

Device and Equipment Evaluations

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Device evaluation, which is an essential skill set for the respiratory therapist, ranges from comparing manufacturer's specifications to comprehensive device testing, either with patients or on the bench. Good device evaluations help guide decisions about device selection, procedure development, and risk and failure analysis. Poor evaluations cost time and money and fail to return value. Manufacturer's specifications alone are poor criteria for device selection, because of how and why those specifications are created and the potential gap between the manufacturer's test methods and the complexity of clinical situations. Proper clinical evaluation of devices with patients requires extensive preparation and resource expenditure, and clinical evaluations may not allow isolating key variables to determine specifics of device performance. In vitro testing, using models to simulate discrete components of device/patient interface, is less expensive and easier to conduct. This article discusses the process of experiment design and model development for device and equipment evaluations. *Key words: device evaluation, models, in vitro testing, research methodology, laboratory research, clinical trials, safety.* [Respir Care 2004;49(10):1157–1164. © 2004 Daedalus Enterprises]

Introduction

Every time you select a tool to use for a particular job, you are participating in an aspect of device evaluation. However, device evaluation is more often discussed in the context of management activities¹ than of research.² Making good decisions about whether to use existing technology or to adopt new technology requires accurately differentiating between device options and performance. Device evaluation has huge economic impact on our organizations and profession. These decisions are based on various levels of research and evaluation. The best decisions are based on the best research. The research ranges from comparison of price and manufacturer specifications to in-house evaluation with extensive clinical use prior to a purchase decision. Rigorous device evaluation can help you and your organization select the best device for the best price or to analyze and avoid device failure during use. All research takes time and has associated costs, but good research provides value, whereas poor research just consumes time and money without adequate return on that investment. Proper planning and execution is the key to cost-effective, high-value, device evaluation.

Definition of Device Evaluation

Device evaluation helps determine how a device functions or performs and its ability to provide value or meet a need in the clinic. This includes assessing new and existing technologies, with activities ranging from simply comparing advertising, reviewing the literature, seeing the device at a meeting, or receiving a demonstration, to evaluating how the device works under simulated (ie, bench or in vitro) conditions, and observing or testing the device with patients. More than just guiding purchasing decisions, device evaluations can help to determine how best to apply the technology, and can identify device limitations or failures so that risk from the device can be reduced or eliminated.

Who Should Evaluate Devices?

Device evaluation is a mainstream activity for respiratory therapists, performed in collaboration with various

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Table 1. Who Should Be Involved in Device Evaluation

Managers and supervisors
Clinical staff
Care providers
Team members
Nursing staff
Physicians
Primary users of the device
Support Services
Biomedical
Central supply
Central processing
Patients
Students
Educators

Table 2. When to Evaluate Devices

To assess new technology
-Ask if it performs to the manufacturer's specifications
-Identify advantages
-Identify disadvantages
-Evaluate interface
-Evaluate safety
To understand existing technology
-Ask how it performs
-Differentiate performance among device types
-Analyze device failure
When making purchasing decisions
-Establish suitability for use in clinical practice
-Establish cost/benefit relationship
-Undertake comparative analysis across device options
To assure proper device performance
-Test (functional check) routinely prior to each device use
-Re-create situations to identify possible device malfunctions
-Isolate performance problems to guide repairs and fix problems in the field

other practitioners, in home^{3,4} and hospital⁵⁻¹² settings. Device evaluation is an important aspect of any technical medical specialty such as respiratory care, and should be done by a range of individuals (Table 1), for various reasons (Table 2). Device evaluation is not an arcane activity relegated to researchers outside of the context of mainstream respiratory care.

Why Evaluate Devices?

Devices are evaluated to determine if they will be useful and serviceable tools in a specific environment or situation. The goal is to match the device options with the job at hand. We evaluate devices to learn what they can and cannot do. It is arguably more important to know the device's limitations than how it performs against published

specifications. Most marketing data emphasize what a product *can* do and avoids describing what it can *not* do. All devices have limitations, and you must identify those limitations prior to adopting the device, to ensure that you will not put your patients at risk by expecting more than the device can deliver.

