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Continuous Measurement of Endotracheal Tube Cuff Pressure:

How Difficult Can It Be?

Mary Lou Sole, PhD, RN, CCNS, FAAN,
Professor, University of Central Florida College of Nursing, 4000 Central Florida Blvd—HPA 220, Orlando, FL 32816-2210 (msole@mail.ucf.edu).

Daleen Aragon, PhD, RN, FCCM,
Director, Advanced Practice Nursing and Research, Orlando Regional Healthcare, Orlando, Florida.

Melody Bennett, MN, RN, CCRN, and
Project Director, University of Central Florida, Orlando, Florida. She is also Staff Nurse, Orlando Regional Medical Center, Orlando, Florida.

Randall L. Johnson, PhD, ARNP
Associate Professor, Florida Hospital College of Nursing, Orlando, Florida.

Abstract

Continuous monitoring and download of endotracheal tube cuff pressure for a 12-hour period were required to collect data for an ongoing program of research related to airway management of the critically ill patient. On the basis of reports from the anesthesia literature, continuous monitoring of cuff pressure via a traditional pressure transducer and monitor was identified as the best method to collect data. Although continuous pressure monitoring of many physiologic variables is routine in critical care settings, application of the technology to measurement of endotracheal tube cuff pressure has not been reported outside the operating room. The research team conducted bench testing and pilot testing in human subjects to establish feasibility, accuracy, and safety of continuous cuff pressure monitoring. Monitoring was feasible with stringent procedures applied to ensure safety. A bias of 0.5 cm H_2O between continuous and intermittent measures was obtained in both in vitro and in vivo testing.

Keywords

endotracheal tube; monitoring; nursing; pressure; research

Physiologic data provide a quantitative assessment of a patient's clinical status and response to nursing interventions and medical treatment. Although nurses are knowledgeable and skilled in collecting data for clinical decision making, they do not often use physiologic outcome data in their research studies.[1] Collecting physiologic data requires knowledge and expertise with biomedical instrumentation—electrical devices that measure physiologic parameters.[1,2] A variety of physiologic variables can be captured with biomedical instrumentation, including pressures, electrical potentials, mechanical waves, gases, and temperature.[1,2] Data can be collected in vitro (outside the subject) or in vivo (directly from a subject).[1] Biomedical instruments have common components (Table 1) and factors (Table 2), which must be assessed and tested by the researcher.

This case report describes the steps we took to record continuous real-time measurements of endotracheal (ET) tube cuff pressure (P_{CUFF}) in critically ill patients. As clinicians experienced in physiologic pressure monitoring, our original thought regarding measuring

and recording P_{CUFF} for research purposes was, “how difficult can this be?” Accomplishing this outcome was much harder and took more time than we anticipated. We encountered several challenges as we systematically developed procedures for measuring a parameter not previously described in clinical studies. Our emphasis was on obtaining data safely, accurately, and in a format for statistical analysis.

Physiologic Data for Airway Management Research

The focus of our research studies has been on airway management of the critically ill patient. We have been interested in the phenomenon of ET tube P_{CUFF} management to identify best practices in measuring ET tube P_{CUFF} and to test interventions for maintaining pressures within a therapeutic range to prevent complications.

In previous studies, we measured P_{CUFF} intermittently with a commercial pressure monitoring device, the Posey Cufflator Endotracheal Tube Inflator and Manometer (Posey, Arcadia, California). (The term *cufflator* will be used in the remainder of this article in reference to this device.) To assess P_{CUFF} over time and test an intervention, we needed a method for continuous measurement and recording of ET tube P_{CUFF} for a 12-hour period.

Overview of Endotracheal Tube Cuff Pressure Measurement

Endotracheal tube cuff pressure is regularly measured in critically ill patients to ensure that the pressure is within a narrow therapeutic range of approximately 20 to 30 cm H_2O.[3–7] The pressure must be high enough to ensure adequate ventilation and prevent aspiration of secretions that accumulate above the ET tube cuff. However, high pressure must also be avoided to prevent tracheal damage from compromised tracheal capillary perfusion pressure.[4] In the clinical setting, P_{CUFF} is measured every 8 to 12 hours, usually at the beginning of the shift, or if a cuff leak is audible.[8–11]

