87

Medical Instruments and Devices Used in the Home

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87.1 Scope of the Market for Home Medical Devices
87.2 Unique Challenges to the Design and Implementation of High-Tech Homecare Devices
The Device Must Provide a Positive Clinical Outcome • The Device Must be Safe to Use • The Device Must be Designed So That It *Will* be Used
87.3 Infant Monitor Example
87.4 Conclusions

87.1 Scope of the Market for Home Medical Devices

The market for medical devices used in the home and alternative sites has increased dramatically in the last 10 years and has reached an overall estimated size of more than $1.6 billion [FIND/SVP, 1992]. In the past, hospitals have been thought of as the only places to treat sick patients. But with the major emphasis on reducing healthcare costs, increasing numbers of sicker patients move from hospitals to their homes. Treating sicker patients outside the hospital places additional challenges on medical device design and patient use. Equipment designed for hospital use can usually rely on trained clinical personnel to support the devices. Outside the hospital, the patient and/or family members must be able to use the equipment, requiring these devices to have a different set of design and safety features. This chapter will identify some of the major segments using medical devices in the home and discuss important design considerations associated with home use.

Table 87.1 outlines market segments where devices and products are used to treat patients outside the hospital [FIND/SVP, 1992]. The durable medical equipment market is the most established market providing aids for patients to improve access and mobility. These devices are usually not life supporting or sustaining, but in many cases they can make the difference in allowing a patient to be able to function outside a hospital or nursing or skilled facility. Other market segments listed employ generally more sophisticated solutions to clinical problems. These will be discussed by category of use.

The incontinence and ostomy area of products is one of the largest market segments and is growing in direct relationship to our aging society. Whereas sanitary pads and colostomy bags are not very "high-tech," well-designed aids can have a tremendous impact on the comfort and independence of these patients. Other solutions to incontinence are technically more sophisticated, such as use of electric stimulation of the sphincter muscles through an implanted device or a miniature stimulator inserted as an anal or vaginal plug to maintain continence [Wall et al., 1993].

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iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1044
Page 1

TABLE 87.1 Major Market Segments Outside Hospitals

Market Segment	Estimated Equipment Size 1991	Device Examples
Durable medical equipment	$373 M*	Specialty beds, wheelchairs, toilet aids, ambulatory aids
Incontinence and ostomy products	$600 M*	Sanitary pads, electrical stimulators, colostomy bags
Respiratory equipment	$180 M*	Oxygen therapy, portable ventilators, nasal CPAP, monitors, apnea monitors
Drug infusion, drug measurement	$300 M	Infusion pumps, access ports, patient-controlled analgesia (PCA), glucose measurement, implantable pumps
Pain control and functional stimulation	$140 M	Transcutaneous electrical nerve stimulation (TENS), functional electrical nerve stimulation (FES)

**Source:* FIND/SVP [1992].

Many forms of equipment are included in the Respiratory segment. These devices include those that maintain life support as well as those that monitor patients' respiratory function. These patients, with proper medical support, can function outside the hospital at a significant reduction in cost and increased patient comfort [Pierson, 1994]. One area of this segment, infant apnea monitors, provides parents or caregivers the cardio/respiratory status of an at-risk infant so that intervention (CPR etc.) can be initiated if the baby has a life-threatening event. The infant monitor shown in Fig. 87.1 is an example of a patient monitor designed for home use and will be discussed in more detail later in this chapter. Pulse oximetry monitors are also going home with patients. They are used to measure noninvasively the oxygen level of patients receiving supplemental oxygen or ventilator-dependent patients to determine if they are being properly ventilated.

Portable infusion pumps are an integral part of providing antibiotics, pain management, chemotherapy, and parenteral and enteral nutrition. The pump shown in Fig. 87.2 is an example of technology that allows the patient to move about freely while receiving sometimes lengthy drug therapy. Implantable drug pumps are also available for special long-term therapy needs.

FIGURE 87.1 Infant apnea monitor used in a typical home setting (photo courtesy of EdenTec Corporation).

