer be used to help design and manufacture the product. More generally, QFD stresses that product-development is more successful if there is good communication among all people that are involved in designing, building, and delivering the product to the customer. Jean and Oscar put together a working team drawn from marketing, customer service, sales, engineering, R&D, manufacturing, and management. This team would stay together throughout the development of a new spirometer and would be involved in all market research, all technical design, and all introductory plans. In this way engineering and R&D personal would experience first-hand the expressed needs of the customer; marketing, customer service, and sales would understand the technology behind the product, how that technology was used, and what improvements were likely to be feasible in the future; and the product would be designed for cost-effective manufacture and shipping. Any strategic decisions would be made with full knowledge of the customer and the technology and with the support of the team.

The Voice of the Customer

With help from AMS, the PB new-product-development team got in touch with spirometry customers. Through a combination of focus groups¹ and telephone interviews customers were asked to describe their experiences, indicate how they use spirometers, and make product decisions. When a need or experience is mentioned, the interviewer probes until he (she) achieves a deep understanding of that need from the customer's perspective. The interviews are recorded, transcribed to a typed page, and analyzed carefully. The analysts look for any and all needs that are mentioned including basic needs which the customer assumes that any spirometry system must satisfy and articulated needs that the customer is likely to raise. When possible the analysts seek to identify excitement needs -- those needs which, if fulfilled, would delight and surprise the customer but which are not yet available with any current spirometry system.

Often customer interviews identify as many as 200-400 distinct phrases which express customer needs. To select a strategy for product design, this longer list is distilled to a smaller

¹In a focus group 6-8 customers are brought together to discuss their experience and their needs with respect to the product category of interest, in this case spirometry.

Table 1. Customer Needs

set of primary and secondary needs. This smaller set balances the desire for detail in the engineering design with a desire for the "big picture." Table 1 summarizes the secondary needs that AMS and PB identified for spirometry.

· Product is affordable	· Fast to use
· Easy to operate	· Easy to hold
· Easy to clean	· Right size for patient
· Convenient-sized output	· Easy to set up the first time
· Sanitary	· Easy to calibrate
· Quick service response	· Availability machine/ supplies
· Provides accurate readings	· Good training/education
· Eliminates technician variability	· Sleek appearance
· Good printout quality	· Good printer quality
· Reliability	· Low cost of repairs/service
· Diagnostic information meets needs	· Portability
· Easy-to-interpret diagnostic information	· Effective data storage/ retrieval
	· Environmentally safe

In order to make tradeoffs in the design of a spirometry system, AMS and PB determined the priorities that customers assign to each of the twenty-five customer needs. For example, "product is affordable" is extremely important (100 points) while "effective data handling" is less important for spirometry (48 points). (These are the importances for one segment of the spirometry market. AMS and PB obtained importances for each of the segments in which PB planned to compete.)

The priorities that PB assigns to the customer needs depend upon customer priorities, the costs and feasibility of fulfilling the customer needs, and the grades that customers assign to their existing spirometry systems. For example, affordability, accurate readings, and ease of operation are extremely important -- a new spirometry system must satisfy these needs. Customers give poor grades (relative to competition) to the PB900A on "good printout quality²." Thus, printout quality also represents an opportunity for improvement.

Translating Customer Needs into Engineering Targets

Suppose that PB decides to focus on good printout quality. The words "printout quality" express the customer's concept, but to build a spirometer, these words must be translated into an engineer's vocabulary. In this case, engineering targets are specified in terms of printer resolution, fade resistance, and paper-feed failure rate. Notice that the engineering design attributes are generic descriptions of the spirometry system. They are not solutions such as a 4¼" thermal printer or a build-in, letter-quality, 8½" x 11" printer. Such solutions may be part of the final design that the team develops, but if such solutions are listed in the first House of Quality, they constrain the range of possible solutions. For example, PB might consider having no printer at all but making it easy for the customer to printout spirometry results on another printer that the customer already has in the office. This more creative solution may not have been identified if the technical problem was defined initially as a choice between a 4¼" thermal

²The PB900A was given a grade of 75 (out of 100) while competitors such as Spirometrics were given better grades. Good printout quality is very important (95 out of 100).

printer and an 8½" x 11" letter-quality printer.

In total, PB specified fifty-six engineering design attributes as means to fulfill the twenty-five customer needs. These design attributes are listed at the top of the House of Quality in Exhibit V. The body of the House indicates which design attributes fulfill which customer needs. For example, printer resolution has a strong relationship to printout quality. Finally, the bottom of the House provides measures of how PB and each competitor performs with respect to the design attributes. Also at the bottom of the House is a measure of "absolute technical importance" which is derived from the importances and the customer-need-design-attribute relationships.

Using the House of Quality

Once completed the House of Quality became a vehicle for communication. The House of Quality did not automate PBs design -- the success of the endeavor depended upon the skill of the people involved and upon PBs expertise and experience in spirometry. But the House of Quality did ensure that technical tradeoffs reflected the needs and desires of the customer and that the customer-contact people understood the technical tradeoffs. Throughout the development process the House of Quality provided an organizational history and a framework for making decisions. It suggested areas of investigation and provided a means to evaluate potential solutions. It provided a common language (the customer's language) to discuss and resolve alternative approaches. It made sure that the right information got to the people who needed that information at the time that they needed that information. In short, it enhanced communication and focused the design process on the customer.

