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附件 1

医疗器械召回事件报告表

提交：□企业所在地省级食品药品监督管理部门　　■器械注册/备案部门

产品名称	呼吸机	注册证或备案凭证编码	国械注进 20163545139
生产企业名称	Respironics California, Inc.		
代理人名称	飞利浦（中国）投资有限公司		
召回单位负责人和联系方式，经办人和联系方式	闫韬 010-85273802		
产品的适用范围	带成比例压力通气和 Auto-Trak+软件选项的 V60 呼吸机是一种辅助呼吸机，用于加强患者呼吸，预期用于需要机械通气的自主呼吸患者：医院或其他机构中医师指导下的呼吸衰竭、慢性呼吸功能不全、阻塞性睡眠呼吸暂停患者。该呼吸机预定支持体重大于 20 千克的儿科患者及成年患者，也适用于与无创应用选择标准相同的气管插管患者。应由合格的医疗专业人员如医师、护士和呼吸治疗师使用，且只能与各种 Respironics 推荐的患者回路、界面（面罩）、加湿器组件和其他附件一起使用。		
涉及地区和国家	全球	召回级别	一级召回
涉及产品生产（或进口	3442 台	涉及产品	V60 呼吸机

中国）批次、数量		型号、规格	
识别信息 （如批号）	请见附页	涉及产品在中国的销售数量	3441 台，库存 1 台
召回原因简述	随着时间的推移，低频震动可能使内部的"马达控制板至数据采集板"带状电缆上母接头内的针脚发生部分位移，这就会在某些时候导致阻抗过高，从而影响数据的传输。因此，在使用过程中，或是在医院移动的过程中，呼吸机可能出现"通电自检"失败或"持续自检"失败，并最终出现错误和关机。 如果 V60 呼吸机在使用电池电源的过程中出现关机现象，那么就会听到至少持续 2 分钟的紧急报警声。如果 V60 呼吸机连接的是交流电源，那么报警声就会不断的持续下去，除非有操作员进行干预方能停止报警。如果 V60 连接到远程报警系统，那么报警系统在被触发后将不会停止，直到操作人员采取措施。 设备屏幕上可能显示如下错误代码：100A、1006、1007、或者 1008。如果呼吸机显示任一上述代码，就说明呼吸机已经出现通信错误，这可能就是上述缆线造成的。 (召回文件内部编号：FCO 86600037)		

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纠正行动简述（包括召回要求和处理方式等）	飞利浦将安排现场服务工程师或经批准的服务提供商免费为用户更换有潜在风险的缆线。

报告单位：（盖章）　　负 责 人：（签字）梁壮

报 告 人：（签字）闫韬　　报告日期：2017 年 5 月 2 日

附页：受影响设备序列号：

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100069611	100100285	100053592	100149998	201008008	100046160
100069745	100100286	100053593	100149999	201008010	201003379
100069957	100100288	100060405	100150000	201009622	201003428
100069960	100100311	100060415	100150001	201009735	201003436
100069966	100107016	100060585	100150002	201009736	100035900

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100069967	100107129	100060597	100150003	201009738	100036047
100069969	100107134	100060599	100150004	201009761	100036306
100069986	100107140	100071927	100150005	201009763	100047058
100069987	100107440	100071976	100150006	201009802	100049070
100069992	100107449	100072022	100150007	201009804	100049076
100078382	201007452	100072023	100150009	201009805	100052403
100078383	201007654	100072053	100150010	201009808	100052532
100078384	201007666	100072054	100150011	201009812	100052535
100078386	201007672	100072055	100150012	201009867	100053058
100078690	201007673	100072059	100150013	201009868	100053062
100078695	201007674	100072061	100150014	201009955	201003093
100078697	201007677	100072128	100150015	201009957	201003109
100078698	100115467	100078709	100150016	201009959	100033573
100078700	100115471	100078711	100150017	201010612	100034502
100078703	100115475	100078713	100150163	201010613	100034503
100034505	100034506	100034516	100034504		