Indirect and direct methods for measuring P_{CUFF} are described in the literature. The P_{CUFF} is indirectly measured by palpating the ET tube pilot balloon to estimate the pressure; however, palpation techniques are in accurate and tend to overestimate the pressure.[12,13] The P_{CUFF} is directly measured by connecting a pressure gauge device to the pilot balloon of the ET tube. Some devices, such as the cufflator, allow the clinician to measure and adjust the P_{CUFF}. User variability and a lack of precision have been reported with commercial devices.[14]

Measurement Needs for Research

One of our research goals was to assess changes in P_{CUFF} over time. We needed to record and download P_{CUFF} data for a 12-hour period. Two brief articles published in the anesthesia literature described monitoring P_{CUFF} during surgery with a pressure transducer. [15,16] Because continuous pressure monitoring is routinely done in critically ill patients, this method for monitoring P_{CUFF} seemed to be a good option for the research study. We contacted Dr Doyle, who first described continuous P_{CUFF} monitoring,[15] to discuss the technique and the feasibility of applying the procedure in our proposed study. He discussed the procedures for monitoring and described download of data to a computer with the use of a data logger. Following our conversation with Dr Doyle, we developed a systematic approach to test the feasibility, safety, and accuracy of continuous P_{CUFF} monitoring for research. We then investigated the best way to acquire and download data for statistical analysis.

Consultation

Members of our research team have varied expertise in clinical nursing research, including conducting studies with physiologic variables. However, we did not have expertise in biomedical engineering and identified the need for consultation in this area because we were using a new method for P_{CUFF} monitoring. We consulted with nursing and biomedical engineering colleagues who had expertise in collecting continuous physiologic data in critically ill patients. These individuals work at an academic health science center with an established research team and many available resources. We met with them at their site to observe data collection on several physiologic variables. They made the process of complex data collection and downloading of real-time data look relatively easy. The biomedical engineer on the team designed software programs to record and download a variety of physiologic data and was a key member of the research team.

Phase 1—Bench Testing for Feasibility, Validity, and Safety

We conducted in vitro testing during the first phase of our research to assess the ability of a traditional pressure transducer system connected to the pilot balloon of the ET tube to record pressures (feasibility and validity). We also wanted to ensure that no leaks were present in the transducer and pressure tubing system (safety). “What procedures were needed to set up the transducer and monitor system? Could we collect continuous P_{CUFF} data, and was it safe for the patient?”

We had a portable Philips M3 monitor with a pressure module (M3001A, Philips Medical Systems, Bothell, Washington). We ordered transducers, tubing, and ET tubes to conduct the in vitro testing. The Philips pressure module measures pressures within a −40 to 360 mm Hg range. The reported accuracy excluding the transducer is ±1%. The accuracy of the zero adjustment is ±1 mm Hg (Philips M3001A, *Instructions for Use*). Pressures are averaged every 3 seconds.

The procedure for testing was as follows:

1. Insert a size 8.0 ET tube (Portex Inc, Keene, New Hampshire) into a simulated trachea (corrugated tubing with an inner diameter of 1.9 cm).[17]
2. Position ET tube 2.5 cm from the distal end of the tubing to simulate distance from the carina, and secure the proximal end of the tubing with a Velcro tube holder at the 23-cm marking on the ET tube.
3. Place the airway and ET tube assembly into a capped 60-mL syringe and immerse at a 45° angle into a water bath maintained at 37°C to simulate body positioning and temperature.
4. Inflate the ET tube cuff to 20 cm H_2O (14.7 mm Hg) with the cufflator. (We used 20 cm H_2O as a reference because that is the standard of care for inflating the ET tube at the hospital.)
5. Connect the pressure transducer (Medex TranStar MX950, Dublin, Ohio) to a 6-in pressure tubing and a stopcock. Connect the transducer-tubing setup to the pilot balloon of the ET tube. (Because the ET tube cuff is inflated with air, a fluid-filled transducer system is not necessary.[15])
6. Zero reference the stopcock and establish continuous pressure monitoring. (Leveling the zeroing stopcock is not needed because an air-filled system is used.[15]) We validated that pressures remained the same regardless of where the zeroing stopcock was placed.