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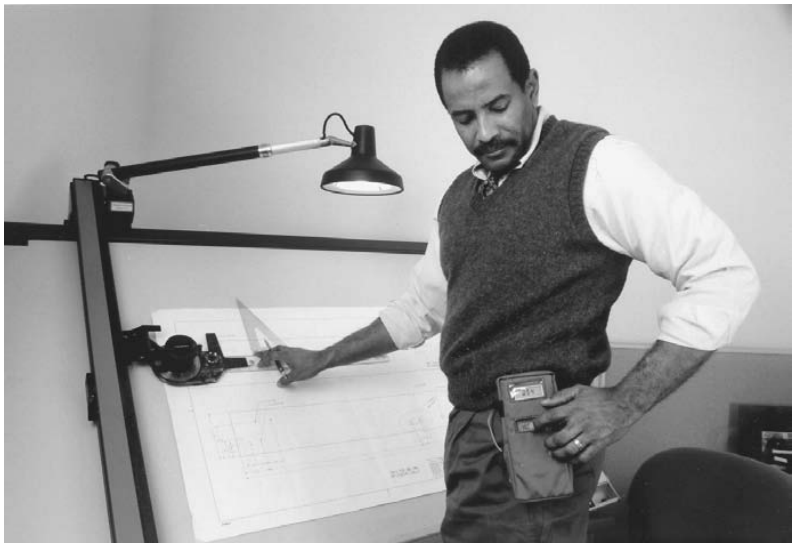

FIGURE 87.2 Portable drug pump used throughout the day (photo courtesy of Pharmacia Deltec Inc.).

Pain control using electric stimulation in place of drug therapy continues to be an increasing market. The delivery of small electric impulses to block pain is continuing to gain medical acceptance for treatment outside the hospital setting. A different form of electric stimulation called functional electric stimulation (FES) applies short pulses of electric current to the nerves that control weak or paralyzed muscles. This topic is covered as a separate chapter in this book.

Growth of the homecare business has created problems in overall healthcare costs since a corresponding decrease in hospital utilization has not yet occurred. In the future, however, increased homecare will necessarily result in reassessment and downsizing in the corresponding hospital segment. There will be clear areas of growth and areas of consolidation in the new era of healthcare reform. It would appear, however, that homecare has a bright future of continued growth.

87.2 Unique Challenges to the Design and Implementation of High-Tech Homecare Devices

What are some of the unique requirements of devices that could allow more sophisticated equipment to go home with ordinary people of varied educational levels without compromising their care? Even though each type of clinical problem has different requirements for the equipment that must go home with the patient, certain common qualities must be inherent in most devices used in the home. Three areas to consider when equipment is used outside of the hospital are that the device (1) must provide a positive clinical outcome, (2) must be safe and easy to use, and (3) must be user-friendly enough so that it will be used.

The Device Must Provide a Positive Clinical Outcome

Devices cannot be developed any longer just because new technology becomes available. They must solve the problem for which they were intended and make a significant clinical difference in the outcome or management of the patient while saving money. These realities are being driven by those who reimburse for devices, as well as by the FDA as part of the submission for approval to market a new device.

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The Device Must Be Safe to Use

Homecare devices may need to be even *more* reliable and even *safer* than hospital devices. We often think of hospitals as having the best quality and most expensive devices that money can buy. In addition to having the best equipment to monitor patients, hospitals have nurses and aids that keep an eye on patients so that equipment problems may be quickly discovered by the staff. A failure in the home may go unnoticed until it is too late. Thus systems for home use really need extra reliability with automatic backup systems and/or early warning signals.

Safety issues can take on a different significance depending on the intended use of the device. Certain safety issues are important regardless of whether the device is a critical device such as an implanted cardiac pacemaker or a noncritical device such as a bed-wetting alarm. No device should be able to cause harm to the patient regardless of how well or poorly it may be performing its intended clinical duties. Devices must be safe when exposed to all the typical environmental conditions to which the device could be exposed while being operated by the entire range of possible users of varied education and while exposed to siblings and other untrained friends or relatives. For instance, a bed-wetting alarm should not cause skin burns under the sensor if a glass of water spills on the control box. This type of safety issue must be addressed even when it significantly affects the final cost to the consumer.