Few consumers would buy a car without a test drive, so of course no one would buy a major piece of capital equipment without some form of test drive. Even a disposable supply item, such as a pulse oximeter probe, can account for hundreds of thousands of dollars of expenditure over the course of a year, so whether considering a large or seemingly small item, it generally pays to evaluate devices prior to adoption or purchase.

Testing to Specifications

Just as “you can’t judge a book by its cover,” it is difficult to evaluate a device based solely on its manufacturer’s specifications. In the realm of medical devices there is little standardization of how key specifications are set and measured. In fact, few manufacturers provide sufficient detail as to how they test their devices, so clinicians usually cannot reproduce the manufacturer’s testing experiments to verify the manufacturer’s claims. This is in part a consequence of how specifications are created in the product development process.

Where Do Manufacturer Specifications Come From?

Most products start conceptually, in a manufacturer’s marketing department, with the generation of a *customer requirements document*, which describes what the device should look like, how it should perform, desired specific functions, range of performance, size, weight, and patient interface, so that target consumers will buy it. This is the “wish list” from the marketing department to the product design team. The design team reviews the customer requirements document and begins to separate real engineering possibilities from wishful thinking, identifying the limits of available technology that can be included in the device design. The *design input requirements* document is the engineering translation of what the proposed product will need to do to fulfill most of the marketing requirements. The design input requirements document refines the wish list from the customer requirements document, producing a more realistic specification target to which the product will be designed. Every specification requires testing to demonstrate that the device meets or exceeds the specification. To succeed and be released the device will have to pass each test. *Design verification testing* is bench testing to determine that the device will meet the performance specifications in relation to the design input requirements.

In the United States, many medical device manufacturers pursue “510(k) clearance” from the Food and Drug Administration (FDA), which means that the FDA determines that the new medical device performs similarly to other previously FDA-cleared “predicate” devices. This requires new-product claims and specifications to be based on predicate devices that have been marketed and sold in the United States. This raises the question: if the devices are the same, how can a new device be different? A 510(k) submission process may include a patchwork of attributes and specification from several predicate products, in support of a new product application. The 510(k) clearance allows the manufacturer to market a new device without the extensive and expensive clinical testing that would be required if the new device had no predicate device. Consequently, newly 510(k)-cleared devices may not have been used or tested clinically prior to marketing and sale.

For the clinical user the biggest questions are (1) how well have the marketing group and design team divined what characteristics will meet real clinical needs? and (2) how accurately did their design verification testing reflect how the device will actually be used? Your methods to test or check a particular specification may be considerably different from those used by the manufacturer.

Economic Argument for Proper Device Evaluation?

Even the best designed product might not work well in your clinical setting. During clinical use nothing can change the function of a device like sputum or other bodily fluids. Competitive devices may have similar manufacturer specifications but function quite differently in your evaluation. If the device looks good and has great specifications but does not work well with your patients, it’s a waste of money for your institution.

With shrinking financial resources in our health care organizations, research is often seen as a nice but not necessary activity, and it is one of the first line items to disappear from a department’s budget. That is a short-sighted approach that can result in massive misallocation of funds in both device acquisition and day-to-day operations. Just as you can’t judge a book by its cover, you can’t predict how a device will perform from the manufacturer’s specifications. Capital and operating funds can be wasted on a poorly researched purchase. The manager or purchasing agent who purchases a fleet of new ventilators without carefully researching and comparing the available ventilators may find that the units perform as advertised but do not meet the needs of the patients and clinicians. Too many departments have a corner of their equipment space dedicated to very expensive and rarely used equipment that was not carefully researched before purchase; these “boat anchors” collect dust for years until they are unloaded or replaced. In those situations no one wins: the

manager is perceived as clueless, staff has to muddle through with inferior equipment, and even the manufacturer of the device who “won the bid” loses in the long run, because people in the department will “bad mouth” the equipment to peers in and out of the institution.