7. Assess pressure on monitor display; a value of 15 mm Hg should be displayed.

We recorded pressures for 8-hour periods and noted a drift of 1 mm Hg after approximately 4 hours of monitoring. A slight drift in pressures often occurs with physiologic monitoring. [1] Although air bubbles were not seen when we immersed the setup in water, we suspected a small leak in the stopcock-tubing setup. We purchased a 6-in pressure tubing that was premolded to a stopcock (Medex MS 43660, Dublin, Ohio) to eliminate a potential leak source. When we tested this new setup for 8 hours, pressures remained stable and no drift was noted. Values were considered to be stable over time.

During this phase of testing, we established feasibility and validity of continuous monitoring and identified the equipment needed to ensure safety. We recorded data manually from the "trend" view on the monitor and did not investigate capabilities for downloading the data.

Phase 2—Bench Testing for Accuracy

The next phase of the bench testing was to compare values of P_{CUFF} measured with a calibrated cufflator and those obtained via a transducer. "Are pressures obtained from continuous monitoring congruent with those obtained with the cufflator (standard of care)?" The cufflator measures pressures from 0 to 120 cm H_2O with a specified accuracy of ±2 cm H_2O.

We tested 15 new ET tubes (Portex Inc, Keene, New Hampshire) of 3 different inner diameters: 7.5 mm (n = 5), 8.0 mm (n = 5), and 8.5 mm (n = 5). We inserted each ET tube into a simulated airway as described in phase 1 and used the following procedures for testing:

1. Initiate continuous ET tube P_{CUFF} monitoring; zero the stopcock to atmospheric pressure.
2. Attach cufflator to the stopcock of the transducer-tubing system and adjust ET tube P_{CUFF} to 20 cm H_2O. Remove cufflator, allow pressure to stabilize, and record pressure from monitor (in millimeters of mercury). Repeat the procedure 2 additional times.
3. Repeat step 2 with second investigator.
4. After each set of measurements, test another ET tube under the same conditions and procedures.

We collected 90 paired measurements of pressures obtained via cufflator and transducer (15 ET tubes × 3 paired measurements × 2 investigators). Pressures were converted from millimeters of mercury to centimeters of water for analysis (1.36 cm H_2O = 1 mm Hg) and the Bland-Altman technique was used.[18,19] A bias of 0.5 cm H_2O was noted between intermittent and continuous measures.[20] This value was within the ±2 cm H_2O accuracy reported for the cufflator, and we concluded the continuous values to be an accurate reflection of ET tube P_{CUFF}. Pressures recorded by the transducer should be more accurate than those obtained with the cufflator because measurements are obtained from sophisticated biomedical equipment and values are averaged every 3 seconds. Measurements with the cufflator are less precise; the markings on the cufflator are in 2 cm H_2O increments, and one must estimate the value if the dial on the pressure gauge is not directly in line with a unit of measurement.

During this phase, we also tested a wide range of P_{CUFF} data by inflating the ET tube from 10 to 30 cm H_2O with the cufflator. We observed the corresponding values on the monitor display to ensure that the cufflator and monitor values were equivalent. We created a

conversion chart that listed pressures in centimeters of water and the corresponding value in millimeters of mercury that we used in our assessment.

An additional finding of this testing was that ET tube P_{CUFF} decreased an average of 2.2 (±0.4) cm H_2O each time we attached the cufflator to the pilot balloon of the ET tube. Similar results have been reported in the literature. [14] This finding has clinical significance in that attaching a device to assess and ensure safe ET tube P_{CUFF} may cause a decrease in pressure, which increases the risk for aspiration of secretions.

During this phase of testing, we established accuracy of continuous ET tube P_{CUFF} monitoring. We also created charts for converting data obtained in millimeters of mercury (continuous monitoring) to centimeters of water (cufflator) for comparison.

Phase 3—Data Acquisition and Download

Although we established feasibility, safety, and accuracy of continuous monitoring in vitro, several additional steps and processes were needed before application in human subjects. We encountered many challenges in translating findings from the bench to the bedside. Our question at this point was, “how do we download data from the monitor to a computer for analysis?”

Portable Monitor Capability

Our plan for the clinical feasibility study was to assemble all calibrated equipment on a cart, collect ET tube P_{CUFF} data for 12 hours on the portable monitor, and download data from the portable monitor to a laptop. As we developed the procedures for this phase of our research, we identified 2 critical issues: (1) the monitor stored data for a maximum of 10 hours and the research protocol required data to be collected and stored for a 12-hour period, and (2) it was not possible to download data directly from the monitor.