Other safety issues are not obviously differentiated as to being actual safety issues or simply nuisances or inconveniences to the user. It is very important for the designer to properly define these issues; although some safety features can be included with little or no extra cost, other safety features may be very costly to implement. It may be a nuisance for the patient using a TENS pain control stimulator to have the device inadvertently turned off when its on/off switch is bumped while watching TV. In this case, the patient only experiences a momentary cessation of pain control until the unit is turned back on. But it could mean injuries or death to the same patient driving an automobile who becomes startled when his TENS unit inadvertently turns on and he causes an accident.

Reliability issues can also be mere inconveniences or major safety issues. Medical devices should be free of design and materials defects so that they can perform their intended functions reliably. Once again, reliability does not necessarily need to be expensive and often can be obtained with good design. Critical devices, i.e., devices that could cause death or serious injury if they stopped operating properly, may need to have redundant systems for backup, which likely will increase cost.

The Device Must be Designed So That It *Will* Be Used

A great deal of money is being spent in healthcare on devices for patients that end up not being used. There are numerous reasons for this happening including that the wrong device was prescribed for the patient's problem in the first place; the device works, but it has too many false alarms; the device often fails to operate properly; it is cumbersome to use or difficult to operate or too uncomfortable to wear.

Ease of Use

User-friendliness is one of the most important features in encouraging a device to be used. Technological sophistication may be just as necessary in areas that allow ease of use as in attaining accuracy and reliability in the device. The key is that the technologic sophistication be transparent to the user so that the device does not intimidate the user. Transparent features such as automatic calibration or automatic sensitivity adjustment may help allow successful use of a device that would otherwise be too complicated.

Notions of what makes a device easy to use, however, need to be thoroughly tested with the patient population intended for the device. Caution needs to be taken in defining what "simple" means to different people. A VCR may be simple to the designer because all features can be programmed with one button, but it may not be simple to users if they have to remember that it takes two long pushes and one short to get into the clock-setting program.

Convenience for the user is also extremely important in encouraging use of a device. Applications that require devices to be portable must certainly be light enough to be carried. Size is almost always important for anything that must fit within the average household. Either a device must be able to be left in place

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in the home or it must be easy to set up, clean, and put away. Equipment design can make the difference between the patient appropriately using the equipment or deciding that it is just too much hassle to bother.

Reliability

Users must also have confidence in the reliability of the device being used and must have confidence that if it is not working properly, the device will tell them that something is wrong. Frequent breakdowns or false alarms will result in frustration and ultimately in reduced compliance. Eventually patients will stop using the device altogether. Most often, reliability can be designed into a product with little or no extra cost in manufacturing, and everything that can be done at no cost to enhance reliability should be done. It is very important, however, to understand what level of additional reliability involving extra cost is necessary for product acceptance. Reliability can always be added by duplicated backup systems, but the market or application may not warrant such an approach. Critical devices which are implanted, such as cardiac pacemakers, have much greater reliability requirements, since they involve not only patient frustration but also safety.

Cost Reimbursement

Devices must be paid for before the patient can realize the opportunity to use new, effective equipment. Devices are usually paid for by one of two means. First, they are covered on an American Medical Association Current Procedural Terminology Code (CPT-code) which covers the medical, surgical, and diagnostic services provided by physicians. The CPT-codes are usually priced out by Medicare to establish a baseline reimbursement level. Private carriers usually establish a similar or different level of reimbursement based on regional or other considerations. Gaining new CPT-codes for new devices can take a great deal of time and effort. The second method is to cover the procedure and device under a capitated fee where the hospital is reimbursed a lump sum for a procedure including the device, hospital, homecare, and physician fees.

Every effort should be made to design devices to be low cost. Device cost is being scrutinized more and more by those who reimburse. It is easy to state, however, that a device needs to be inexpensive. Unfortunately the reality is that healthcare reforms and new regulations by the FDA are making medical devices more costly to develop, to obtain regulatory approvals for [FDA, 1993], and to manufacture.

Professional Medical Service Support

The more technically sophisticated a device is, the more crucial that homecare support and education be a part of a program. In fact, in many cases, such support and education are as important as the device itself.