Timing

If the Voice of the Customer and the House of Quality seems like a lot of work, it is! The entire process of up-front research took approximately four months. However, one idea behind QFD is to invest time early in the design process to avoid costly redesign and other rework to "get the bugs out" of a product that does not meet customer expectations. QFD's promise, relative to a traditional design approach, is that the total process will be shorter, less costly, and more effective. But four months into QFD, under direct competitive pressure for a rapid response, with no detailed design work yet completed, it required faith for the team not to rush to a quick engineering design.

With the House of Quality complete in October 1990, Puritan-Bennett began to develop a new spirometry system. Engineers studied the House of Quality, proposed solutions, tested these with customers by showing specifications, then a visual model, and finally working prototypes. By September 1991, a new spirometry system was ready to launch. The team's faith was rewarded, the new spirometry system had been designed in record time at an acceptable cost. But the real reward was customer reaction.

Renaissance™ Spirometry System

By the summer of 1991, Puritan-Bennett had achieved the breakthrough they needed. Rather than designing an integrated unit such as the PB900A, they designed the modular system shown in Exhibit VI. Each customer segment could use the Renaissance™ system to best meet their needs. Larger clinics could place it on a desk or laboratory table; clinics or general practitioners, for whom space was a premium, could attach it to the wall or carry it in their pockets. The spirometer could even fit in a briefcase for visits to patients.

In particular, the Renaissance™ system consists of a 5" x 7" x 2" PB100 spirometer which can be run from either an AC adapter or a rechargeable battery. See Exhibit VII. It attaches to a PB110 Base Station for recharging the battery and for downloading patient information to a separate printer. (Puritan-Bennett offers Canon Bubblejet and Citizen Dot-matrix printers as options, but the spirometry system also works with most existing office printers.) Data is stored on removable PB130 Patient Data Memory Cards to provide almost unlimited data storage, the ability to do pre/post analyses, and the ability to share data across spirometers. Naturally, the spirometer uses PB disposable pneumotachs.

Because the user can buy only modules as they are needed, an occasional-screening system (spirometer and base station) is priced at \$1590, \$405 below Welch-Allyn, but with more functions. However, if the customer wants to enhance the PB system to increase productivity for busy routine testing in three or more examination rooms, the customer can purchase the three spirometers, one base station, two charging stations, two memory cards, and a Canon Bubblejet printer for a total cost of \$4,088.

Referring back to table 1, we can see how each of the customer needs are met by the Renaissance™ system. For example, the modular prices give "affordability" for each segment. "Good printout quality" is achieved by using the customer's existing printers (or reselling a Canon or Citizen printer). "Easy to hold" is achieved with the small spirometer and the PB pneumotachs. The system is clearly "portable," especially with the patient data cards. These cards also deliver "effective data storage and retrieval." The five-year warranty/exchange program, made easier to provide and service by the modular design, provides a "low cost of repair and service" (actually no cost³) that signals high "reliability." Etc. In the design, the new-product team chose each feature based on the needs expressed in table 1.

Furthermore, the modularity of the Renaissance™ system makes it easy for future R&D efforts to improve the system with respect to customer needs. ("Reusable design" was one of Puritan-Bennett's company requirements in the House of Quality.) As new printers become

³The customer incurs no out-of-pocket cost. PB dispatches a new unit on the same day and pays all shipping costs to and from the customer. The customer need only place the old unit in the box in which the new unit was shipped, affix an enclosed label, and call. PB arranges for pick-up. In other words, customer service programs were also based on the customer needs listed in table 1.

