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Medical Device Reporting (MDR) - General Information



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What is Medical Device Reporting (MDR)?

Medical Device Reporting (MDR) is the mechanism for the Food and Drug Administration to receive significant medical device adverse events from **manufacturers, importers and user facilities**, so they can be detected and corrected quickly. If you are a consumer or health professional you should use the [MEDWATCH](#) program for reporting significant adverse events or product problems with medical products.

User Facilities and MDR

User Facilities (e.g., hospitals, nursing homes) are required to report suspected medical device related deaths to both the FDA and the manufacturers. User facilities report medical device related serious injuries only to the manufacturer. If the medical device manufacturer is unknown, the serious injury is reported by the facility to FDA. Health professionals within a user-facility should familiarize themselves with their institution procedures for reporting adverse events to the FDA.

Guidance for User Facilities Medical Device Reporting [is available](#).

Note: Please do not send the actual device to FDA as stated in Block D9 of the MEDWATCH 3500A form. In Block D9 indicate that you are keeping the device or returning it to the manufacturer.

History of MDR Regulation

Legislation requiring device user facility reporting was enacted by Congress to increase the amount of information the Food and Drug Administration (FDA) and device manufacturers receive about problems with medical devices. Although manufacturers and importers of medical devices have been required since 1984 to report to FDA all device-related deaths, serious injuries, and certain malfunctions, numerous reports have shown there is widespread underreporting. A 1986 General Accounting Office (GAO) study showed that less than one percent of device problems occurring in hospitals are reported to FDA, and the more serious the problem with a device, the less likely it was to be reported. A GAO followup study in 1989 concluded that despite full implementation of the Medical Device Reporting (MDR) regulation, serious shortcomings still existed.

Under the Safe Medical Devices Act of 1990 (SMDA), device user facilities must report device-related deaths to the FDA and the manufacturer, if known. Device user facilities must also report device-related serious injuries to the manufacturer, or to the FDA if the manufacturer is not known. In addition, SMDA also required that device user facilities submit to FDA, on a semiannual basis, a summary of all reports submitted during that time period. The device user facility reporting section of SMDA became effective on

November 28, 1991.

To implement SMDA, FDA published a tentative final rule in the Federal Register on November 26, 1991, and invited comments on the regulation. Over 300 comments were received by FDA. Then, on June 16, 1992, the President signed into law the Medical Devices Amendments of 1992 (Public Law 102-300; the Amendments of 1992), amending certain provisions (section 519 of the Food, Drug, and Cosmetic Act) relating to reporting of adverse events. The primary impact of the 1992 Amendments on device user facility reporting was to clarify certain terms and to establish a single reporting standard for device user facilities, manufacturers, importers, and distributors. A final rule published in the Federal Register on December 11, 1995, addresses the comments received by the FDA and the changes mandated by the Amendments of 1992.

Update on FDAMA:

The Food and Drug Administration Modernization Act (FDAMA) was signed on 11/21/97 and became effective on 2/19/98. There were four changes that affected MDR:

1. Manufacturers and distributors/importers do not need to submit annual certification.
2. Domestic distributors are no longer required to file MDR reports, but must continue to maintain complaint files. [Importers (initial distributors for devices manufactured overseas and imported into the USA) must continue to file MDR reports.]
3. User facilities must now file an annual report instead of semiannual reports to summarize their adverse event reports.
4. Sentinel reporting by user facilities was proposed.
The MDR regulation was revised on 1/26/2000 and 5/8/2000 to incorporate the changes under FDAMA

[Note Concerning the Amendments to the MDR Regulation to Implement FDAMA Changes](#) (effective March 27, 2000)

Updated 9/22/2002

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Adverse Event Report

RESPIRONICS COLORADO, INC LIFECARE PORTABLE VOLUME VENTILATOR

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Model Number PVV

Event Type Death **Patient Outcome** Death;

Event Description

On 05/12/97, respironics became aware that a patient had expired while using a lifecare pvv ventilator. Apparently, the caregiver turned the machine off to suction the patient and neglected to turn the ventilator back on. The machine was picked up by the local sheriff's department for subsequent evaluation.

Manufacturer Narrative

Although the device was not returned to respironics, a company rep. Was permitted to attend a brief meeting where a respiratory therapist ran the machine through testing. The device was found to be operating to specifications. The medical examiner was present for this testing. Based on all available information, it can be concluded that user error caused this event, as the machine was not turned on while attached to the patient. *note: no user facility report was received. Part f completed by mfr. * standard disclaimer on file. The ventilator involved in this incidnet was confiscated by the sheriff's dept and was not returned to respironics for a complete evaluation. However, a company representative was present when the machine was run through operational tests by a respiratory therapist as requested by the medical examiner. The device was found to be operating properly. There is no evidence suggesting that malfunction caused or contributed to the patient's death.