We communicated extensively via phone and e-mail with the hospital biomedical engineering department and representatives from the monitor manufacturer to determine the best approach for recording and downloading data. We learned that we needed a monitor with an RS-232 output to transfer data to a computer. This concept was not mentioned during any of our preliminary planning and consultation. Dr Doyle described use of a data logger, but we erroneously assumed that the monitor would take the place of a data logger. Table 3 defines terms related to download of physiologic data that we quickly learned.

Because the portable monitor did not have the ability to meet the needs for the proposed research, we debated the pros and cons of 3 options for collecting data (Table 4): (1) use the available portable monitor and modify the protocol; (2) use the bedside monitor to record P_{CUFF}; or (3) obtain a monitor that meets the specifications for the research protocol and has the capability of downloading data. Given the goals of the research study, we identified option 3 as the best one. Per recommendations from manufacturer representatives, the hospital biomedical engineering department loaned us an Intellivue V24 monitor with the RS-232 output capability (Philips Medical Systems, Bothell, Washington) and purchased the cable to connect the monitor to the laptop. Biomedical engineering staff also helped set the internal settings on the monitor to the correct baud rate for transmitting data.

Download of Data

The loaner monitor with the RS-232 serial port and cable were available and we were excited to finally begin data collection. We took the laptop to the biomedical engineering department and connected the equipment as established via bench testing to validate that download of data was possible. The monitor recorded pressures, but when it was connected

to the laptop with the cable that was provided, nothing happened. After several more calls and e-mail communications with the manufacturer, we learned that RS-232 data acquisition software was needed to allow the monitor to "communicate" the data to the computer; data did not automatically transfer from the monitor. We downloaded 3 different trial versions of RS-232 software programs. None could establish communication between the monitor and laptop; even those that were "guaranteed" did not work. We learned from one of the software manufacturers that there was likely a proprietary issue related to the monitor that prevented the software from working.

We again contacted the manufacturer representatives to discuss the data-acquisition software issues and attain a solution. Philips notified us that one software program would work—Dataplore (iXellence, Wildau, Germany). This software is designed specifically to work with monitors manufactured by Philips and Datascope. The software was expensive, costing $1200 for a 1-year site license.

Before purchasing the software, we downloaded the demo version of the software, which permitted data collection for a 10-minute interval. After the many issues we had encountered, we wanted to test the software before finalizing the purchase. We connected the monitor to the computer and started the software according to the directions. However, we were unable to retrieve data from the monitor. We received the error code, "unable to open serial port." We followed the troubleshooting guide and checked and rechecked all of the cable connections as well as the internal settings on the monitor. Everything appeared to be in working order; however, the monitor would not communicate with the computer. We contacted our external biomedical engineer consultant for advice. He was helpful but noted, "I write my own programs, so I'm not familiar with the commercial programs. You just need a 9-pin (monitor) to a 9-pin serial cable (computer) to connect the devices and it should work."

We continued to review the software and monitor instruction manuals to identify the potential source of the problem. We sought expertise from our university, but no one had the biomedical engineering experience that we needed. We again explored options for collecting data (Table 4), and we reaffirmed that precise data were needed and option 3 was still the best one.

A nurse colleague employed at the hospital information systems (IS) department met with us to explore options. She stated that we might be able to download data from the bedside monitors. However, the monitors were about 15 years old, proprietary software would need to be installed, and someone from IS would have to download the data from the server. She agreed to investigate this option. At this meeting, she also suggested that we meet with one of her coworkers who could troubleshoot most computer-related issues. We made an appointment with this colleague.

We transported all of the equipment— monitor, ET tube, transducer, cables, and laptop—to the hospital IS department. We connected the monitor to the computer and started the Dataplore software to replicate the problem. The IS staff member looked at the connections and immediately identified the problem—the cable was connected to the wrong port on the laptop. Using the cable provided, we connected the monitor to the only port on the computer that fit the connection; however, this was the 23-pin female parallel (printer) port of the laptop, not the 9-pin male serial port. The IS consultant told us that we needed a "gender converter" to change the 23-pin male serial connector on the cable to a 9-pin female serial connector. He borrowed an adaptor for us to try. We connected the cable and adapter to the serial port, and communication between the monitor and computer was established. The software worked fine and we were able to download and save continuous ET tube pressure

data. Had we listened to our engineering consultant who told us we needed a 9-pin connection, we could have solved this problem earlier. However, we used the cable provided by the manufacturer specifically for downloading data and assumed it to be correct.

