Computer Guidelines for Pulmonary Laboratories

This paper has been prepared by the Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories for MEMBERSHIP, REVIEW AND COMMENT. Please send your written comments to the ATS **no later than January 4, 1984.**

Members of the Committee:
REED M. GARDNER, PH.D., *Chair*
JACK L. CLAUSEN, M.D.
DAVID J. COTTON, M.D.
ROBERT O. CRAPO, M.D.
GARY R. EPLER, M.D.
JOHN L. HANKINSON, PH.D.

Introduction

With the decrease in size and cost of microprocessors and the increase in their speed and reliability, most future pulmonary function instrumentation will probably contain some type of digital computer. New quality assurance problems will occur as pulmonary function laboratories become more reliant on digital computers and associated automation.

While it is important to address these new problems, the advantages offered by digital computers far outweigh the disadvantages. Some typical advantages are: (*1*) complete automation of a procedure, resulting in significantly reduced time and cost, and in increased accuracy; (*2*) assurance that standardized procedures are followed; (*3*) significant reduction in major measurement errors (1); (*4*) storage and retrieval of information quickly and efficiently; (*5*) implementation of automated calibration and system check procedures within the instrument; and (*6*) standardized and consistent interpretation of results.

When a microprocessor or computer is added to instrumentation, the performance of the entire system must be considered. With analog systems, the concept of accuracy is easily understood. However, when a microprocessor is added to an instrument, software may become an important component of overall system accuracy. For example, an extremely accurate spirometer has little advantage if it is connected to a microprocessor with a low resolution analog-to-digital converter or if a low sampling rate is used. Likewise, if only eight-bit signed integer arithmetic is used, accuracy will be compromised.

With the increase in complexity of software and hardware, it is often difficult for any one individual to completely understand all aspects of a computerized system, and errors may go undetected for months. In addition,

attempts to correct programs and software problems are often complicated by the unavailability of the original software designer or lack of documentation. The improved software may correct a problem, but it may also introduce new problems.

Because of the increased utilization of computers, comprehensive quality assurance guidelines must cover the use of digital computers. The following minimal guidelines for use of computers in the pulmonary laboratory are suggested:

1. Comprehensive performance testing is generally beyond the capability of most pulmonary function laboratories, and this responsibility must reside with the manufacturer. However, individual users should undertake an extensive initial review of instrument specifications and other technical data prior to instrument use or procurement. Indeed, provision that such information be provided with the instrument should be a condition of purchase.

2. While it may not be feasible for manufacturers to provide source code listings, they should at a minimum provide flow charts or an equivalent description of software function. Every laboratory should be provided with complete documentation of all procedures and pattern recognition algorithms implemented within computer software. For example, with spirometry, documentation of the method used for beginning and end of test determinations should be provided (see DISCUSSION).

3. Every laboratory must have readily available, complete documentation of all formula(s) and reference equations used to calculate and interpret results. For example, the prediction equations used to calculate a patient's predicted FVC, FEV_1, etc., should be provided or referenced. Similarly, the BTPS correction calculation technique and the use of barometric pressure in the calculation should be documented.

4. If any software modifications or changes are anticipated, a laboratory should document in the operating manual the personnel authorized to implement software changes and document procedures for implementation and testing of new software. Software modifications should be evaluated with the same caution as hardware changes.

5. Since software may not always be completely free of major or minor errors, a software and hardware performance log should be maintained. In this log, all possible and definitive software and hardware errors should be recorded and reported to the appropriate personnel. In addition, any software modifications or updates as well as routine preventive and corrective maintenance should be recorded. The date the changes were implemented, the reasons for the changes, and

any quality assurance results (calibration checks) should be entered into the log.

6. Perhaps the greatest potential problem associated with computers is the potential loss of large amounts of information stored on a single mass storage medium. Therefore, it is essential that duplicate copies of all data be maintained. In addition, these copies should be stored with limited access to prevent inadvertent destruction. Schedules for developing back-up discs or tapes should be established and followed.