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Brand Name LIFECARE

Type of Device PORTABLE VOLUME VENTILATOR

Baseline Brand Name LIFECARE

Baseline Generic Name PORTABLE VOLUME VENTILATOR

Baseline Catalogue Number 33001

Baseline Model Number PVV

Baseline Device Family PVV
Baseline Device 510(K) Number [K791033](#)
Is Baseline PMA Number Provided? No
Baseline Preamendment? No
Transitional? No
510(K) Exempt? No
Shelf Life(Months) NA
Date First Marketed 11/22/1978
Manufacturer (Section F) RESPIRONICS COLORADO, INC
 1401 West 122nd Ave.
 Westminster CO 80234 3421
Manufacturer (Section D) RESPIRONICS COLORADO, INC
 1401 West 122nd Ave.
 Westminster CO 80234 3421
Manufacturer (Section G) RESPIRONICS COLORADO, INC.
 1401 West 122nd Ave.
 Westminster CO 80234 3421
Manufacturer Contact Tim Giblin
 1401 W. 122nd Ave.
 Westminster , CO 80234-3421
 (303) 457 -9234 ext 1052
Device Event Key 94838
MDR Report Key 96049
Event Key 90396
Report Number 1718784-1997-00017
Device Sequence Number 1
Product Code [CBK](#)
Report Source Manufacturer
Source Type Company Representative
Type of Report Initial
Report Date 06/05/1997
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received 06/05/1997
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Lay User/Patient

Device MODEL Number PVV
Device Catalogue Number 33001
OTHER Device ID Number 29963
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? No
Was the Report Sent to FDA? No
Device Age 13 yr
Event Location Home
Date Manufacturer Received 05/12/1997
Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer
Date Device Manufactured 01/01/1984
Is The Device Single Use? No
Type of Device Usage Unkown

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Adverse Event Report

PURITAN BENNETT CORP. OXICLIP PC 20 PERSONAL OXYGEN CONSERVER

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Model Number OXICLIP PC 20

Event Type Injury

Event Description

The hcp driver went to the patient's home around 7:40 a. M. To switch out the pc 20 because the patient said it was failing. The driver switched out the pc 20 but did not perform an evaluation. The driver then left. Later that day, the patient went to the hospital.

Manufacturer Narrative

The patient is prescribed 2 lpm. The patient was using the pc 20 with liquid oxygen. Backup e-cylinder oxygen sources were also in the patient's home. Device has been returned but evaluation is not yet complete. Product labeling warns the oxygen supplied is for supplemental use only and is not intended to be life supporting or life sustaining. Labeling warns equipment is not intended for use by patients who would suffer immediate, permanent, or serious health consequences as a result of an interruption in their oxygen supply.

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Brand Name OXICLIP PC 20

Type of Device PERSONAL OXYGEN CONSERVER

Baseline Brand Name OXICLIP PC 20

Baseline Generic Name PERSONAL OXYGEN CONSERVER

Baseline Catalogue Number B-701442-00

Baseline Model Number OXICLIP PC 20

Baseline Device Family OXYGEN CONSERVER

Baseline Device 510(K) Number [K873901](#)

Is Baseline PMA Number Provided? No

Baseline Preamendment? No

Transitional? No
510(K) Exempt? No
Shelf Life(Months) NA
Date First Marketed 08/26/1999
Manufacturer (Section F) PURITAN BENNETT CORP.
5647 Dividend Dr.
Cryogenic Equipment Division
Indianapolis IN 46241
Manufacturer (Section D) PURITAN BENNETT CORP.
5647 Dividend Dr.
Cryogenic Equipment Division
Indianapolis IN 46241
Manufacturer Contact Angela Dickson
5647 Dividend Drive
Indianapolis , IN 46241
(317) 837 -6217
Device Event Key 440377
MDR Report Key 451379
Event Key 427473
Report Number 1825511-2003-00006
Device Sequence Number 1
Product Code [BYJ](#)
Report Source Manufacturer
Source Type Other
Type of Report Initial
Report Date 04/01/2003
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received 04/01/2003
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? Yes
Device Operator Lay User/Patient
Device MODEL Number OXICLIP PC 20
Device Catalogue Number B-701442-00
Was Device Available For Evaluation? Device Not Returned To Manufacturer
Date Returned to Manufacturer 03/25/2003
Is The Reporter A Health Professional? No