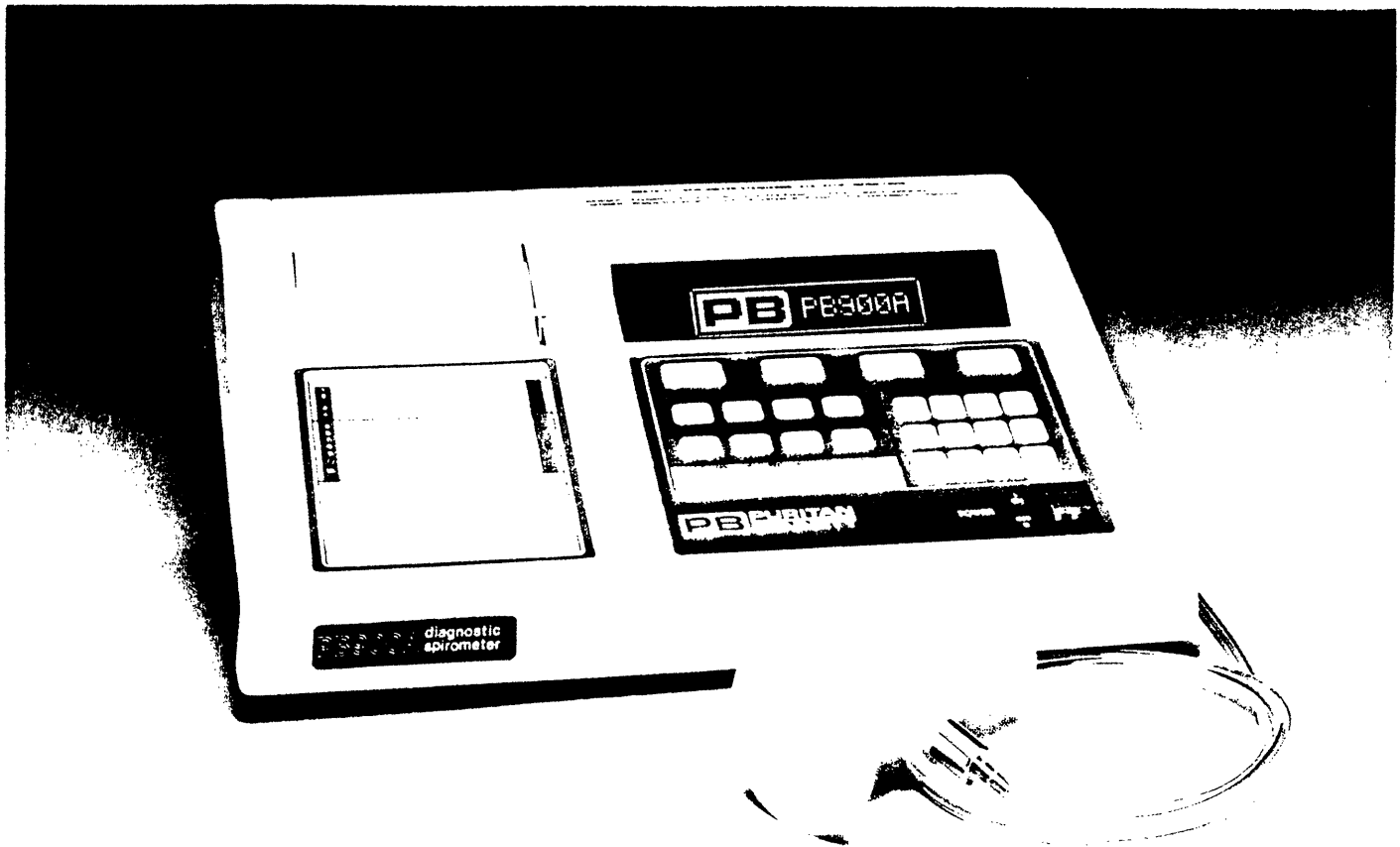
popular, PB can add compatibility. Improved software can add new functions, new pneumotach technology can be introduced without major changes in the spirometer, new modules can be designed to add functions or improve existing functions, etc. With careful management and creative engineering solutions Puritan-Bennett can gain market share, enhance its profits and consolidate its position in the market.

On December 12, 1991, the FDA approved the Renaissance™ system and PB began shipping to customers. Through the next few months they continued to ship all of their production capacity. (The order rate was well above capacity.) Jean and Oscar are looking to expand the PB presence in new spirometry markets.

The Boston Division attributes the success of the Renaissance™ system to the interfunctional cooperation of the new-product team and to the careful use of QFD and the voice of the customer. Not only did the Renaissance™ system satisfy customers and greatly increase PBs market share, but Oscar and Jean both agreed that the development process went faster and more smoothly. The Boston Division is continuing the process to improve the Renaissance™ system and to develop new medical products. They are planning for the future with the full involvement of marketing, sales, customer service, engineering, R&D, manufacturing, and management personnel.