PHILIPS

召回计划（FCO 86600037）

1. 医疗器械销售情况及拟召回数量

- 此次召回的产品 V60 呼吸机系进口产品，目前中国市场涉及此次有问题的序列号产品数量为 3442 台。

2. 召回措施的具体内容

- 飞利浦通过安全通知告知涉及的用户并发布变更订单（FCO）纠正此问题。飞利浦自主发起本次纠正措施，并向受影响设备的全部经销商提供客户通知信。
- 本次召回预计将于 2017 年 11 月完成，预计将于 2018 年 5 月递交召回总结报告等（其中 6 个月用于观察召回效果)。

3 召回信息的公布途径与范围

- 飞利浦会将相关客户信通知所涉及的经销商，由经销商通知最终用户。此次召回为主动召回，仅限通知受影响的用户。

4 召回的预期效果

- 飞利浦通过主动免费为用户更换问题电缆来消除如果在患者使用呼吸机过程中出现呼吸机停止工作的情况，可能导致患者的 SpO2 下降、如果尚未及时注意报警，就可能导致低氧血症或高碳酸血症的风险。

5 医疗器械召回后的处理措施

- 飞利浦将安排现场服务工程师或经批准的服务提供商免费为用户更换问题缆线。

---------- 结束 ----------

PHILIPS

调查评估报告（FCO86600037）

1.召回医疗器械的具体情况：

- 此次召回的产品名称为 V60 呼吸机。
- 此次召回的产品序列号请见召回报告表。

2. 实施召回的原因：

- 随着时间的推移，低频震动可能使内部的“马达控制板至数据采集板”带状电缆上母接头内的针脚发生部分位移，这就会在某些时候导致阻抗过高，从而影响数据的传输。因此，在使用过程中，或是在医院移动的过程中，呼吸机可能出现“通电自检”失败或“持续自检”失败，并最终出现错误和关机。

  如果 V60 呼吸机在使用电池电源的过程中出现关机现象，那么就会听到至少持续 2 分钟的紧急报警声。如果 V60 呼吸机连接的是交流电源，那么报警声就会不断的持续下去，除非有操作员进行干预方能停止报警。如果 V60 连接到远程报警系统，那么报警系统在被触发后将不会停止，直到操作人员采取措施。

  设备屏幕上可能显示如下错误代码：100A、1006、1007、或者 1008。如果呼吸机显示任一上述代码，就说明呼吸机已经出现通信错误，这可能就是上述缆线造成的。

3. 调查评估结果

- 经专业健康危险评估分析，评估确认此类问题的发生几率很低。但是，如果在患者使用呼吸机过程中出现呼吸机停止工作的情况，压力支持和氧气输送的过程将会终止。这可能导致患者的 SpO2 下降，这时如果尚未及时注意报警，就可能导致低氧血症或高碳酸血症。

4.召回分级

- 根据以上评估结果，此次召回的分级为一级召回。目前尚未取得美国 FDA 对此召回的召回分级。

---------- 结束 ----------

PHILIPS

召回递交文件清单

FCO86600037

日期：2017 年 5 月 2 日

1. 医疗器械召回事件报告表
2. 召回调查评估报告
3. 召回计划
4. 中英文版召回通知书
5. 产品注册证复印件
6. 英文 FDA HHE 健康危害评估表格

---------- 结束 ----------

PHILIPS
Respiratory Ventilation

20 April 2017
FSN 86600037A

NOTICE OF FIELD SAFETY ACTION
Medical Device Correction
V60 VENTILATORS MANUFACTURED BEFORE 15 SEPTEMBER 2015
INTERNAL CABLE REPLACEMENT

Dear Distributor,

Our records show that you purchased a Philips V60 Ventilator in the past.

Respironics California, LLC ("Respironics") is proactively initiating a Correction for all Philips V60 Noninvasive Ventilators (NIV) manufactured before 15 September 2015, which involves replacing an internal cable within the ventilator.

Respironics began distributing V60 Ventilators in 2009. All V60s with date of manufacture before 15 September 2015 are subject to this correction.

V60 Ventilators manufactured on or after 15 September 2015 incorporate a different internal cable and, therefore, are not included in this Correction and no action is required for them.

This document contains important information for the communication to your end-customer

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy of this information in your records.

Please perform the instructions attached to this letter. As a distributor it is your responsibility to contact each of your end-customers and perform the correction.

This notice has been reported to the appropriate Regulatory Agencies. Philips apologizes for any inconveniences caused by this problem.