Was the Report Sent to FDA? No

Date Manufacturer Received 03/05/2003

Was Device Evaluated By Manufacturer? No

Is The Device Single Use? No

Type of Device Usage Unkown

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Adverse Event Report

RESPIRONICS, INC. PLV 100 CONTINUOUS VENTILATOR

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Event Type Injury **Patient Outcome** Disability;

Event Description

Report received from distributor that a patient reportedly became disconnected from the ventilator (tubing disconnected from exhalation valve) and no alarm sounded. The patient's pulse oximetry level was reported to be 53% and subsequently the patient allegedly suffered brain damage due to hypoxia. Additional information received as follows: doctor's report received. Diagnosis=hypoxic brain damage following an unnoticed disconnection from the respirator; the surgery physician expressed that he suspected hypoxic brain damage. No further therapeutic or diagnostic measures initiated due to unfavorable underlying disease. The distributor's report as follows: both devices were tested and no problems found. An oximeter was available but not reportedly used at the time of event. The caregiver reported that the patient had copious amounts of secretions and that the patient should have been suctioned. Copious secretions were reported in the circuit at the time of the event. Caregiver reportedly stated that the patient's diagnosis (from event) was no different from the diagnosis made when the patient was first placed on the ventilator in 1998. It is unknown as to the amount of time the patient was reportedly disconnected.

Manufacturer Narrative

Two techs from the distributor evaluated both devices in the pt's home in the presence of the caregiver. It is unknown which unit was involved at the time of the alleged incident. Testing was performed at the pt's settings (ac, rate=12, vt=900ml, i/e=1:2, flow=54 l/min, sensitivity=-4, low pressure alarm=10, high pressure alarm=30) and no problems were found. Testing included the removal of the tubing from the exhalation valve and both devices sounded an alarm as appropriate. An oximeter (alarm) was available but was reportedly not in use at the time of the reported incident. Manufacturer labeling warns that "if there is any doubt that the pt connected for ventilatory support may possibly be fully dependent on ventilation, there must be add'l alarms and monitoring equipment sufficient to notify the trained caregivers to respond within one minute after the alarm was activated". The techs supplied the caregiver with add'l sensors. It appears the device functioned as intended and user error may have contributed to the event due to the excessive amounts of secretions reported at the time of the event.

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Brand Name [PLV 100](#)

Type of Device CONTINUOUS VENTILATOR

Manufacturer (Section F) RESPIRONICS, INC.
1001 Murry Ridge Lane
Murrysville PA 15668 8550

Manufacturer (Section D) RESPIRONICS, INC.
1001 Murry Ridge Lane
Murrysville PA 15668 8550

Manufacturer Contact Calvin Eggers
1001 Murry Ridge Drive
Murrysville , PA 15668-8550
(724) 387 -4217

Device Event Key 336919

MDR Report Key 347608

Event Key 327372

Report Number 2518422-2001-00044

Device Sequence Number 1

Product Code [CBK](#)

Report Source Manufacturer

Source Type Distributor

Type of Report Initial

Report Date 08/17/2001,07/18/2001

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 08/17/2001

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Lay User/Patient

Was Device Available For Evaluation? Yes

Is The Reporter A Health Professional? No

Was the Report Sent to FDA? No

Distributor Facility Aware Date 07/08/2001

Device Age 7 yr

Event Location Home

Date Manufacturer Received 07/18/2001

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Date Device Manufactured 01/01/1994

Is The Device Single Use? No

Type of Device Usage Unkown

Patient TREATMENT DATA

Date Received: 08/17/2001 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,	EXHALATION VALVE, MR700 WITH HEATED HOSE ASSEMBLY,,	
2,	TRACH.,	

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Adverse Event Report

RESPIRATORY KIT

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Model Number RES90RESUB

Event Type Other **Patient Outcome** Other;

Manufacturer Narrative

No sample was retained for evaluation. The product in question is part of an allegiance custom products kit, resuscitation bag, catalog number 2k8005, which is an allegiance product. Investigation was initiated at the allegiance facility as well as at another facility. No issues were noted. The product is an adult resuscitation bag with a 30mm bacteria filter attached to the exhalation port, with a mask attached to the pt port. There were no abnormalities in the production of the product. Info received from the user facility notes that the nurse placed the mask onto the filter instead of the pt port. It is unclear as to how this could have been done since the mask is not able to fit to the filter port. This report appears to be due to user error. The instructions for use states that the resuscitator be used by trained personnel only and the exhalation port is marked clearly. Do not occlude exhalation port.