Software Capabilities Enhance Precision

The Dataplore software assisted in further establishing validity of the continuous P_{CUFF} monitoring. High-resolution pressure waveforms were displayed for each breath. These waveforms were much more distinctive than those observed on the portable monitor display. The software also resulted in greater sensitivity and precision. Pressures displayed on the portable monitor were whole numbers averaged every 3 seconds. Pressures obtained via the software were reported to 5 decimals (eg, 15.222 45 mm Hg) and recorded every 0.008 seconds. Both waveforms and text files were downloaded for statistical analysis. The increased precision resulted in very large data files that were reduced to 1-minute averages by our statistician.

International Challenges

Additional challenges were encountered when purchasing software from an international company. We ordered the full version of the software as soon as the demo version worked; however, the software company accepted only checks or bank wire transfers for purchase. The company issued us a 14-day license while the purchase was finalized.

We had several electronic and phone communications with the software company while testing the demo version and getting the license key. A 6-hour time difference between Florida and Germany required that calls and communication be done early in the morning. Because the purchase was made in the summer, some of the representatives were on “holiday” and not always available during our emergencies.

Phase 4—Pilot Testing in Human Subjects

Because we were confident that data acquisition would work in the clinical setting, patients were enrolled in a study to assess changes in pressure over time and the effect of activities and interventions on P_{CUFF}. We established detailed procedures and refined them throughout the pilot study. Procedures included equipment setup and safety, downloading and saving data, and cleaning equipment after use.

Additional safety procedures were implemented during this phase. We double-checked that all connections on the transducer and tubing were tightened and then taped them. We affixed bright green labels to the transducer and cable that stated “for respiratory use only.” Only those trained in the procedure (M.L.S. and M.B.) connected and zeroed the transducer. A member of the research team reviewed the equipment with the nurses and respiratory therapists assigned to care for each patient and remained in the room during data collection, which also include recording data related to patient activity and nursing interventions.

One issue we encountered during pilot testing was that data were transferred from the serial port of the monitor to the serial port of the computer more slowly than anticipated (serial data are transmitted 1 bit at a time). It was important to leave both the monitor and the computer on until all data were downloaded and saved; this step often took several minutes and research team members had to learn to be patient with the software. Because we did not want to lose 12 hours of data, we established additional procedures: (1) download and save data at least every 4 hours (rather than the 12-hour time period) and (2) back up data by recording the 1-minute trend values stored on the monitor. This backup took additional researcher time but was considered to be important so that data were not lost should something fail during data acquisition.

Procedures for acquisition and backup of data worked well throughout the pilot study. It took data collection on 6 subjects before team members were comfortable and confident in the procedures. All data were captured, data were backed up, no data were lost, no safety issues were identified, and systematic procedures were established.

As part of ongoing assessment of accuracy, P_{CUFF} values obtained with the cufflator at the beginning of the study for each patient were compared with those obtained via the transducer. Again, a bias of 0.5 cm H_2O was noted; this is the same bias found during in vitro testing. [20, 21] (Results of the pilot study have been submitted for publication and are available upon request.)

Phase 5—Ongoing Intervention Study

Upon completion of the pilot study, we were awarded a federal grant to test an intervention to maintain ET tube P_{CUFF} within a therapeutic range. On the basis of our pilot work, we believed that we had the necessary equipment and detailed procedures to begin the study. We encountered a few additional challenges in starting the intervention study. We requested a loaner Intellivue V24 monitor from the hospital biomedical department for data collection; however, the monitor was not available. The local manufacturer representative loaned us an upgraded Intellivue monitor for the duration of the study. As we tested this new monitor in vitro, we learned that our cable with the gender-converter and Dataplore software would not work with the upgraded monitor. To download data, this monitor required a local area network cable, a different adaptor, and another software program (Trendface, iXellence, Wildau, Germany). We tried the demo version of Trendface with a special adaptor and did not have successful communication between the monitor and the computer; we believed the issue to be with the adaptor. We did not want to spend additional time troubleshooting data download issues that took much time and resources to solve over a year ago, when we knew we had a reliable method for gathering data. We were able to borrow an Intellivue V24 monitor and use the equipment, software, and procedures that we knew would work.