7. Since a computer, like any instrument, is subject to malfunctions, procedures to be used in case of computer failure should be established.

8. For protection of confidential patient data, guidelines should be established as to the personnel who have access to information, access procedures, and software security codes.

These computer quality assurance guidelines are minimum guidelines and are neither unique nor exhaustive. Additional guidelines may be necessary for some instruments. Guidelines suggested by the manufacturer should be followed.

Discussion

Perhaps the most controversial recommendations in this document are the nature and extent of hardware and software documentation. The user, producer, and manufacturer of software have differing and sometimes conflicting perspectives of software documentation. The users need complete documentation, while the manufacturer needs to protect the software from unauthorized copying. The more innovative the software, the greater the need for documentation, and the less willing the manufacturer may be to provide complete documentation. However, a reliable method of protecting software from unauthorized copying may also be beneficial to the users, since without this protection, manufacturers may be reluctant to invest in new innovative software development.

Regardless of the problems, software users need complete documentation of the software, or at a minimum, sufficient information to determine how data are manipulated within the instrument. As with any scientific experiment, the methods used to conduct the experiment must be sufficiently documented so that the experiment can be repeated elsewhere. There are at least four different methods of software documentation:

1. Software source code listing furnished by the manufacturer. This documentation method should allow duplication of the method, but may be difficult for the individual user to comprehend, particularly if the source code is in assembly language or a software language

Computer Guidelines

in which the user is not proficient.

2. Flow charts provided by the manufacturer instead of source code listings. This documentation method should be somewhat independent of software language, but has the disadvantage of not being entirely accurate or as complete as source code listings.

3. A narrative provided by the manufacturer giving a brief description of software function. This documentation method would provide the least complete documentation and therefore is least desirable.

4. Software performance evaluation conducted by the manufacturer. An entirely different approach is to validate the software instead of providing complete documentation. Standard raw data could be provided to the manufacturers by the ATS, and each manufacturer could provide the user with the results of the analysis of this raw data. For example, a set of 24 standard spirometric waveforms could be provided for each spirometer manufacturer. Instead of providing source code listings, the manufacturer could elect to provide results for FVC, FEV_1, peak flow, etc., using this software to analyze the standard raw data. For the single breath DL_{CO}, a set of typical volume time curves with breath-holding could be provided to each manufacturer. The manufacturer could then provide the user with the corresponding breath-holding times and inspired volumes obtained when the manufacturer's software was used to analyze these raw data. DL_{CO} values could also be calculated if gas concentrations were provided. This documentation method provides very little actual software documentation for the user, but does provide some functional information of the methods used to perform various calculations and measurements. However, it may be difficult to produce standard raw data sets in a form which can be used by all manufacturers. For example, manufacturers may use different sampling rates and different analog-to-digital converters. Some spirometer manufacturers sample volume as a function of time, while others sample time as a function of volume.

In summary, there are obvious conflicts between the needs of the user and the needs of the manufacturer to protect software. Since the results of any test are very dependent on the methods used, the user must be provided with detailed documentation of methods implemented within software. This documentation must be sufficient for the user to understand software function as clearly as with manual measurements and calculations.

References

1. Gardner RM, Crapo R, Billings RG, Shezeoka JW, Hankinson JL. Spirometry—what paper speed. Chest 1983:84(2); 161–65.

COURSES AND WORKSHOPS

8th Annual Infectious Diseases in Clinical Practice, January 19–26, 1985, Steamboat Springs, CO, sponsored by University of California San Francisco, School of Medicine, Division of Infectious Diseases and Extended Programs in Medical Education. The program is designated for primary care physicians, including internists, pediatricians, family and general practitioners, and emergency medicine specialists. It offers 24 credit hours in Category I of the Physicians Recognition Award of the AMA and the Certification Program of the California Medical Association. It is acceptable for 24 prescribed hours by the American Academy of Family Physicians and 24 hours in Category I by the American College of Emergency Physicians. Allied health CME credits are also available. Fees: $350 for physicians; physician's assistants, nurse practitioners, nurses and other allied health professionals, $300; interns and residents, $250. For information contact Extended Programs in Medical Education, University of California San Francisco, San Francisco, CA 94143, or phone (415) 666-4251 (program information) (415) 666-5808 (registration information).