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Brand Name RESPIRATORY KIT
Type of Device RESPIRATORY KIT
Baseline Device Family RESPIRATORY KIT
Is Baseline PMA Number Provided? No
Is Baseline 510(K) Number Provided? No
Baseline Preamendment? No
Transitional? No
510(K) Exempt? Yes
Shelf Life(Months) NA
Date First Marketed 04/13/1999
Manufacturer Contact Patricia Sharpe-Gregg
 1500 Waukegan Road

McGaw Park , IL 60085
(847) 578 -3636

Device Event Key 241677
MDR Report Key 257306
Event Key 233943
Report Number 1423507-1999-00374
Device Sequence Number 1
Product Code [MOD](#)
Report Source Manufacturer
Source Type Health Professional,User facility
Type of Report Initial
Report Date 12/30/1999
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received 12/30/1999
Is This An Adverse Event Report? No
Device MODEL Number RES90RESUB
Device Catalogue Number RES90RESUB
Is The Reporter A Health Professional? Yes
Was the Report Sent to FDA? No
Date Manufacturer Received 11/30/1999
Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer
Date Device Manufactured 04/01/1999
Is The Device Single Use? No
Type of Device Usage Unkown

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Adverse Event Report

RESPIRONICS COLORADO, INC. LIFECARE PORTABLE VOLUME VENTILATOR

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Model Number PLV 100

Event Type Death **Patient Outcome** Death;

Event Description

It was reported that a patient became disconnected from a ventilator. The ventilator allegedly did not alarm and the patient expired.

Manufacturer Narrative

It was reported that a patient expired after becoming disconnected from the ventilator. It was reported that no alarm sounded. Preliminary checks of the machine (as reported to respironics) indicate that the low pressure alarm was set near 2 cmh20, which is typically too low a setting based on patient ventilating pressures. When the low pressure alarm setting was increased to 10 cmh20, a more realistic setting for normal use, the device alarmed properly. The customer does not wish to return the device for further evaluation. The cause of the alarm failure is attributable to user error, based on available information. The customer was unable to provide any additional patient information. Note: no user facility report was received. Parts of section f were completed by the mfr.

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Brand Name LIFECARE

Type of Device PORTABLE VOLUME VENTILATOR

Baseline Brand Name LIFECARE

Baseline Generic Name PORTABLE VOLUME VENTILATOR

Baseline Catalogue Number 35001

Baseline Model Number PLV 100

Baseline Device Family PLV 100

Baseline Device 510(K) Number [K832467](#)

Baseline Shelf Life Information A

Is Baseline PMA Number Provided? No

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Date First Marketed 10/20/1983

Manufacturer (Section F) RESPIRONICS COLORADO, INC.
1401 West 122nd Ave.
Westminster CO 80234 3421

Manufacturer (Section D) RESPIRONICS COLORADO, INC.
1401 West 122nd Ave.
Westminster CO 80234 3421

Manufacturer (Section G) RESPIRONICS COLORADO, INC.
1401 West 122nd Ave.
Westminster CO 80234 3421

Manufacturer Contact Tim Giblin
1401 W 122nd Ave
Westminster , CO 80234-3421
(303) 457 -9234 ext 1052

Device Event Key 204735

MDR Report Key 210979

Event Key 197963

Report Number 1718784-1999-00002

Device Sequence Number 1

Product Code [CBK](#)

Report Source Manufacturer

Source Type Health Professional,Company Representative

Type of Report Initial

Report Date 01/22/1999

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 02/23/1999

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Lay User/Patient

Device MODEL Number PLV 100

Device Catalogue Number 35001

OTHER Device ID Number 37641
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? Yes
Was the Report Sent to FDA? No
Device Age 33 mo
Event Location Home
Date Manufacturer Received 01/22/1999
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 04/01/1996
Is The Device Single Use? No
Type of Device Usage Unkown

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Adverse Event Report

RESPIRONICS, INC. PLV 100 CONTINUOUS VENTILATOR

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Model Number 37001

Event Type Death **Patient Outcome** Death;

Event Description

Medwatch rec'd from user facility that a pt was found unresponsive while using the device, cpr was initiated without success. Further info obtained from the user facility (risk management) as follows: a nurse and pt care aides were in the pt's room shortly before the incident occurred. The pt was placed in bed, the nurse connected the ventilator circuit to the pt and left the room. The aides completed their work with the pt and also exited the room shortly after the nurse. After an undisclosed period of time, the pt was found unresponsive. No alarms were reported to have sounded. A remote alarm was also in use and not reported to have sounded either. However, when hosp personnel inspected the device, the power was turned off. The user facility sent the device to an independent third party for eval and it is reported that the device operated properly and as intended.