PB900A

D I A G N O S T I C S P I R O M E T E R



Description

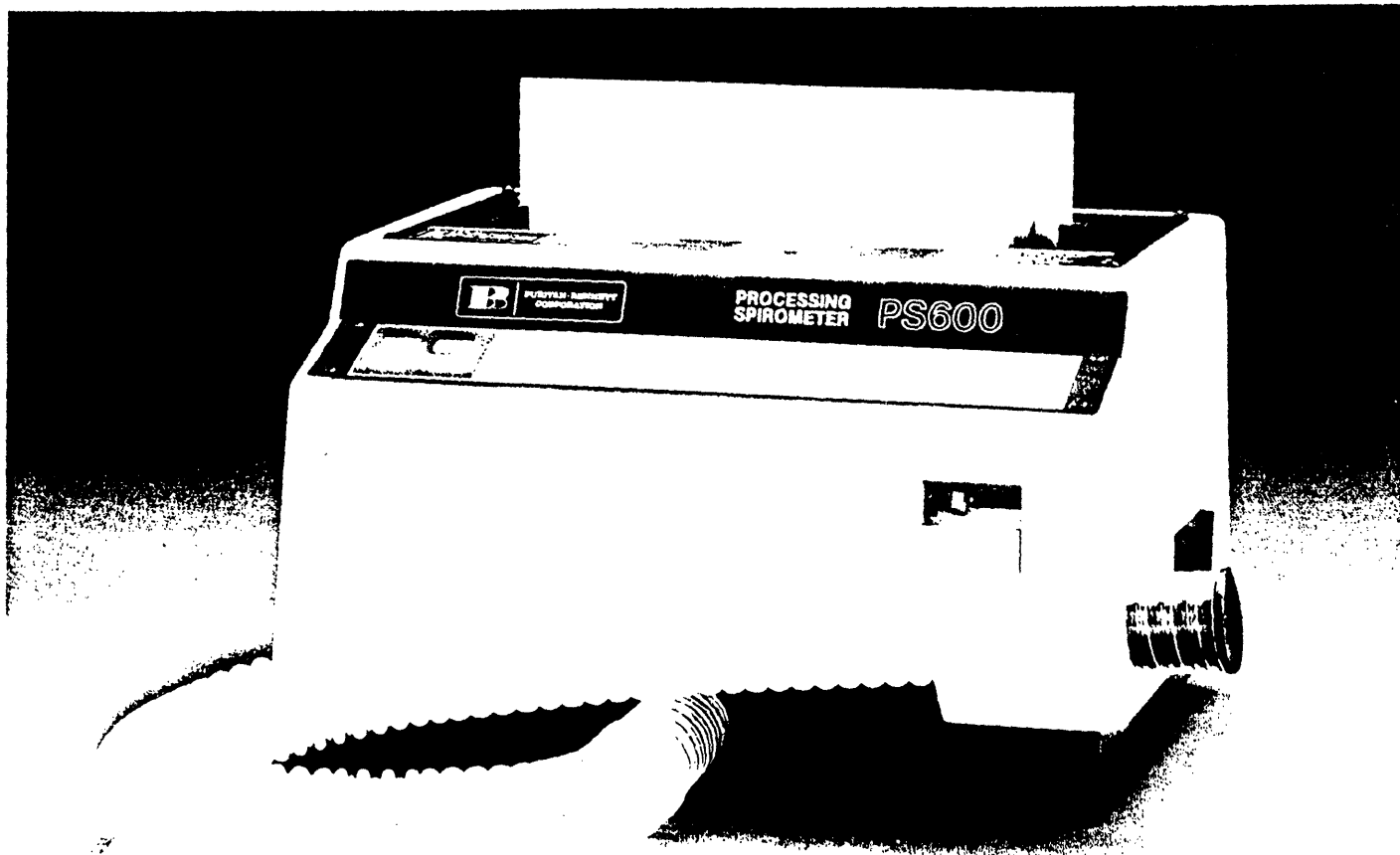
The PB900A Diagnostic Spirometer is the ideal instrument for simple, but complete, screening spirometry. It combines all the necessary pulmonary criteria with flexible programming to meet the specific needs of physician's offices, hospital labs and industrial clinics.

A large fluorescent display, silent thermal printer and modern touch panel keyboard are incorporated into a single compact instrument to make the PB900A today's state-of-the-art automated spirometer.

Like all Puritan-Bennett spirometers, the PB900A Diagnostic Spirometer complies with all published spirometry standards.

Features

- Two disposable pneumotachs: eliminate cleaning and minimize the risk of cross-infection for both patients and staff
 - The FS200 is used for expiratory testing only (FVC, MVV, SVC)
 - The BD250 can be used for expiratory and inspiratory testing (FVC, FVL, MVV, SVC)
- Pre- and post-bronchodilator comparisons
- Large "incientigraph" display of patient's effort
- Suggested interpretation of test results
- RS232C serial port
- Unprecedented 5-Year Warranty Program

PS600**P R O C E S S I N G S P I R O M E T E R**

Description

The PS600 Processing Spirometer by Puritan-Bennett Corporation is the first instrument to combine traditional volume displacement accuracy with a built-in microprocessor for time and labor saving efficiency. Designed to meet the challenge of today's demanding medical market, the PS600 is available in two models to meet the specific needs of hospitals, physicians, and industrial clinics.

The PS600 includes all the basic information for rapid assessment of pulmonary function screening. It includes a hard copy of volume-time tracings along with a tape printout of all test data. Simple to operate, color coded instructions and coaching messages aid the technician in obtaining maximum subject effort and results.

The PS600E model features capabilities of interpretation* and pediatric predicted normals. It also offers industrial users the opportunity to record only the parameters required (FVC, FEV₁, %FEV₁) thereby saving time and facilitating record keeping.

The PS600I model includes an RS232C for interface to personal computers, mainframes, modems, or cassettes, to meet the need of today's information systems. In addition, the PS600I still provides the hard copy printout of data and curves for on-site storage.