Medical service can be offered by numerous homecare service companies. Typically these companies purchase the equipment instead of the patient, and a monthly fee is charged for use of the equipment along with all the necessary service. The homecare company then must obtain reimbursement from third-party payers. Some of the services offered by the homecare company include training on how to use the equipment, CPR training, transporting the equipment to the home, servicing/repairing equipment, monthly visits, and providing on-call service 24 hours a day. The homecare provider must also be able to provide feedback to the treating physician on progress of the treatment. This feedback may include how well the equipment is working, the patient's medical status, and compliance of the patient.

87.3 Infant Monitor Example

Many infants are being monitored in the home using apnea monitors because they have been identified with breathing problems [Kelly, 1992]. These include newborn premature babies who have apnea of prematurity [Henderson-Smart, 1992; NIH, 1987], siblings of babies who have died of sudden infant death syndrome (SIDS) [Hunt, 1992; NIH, 1987], or infants who have had an apparent life-threatening episode (ALTE) related to lack of adequate respiration [Kahn et al., 1992; NIH, 1987]. Rather than keeping infants in the hospital for a problem that they may soon outgrow (1–6 months), doctors often discharge

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them from the hospital with an infant apnea monitor that measures the duration of breathing pauses and heart rate and sounds an alarm if either parameter crosses limits prescribed by the doctor.

Infant apnea monitors are among the most sophisticated devices used routinely in the home. These devices utilize microprocessor control, sophisticated breath-direction and artifact rejection firmware algorithms, and internal memory that keeps track of use of the device as well as recording occurrence of events and the physiologic waveforms associated with the events. The memory contents can be downloaded directly to computer or sent via modem remotely where a complete 45-day report can be provided to the referring physician (see Fig. 87.3).

Most apnea monitors measure breathing effort through impedance pneumography. A small (100–200 uA) high-frequency (25–100 kHz) constant-current train of pulses is applied across the chest between a pair of electrodes. The voltage needed to drive the current is measured, and thereby the effective impedance between the electrodes can be calculated. Impedance across the chest increases as the chest expands and decreases as the chest contracts with each breath. The impedance change with each breath can be as low as 0.2 ohms on top of an electrode base impedance of 2000 ohms, creating some interesting signal-to-noise challenges. Furthermore, motion artifact and blood volume changes in the heart and chest can cause impedance changes of 0.6 ohms or more that can look just like breathing. Through the same pair of electrodes, heart rate is monitored by picking up the electrocardiogram (ECG) [AAMI, 1988].

Because the impedance technique basically measures the motion of the chest, this technique can only be used to monitor central apnea or lack of breathing effort. Another less common apnea in infants called obstructive apnea results when an obstruction of the airway blocks air from flowing in spite of breathing effort. Obstructive apnea can not be monitored using impedance pneumography [Kelly, 1992].

There is a very broad socioeconomic and educational spectrum of parents or caregivers who may be monitoring their infants with an apnea monitor. This creates an incredible challenge for the design of the device so that it is easy enough to be used by a variety of caregivers. It also puts special requirements on the homecare service company that must be able to respond to these patients within a matter of minutes, 24 hours a day.

The user-friendly monitor shown in Fig. 87.1 uses a two-button operation, the on/off switch, and a reset switch. The visual alarm indicators are invisible behind a back-lit panel except when an actual alarm occurs. A word describing the alarm then appears. By not showing all nine possible alarm conditions unless an alarm occurs, parent confusion and anxiety is minimized. Numerous safety features are built into the unit, some of which are noticeable but many of which are internal to the operation of the monitor. One useful safety feature is the self-check. When the device is turned on, each alarm LED lights in sequence, and the unit beeps once indicating that the self-check was completed successfully. This gives users the opportunity to confirm that all the alarm visual indicators and the audible indicator are working and provides added confidence for users leaving their baby on the monitor. A dual-level battery alarm gives an early warning that the battery will soon need charging. The weak battery alarm allows users to reset the monitor and continue monitoring their babies for several more hours before depleting the battery to the charge battery level where the monitor must be attached to the ac battery charger/adapter. This allows parents the freedom to leave their homes for a few hours knowing that their child can continue to be monitored.