Manufacturer Narrative

Note: user facility report received. Information transferred onto this report. Functional tests were performed on the device, by a manufacturer technician, at the user facility's location in the presence of hospital staff. The device operated according to specifications. It was also reported by the user facility that an independent third party evaluated the device prior to the manufacturer's evaluation and no problems were found; the device functioned normally. From the available information, it appears that no device malfunction occurred and that user error may have contributed to the reportable event.

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Brand Name PLV 100

Type of Device CONTINUOUS VENTILATOR

Baseline Brand Name PLV-102 VENTILATOR, 110V

Baseline Generic Name CONTINUOUS VENTILATOR

Baseline Catalogue Number 37001

Baseline Model Number 37001
Other Baseline ID Number 300104838
Manufacturer (Section F) RESPIRONICS, INC.
 1001 Murry Ridge Drive
 Murrysville PA 15668 8550
Manufacturer (Section D) RESPIRONICS, INC.
 1001 Murry Ridge Drive
 Murrysville PA 15668 8550
Manufacturer Contact Calvin Eggers
 1001 Murry Ridge Drive
 Murrysville , PA 15668-8550
 (724) 387 -4217
Device Event Key 339231
MDR Report Key 349923
Event Key 329608
Report Number 2518422-2001-00047
Device Sequence Number 1
Product Code [CBK](#)
Report Source Manufacturer
Source Type Health Professional,User facility
Type of Report Initial
Report Date 07/20/2001,08/06/2001
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received 09/05/2001
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number 37001
Device Catalogue Number 37001
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Was the Report Sent to FDA? Yes
Date Report Sent to FDA 07/20/2001
Distributor Facility Aware Date 07/11/2001
Device Age 6.2 yr

Event Location Nursing Home
Date Report TO Manufacturer 07/20/2001
Date Manufacturer Received 08/06/2001
Was Device Evaluated By Manufacturer? Yes
Date Device Manufactured 06/01/1995
Is The Device Single Use? No
Type of Device Usage Unkown

Patient TREATMENT DATA

Date Received: 09/05/2001 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,REMOTE ALARM.,		

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Adverse Event Report

NELLCOR PURITAN BENNETT 7200AE MICROPROCESSOR VENTILATOR VOLUME VENTILATOR

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Model Number 7200AE

Event Type Death **Patient Outcome** Death;

Event Description

The customer alleged that the 7200 ae ventilator alarm sounded and the registered nurse checked the device for loose connections. Finding none, the registered nurse silenced the alarm then went to get the family as pt was a do not resuscitate. The alarm went off again and a nearby respiratory therapist responded and found a loose connection where the tubing connects to the filter. The pt then later expired that day within a short time frame. It is believed this action by the therapist corrected the original reported problem. The reporter states that the staff member did not follow protocol at the facility to provide alternate support to the pt while getting additional assistance. The reporter does not feel they need additional training and the staff has had re-reinforcement of the accepted protocol for this type event. It is not verified that the ventilator had a loose connection, and no malfunction may have occurred. The reporter is calling for an evaluation of the device by an outside third party. Co has requested results of the device evaluation for the co records. The time line for the evaluation was expected to be within a week, if the holidays allow. At the time of filing this report, the device has not been evaluated and is not available for evaluation by the mfr. This report is not an admission by nellcor puritan-bennett that this device caused or contributed to the event alleged in this report.

Manufacturer Narrative

Based upon info in co's possession, it is unknown whether this event has occurred at a greater frequency or severity than is usual for the device.

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Brand Name 7200AE MICROPROCESSOR VENTILATOR

Type of Device VOLUME VENTILATOR

Baseline Brand Name 7200 SERIES VENTILATOR

Baseline Generic Name VOLUME VENTILATOR

Baseline Catalogue Number NA
Baseline Model Number 7200AE
Baseline Device Family 7200 SERIES VENTILATOR
Baseline Device 510(K) Number [K823858](#)
Is Baseline PMA Number Provided? No
Baseline Preamendment? No
Transitional? No
510(K) Exempt? No
Shelf Life(Months) NA
Date First Marketed 01/01/1993
Manufacturer (Section F) NELLCOR PURITAN BENNETT
 2200 Faraday Ave.
 Carlsbad CA 92008
Manufacturer (Section D) NELLCOR PURITAN BENNETT
 2200 Faraday Ave.
 Carlsbad CA 92008
Manufacturer (Section G) PURITAN BENNETT CORP.
 5931 Priestly Dr., Suite 100
 Carlsbad CA 92008
Manufacturer Contact Julie Mallett
 2200 Faraday Ave
 Carlsbad , CA 92008
 (800) 362 -4594 ext 6632
Device Event Key 197895
MDR Report Key 206410
Event Key 191385
Report Number 2024500-1999-00007
Device Sequence Number 1
Product Code [CBK](#)
Report Source Manufacturer
Source Type Health Professional,User facility
Type of Report Initial
Report Date 01/12/1999
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received 01/12/1999
Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device MODEL Number 7200AE

