Class 1 Recall Continuous Ventilator

See Related Information[23]

Date Posted	November 04, 2015
Recall Status[1]	Open
Recall Number	Z-0151-2016
Recall Event ID	72319[24]
Premarket Notification 510(K) Number	K131744[25]
Product Classification	Ventilator, Continuous, Facility Use[26] - **Product Code** CBK[27]
Product	HAMILTON-G5 Ventilator with software versions between V2.00 and V2.31. Anesthesiology: The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients
Code Information	software versions between V2.00 and V2.31. Ventilator catalog number: 1590001; Software catalog number: 159700. Serial numbers: 1231 1233 1234 1235 1014 1296 1593 1594 1595 1626 1628 1629 1631 1632 1633 1634 1637 1693 1697 1862 1863 2021 2411 2412 2413 2414 2416 2417 2418 2591 2592 2593 2594 2595 2681 2683 2686 2687 2689 2776 2777 2778 2779 2780 2781 2784 2785 2786 2787 2789 2790 2793 2794 2798 2803 2887 2947 2948 2951 2952 2953 2954 2958 2959 3362 3366 3368 3369 3371 3372 3375 3376 3377 3378 3379 3382 3383 3384 3548 3596 3598 3599 3600 3602 3609 3610 3612 3861 3869 3911 3912 3913 3976 3977 3978 3981 3987 3988 3990 3991 4004 4009 4012 4015 4016 4017 4019 4021 4023 4024 4026 4027 4028 4029 4030 4031 4034 4035 4037 4038 4050 4052 4053 4054 4059 4060 4071 4072 4076 4078 4083 4084 4086 4087 4089 4153 4155 4156 4159 4161 4180 4196 4197 4200 4202 4206 4207 4377 4394 4395 4396 4399 4401 4402 4403 4404 4405 4444 4447 4448 4449 4450 4452 4453 4459 4463 4465 4468 4469 4470 4471 4474 4475 4476 4477 4478 4483 4484 4485 4487 4488 4489 4490 4491 4492 4493 4494 4498 4560 4567 4568 4569 4570 4571 4572 4575 4578 4580 4583 4586 4588 4589 4596 4597 4599 4601 4607 4611 4615 4618 4619 4620 4622 4623 4625 4627 4629 4630 4632 4657 4664 4666 4667 4668 4671 4672 4673 4675 4676 4677 4679 4681 4682 4695 4698 4699 4700 4701 4702 4703 4774 4775 4776 4777 4778 4779 4780 4781 4782 4794 4903 4904 4907 4937 4938 4939 4940 4941 4942 4943 4945 4946 4947 4948 4949 4950 4951 4952 4953 5025 5038 5044 5049 5050 5054 5055 5057 5058 5059 5061 5062 5063 5064 5065 5253 5254 5256 5257 5262 5302 5304 5307 5308 5309 5310 5311 5312 5313 5357 5361 5362 5363 5374 5437 5452 5462 5468 5523 5764 5774 5791 5794 5803 5815 5816 5818 5820 5825 5826 5829 5831 5832 5835 5836 5839 5842 5843 6118 6119 6144 6152 6159 6319 6320 6336 6337 6345 6537 6556 6557 6561 6562 6829 6832 6833 6834 6835 6836 6837 6838 6841 6851 6856 6859 6867 6868 6869 6888 6889 6890 6985 6987 6989 6992 6994 7077 7078 7086 7329 7330 2684 2802 4025 4598 6806 6811 7526 7528 7529 7530 7531 7532 7684 7685 7706 7707 7770 7919 7948 7965 7971 7973 7984 7994 7996 7999 8119 8120 8122 8123 8131 8133 8134 8141 8506 8510 8516 8517 8520 8523 8531 8534 8535 8536 8539 8570 1278 1294 1413 1414 1415 1417 1418 1419 1420 2024 2025 2026 2027 2301 2302 2303 2888 28891599 1600 1601 1602 1603 1605 1606 1607 1608 1609 1610 1611 1612 1613 1614 1615 1616 1617 1618 1619 1865 1866 1867 1868 1869 1870 1871 1872 1873 1874 1875 1876 1877 1878 1879 1880 6620 6652 6665 6666 6668 6672 7588 7589 7590 2020 7993 2506 2521 2522 2523 2525 2526 2527 2530 2531 2532 2877 2878 2880 2881 2882 2883 2884 2885 2886 2890 2894 5026 5027 5028 5029 5030 5032 5039 5040 5045 5046 5047 5048 5051 5052 5053 3885 3887 3888 3889 4044 4047 4057 4073 4074 4075 4077 4079 4080 4081 4088 4090 4091 4092 4093 4094 4095 4097 4098 4099 4100 4103 4104 4106 4108 4109 4110 4111 4112 4113 4115 4117 4118 4141 4144 4145 4147 4148 4149 4150 4223 4225 4227 4345 4348 4351 4353