Sincerely,

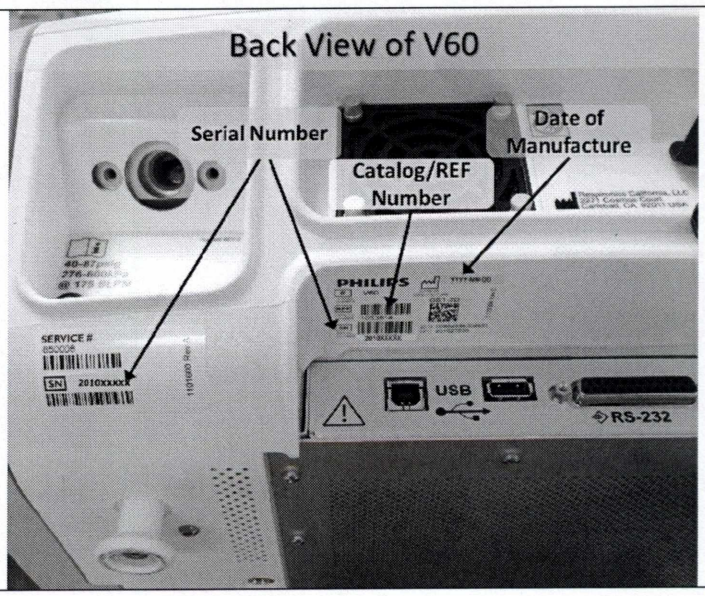
Donald J. Sherratt
Head of Quality and Regulatory, Hospital Respiratory Care

PHILIPS

Effective 20 April 2016

FSN 86600037A

NOTICE OF FIELD SAFETY ACTION
Medical Device Correction n
PHILIPS V60 VENTILATORS MANUFACTURED BEFORE 15 SEPTEMBER 2015 – INTERNAL CABLE REPLACEMENT

AFFECTED PRODUCTS	All V60 Ventilators with a date of manufacture before15 September 2015. 
PROBLEM DESCRIPTION	Over time, low-frequency vibrations can cause the pins within the female connectors on the internal Motor Controller to Data Acquisition Board ribbon cable to become partially displaced, which causes momentary high resistance that interferes with data transfer. This may cause the ventilator to fail Power on Self Testing (POST) or cause Continuous Built in Test (CBIT) to detect a fault and lead to a ventilator shut down with alarm during use or during intra-hospital transport. If the V60 shuts down for any Vent Inop condition and is operating on battery power, an audible high-priority alarm will sound continuously for at least 2 minutes. If the V60 is connected to AC power (mains supply), the alarm will continue to sound until an operator intervenes. If the V60 is connected to a remote alarm system, the alarm system will be activated until action is taken by the operator. The device may display an error code 100A, 1006, 1007, or 1008 on the screen. Displaying one of these error codes indicates that the ventilator has had a communication failure that may be caused by the cable.
HAZARD INVOLVED	If a Vent Inop event occurs when a patient is connected, pressure support and O_2 delivery will cease. Such cessation may cause the patient's SpO_2 to drop and, if the alarm is not attended to promptly, may lead to Hypoxemia or Hypercarbia.
HOW TO FIND THE DATE OF MANUFACTURE OF A V60 VENTILATOR	

PHILIPS

Effective 20 April 2016

FSN 86600037A

URGENT - Field Safety Notice
Medical Device Correction
PHILIPS V60 VENTILATORS MANUFACTURED BEFORE 15 SEPTEMBER 2015 – INTERNAL CABLE REPLACEMENT

ACTION TO BE TAKEN BY DISTRIBUTOR	Send a copy of the customer letter attached with your contact details – phone and e-mail information: 1. When asked, inform your customers they should continue using the V60. The incidence of failure is low. 2. Advise customers to operate the V60 as directed or recommended in the operator's manual, including by a. Promptly attending to all alarms presented by the V60 Ventilator. b. Using an external O_2 monitor/analyzer and setting the alarm thresholds appropriately. c. Ensuring the correct circuits and masks identified in the operator's manual are used with the V60. d. Wherever possible, connecting the V60 to a remote call system. 3. If a V60 you sold shuts down before you install a new cable, and displays any of the error codes 100A, 1006, 1007, or 1008, then (i) turn the V60 off, (ii) discontinue use of the V60, and (iii) use an alternate ventilator. Call your local customer service contact and report the failure. Please reference FCO86600037A. ***4. You must acknowledge receiving this notification by either:*** : **INSERT INFO HERE FOR THE APPROPRIATE MARKET**