Device Catalogue Number 7200

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Distributor Facility Aware Date 12/14/1998

Device Age 7 yr

Date Manufacturer Received 12/14/1998

Was Device Evaluated By Manufacturer? No

Date Device Manufactured 01/01/1992

Is The Device Single Use? No

Type of Device Usage Reuse

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Adverse Event Report

RESPIRONICS GEORGIA, INC. SMARTMONITOR INFANT/APNEA MONITOR

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Model Number 970S

Event Type Death **Patient Outcome** Death;

Event Description

Patient expired from ligature strangulation when the smartmonitor cord become entangled around the patient's neck.

Manufacturer Narrative

Patient expired from ligature strangulation by the cords attached to the device. The monitor wires were stuck down between the crib and the crib wall and then came up over the top of the crib to the monitor that was propped up on top of phone books. Device alarmed for 4 hours before the victim's family member responded. Investigation by the medical examiners staff concluded the manner of death was accidental. The device was not returned to the manufacturer for evaluation. Device warning and caution labeling indicates: "always keep the smartmonitor and accessories out of the reach of children". And "do not allow the patient cable, lead wires, or battery charger cable to become tangled, coiled, or crossed, or wrapped around the patient's neck, arms or legs. This condition may cause strangulation".

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Brand Name SMARTMONITOR

Type of Device INFANT/APNEA MONITOR

Baseline Brand Name SMARTMONITOR W/ STANDARD MEMORY

Baseline Generic Name CARDIAC MONITOR

Baseline Catalogue Number NA

Baseline Model Number 970S

Baseline Device Family NA

Baseline Device 510(K) Number [K903287](#)

Is Baseline PMA Number Provided? No
Baseline Preamendment? No
Transitional? No
510(K) Exempt? No
Shelf Life(Months) NA
Date First Marketed 12/01/1989
Manufacturer (Section F) RESPIRONICS GEORGIA, INC.
 175 Chastain Meadows Court
 Kennesaw GA 30144 3724
Manufacturer (Section D) RESPIRONICS GEORGIA, INC.
 175 Chastain Meadows Court
 Kennesaw GA 30144 3724
Manufacturer Contact Kathy Reagin
 175 Chastain Meadows Court
 Kennesaw , GA 30144-3724
 (770) 429 -2840
Device Event Key 340967
MDR Report Key 351682
Event Key 331300
Report Number 1040777-2001-00021
Device Sequence Number 1
Product Code [DRT](#)
Report Source Manufacturer
Type of Report Initial
Report Date 09/18/2001
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received 09/18/2001
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Lay User/Patient
Device MODEL Number 970S
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? No
Was the Report Sent to FDA? No
Date Manufacturer Received 08/13/2001

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Date Device Manufactured 02/01/1990

Is The Device Single Use? No

Type of Device Usage Reuse

Patient TREATMENT DATA

Date Received: 09/18/2001 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,OXYGEN.,		

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Adverse Event Report

RESPIRONICS COLORADO, INC. LIFECARE PORTABLE VOLUME VENTILATOR

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Model Number PLV 100

Event Type Death **Patient Outcome** Death;

Event Description

On 10/15/97 a pt found to have expired while using the suspect device. Although it was noted that the device was delivering breaths, no significant pressure was being registered on the pressure manometer. It was noted that the exhalation valve was wrapped in a towel or rag. When the rag was removed, it was observed that the exhalation valve tubing had been disconnected. Although the device was not returned for eval, a designated employee was permitted to observe testing of the unit by an independent respiratory therapist. This testing was also witnessed by an officer from the police dept. The device was found to be operating to specs. The low pressure alarm was set at 4-5 cmh20 pressure.

Manufacturer Narrative

The brief testing of the suspect device by an independent r. T. Revealed that the device was operating to specs. All alarms were functional. However, the low pressure alarm was found to be set too low to detect small leaks, such as the disconnected exhalation valve tubing. (as was found at the scene.) user error may have contributed to this event. Note: no user facility report was rec'd. Parts of section f were completed by the mfr. Standard disclaimer on file.