From capital equipment to disposable supplies commonly used at the bedside, there are a number of manufacturers offering competitive devices. They all claim their products work well and have similar specifications, so how is the consumer to choose? A bad choice can waste a great deal of money. The goal is always to select the device with the best performance at the lowest cost. It is incorrect to assume that the most expensive device will be the best device for your needs. Often the item with the highest or lowest price is not the best option for a specific situation, and price is an inadequate basis for device selection.

Why Clinical Trials?

Determining whether the device will work in your clinical environment is critical, and clinical testing is ultimately the best evaluation. Clinical experience in your environment with feedback from your staff is very valuable, but very expensive. Bench studies cannot determine the suitability of the interface between the device, the user, the patient, and support systems. Many an attractive device or technology has failed in clinical use. But clinical trials are the most expensive form of evaluation, and some aspects of device performance cannot be readily determined during patient use.

Like any research, clinical trials can be done poorly or well. Relying on the results of a poorly designed bench study could bring a new device into the clinic for evaluation that could be dangerous and could, in the long run, be even more expensive than a well designed trial. Consider a hypothetical manager who brings a new ventilator or device into the intensive care unit in the middle of the day shift, using it with a critically ill patient and observing its performance over a few hours until comfortable that it is working to his or her satisfaction, and possibly even benefiting the patient. The manager or a physician on duty decides to leave the patient on the device, with a few minutes of orientation provided to the staff coming in for the next shift, including giving them the instruction manual and directing them to provide similar instruction to the following shift. This type of impromptu evaluation places the patient, staff, and hospital at tremendous risk, while all but guaranteeing that the clinical evaluation will yield no valuable data. Failure to provide proper staff training will result in little if any usable information. This type of poorly-structured, impromptu evaluation may be grounds for having the manager’s license revoked for reckless patient endangerment.

Table 3. Steps in Planning a Clinical Evaluation of a Device

Select the device to be evaluated
Review device instruction manual
Develop policies and procedures for device use
Validate procedures
Create competency check-off sheet (for training device users)
Develop tool for collecting feedback from users
Train all staff who will use the device
Allow time for staff to “play” with the device
Simulate use prior to actual clinical use
Use the check-off sheet to test users’ competency with the device
Acquire enough units of the device for sufficient duration to gain experience: 2–4 devices evaluated for 2–4 weeks
Conduct biomedical safety evaluation and electrical checks prior to clinical use
Solicit, collect, and interpret user feedback

Planning Is Key

A good in-house device evaluation in a clinical setting requires considerable planning and training, with a big investment in staff resources that can easily cost more than \$10,000 for each device evaluated. Table 3 shows the steps in a well planned evaluation.

Once you narrow down the candidate devices to be evaluated, you need to make arrangements to have one of the devices on hand while you review its instruction manual and develop the policies and procedures for the device, develop a competency check-off sheet, training materials, and a feedback collection instrument prior to beginning the clinical evaluation. After those materials are prepared, all staff who will be using the device need to be trained in its use, with return demonstration required to evidence the device’s proper use, and successful completion of the competency check-off sheet. Make the device available for staff to “play” with between training and the beginning of the clinical trial. Before clinical use the device may need to be inspected by the biomedical department and certified safe to use in your clinical environment.

At the beginning of the trial, have a sufficient number of the devices on hand so that the staff can get meaningful experience in a reasonably short period (2–4 weeks).

The device’s “champion” must be available to support the staff during their first clinical uses of the device. The feedback instrument must be easily accessible to the staff, and you must encourage the staff to submit feedback frequently. The feedback instrument provides your primary concrete evidence of how the device performed and how the staff liked it.