*Ellis, Chest; 1975, Vol. 68, P209-213

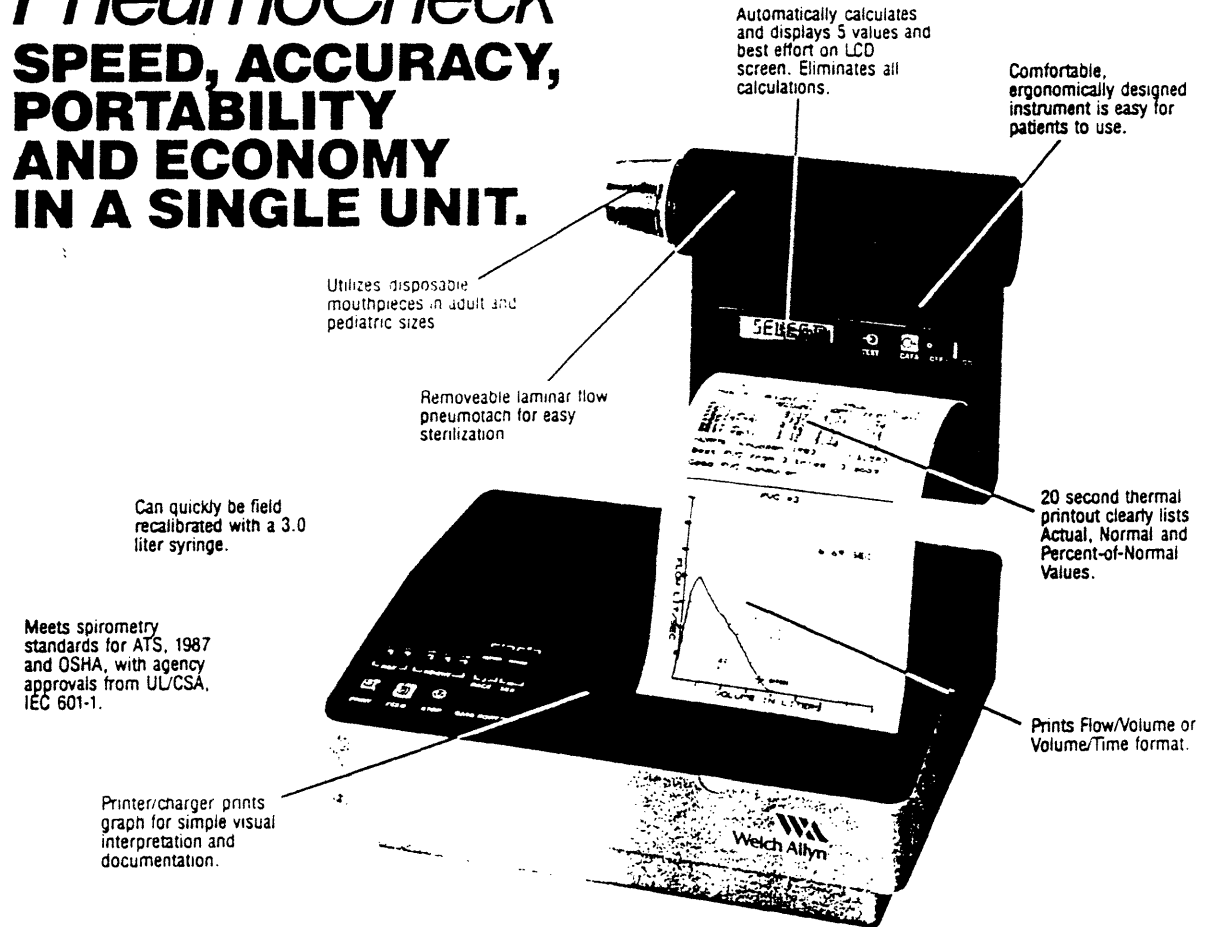
† Morris, et al; American Review Respiratory Disease, 1971, 103:1
Knudson; Federal Register, 6/23/78, Vol. 43, No. 122
Crapo et al; American Review Respiratory Disease, 1981; 123-639-664

Features

- Total automation in a single compact instrument
- File size patient record complete with graph
- Color coded instructions for ease of use
- Available with interpretation, pediatric normals or RS232C interface
- Measures actual, predicted, % predicted; FVC, FEV₁, %FEV₁, FEV₃, FEF 25-75, PEF, MVV, VC
- Choice of predicted normals[†] adjustable for racial correction
- Simple disassembly for ease of cleaning
- Low cost per test
- Complies with ATS, ACCP, NIOSH/OSHA, Social Security published spirometer standards

PneumoCheck™

SPEED, ACCURACY, PORTABILITY AND ECONOMY IN A SINGLE UNIT.



Automatically calculates and displays 5 values and best effort on LCD screen. Eliminates all calculations.

Comfortable, ergonomically designed instrument is easy for patients to use.

Utilizes disposable mouthpieces in adult and pediatric sizes

Removeable laminar flow pneumotach for easy sterilization

Can quickly be field recalibrated with a 3.0 liter syringe.

Meets spirometry standards for ATS, 1987 and OSHA, with agency approvals from UL/CSA, IEC 601-1.

20 second thermal printout clearly lists Actual, Normal and Percent-of-Normal Values.

Prints Flow/Volume or Volume/Time format.

Printer/charger prints graph for simple visual interpretation and documentation.