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Brand Name LIFECARE
Type of Device PORTABLE VOLUME VENTILATOR
Baseline Brand Name LIFECARE
Baseline Generic Name PORTABLE VOLUME VENTILATOR
Baseline Catalogue Number 35800
Baseline Model Number PLV 100
Baseline Device Family PLV 100

Baseline Device 510(K) Number [K832467](#)

Baseline Shelf Life Information A

Is Baseline PMA Number Provided? No

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Date First Marketed 10/20/1983

Manufacturer (Section F) RESPIRONICS COLORADO, INC.
1401 W. 122nd Ave.
Westminster CO 80234 3421

Manufacturer (Section D) RESPIRONICS COLORADO, INC.
1401 W. 122nd Ave.
Westminster CO 80234 3421

Manufacturer (Section G) RESPIRONICS COLORADO, INC.
1401 West 122nd Ave.
Westminster CO 80234 3421

Manufacturer Contact Tim Giblin
1401 W 122nd Ave
Westminster , CO 80234-3421
(303) 457 -9234 ext 1052

Device Event Key 128344

MDR Report Key 131305

Event Key 123414

Report Number 1718784-1997-00042

Device Sequence Number 1

Product Code [CBK](#)

Report Source Manufacturer

Source Type Health Professional

Type of Report Initial

Report Date 10/15/1997

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 11/13/1997

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Lay User/Patient

Device MODEL Number PLV 100

Device Catalogue Number 35001
OTHER Device ID Number 42849
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? Yes
Was the Report Sent to FDA? No
Device Age 13 yr
Event Location Home
Date Manufacturer Received 10/15/1997
Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer
Date Device Manufactured 08/01/1984
Is The Device Single Use? No
Type of Device Usage Unkown

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Adverse Event Report

DRAGER MEDICAL AG & CO. KGAA EVITA 2 DURA VENTILATOR CONTINUOUS

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Model Number EVITA 2 DURA

Event Type Death **Patient Outcome** Death;

Event Description

A nurse noticed the evita 2 dura posted suddenly an audible alarm while using on a patient. The ventilator was set as cpap/asb mode, apnea backup vent function was switched off. One and a half hours later the patient died.

Manufacturer Narrative

The investigation of the device revealed, that it worked within it's specification and had no malfunction. The patient's breathing was supported with the assistant ventilation mode cpap/asb. When the spontaneous breathing of the patient stopped, the device has responded as specified with an optical and acoustical apnoea-alarm. The additional option "apnoea ventilation", which is a safeguard for minimal ventilation during apnoea situations, was switched off by the user. The evita 2 dura is designed and behaved in accordance to the international standards. The required apnoea-alarm was active. It is the responsibility of the user to choose the right parameters and safeguards of the ventilator in accordance to the patient's needs.

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Brand Name EVITA 2 DURA
Type of Device VENTILATOR CONTINUOUS
Baseline Brand Name EVITA 2 DURA
Baseline Generic Name VENTILATOR, CONTINUOUS
Baseline Catalogue Number UNK
Baseline Model Number EVITA 2 DURA
Manufacturer (Section F) DRAGER MEDICAL AG & CO. KGAA
 Moislinger Allee 53-55
 Luebeck

Manufacturer (Section D) GERMANY 23542
 DRAGER MEDICAL AG & CO. KGAA
 Moislinger Allee 53-55
 Luebeck
 GERMANY 23542

Manufacturer Contact Frank Clanzett
 Moislinger Allee 53-55
 Lubeck
 GERMANY 23542
 011 494 518822868

Device Event Key 428524

MDR Report Key 439585

Event Key 416051

Report Number 9611500-2003-00001

Device Sequence Number 1

Product Code [CBK](#)

Report Source Manufacturer

Source Type Company Representative

Type of Report Initial

Report Date 01/28/2003

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 01/28/2003

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? Yes

Device Operator Health Professional

Device MODEL Number EVITA 2 DURA

Was Device Available For Evaluation? Yes

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age na

Event Location Not Applicable

Date Manufacturer Received 01/20/2003

Was Device Evaluated By Manufacturer? Yes

Date Device Manufactured 08/01/1999

Is The Device Single Use? No

Type of Device Usage Reuse

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Adverse Event Report

RESPIRONICS, INC. MONARCH MINI MASK NASAL MASK

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Model Number 572003

Event Type Injury **Patient Outcome** Required Intervention;

Event Description

Pt's wife applied mask for first time, noted during the first 10-15 minutes, pt was very comfortable. Pt than began having difficulty breathing, color became dark, and pt signaled "he was in distress". When mask was removed and replaced with pt's regular nasal mask, color and breathing returned to normal. Pt suffered no harm or lasting affect from the reported event.