The steps listed above represent a comprehensive and rather expensive process. Before your institution and the device manufacturer/distributor goes to the expense of in-house clinical evaluation, efforts should be made to deter-

Table 4. Common Problems in Bench-Study Device Evaluations

Attempting to determine too much in a single experiment
Weak model
Inaccurate measurements
Device improperly or inconsistently used
Data not consistently or accurately recorded
Too few experiment repetitions
Wrong statistical method
Record of methods and/or data are incomplete or scattered, thus experiment is not reproducible
Results are not reported to full impact

mine which technology or device is worth that level of commitment. That can be best determined with a systematic device evaluation process.

Why Bench Testing?

Bench testing is easier, cheaper, and faster than clinical evaluation. Patients are complex and fragile, and many variables affect how they react to and interface with a device, so it is difficult to make easily interpretable measurements and observations. With a clinical study it is impossible to determine the limits of device performance, because those limits exceed appropriate patient treatment. In contrast, bench testing allows isolation and thus better measurement of key variables. Bench testing allows you to better understand how and when the device works—and does not work. This may provide vital information for determining, prior to clinical use, how to take advantage of the device’s attributes and how to avoid or compensate for its deficits. If the results of a bench study correlate to clinical experience, then the bench model can be taken as a reliable predictor of in vivo results.¹³

Limitations of In Vitro Testing

Whereas patients can be too complex, in vitro tests can be too simplistic. Table 4 lists common problems in bench-study device evaluations. Bench testing cannot simulate the complexity of in vivo interactions, and care must be taken not to over-interpret bench-test results for a single tested variable. In vitro tests are only as relevant as the specific model being used. The less like a real clinical situation the bench model is, the less relevant the findings. In addition, bench-test results are only as accurate as the instruments used to conduct the test.

Steps in Device Evaluation

Effective device evaluation requires planning and discipline. Just like your laboratory activities in the classroom, it is important to clearly identify the question you

wish to answer, what materials you need, how you will perform the tests, and how you will process the data. The better you determine those things prior to the test, the better your chance of successfully answering the question. Attention to several key activities will help to assure that the device evaluation will achieve its goals and provide valuable information. The first of these is to establish the goals of the evaluation; this is facilitated by doing background research.

Background

Background information should be gathered and reviewed prior to initiating any evaluation, and should be the first step in establishing your objectives and hypothesis, as well as identifying the components of successful models. This is the initial process to determine what your needs are, what you want to know about the device, and what information already exists (eg, reviews, reports, and other published materials).

As you determine what you want to know about a device, you need to find out who else may have asked or answered the same or similar questions. A literature search can help you identify previous reviews, product alerts, and published research. If the previous research answers your questions, then you have saved considerable effort. If the literature does not answer your questions, it may lead you to components of a validated method that can help you answer your questions.

Safety alerts and recalls can be found at the Web site of the Food and Drug Administration’s Center for Devices and Radiological Health (<http://www.fda.gov/cdrh>). Many biomedical departments subscribe to device evaluation services such as ECRI (formerly the Emergency Care Research Institute), which is an independent, nonprofit health services research agency that performs comparative device evaluations and reviews. ECRI publishes monthly publications such as *Health Devices* and *Health Devices Alerts*. Their searchable *Health Device Index* is at <http://www.ecri.org>.

Reports indexed in *Index Medicus* can be searched via the National Library of Medicine’s PubMed Web site (<http://www.pubmed.gov>).

Let the device’s instruction manual be your guide. Many device evaluations have been undermined by not operating the device in accordance with the manufacturer’s recommendations. The manufacturer’s specifications and directions for use are essential reading prior to designing a device evaluation. It is also reasonable to ask the device manufacturer for contact information and references from current customers to help identify key performance issues that you might want to investigate.

Objectives/Hypothesis

Once you complete the literature review and background research, you should state your objectives or hypothesis, possibly in the form of research question. This is a statement of what you want to know, and it should identify critical performance issues and should move from general to specific. The specifics may become the basis for your methods.

