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Computerized Anesthesia Records May Have Drawbacks

To the Editor:—To date no pursuit in anesthesiology technology has claimed more and delivered less than the search for a "computerized anesthesia record." Such again is the case in the recent letter to the editor by Rosen and Rosenzweig[1] that reports "on a system that uses proprietary software to generate an anesthesia record . . . used is the Radio Shack® Model 100, which is lightweight and portable."

The letter is often misleading and minimizes or fails to disclose drawbacks in the system as structured. It is stated that "vital signs may be entered manually or automatically through the RS-232 interface." In truth, manual entry would require multiple repetitive key strokes, a tedious and time-consuming process. No simple solution is provided either by the RS-232 interface. This is solely a mechanical design standard dealing with connector architecture and does not deal with the manner in which information is sent, received, and acknowledged. This requires special communications software. It's not enough that the plugs match!

Just this problem, data communication between monitoring equipment, has been the subject of a whole proposed standards writing effort with the Association for the Advancement of Medical Instrumentation (AAMI). The proposal was an outgrowth of a 1982 AAMI roundtable discussion that identified specifically the problem of interfacing equipment from various manufacturers. It was the consensus that entirely too much time was being taken up with software and hardware efforts to reinvent the interfacing solution while more important aspects of monitoring were not being addressed. Ultimately, the effort was tabled because of shifting priorities within AAMI and the sheer magnitude of the project itself.

The authors also did not address the issue of the time required to print the representative anesthesia record they displayed in the letter to the editor. Anyone who has watched low-cost plotters chug away knows that considerable time is required to generate the sample records depicted. The hardware and software aspects aside, the authors claim that it provides a more legible and accurate anesthesia record. This is a contention that I wholly reject. While the clarity of the characters may be improved by mechanical penmanship, the information is no more accurate or precise as to time or value than the key stroke or transducer that provided the signal. To use the old computer adage, "Garbage in equals garbage out," only this time the garbage is bagged. The authors state that "entries can be made in any order at any time before, during, or after the case." How then can random entries contribute to greater accuracy and precision in recording physiologic and pharmacologic data generated during the case?

The inference that somehow or other by using this magic box a successful defense is mounted to malpractice litigation is completely unsubstantiated. A sloppy anesthesia record may help lead the jury to the presumption of a sloppy anesthetic administration, but artful depiction of an otherwise poor anesthetic administration will not prevent malpractice judgments.

Finally, it should be noted that the Center for Medical Devices and Radiologic Health of the Food and Drug Administration considers software written for devices with microprocessors that interface with medical instruments to be classified as a medical device itself.* Assuming this to be a class II medical device, was premarket notification of the Food and Drug Administration made under regulation 510(k) of the Federal Food, Drug and Cosmetic Act?

* Jorgens J, Bruch CW, Houston F: FDA regulation of computerized medical devices. Byte, September, pp 204–214, 1982

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In reply:—The criticisms by Dr. Lees of our computerized anesthesia record are based mainly on some commonly held misconceptions. We think that he would be convinced his search for the computerized anesthesia record has ended if we could dispel some of these misconceptions.

In regard to the RS-232 interface, standards have been established by the Electronics Industry Association (EIA) that go beyond just matching plugs but extend to communications protocols, which include signal voltages, frequencies, and data formats. A number of monitor manufacturers are making available interfaces in compliance with these standards. United Medical Technologies customizes the program to the protocol, data format, and information content offered by the manufacturer. As a result, and contrary to the implications of Dr. Lees' criticism, the operation of the RS-232 interface is completely transparent to the user.

As for the difficulty of manual data entry, this is a matter of individual ability. In any case, it comes down to exchanging keystrokes for pen strokes.

The plotting time for the entire record depicted in our article was 14 min, starting from a blank sheet of paper. With reduced information content, the plotting time is less. It may be tedious to watch the plotting process, but it does work unattended. United Medical Technologies now has a version of the program that runs on IBM® compatible computers. These can accommodate up to four RS-232 interfaces, which allow one interface to communicate with the monitor and another to communicate with the plotter so that plotting can be done during the case. Plotting time then becomes inconsequential.

The accuracy referred to in our letter indicates the preciseness with which the plotter can produce points on a calibrated grid. No claim was made or could reasonably be inferred that this could make up for errors in transducer function or poor manual techniques of blood pressure acquisition. There still needs to be a doctor in the house.

Entries to be made in any order at any time naturally refers only to information that is known. Prior to the case this would include patient name and preop data, OR team, and anesthesia plan. This certainly could not include information only obtainable during the case, though this can be recorded after the fact if necessary. Condition of the patient in recovery and last details of the record are usually inserted after the case is over.

It is obvious that a good record cannot cover up a bad anesthetic. This was not stated nor implied. This does not, however, minimize the importance of a well-kept record.

The FDA has been contacted to determine whether this computer application requires premarket notification under regulation 510(k). No determination has yet been made.

A demonstration disc that runs on IBM®-compatible computers is available from United Medical Technologies for those interested in testing the system. We invite Dr. Lees to try it. He may like it.

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Bilateral Amaurosis Following Unilateral Retrobulbar Block

To the Editor:—Numerous complications of retrobulbar block have been described, including brain stem anesthesia with unconsciousness and apnea,[1,2] grand mal seizures,[3] retrobulbar hemorrhage,[4] elicitation of the oculocardiac reflex,[4] toxic reaction from intravascular injection,[4] central retinal artery occlusion,[4] optic nerve neuropathy,[4] and perforation of the globe.[5] The following is a case of transient bilateral blindness following unilateral retrobulbar block, which we have been unable to find previously reported in the literature.

The patient was a 67-year-old, 66-kg male who was having repair of a leaking corneal suture line of the left eye. The patient had undergone a left corneal transplant for an infected perforated corneal ulcer under uneventful