BUSINESS REPLY MAIL

FIRST CLASS PERMIT NO. 1 SKANEATELES FALLS, N.Y.

POSTAGE WILL BE PAID BY ADDRESSEE



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4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-7900

NO POSTAGE
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IN THE
UNITED STATES

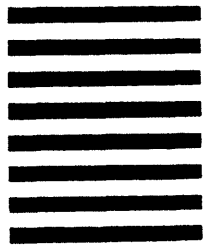


Exhibit IV QFD and The House of Quality

Quality Function Deployment (QFD) was developed in 1972 at Mitsubishi's Kobe shipyard, brought to the United States by Ford and Xerox in 1986 and, in the last five years, has been adopted widely by Japanese, United States, and European firms. In some applications it has reduced design time by 40% and design costs by 60% while maintaining and enhancing design quality¹. QFD helps an interfunctional team of marketing, R&D, manufacturing, and sales work together to focus on product development. It provides procedures and processes to enhance communication by focusing on the language of the customer.

QFD uses four "houses" to integrate the informational needs of the product development team. Applications begin with the first house, the House of Quality (HOQ), which is shown conceptually in figure IV-1. Together the team uses the HOQ to understand the voice of the customer and to translate it to the voice of the engineer.

The Voice of the Customer

Identifying customer needs. A customer need is a description, in the customer's own words, of the benefit which he, she, or they want fulfilled by the product or service. For example, spirometry users stated needs such as the "product is affordable," "easy to hold," "easy to clean," and provides "convenient-sized output."

Normally, discussions with customers identify 100-400 customer needs including basic needs (what the customer just assumes a spirometer will do), articulated needs (what the customer will tell you that he, she, or they want the spirometer to do), and excitement needs (those needs, which, if they were fulfilled, would delight and surprise the customer). However, it is difficult for a team to work with 200-400 customer needs simultaneously.

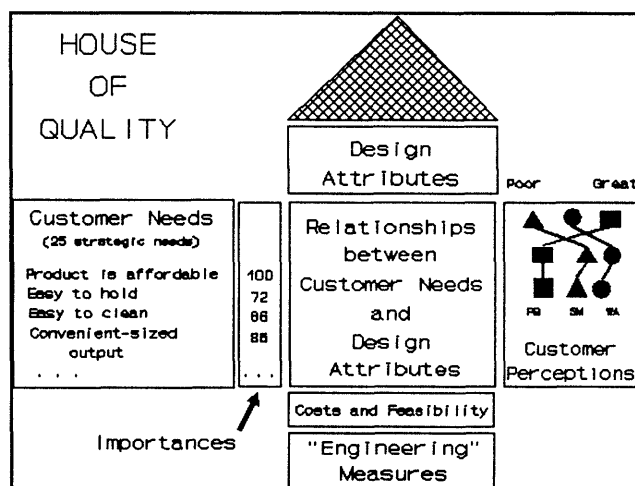


Figure IV-1. The House of Quality

Structuring the needs. To make customer needs manageable, they are structured into a hierarchy. The primary needs, also known as strategic needs, are generally the five-to-ten top-level needs that set the strategic direction for the product. For example, "easy to use" is a strategic need for spirometry. Secondary needs, also known as tactical needs, are elaborations of the primary needs -- each primary need is usually elaborated into three-to-ten secondary needs. These needs indicate more specifically what can be done to fulfill the corresponding strategic (primary) need. For example, "easy to use" is elaborated to "easy to set up the first time," "easy to operate," "fast to use," and "easy to calibrate." In most cases the secondary needs are themselves elaborated to very detailed tertiary needs. Such tertiary needs indicate specifically how the design team can fulfill the secondary needs. (For ease of exposition, we emphasize the secondary needs in the Puritan-Bennett case study.)

Importances of the needs. Customers want their needs fulfilled, but some needs have higher priorities than others. These priorities help the QFD team make decisions which balance the cost of fulfilling a need and the benefit to the customer. For example, if it is equally costly to fulfill two needs, then the need which the customer rates as more important should be given higher priority. Puritan-Bennett measured importances on a 100-point scale.

¹John R. Hauser and Don P. Clausing (1988), "The House of Quality," *Harvard Business Review*, May/June, 63-73.

Exhibit IV, QFD and The House of Quality

Customer perceptions. Customer perceptions describe how customers evaluate Puritan Bennett and competitive products in terms of the spirometry systems' abilities to fulfill the customer needs. By understanding which products fulfill customer needs best, how well those customer needs are fulfilled, and whether there are any gaps between the best product and Puritan-Bennett's product, the QFD team provides goals and identifies opportunities for product design.

The Voice of the Engineer

Design attributes. To fulfill customer needs, the product (or service) must fulfill measurable requirements. For example, if a spirometry system provides hard-copy output, then design attributes might include resolution, fade resistance, paper loading time, printing noise, and paper-feed failure rates. These design measures are listed at the top of the house. They are measured in physical measurement units that become targets for an R&D design. However, they are not product solutions. Solutions come in the second house of QFD. If solutions are specified too early, the R&D process becomes constrained to existing solutions. New, creative directions may be missed.