PHILIPS

Effective 20 April 2016

FSN 86600037A

URGENT - Field Safety Notice
Medical Device Correction
PHILIPS V60 VENTILATORS MANUFACTURED BEFORE 15 SEPTEMBER 2015 – INTERNAL CABLE REPLACEMENT

ACTIONS PLANNED BY PHILIPS	Philips will Provide replacement cables and parts and instructions for installing the new cable and other parts as needed.
FURTHER INFORMATION AND SUPPORT	**Contact information:** **Local Contact** Enter local contact info here

PHILIPS

Respiratory Ventilation

2017 年 4 月 20 日

FSN 86600037A

医疗器械纠正/现场安全通知

2015 年 9 月 15 日前生产的 V60 呼吸机的内部线缆更换

尊敬的分销商：

我们的记录显示您购买了飞利浦 V60 呼吸机。

Respironics California, LLC（“Respironics”）目前正主动对 2015 年 9 月 15 日前生产的所有 Philips 无创呼吸机（NIV）进行改进，这涉及更换呼吸机内部的一根缆线。

Respironics 公司从 2009 年开始分销 V60 呼吸机。所有在 2015 年 9 月 15 日前生产的 V60 型号机都需要进行改进。

2015 年 9 月 15 日及此后生产的 V60 呼吸机已使用改进后的内部缆线，因此，它们不在纠正范围之内，不需要对它们采取任何（纠正）措施。

本文件包含呈递给终端客户的重要信息

请贵方与需要知晓本文件内容的所有相关人员共同阅读下列信息。充分理解本文件含义非常重要。

请贵方在记录中保留此信息副本。

请执行本文件所附指示。作为分销商，贵方有责任联系您的每一位终端客户来执行此次纠正行动。

本通知已经上报给相关的管理部门。对于该问题给贵方带来的任何不便，Philips 深表歉意。

顺颂商祺！

Donald J. Sherratt
质量管理法规总监，医院呼吸医护部

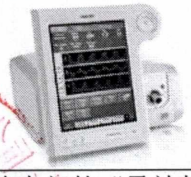
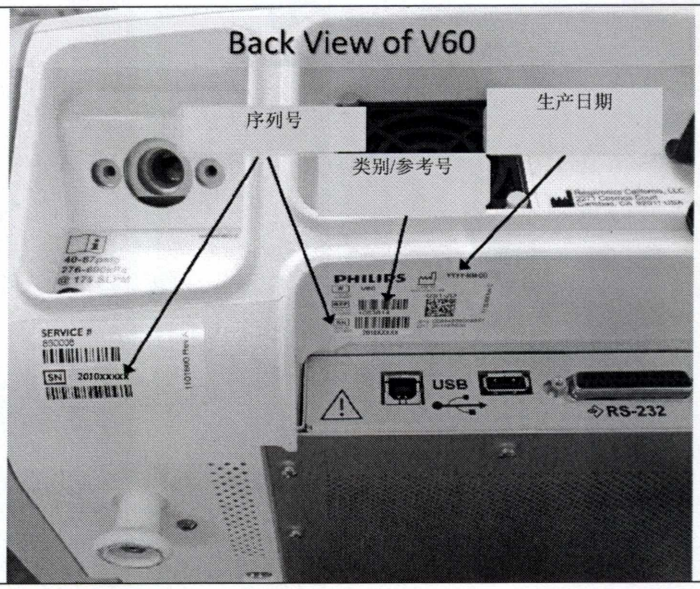
PHILIPS

