



“Getting More Information”

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

Mail: Office of Surveillance and Biometrics (HFZ 510)
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Rockville, MD 20850

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FDA SAFETY ALERT
IMPORTANT TIPS FOR APNEA MONITOR USERS

February 16, 1990

To Health Professionals, Manufacturers and Distributors of Infant Apnea Monitors:

This is to stress the need to educate home users of infant apnea monitors about the limitations of these devices and how to use them properly. We ask that you pass this information on to those using these monitors in their homes.

We have two basic concerns about apnea monitors used in home settings. First, parents and caregivers may not fully understand the limitations of these devices--that is, they may place more confidence in the device than the technology warrants. Second, they may not always know how to properly use and care for the monitor; this is particularly troublesome in view of the fact that the incidence of "false alarms" and missed apneic events can be lessened by proper operation and maintenance of the monitor.

To help parents and caregivers understand the limitations of infant apnea monitors and to help them achieve optimum results in using these devices, we have prepared the attached Safety Alert, "Important Tips for Apnea Monitor Users." We encourage health professionals who prescribe and supervise the use of apnea monitors to use this material as an aid in discussing proper use with parents and caregivers, and to photocopy and distribute it as needed.

Extra copies are available from:

FDA
HFZ-240
Rockville, MD 20857

Thank you for your help in this important effort.

Sincerely,
John C. Villforth
Director
Center for Devices and
Radiological Health

SAFETY ALERT:

IMPORTANT TIPS FOR APNEA MONITOR USERS

Be aware that apnea monitors are not perfect.

Most apnea monitors will miss some apneas (stopped breathing). For example, they may mistake body movement for breathing. Also, if your baby has apnea due to choking, the monitor could mistake the movement caused by choking for breathing

Use your monitor.

Be certain to monitor your baby as prescribed. Although it is not perfect, the monitor will detect most apneas not caused by choking. Most monitors will also warn you if your baby's heart rate becomes abnormal. But the monitor can only do its job if it is turned on and properly connected to your baby. Don't stop using monitor until your doctor says it's OK.

Be tolerant of false alarms.

False alarms can't be completely avoided . Some of them actual apneas where the monitor alarm has stimulated your baby to breathe again. Many false alarms may be caused by movement, loose lead wires or improperly placing the electrodes. Sometimes adjusting the monitor to reduce the number of false alarms may increase the chance that the monitor would miss a real apnea. Do not try to adjust the monitor yourself.

Do not sleep in the same bed as your monitored baby.

Touching or moving near your baby the monitor, or the cables could fool the monitor and cause it to miss apneas. This can accidentally happen when a person or a pet sleeps in the same bed as the monitored baby.

Keep children and pets away from the monitor and your baby.

Children and pets might disconnect the the monitor or cause other accidents, particularly when you are asleep or out of the room.

Be sure that the alarm is working.

Be sure that the alarm works during the monitor self-test. Check the alarm before each use. If the alarm does not work, call your equipment provider immediately. Watch your baby closely until the problem is solved.

Be sure that you can hear the alarm.

Make sure you can hear the alarm from other rooms or while there is noise in the house. Have someone test the monitor alarm

while you are in those rooms or noisy environment. If the alarm is not loud enough to be heard in the rooms where you need to hear it, ask your equipment provider for a remote alarm

Check the monitor's breath detection indicator.

Listen while your baby breathes and watch the "breath" or "respiration" light on the monitor (if your unit has one). While your baby is breathing quietly, the light should flash once and only once for each breath your baby takes, although it may flash additional times when your baby is moving. If your baby is breathing quietly and "breath" or "respiration" light flashes more or fewer times than your baby breathes, contact your equipment provider immediately.

Check the battery or charger connection.

If your monitor has an outside battery or charger, gently wiggle and twist the connectors to be sure they are tight. If the monitor has a light that indicates when the battery is charging, it should not flicker when the connectors are gently wiggled or twisted

Keep the monitor at least a foot away from sources of interference.

Interference could fool the monitor and cause it to miss apneas. Sources of interference include electrical appliances, such as electric blankets, electric water-bed heaters, TV sets, air conditioners, and remote telephones. Sometimes draperies or rugs made of synthetic fabric can also cause interference with the monitor due to static electricity. If you feel that your monitor is not working properly, immediately contact the equipment provider and ask them to check the monitor in your environment.

Be aware that radio signals may interfere with monitor operation.

If you live close to a strong transmitter such as TV, AM or FM radio, police or fire stations, a HAM radio operator or an airport, their signals could be picked up as heart and/or breath signals by your monitor. Checking your monitor's heart indicator and breath detection indicator (see above) can help to determine if your monitor is affected by this interference. In some locations it may not be possible for the monitor to work properly. If so, check with your doctor about other types of monitors.

Follow the manufacturers recommendations.

Be sure to read, understand and follow the instructions in the manual that comes with the apnea monitor. If you don't have a manual, ask your equipment provider for one.

**Report major
problems with the
monitor.**

If the monitor isn't working properly, contact your equipment provider immediately for service and watch your baby closely while the monitor is not working properly. If your equipment provider can't help you, contact the manufacturer.

Attention

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