A multistage alarm reduces the risk of parents sleeping through an alarm. Most parents are sleep-deprived with a new baby. Consequently, it can be easy for parents in a nearby room to sleep through a monitor alarm even when the monitor sounds at 85 dB. A three-stage alarm helps to reduce this risk. After 10 seconds of sounding at 1 beep per second, the alarm switches to 3 beeps per second for the next 10 seconds. Finally, if an alarm has not resolved itself after 20 seconds, the alarm switches to 6 beeps per second. Each stage of alarm sounds more intense than the previous one and offers the chance of jolting parents out of even the deepest sleep.

The physician always prescribes what alarm settings should be used by the homecare service company when setting up the monitor. As a newborn matures, these settings may need to be adjusted. Sometimes the parents can be relied upon for making these setting changes. To allow both accessibility to these switches as well as to keep them safe from unauthorized tampering from a helping brother or sister, a

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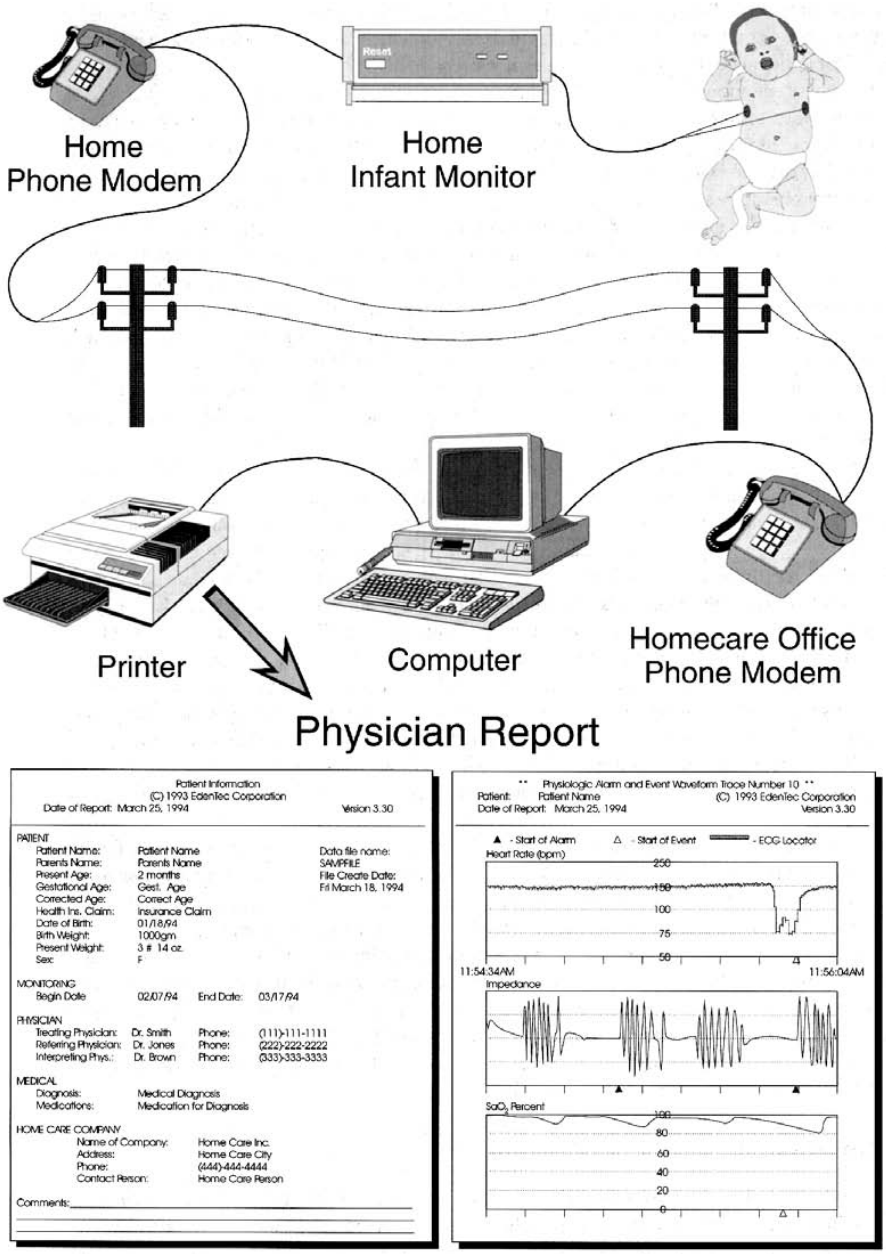