Summary

We used a detailed approach to develop procedures for continuous monitoring of ET tube P_{CUFF} for research in critically ill patients. We established validity, safety, and accuracy of the monitoring. Specialized software allowed for data acquisition with sensitivity and precision. Pilot work is essential when establishing processes, and it is important to keep a log of issues and how they were addressed.

Collecting physiologic data may be easier in an academic health science center with many experienced researchers and equipment resources (eg, strong biomedical and electrical engineering departments). However, our research team was able to use consultants, contacts, textbooks, and Web sites to achieve the research goals. It takes considerable time and effort to conduct these types of physiologic studies, especially in the early developmental stages. It is essential to learn from colleagues and consultants in many fields to solve research data-collection issues in the clinical setting. The one major change that would have made our work much easier was having a biomedical engineer with research experience on our team. We would not have made the assumptions and mistakes that we did. However, we also would not have learned the many biomedical concepts related to instrumentation that we now know.

Our original question was, “how difficult can this be?” The process was much harder and took much longer than we anticipated. The process of conducting these various studies took a lot of communication and brainstorming, tenacity, tears, and laughter to achieve our goals.

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Table 1

Biomedical Instrumentation to Measure Pressures[a]

Component	Definition
Transducer	Device that senses an event and converts to electrical signals
Signal conditioning equipment	Processes the signal to that it can be understood or interpreted. May involve amplification of the signal and/or modification of the signal to reduce extraneous “noise”
Display	Converts the electrical signal into a form that can be interpreted by the practitioner/researcher; oscilloscope is commonly used
Recording and data-processing equipment	Device to store and/or record signals; includes recorders and computers

[a]Based on Stone and Frazier[1] and Ganz and Pugh.[2]

Table 2

Research Terms Used in Physiologic Monitoring[a]

Characteristic	Definition
Range	Set of values that can be captured by the instrumentation
Validity	Ability of the instrument to measure the variable of interest
Accuracy	Degree to which the physiologic variable measures the actual value
Precision	Amount of change that is detected by the instrument; the smaller the change detected (high sensitivity), the greater the precision
Reliability/stability	Accuracy over time
Drift	Slow change in output signal independent of the measured property (eg, pressure); associated with time, temperature, or other factors

[a]Based on Stone and Frazier[1] and Ganz and Pugh.[2]

Table 3

Concepts Related to Download of Data[a]

Concept	Definition
RS-232	Abbreviation for Recommended Standard 232. Serial ports on devices use this method of communication to transfer data from 1 device to another
Serial port	Interface on a computer that allows information to be transferred in or out of the device 1 bit at a time. A bit is the basic unit of information in computing and has a value of “0” or “1”
Parallel port	Interface on a computer that allows several bits to be transferred simultaneously
Connector	Method of linking 2 devices; includes the 25-pin D-type and 9-pin. Newer devices use USB, LAN, and firewire connections
Baud rate	Number of times per second that a line changes state; related to speed of transfer of data

Abbreviations: LAN, local area network; USB, Universal Serial Bus.

[a]Data compiled from http://www.taltech.com and http://www.linfo.org/serial_port.html. Accessed December16, 2007.

Table 4

Options for Retrieving Continuous Physiologic Data to Measure Endotracheal Tube Cuff Pressure

Option	Positive	Negative
Use the portable monitor; record the data manually from the trend view	Monitor available Monitor worked well in bench testing Familiarity with monitor	Data stored for only 10 hours; protocol specified a 12-hour period for data collection Unable to download data to computer; minute-by-minute values need to be transcribed from monitor to paper/pencil or electronic spreadsheet format, increasing the risk for error
Use the bedside monitors. Attach the transducer to one of the pressure modules on the bedside monitor. Record the data manually from the trend view	Bedside monitors in all patients' rooms Familiarity with bedside equipment Could collect data from more than 1 patient at a time Able to print trend data to verify accuracy of manual data entry	Bedside monitors were older models; not able to download data directly to laptop Antiquated dot matrix printers used to record trend data from the monitor. Data available only in graphic view—not minute-by-minute values Printers did not always work
Seek access to another portable monitor with capability of downloading data	Equipment can be self-contained on a cart for ease of use by research assistants Software provides more precise data and ability to download data into text, graphic, and spreadsheet formats	Additional time needed to acquire a monitor to meet the needs of the study Data-acquisition software needed to facilitate download of data