4354 4356 4357 4358 4359 4360 4365 4366 4367 4372 4096 4101 4102 4107 4222 4224 4226 4584 4591 4603 4604 4606 4654 4655 4658 4659 4660 4661 4662 4663 4665 4119 4120 4142 4143 4146 4152 4157 4158 4160 4162 4164 4454 4456 4464 4467 4472 4954 4955 4956 4957 4958 4959 4960 4961 4962 4963 6308 6311 6312 6314 6318 6323 7079 7085 7090 7091 7092 7095 7083 4600 4605 4608 4609 4610 4612 4613 4614 4616 4617 4656 5248 5251 5245 5246 5249 5250 5255 5258 5259 5260 5261 5263 5332 5344 5345 5346 5347 5350 5351 5352 5353 5395 5397 5457 5465 5466 5481 5827 5830 6031 6039 6062 5451 5512 5516 5518 5592 5740 5533 5535 5456 5511 5522 5568 5569 5577 5624 5629 5651 5531 5542 5697 5704 5706 5709 5710 5712 5720 5723 5730 5732 5733 5824 5846 5851 5853 5857 5858 5876 5915 5930 5932 5933 5941 5948 6015 6024 6025 6026 6027 6028 6029 6030 6032 6033 6034 6049 6050 6055 6067 6069 6081 6072 6074 6075 6077 6078 6079 6080 6082 6083 6293 6303 6305 6306 6309 6315 6247 6265 6276 6292 8511 8512 8513 6247 6265 6276 6292 8511 8512 8513 6247 6265 6276 6292 8511 8512 8513 6247 6265 6276 6292 8511 8512 8513 6277 6278 6279 6291 6300 6307 6377 6409 6419 6432 6434 6438 6440 6441 6495 6498 6499 6621 6251 6289 6457 6460 6487 6489 6743 6749 6422 6423 6451 6454 6470 6503 6504 6506 6507 6509 6511 6512 6515 6517 6710 6740 6804 6893 6445 6446 6455 6469 6505 6508 6510 6522 6523 6437 6439 6442 6497 6588 6494 6560 6563 6574 6575 6576 6578 6579 6580 6582 6585 6586 6587 6589 6593 6594 6595 6597 6598 6599 6600 6601 6602 6603 6604 6605 6606 6607 6608 6609 6610 6611 6612 6596 6642 6649 6651 6654 6656 6669 6670 6625 6644 6646 6647 6648 6650 6653 6655 6657 6658 6659 6661 6662 6664 6671 6673 6995 6996 6999 7001 7022 7021 6739 6750 6752 6753 6755 6758 6870 6763 6791 6795 6887 7358 7376 7377 7400 7411 6991 7030 7061 7100 7706 7069 7072 7336 7409 7559 7560 7564 7575 7581 7585 7586 7593 7597 7604 7606 7646 7657 7658 7659 8256 7388 7391 7401 7402 7403 7412 7416 7428 7429 7433 7440 7445 7446 7447 7448 7449 7450 7451 7452 7453 7454 7455 7456 7457 7458 7459 7460 7461 7462 7463 7464 7465 7467 7468 7469 7470 7533 7534 7535 7536 7537 7538 7539 7566 7570 7599 7605 7996 7709 7854 7855 7857 7858 7853 7856 8118 8121 8124 8135 8136 8137 8238 8239 8240 8241 8362 8363 8364 8365 8368 8366 8367 8369 8371 8372 8373 8374 8375 8376 8400 8561 8564 8566 8567 8542 8543 8544 8546 8547 8548 8549 8550 8685 8686 8687 8788 8789 8790.

Recalling Firm/ Manufacturer	Hamilton Medical, Inc. 4990 Energy Way Reno, Nevada 89502-4123
For Additional Information Contact	Daniel Belanger 775-742-2792
Manufacturer Reason for Recall	Ventilation and alarms of a HAMILTON-G5 ventilator can be suppressed unintentionally after the activation of a suctioning maneuver by the operator; this situation can occur regardless of the selected patient group (neonatal, pediatric and adult).
FDA Determined Cause [2]	DESIGN: Device Design
Action	Hamilton Medical issued a letter dated April 22, 2014, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were notified that their Hamilton Medical Account Manager would contact them to coordinate the deactivation of the Ventilation Suppression feature. Customers were asked to review the Medical Device Field Safety Corrective Action. Customers with questions were instructed to call 800-426-6331, Ext 215.
Quantity in Commerce	1128
Distribution	Nationwide Distribution
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = CBK and Original Applicant = TERUMO BCT, INC..[30]

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