Methods

With your goals or research statement clearly in mind, determine how you are going to answer the question. Identify what devices and supplies you will need and the specific steps you will take in the study. Model design is based on simulating a subset of the (more complex) “real world” clinical application. How is the device typically used and what tools and material resources do you have available to make a model of clinical use?

The best models are often the most straightforward, made from readily available components. Most departments have simple test lungs, pressure manometers, calibrated flow meters, and gas analyzers. Be resourceful in finding local resources that you can access for your study. If you need to do cultures or assay drugs with your model, identify who in your institution has the resources and ask them to collaborate in the study. I have been delighted as to how often people are willing to help.

Determine how you will make your measurements. Define how you will measure the interactions between the device and the model. For example, in a study of an aerosol device the aerosolized drug is typically collected on a filter placed between the nebulizer and the lung simulator. The drug is washed or eluted from the filter and analyzed (assayed) to determine the amount of drug that deposited on the filter. It may be reported as μg of drug or as a percentage of the total drug placed into the nebulizer. In contrast, the measurements with a ventilator/lung model may be changes in airway pressure, measured with a manometer or a pressure transducer, volume displacement changes in the lung compartment, or even gas concentration measurements from an in-line gas analyzer. In all those cases you should have a method to calibrate the model to assure that you are getting accurate readings for each series of tests performed.

Design Your Model

Keep your model as simple as possible. The model must be straightforward, easy to use, and able to make consistent, reproducible measurements.

Once you have the key components together, take time to “play” with your model. Operate the device at the ex-

tremes of expected performance ranges. Try various model components and device/lung interfaces, making initial measurements, and develop confidence that the model simulates what you want to explore. Once you are satisfied with your model’s performance, write your methods section.

Describe your model in sufficient detail that it could be constructed by someone who has not seen it. List all devices, materials, and supplies. Include detailed, step-by-step instructions of how the model was constructed, calibrated, and used. The more detailed your description of each step, the more consistently it can be applied. Be sure to specify the number of repetitions of each measurement. For in vitro testing, 3–5 repetitions are generally sufficient to determine if the differences are statistically significant.

Determine how data will be collected and analyzed. Draft a data collection sheet that flows with the steps of your research. Data sheets should identify the date and time of the experiment, who performed the experiment, and who audited the data. Reference your methods on the data collection sheet and record what device is being tested, with model number, manufacturer, serial number, and lot.

Lay out the data sheet to follow the steps of your experiment. If you are measuring a variable before and after, you might want to include space to calculate and record the difference. Allow space for simple calculations, so you do not have to re-enter data on another sheet. Allow entry space for each repetition of each test run and for calculation and entry of mean and standard deviation values. Also include space on the sheet to record observations during the experiments and any deviations from the protocol.

Statistics

Statistical analysis is the key to determining whether your findings are statistically significant. Your methods section should describe the statistical tests you select to analyze your data. For instance, with a repetition of 3 experiments, you will want to calculate mean and standard deviation values (note: when your goal is to present the reader with some information about the variation in your data, you should report the standard deviation or interquartile range and not the standard error of the mean). The most common test in bench studies is analysis of variance with a subanalysis to differentiate significant differences between variables. Software for descriptive statistics and analysis of variance is available in programs such as Microsoft Excel and statistics software packages.

If you are unfamiliar with statistical analysis, seek a local mentor/instructor/expert who can help you select the appropriate tests and understand the steps of analyzing your data. Most hospitals and schools have staff or faculty versed in these techniques, most of whom are quite happy to help bring someone new into the scientific evaluation

process. The key here is to learn how to do the basic calculations yourself.