Postgraduate Courses on Clinical Management and Control of Tuberculosis, January 21–25, 1985, National Jewish Hospital and Research Center/National Asthma Center, 3800 E. Colfax Ave., Denver, CO, sponsored by National Jewish Hospital and Research Center, National Asthma Center. Tuition fee $325. Reduced fee for physicians in training. Program is acceptable for 38 prescribed hours by the American Academy of Family Physicians. NJHRC/NAC designates this CME activity for 38 credit hours in Category I of the Physician's Recognition Award of the AMA. This program has also been approved for 38 contact hours by the Colorado Nurses' Association. For information contact TB Course Office, Dept. of Medicine, National Jewish Hospital and Research Center, 3800 E. Colfax Ave., Denver, CO 80206.

28th Annual Midwinter Conference on Chest Disease, January 23–28, 1985, Snowbird Ski Resort, UT, sponsored by the Intermountain Thoracic Society. The Snowbird Meeting offers first rate medical education (17 hours of Category I) in an informal alpine atmosphere with prime time skiing on the "greatest snow on earth." For information and program contact Intermountain Thoracic Society, 1930 S. 1100 East, Salt Lake City, UT 84105 or phone (801) 484-4456.

Seventh Annual Pulmonary Wintercourse, January 24–27, 1985, Contemporary Hotel in the Magic Kingdom, Lake Buena Vista, FL, sponsored by the Florida Thoracic Society and cosponsored by The University of Florida College of Medicine, The University of Miami School of Medicine and The University of South Florida College of Medicine. The course is designed for practicing internists, family physicians, pediatricians, thoracic surgeons, anesthesiologists, respiratory therapists and technicians with a special interest in pulmonary disorders. This CME activity meets the criteria for 19.5 credit hours in Category I of the Physicians Recognition Award of the American Medical Association, is acceptable for 19.5 prescribed hours by the American Academy of Family Physicians and 19.5 credit hours in Category 2-D by the American Osteopathic Association. For information contact Florida Thoracic Society, P.O. Box 8127, Jacksonville, FL 32239 or phone (904) 743-2933.

Winter Retreat: Update on Pulmonary Disorders, February 4–6, 1985, The Wintergreen Resort, Wintergreen, VA. Major topics of discussion include Management of COPD, Evolving Diagnostic Techniques in Pulmonary Embolism, and Exercise Testing, and new advances in the treatment of cancer. Each morning includes didactic presentations as well as case discussions from the lectures. This program meets the criteria of 12 credit hours in Category I of the Physician's Recognition Award of the American Medical Association, 12 prescribed hours by the American Academy of Family Practice and 1.2 Continuing Education Units by the Virginia Commonwealth University. The course fee is $250.00 for physicians and $135.00 for physicians in training and all health care professionals. For further information, please contact: Beth Winn, Continuing Medical Education, .Box 48 — MCV Station, Richmond, VA 23298, or phone (804) 786-0494.

2nd International Symposium on Current Topics in Infectious Diseases, February 9–16, 1985, Grindelwald, Switzerland, sponsored by University of California, San Francisco, School of Medicine, Division of Infectious Diseases and Extended Programs in Medical Education, in cooperation with Division of Infectious Diseases, University of Geneva Hospital. A distinguished group of infectious disease specialists and clinical microbiologists from Europe and the United States will discuss areas of infectious diseases that are controversial or have changed significantly in recent years. The emphasis will be on clinical problems that relate to patient care. Pathogenesis and pathophysiology will be intro-