Manufacturer Narrative

Complaint not received from a user facility, but directly from the user. There was no malfunction of the device; the pt's wife had applied the mask improperly, impeding the air flow to the pt. The pt's wife was instructed in the proper application of the device, and there have been no further reported problems. Labeling that comes with the device instructs the user in the proper application of the device.

Manufacturer Narrative

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Brand Name MONARCH MINI MASK

Type of Device NASAL MASK

Baseline Brand Name MONARCH MINI MASK

Baseline Generic Name NASAL MASK

Baseline Catalogue Number 572003

Baseline Model Number 572003

Baseline Device Family MONARCH MINI MASK

Baseline Device 510(K) Number [K945938](#)

Baseline Shelf Life Information No

Is Baseline PMA Number Provided? No

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Date First Marketed 03/20/1996

Manufacturer (Section F) RESPIRONICS, INC.
1001 Murry Ridge Dr
Murreyville PA 15888 8550

Manufacturer (Section D) RESPIRONICS, INC.
1001 Murry Ridge Dr
Murreyville PA 15888 8550

Manufacturer (Section G) RESPIRONICS, INC.
1001 Murry Ridge Ln.
Murrysville PA 15668

Manufacturer Contact Lou Anne Kinney
1001 Murry Ridge Dr
Murryville , PA 15668
(412) 733 -0200 ext 5329

Device Event Key 38257

MDR Report Key 36863

Event Key 34679

Report Number 2518422-1996-00001

Device Sequence Number 1

Product Code [BZD](#)

Report Source Manufacturer

Source Type Consumer

Type of Report Initial,Followup

Report Date 09/06/1996

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 09/06/1996

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Lay User/Patient

Device MODEL Number 572003

Device Catalogue Number 572003
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? No
Was the Report Sent to FDA? No
Event Location Home
Date Manufacturer Received 08/08/1996
Was Device Evaluated By Manufacturer? No
Is The Device Single Use? No
Type of Device Usage Initial

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Adverse Event Report

FISHER & PAYKEL HEALTHCARE, LTD. HC201 CPAP HUMIDIFIER

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Model Number HC201

Event Type Malfunction

Event Description

Report received of melting to bottom of unit. No injury reported. Sample was returned for evaluation. Water ingress was evident around the power supply pcb section, indicating product misuse. This led to eventual component failure and localised heat damage to pcb and enclosure, including small hole melted in enclosure. Unit was deactivated by component failure.

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Brand Name HC201
Type of Device CPAP HUMIDIFIER
Baseline Generic Name CPAP HUMIDIFIER
Baseline Catalogue Number HC201
Baseline Model Number HC201
Baseline Device Family CPAP HUMIDIFIER
Baseline Device 510(K) Number [K973161](#)
Is Baseline PMA Number Provided? No
Baseline Preamendment? No
Transitional? No
510(K) Exempt? No
Shelf Life(Months) NA
Date First Marketed 07/10/1998
 FISHER & PAYKEL HEALTHCARE, LTD.

Manufacturer (Section F) 15 Maurice Paykel Place
 East Tamaki, Auckland
 NEW ZEALAND

Manufacturer (Section D) FISHER & PAYKEL HEALTHCARE, LTD.
 15 Maurice Paykel Place
 East Tamaki, Auckland
 NEW ZEALAND

Manufacturer Contact David Bousfield, Engineer
 15 Maurice Paykel Place
 East Tamaki, Po Box 14-348
 Panmure, Auckland
 NEW ZEALAND
 649 574 0100

Device Event Key 330856

MDR Report Key 341519

Event Key 321591

Report Number 9611451-2001-00014

Device Sequence Number 1

Product Code [BZD](#)

Report Source Manufacturer

Source Type Distributor

Type of Report Initial

Report Date 06/26/2001

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 06/27/2001

Is This An Adverse Event Report? No

Is This A Product Problem Report? Yes

Device Operator Lay User/Patient

Device MODEL Number HC201

Device Catalogue Number HC201

Was Device Available For Evaluation? Yes

Date Returned to Manufacturer 05/24/2001

Is The Reporter A Health Professional? No Answer Provided

Was the Report Sent to FDA? No

Date Manufacturer Received 04/11/2001

Was Device Evaluated By Manufacturer? Yes

Date Device Manufactured 05/01/2000

Is The Device Single Use? No

Type of Device Usage Reuse

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