2016 年 4 月 20 日生效

FSN 86600037A

医疗器械纠正/现场安全通知

2015 年 9 月 15 日前生产的 PHILIPS V60 呼吸机的内部线缆更换

受影响产品	2015 年 9 月 15 日前生产的所有 V60 呼吸机。 
问题描述	随着时间的推移，低频震动可能使内部的“马达控制板至数据采集板”带状电缆上母接头内的针脚发生部分位移，这就会在某些时候导致阻抗过高，从而影响数据的传输。因此，在使用过程中，或是在医院移动的过程中，呼吸机可能出现“通电自检”失败或“持续自检”失败，并最终出现错误和关机。 如果 V60 呼吸机在使用电池电源的过程中出现关机现象，那么就会听到至少持续 2 分钟的紧急报警声。如果 V60 呼吸机连接的是交流电源，那么报警声就会不断的持续下去，除非有操作员进行干预方能停止报警。如果 V60 连接到远程报警系统，那么报警系统在被触发后将不会停止，直到操作人员采取措施。 设备屏幕上可能显示如下错误代码：100A、1006、1007、或者 1008。如果呼吸机显示任一上述代码，就说明呼吸机已经出现通信错误，这可能就是上述缆线造成的。
相关危害	如果在患者使用呼吸机过程中出现呼吸机停止工作的情况，压力支持和氧气输送的过程将会终止。这可能导致患者的 SpO_2 下降，这时如果尚未及时注意报警，就可能导致低氧血症或高碳酸血症。
查找 V60 呼吸机生产日期的方法	

PHILIPS

2016 年 4 月 20 日生效

FSN 86600037A

紧急—医疗器械纠正/现场安全通知

2015 年 9 月 15 日前生产的 PHILIPS V60 呼吸机的内部线缆更换

分销商应采取的措施	请发送一份客户信函并附上您的详细联系方式——电话和电子邮件信息： 1. 当被问及时，应告诉您的客户继续使用 V60。出现上述故障的概率很低。 2. 建议客户按指令或用户手册说明操作 V60，包括 a. 立即关注 V60 呼吸机显示的所有报警； b. 使用外用 O_2 监护仪/分析仪并酌情设置报警阈值； c. 确保使用操作手册中规定的正确回路和面罩； d. 如有可能，将 V60 连接到远程呼叫系统。 3. 如果在安装新缆线之前 V60 关机，同时显示 100A、1006、1007、或 1008，那么 (i) 关掉 V60 (ii) 停止使用 V60，及 (iii) 使用备用呼吸机，呼叫当地客户服务联系人并报告故障现象。请参考 FC086600037A。 ***4. 您务必确认已收到本通知。***
Philips 计划采取的措施	如有需要，Philips 将提供更换电缆和部件以及安装新电缆和部件的说明。
更多信息和支持	如果贵方需要获得有关本次通知的更多信息或支持，请随时联系贵方的飞利浦当地代表，中国大陆客户请致电飞利浦中国服务电话（800-810-0038/ 400-810-0038）。

PHILIPS
Respiratory Ventilation

2017 年 4 月 20 日

FSN 86600037A

紧急—医疗器械纠正/现场安全通知
2015 年 9 月 15 日前生产的 V60 呼吸机的内部线缆更换

尊敬的用户：

我们的记录显示您购买了一台 PhilipsV60 呼吸机。

Respironics California, LLC（“Respironics”）目前正主动对 2015 年 9 月 15 日前生产的 Philips 无创呼吸机进行改进，这涉及更换呼吸机内部的一根缆线。