Engineering measures. Just as we measured competitive products with respect to customer needs, so do we measure competitive products on the physical units specified by the design attributes.

Relationship matrix. The QFD team judges which design attributes influence which customer needs. Each element of the relationship matrix indicates how much (if at all) each design attribute affects each customer need. The idea is to specify the strongest relationships leaving most of the matrix blank (60-70% blank).

Roof matrix. Finally, the roof matrix, shown as cross-hatched lines in figure IV-1, quantifies the physical interrelations among the design attributes.

33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	1	2	3	4	5	6	7	8	9	10	
Time to re-calibrate (min)	Patient Interface	Time to clean (min)	Mouthpiece cross sectional area (sq cm)	Height of sensor (kg)	Grip perimeter (cm)	Waste per patient (gm)	Bioburden on reusables after test	Data Storage	# of patient records stored	Time to retrieve patient record (min)	Time to do patient trend (min)	Data xfer to computers (y/n)	Equipment/service dependability	Time from order to shipment for machine (day)	Time from order to shipment for supplies (day)	Instrument Failure rate (%failures/100/yr)	Customer downtime (days)	Other	Target date for 1st production run	Schedule for follow-up product releases	Price of base machine (\$)	Price of product upgrades (\$)	Price of disposable (\$)	Overall Importance	Customer Importance	Sales Points	Ratings	P8800A	Spirometrics	MED	CDX	Helich Alllyn		
22 726																								150	100	1.5							1	
																								77	77	1.0							2	
																								59	59	1.0							3	
																								90	90	1.0							4	
																								77	77	1.0							5	
																								100	100	1.0							6	
																								148	100	1.4								7
																								90	90	1.0								8
																								90	90	1.0								9
																								85	88	95	92	75						10
																								48	48	1.0								11
																								94	86	1.1								12
																								95	95	1.0								13
																								85	85	1.0								14
																								130	100	1.3								15
																								90	90	1.0								16
																								88	88	1.0								17
																								100	100	1.2								18
																								86	86	1.0								19
																								80	80	1.0								20
																								90	90	1.0								21
																								90	90	1.0								22
																								100	90	1.2								23
																								86	86	1.0								24
																								90	90	1.0								25
																								45	45	1.0								26
																								72	72	1.0								27
																								88	88	1.0								28
																								88	88	1.0								29
																								84	84	1.0								30
																								80	80	1.0								31
																								80	80	1.0								32
																								100	100	1.0								33
																								80	80	1.0								34
																								80	80	1.0								35
																								1	2	3	4	5	6	7	8	9	10	

Maximum value = 100.0
 O---P8800A
 ▲---Spirometrics
 □---MED
 ●---Helich Alllyn

Minimum value = 50.0

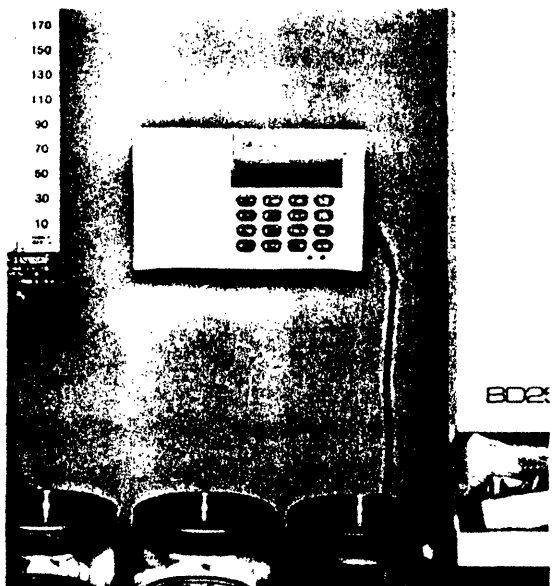
Exhibit VI -- Uses of the Renaissance System



... on the desk



... in your pocket



... on the wall



... on the go



Description

The Renaissance Spirometry System is the simply sophisticated answer to pulmonary function testing. The system features a hand-held spirometer (PB100), offering true portability.

The patient data memory card (PB130) and the rechargeable batteries allow testing of multiple patients away from the office or the pulmonary laboratory.

The base station (PB110) is used for downloading patient information to a choice of two printers available from Puritan-Bennett or to most IBM or Epson-compatible printers. The RS232C port provides the option of sending data to a computer.

A file-size report includes test results compared to a choice of three adult and two pediatric predicted normal values, as well as results from pre- and post-medication testing.

A convenient charging station (PB120) and a wall mount bracket are also available.

The Renaissance spirometer has been validated by an independent laboratory to comply with the 1987 ATS Standards for Spirometry*.

*Independent validation of the American Thoracic Society (ATS) recommendations performed by Robert Crapo, M.D., LDS Hospital, Salt Lake City, Utah. Copy of validation results available from Puritan-Bennett upon request.