Perform the Study

Once the protocol is written, it's time to set up and run the experiment. Use your protocol as the guide for setting up the model. Calibrate your instruments. Perform each step of the experiment as written. Record your findings as you go. If you notice that you have not included a step in the protocol, note the new step on the data collection sheet as a protocol deviation, so you can remember what you did, and consider changing the protocol before the next set of experiments.

Review Your Results

After all the data are gathered and the results are calculated, the fun begins. Your review of the results is where you assess whether the data support or refute your hypothesis. If your results support your hypothesis, congratulations; you were able to predict the obvious. However, it is often the experiments that yield unexpected results that are the key to greatest insight and learning. Data from a well designed and well executed experiment that do not meet initial expectations or objectives can be the most interesting and lead to the greatest new discoveries as well as to new questions, revised hypotheses, and new experiments. CAUTION: This process can be addictive.

Your analysis of your results and your insights on your findings and their implications are the basis of the discussion component of your report. Try to explain how your results answered your research question, how they fit or deviated from your hypothesis, and how your findings might be relevant to use of the device. This analysis is the basis of your recommendations from your evaluation.

Communicate Your Findings

Share your findings. It's nice that you have made observations with your experiments, but it's necessary to communicate your findings to your supervisor, your peers, your institution, and other institutions. You spent considerable time and effort in designing and performing your experiments, and your report justifies those costs and adds to the collective understanding. Table 5 shows the components of a device evaluation report. In effect, you take your written protocol, background statement, hypothesis, and methods, and add your results, a brief discussion of your findings, and your conclusions and recommendations. That report can then be used for internal organizational review and should be submitted for publication, as discussed in the other special articles in this issue of RESPIRATORY CARE.

Table 5. Components of a Device-Evaluation Report

Background
Hypothesis
Methods
Results
Discussion
Conclusions and recommendations
Forms to submit report for publication in a peer-reviewed journal

Table 6. Keys to Proper Evaluation of a Medical Device

<u>Plan the Evaluation</u>
-Conduct a thorough literature search for previous studies about the device, and describe that previous research in the background section
-Clearly state the objectives and end points of your study
<u>Define Your Methods</u>
-Select or create a relevant model
-Write down your methods, including the materials and devices you will use in your study, and the steps and data-collection procedures in your study
-Prepare a data-collection sheet
-Determine how you will statistically evaluate your data
<u>Follow Your Protocol</u>
-Make observations
-Document deviations
<u>Review and Interpret Your Results</u>
-Let your results follow your protocol design
-Understand that unexpected or weird results can be more valuable than anticipated results
-Learn from your mistakes and feedback to improve your model and methods
<u>Publish Your Results</u>
-If you answered your question, inform your department and the professional community, by submitting your report to a peer-reviewed medical journal such as RESPIRATORY CARE

Summary

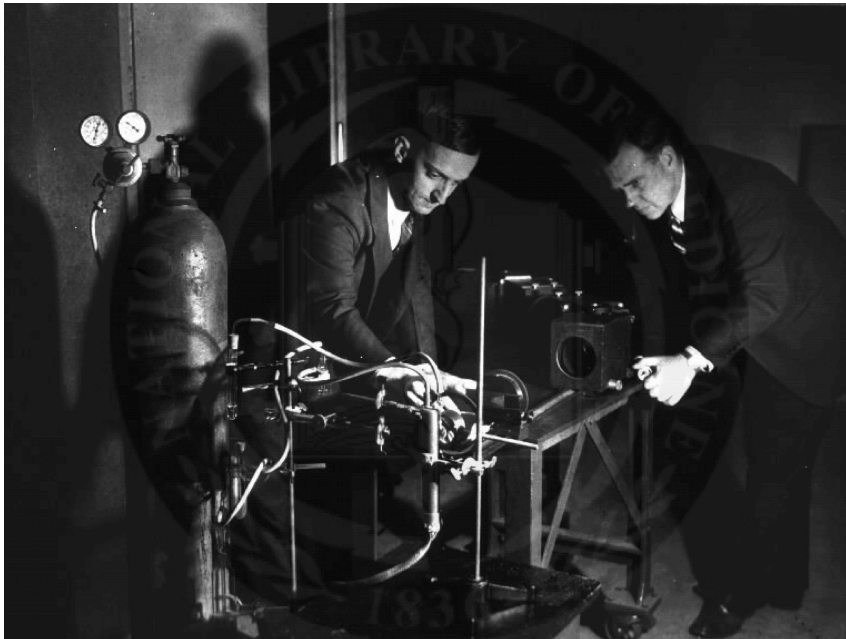
Device evaluation is a form of research that is a necessary part of clinical support. The better you prepare for your evaluation and experiments (Table 6), the easier it will be to consistently gather meaningful data that will guide good decisions about device acquisition and applications. The hours spent gathering background information, formalizing your hypothesis, and writing out your methods can help even first-time researchers produce high quality, meaningful, useful, and reproducible results.

