Computer Guidelines for Pulmonary Laboratories

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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 advantages are:

(*1*) Complete automation of a procedure may result 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.

Some disadvantages include (2):

(*1*) Incremental increase in initial cost of equipment;

(*2*) Requires more careful training of personnel;

(*3*) May limit the flexibility of some testing procedures, manually processed records are very tolerant and flexible of patient maneuvers;

(*4*) Inability of the user to update and correct the software.

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 which has a low resolution analog-to-digital converter or which has too slow a sampling rate. Likewise, if only eight-bit 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 one problem but may also introduce new problems.

Suggested Guidelines

Because of the increased utilization of computers, comprehensive quality assurance guidelines must cover the use of digital computers (3). 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 or an independent certification laboratory. However, individual users should undertake an extensive initial review of instrument specifications and other technical data prior to instrument procurement or use. Indeed, provision of performance validation information by the manufacturer 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 detailed 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 value equations used to calculate and interpret results. For example, the reference value equations used to predict a patient's FVC, FEV_1, etc., must be provided along with its scientific literature citation. 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 made, the change should be documented in the laboratory log book. The log book should also record all equipment (hardware and software) changes along with documentation of the changes. Personnel authorized to implement software changes and document procedures for implementation and testing of new software should be included in the laboratory procedure manual. Software modifications should be evaluated with the same caution as hardware changes. Techniques for manufacturers to validate spirometry performance using standard patient waveforms have recently been proposed (4).

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 software and hardware errors should be recorded and reported to the laboratory medical and technical directors. In addition, any software modifications or updates as well as routine quality control preventive and corrective maintenance procedures 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 book.

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 by the laboratory as to the personnel who have access to information, access procedures, and security codes.

9. When manufacturers provide updates to their hardware or software, they should also provide details of the errors produced by earlier versions, including the magnitude of error and what if anything can be done to correct the values obtained from the earlier version. Manufacturers should notify the laboratory medical and technical directors of any new hardware or software installed.

10. Users should frequently verify the output of the computer system using their own "test" subjects for quality control purposes (3).

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 specific and sometimes conflicting perspectives of software documentation. The users need complete documentation while the manufacturer needs to protect the software from unauthorized use. 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 use

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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 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 provides the least complete documentation and therefore is least desirable.

4. System performance evaluation conducted by the manufacturer or an independent laboratory. An entirely different approach is to validate the complete hardware and software system 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 (4). 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 D_{LCO}, 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. D_{LCO} 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, or may generate a digital signal directly (e.g., from a mechanical shaft encoder [5]). 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.

This paper was prepared by the Committee on Proficiency Standards for Clinical pulmonary Function Laboratories. Members of the Committee are:

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