Features

- Two disposable pneumotachs eliminate cleaning and minimize the risk of cross-infection for both patients and staff
 - The FS200 is used for expiratory testing only (FVC, MVV)
 - The BD250 is used for expiratory and inspiratory testing (FVC, MVV, FVL)
- Choice of synergistic components for a custom system design
- Rechargeable batteries and hand-held design for true portability
- Integrated miniature memory card allows multiple patient storage
- Audio and visual effort incentive
- Built-in quality assurance program
- 8½" x 11" printout
- Unique 5-year warranty/exchange program

Specifications*

Exhibit VII, continued

Renaissance Spirometry System

PB100 Spirometer

- **Dimensions:** 4½" H × 7¼" W × 1¾" D
- **Weight:** 15 oz
- **Accuracy:** Validated to comply with American Thoracic Society Standards for Spirometry (1987 update).
Volume: ± 3% of reading or ± 50 ml, whichever is greater. FEV₁ measured by back extrapolation method.
Flow: ± 5% of reading or ± 200 ml/sec, whichever is greater.
MVV: ± 5% of reading.
- **Volume Range:** 0-12 liters BTPS
- **Flow Range:** - 16 to +16 L/sec
- **Resistance:** Less than 1.5 cmH₂O/L/sec
- **Test Time:** FVC/FVL - 30 seconds; MVV - 12 seconds
- **Display:** Supertwist LCD
- **Parameters Measured:** FVC, FEV₁, %FEV₁, FEV₃, FEF25-75%, PEF, FET, FIVC, PIF, FEF50%/FIF50%, MVV
- **Test Quality Criteria:** Enright PL, Johnson LR, Connert JE, Voelker HT, Buist AS: Spirometry in the Lung Health Study: Methods and Quality Control, *American Review of Respiratory Disease*, June 1991
- **Battery:** 36 V rechargeable NiCad battery pack
- **Power Source:** AC adaptor/charger: 105-130 VAC 60 Hz or 200-260 VAC 50 Hz
- **Warranty:** 5-year exchange program in compliance with Puritan-Bennett Form #063187

PB110 Base Station

- **Dimensions:** 6" H × 5½" W × 3" D
- **Weight:** 1 lb, 3 oz
- **Function:** Provides docking for the PB100 spirometer to charge the NiCad battery pack and interfaces with most external IBM or Epson-compatible printers to produce a data and graphic report.
- **Printout Size:** 8½" × 11"
- **Graph Size:** Selectable - diagnostic size or hand-validation size
- **Graph Options:** Flow-Volume and/or Volume-Time format
- **Predicted Normal Values:**
Adult: Morris et al, 1971; Knudson, 1983;
Crapo (ITS THORACIC), 1981
Pediatric: Polgar, Hsu

- **Interpretation Criteria:** Enright PL, Hyatt RE; *Office Spirometry: A Practical Guide to the Selection and Use of Spirometers*, Lea & Febiger, 1987
- **Interface:** Centronics-compatible parallel port for printer, RS232C-compatible serial port for computer interface
- **Power Source:** Uses AC adaptor supplied with PB100 spirometer
- **Warranty:** 5-year exchange program in compliance with Puritan-Bennett Form #063187

PB120 Charging Station

- **Dimensions:** 6" H × 5½" W × 3" D
- **Weight:** 1 lb, 3 oz
- **Function:** Provides docking for the PB100 spirometer to charge the NiCad battery pack.
- **Power Source:** Uses AC adaptor supplied with PB100 spirometer
- **Warranty:** 5-year exchange program in compliance with Puritan-Bennett Form #063187

PB130 Patient Data Memory Card

- **Dimensions:** 3.37" L × 2.12" W
- **Function:** Stores patient test information for future printing; interfaces with the PB100 spirometer or the PB110 base station.
- **Battery:** 3 volt Lithium (CR2016 or equivalent).



PB300 Calibration Syringe

- **Capacity:** 3 Liters
- **Warranty:** 1 year in compliance with Puritan-Bennett Form #063005

*Specifications are subject to change without notice.

Ordering Information

- 000100 PB100 Portable Spirometer (Includes AC Adaptor, NiCad Battery Pack and Protective Pouch)
- 000110 PB110 Base Station (Includes Printer Cable)
- 000120 PB120 Charging Station
- 000125 Wall Mount Bracket
- 000130 PB130 Patient Data Memory Card
- 000150 Canon Bubblejet Printer (Includes Automatic Paper Feeder and AC Adaptor)
- 000160 Citizen 200GX Dot Matrix Printer
- 000170 Soft Nylon Carry Case (For Spirometer and Base Station)
- 000300 3-Liter Calibration Syringe

FS200 Disposable Expiratory Flow Sensors

- 000200 Box of 50
- 000201 Bulk Pack of 250

BD250 Disposable Bidirectional Flow Sensors

- 000250 Box of 25
- 000251 Bulk Pack of 100

- **Authorized Service Location:** 1-800-255-6774, Option #1, Wilmington, MA

For product and distributor information call: 1-800-842-8023. Fax: 508-657-8305. For order information call: 1-800-255-6773.

PB PURITAN BENNETT BOSTON DIVISION
265 Ballardvale Street
Wilmington, MA 01887

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