REFERENCES

1. Fink JB, Fink AK. The respiratory therapist as manager: tools for transition. Chicago: Elsevier; 1986.
2. Chatburn RL, Craig KC. Fundamentals of respiratory care research. East Norwalk, Connecticut: Appleton and Lange; 1988.

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3. Wilkes W, Fink J, Dhand R. Selecting an accessory device with a metered-dose inhaler: variable influence of accessory devices on fine particle dose, throat deposition, and drug delivery with asynchronous actuation from a metered-dose inhaler. *J Aerosol Med* 2001;14(3): 351–360.
4. Fink JB, Dhand R. Laboratory evaluation of metered-dose inhalers with models that simulate interaction with the patient. *Respir Care Clin N Am* 2001;7(2):303–317.
5. Fink JB, Dhand R, Duarte AG, Jenne JW, Tobin MJ. Aerosol delivery from a metered-dose inhaler during mechanical ventilation: an in vitro model. *Am J Respir Crit Care Med* 1996;154(2 Pt 1):382–387.
6. Goode ML, Fink JB, Dhand R, Tobin MJ. Improvement in aerosol delivery with helium-oxygen mixtures during mechanical ventilation. *Am J Respir Crit Care Med* 2001;163(1):109–114.
7. Mildner RJ, Frndova H, Cox PN. Effect of air and heliox as carrier gas on CO₂ transport in a model of high-frequency oscillation comparing two oscillators. *Crit Care Med* 2003;31(6):1759–1763.
8. Chatmongkolchart S, Schettino GP, Dillman C, Kacmarek RM, Hess DR. In vitro evaluation of aerosol bronchodilator delivery during noninvasive positive pressure ventilation: effect of ventilator settings and nebulizer position. *Crit Care Med* 2002;30(11):2515–2519.
9. Ho SL, Kwong WT, O'Drowsky L, Coates AL. Evaluation of four breath-enhanced nebulizers for home use. *J Aerosol Med* 2001;14(4): 467–475.
10. Oppenheim-Eden A, Cohen Y, Weissman C, Pizov R. The effect of helium on ventilator performance: study of five ventilators and a bedside Pitot tube spirometer. *Chest* 2001;120(2):582–588.
11. Hess D, Simmons M. An evaluation of the resistance to flow through the patient valves of twelve adult manual resuscitators. *Respir Care* 1992;37(5):432–438.
12. Barnes TA, McGarry WP 3rd. Evaluation of ten disposable manual resuscitators. *Respir Care* 1990;35(10):960–968.
13. Fink JB, Dhand R, Grychowski J, Fahey PJ, Tobin M. Reconciling in vitro and in vivo measurements of aerosol delivery from a metered-dose inhaler during mechanical ventilation and defining efficiency-enhancing factors. *Am J Respir Crit Care Med* 1999;159(1): 63–67.



Tissue Culture Research, National Cancer Institute
National Institutes of Health. (Roy Perry, old negative).
Courtesy National Library of Medicine