FIGURE 87.3 Infant apnea monitor with memory allows data to be sent by modem to generate physician report (drawing courtesy of EdenTec Corporation).

special tamper-resistant-adjustment procedure is utilized. Two simultaneous actions are required in order to adjust the alarm limit settings. The reset button must be continually pressed on the front of the unit while changing settings on the back of the unit. Heart rate levels are set in beats per minute, and apnea

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duration is set in single-second increments. Rather than using easy-to-set push-button switches, "pen-set" switches are used which require a pen or other sharp implement to make the change. If the proper switch adjustment procedure is not followed, the monitor alarms continuously and displays a switch alarm until the settings are returned to their original settings. A similar technique is used for turning the monitor off. The reset button must first be pressed and then the on/off switch turned to the off position. Violation of this procedure will result in a switch alarm.

Other safety features are internal to the monitor and are transparent to the user. The monitor's alarm is designed to be normally on from the moment the device is turned on. Active circuitry controlled by the microprocessor turns the alarm off when there are no active alarm conditions. If anything hangs up the processor or if any of a number of components fail, the alarm will not turn off and will remain on in a fail-safe mode. This "alarm on unless turned off" technique is also used in a remote alarm unit for parents with their baby in a distant room. If a wire breakage occurs between the monitor and the remote alarm unit, or a connector pulls loose, or a component fails, the remote alarm no longer is turned off by the monitor and it alarms in a fail-safe condition.

Switches, connectors, and wires are prone to fail. One way to circumvent this potential safety issue is use of switches with a separate line for each possible setting. The monitor continuously polls every switch line of each switch element to check that "exactly" one switch position is making contact. This guards against misreading bad switch elements, a switch inadvertently being set between two positions, or a bad connector or cable. Violation of the "exactly one contact condition" results in a switch alarm.

It is difficult to manage an apnea monitoring program in rural areas where the monitoring family may be a hundred miles or more away from the homecare service company. There are numerous ways to become frustrated with the equipment and stop using the monitor. Therefore, simplicity of use and reliability are important. Storing occurrence of alarms and documenting compliance in internal memory in the monitor help the homecare service company and the remote family cope with the situation. The monitor shown in Fig. 87.1 stores in digital memory the time, date, and duration of (1) each use of the monitor; (2) occurrence of all equipment alarms; and (3) all physiologic alarms including respiratory waveforms, heart rate, and ECG for up to a 45-day period. These data in the form of a report (see Fig. 87.3) can be downloaded to a laptop PC or sent via modem to the homecare service company or directly to the physician.

87.4 Conclusions

Devices that can provide positive patient outcomes with reduced overall cost to the healthcare system while being safe, reliable, and user-friendly will succeed based on pending healthcare changes. Future technology in the areas of sensors, communications, and memory capabilities should continue to increase the potential effectiveness of homecare management programs by using increasingly sophisticated devices. The challenge for the medical device designer is to provide cost-effective, reliable, and easy-to-use solutions that can be readily adopted by the multidisciplinary aspects of homecare medicine while meeting FDA requirements.

Defining Terms

Apnea: Cessation of breathing. Apnea can be classified as **central, obstructive,** or mixed, which is a combination.

Apnea of prematurity: Apnea in which the incidence and severity increases with decreasing gestational age attributable to immaturity of the respiratory control system. The incidence has increased due to improved survival rates for very-low-birth-weight premature infants.

Apparent life-threatening episode (ALTE): An episode characterized by a combination of apnea, color change, muscle tone change, choking, or gagging. To the observer it may appear the infant has died.

Capitated fee: A fixed payment for *total* program services versus the more traditional fee for service in which each individual service is charged.

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