Respironics 公司从 2009 年开始分销 V60 呼吸机。凡是在 2015 年 9 月 15 日前生产的全部 V60 型号机都需要进行改进。

2015 年 9 月 15 日及此后生产的 V60 呼吸机包含一根改进的内部缆线，因此，它们不在纠正范围之内，不需要对它们采取任何（纠正）措施。

本文件包含持续安全和正确使用贵方设备的重要信息。

请贵方与需要知晓本文件内容的所有相关人员共同阅读下列信息。充分理解本文件含义非常重要。

请保留设备使用说明书副本。

生产日期标注于 V60 呼吸机的背面，所以查看（生产）日期无需停用该呼吸机。

确定您的 V60 呼吸机生产日期时，请参见本信件所附的说明。

本通知已经上报给相关的管理部门。对于该问题给贵方带来的任何不便，Philips 深表歉意。

顺颂商祺！

Donald J. Sherratt

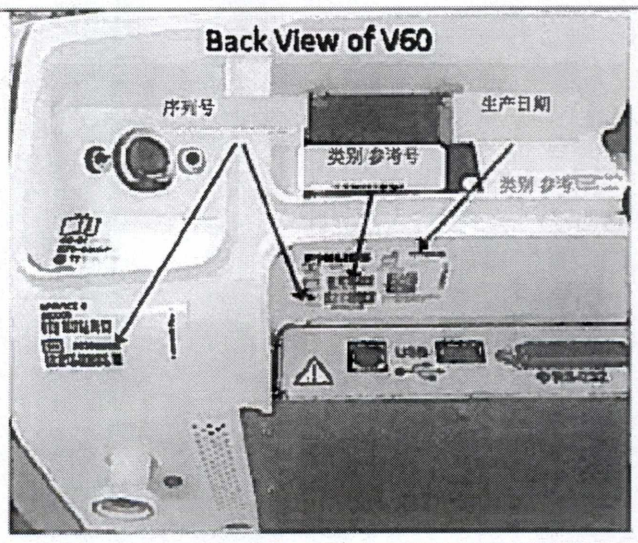
质量管理法规总监，医院呼吸医护部

PHILIPS
Respiratory Ventilation

2017 年 4 月 20 日

FSN 86600037A

紧急—医疗器械纠正/现场安全通知
2015 年 9 月 15 日前生产的 V60 呼吸机的内部线缆更换

受影响产品	2015 年 9 月 15 日前生产的所有 V60 呼吸机。 
问题描述	随着时间的推移，低频震动可能使内部的“马达控制板至数据采集板”带状电缆上母接头内的针脚发生部分位移，这就会在某些时候导致阻抗（电阻）过高，从而影响数据的传输。因此，在使用过程中，或是在医院移动的过程中，呼吸机可能出现“通电自检”失败或“持续自检”失败，并最终出现错误和关机。 如果 V60（呼吸机）在使用电池电源的过程中出现关机现象，那么就会听到至少持续 2 分钟的紧急报警声。如果 V60 呼吸机连接的是交流电（电源），那么报警声就会不断的持续下去，除非有操作员进行干预（干预方能停止报警）。如果 V60 连接到远程报警系统，那么报警系统在被触发后将不会停止，直到操作人员采取措施为止。 设备屏幕上可能显示如下错误代码：100A、1006、1007、或者 1008。如果呼吸机显示任一上述代码，就说明呼吸机已经出现通信错误，这可能就是上述缆线造成的。
相关危害	如果在患者使用呼吸机过程中出现呼吸机停止工作的情况，压力支持和氧气输送的过程将会终止。这可能导致患者的 SpO_2 下降，这时如果尚未及时注意报警，就可能导致低氧血症或高碳酸血症。
查找 V60 呼吸机生产日期的方法	

PHILIPS
Respiratory Ventilation

2017年4月20日

FSN 86600037A

紧急—医疗器械纠正/现场安全通知
2015年9月15日前生产的V60呼吸机的内部线缆更换

客户/用户需采取的措施	如果您检查了 V60 呼吸机的生产日期并确定您的呼吸机在本次纠正范围内，那么： 1. 维续使用 V60。出现上述故障的概率很低。 2. 为了将疾病和伤害降到最低，请按照操作手册的要求进行操作，措施包括： a. 立即关注 V60 呼吸机显示的所有报警； b. 使用外用 O_2 监护仪/分析仪并酌情设置报警阈值； c. 确保使用操作手册中规定的正确回路和面罩； d. 如有可能，将 V60 连接到远程呼叫系统。 3. 如果 V60 关机，并出现报警，同时显示 100A、1006、1007、或 1008，那么（i）关掉 V60，（ii）停止使用 V60，（iii）使用备用呼吸机，呼叫当地客户服务联系人并报告故障现象。请参考 FCO86600037A。 4. **您务必确认已收到本通知。**
Philips 计划采取的措施	Philips将安排Philips现场服务工程师或经批准的服务提供商免费为用户更换问题缆线。Philips将联系每一位收货人，以便安排此服务。
更多信息和支持	如果贵方需要获得有关本次通知的更多信息或支持，请随时联系贵方的飞利浦当地代表，中国大陆客户请致电飞利浦中国服务电话（800-810-0038/ 400-810-0038）。

PHILIPS

Effective 20 April 2016

FSN 86600037A

关于 2015 年 9 月 15 日前生产 Philips V60 呼吸机 MC-DA 线缆更换的医疗器械现场安全通知的回复

回执和收据表

要求回复

用户信息：

用户姓名：				
街道地址：				
城市：		州：	邮编：	国别：
联系人：		电话号码：	电子邮件：	

我已阅读和理解通知书中的更换通知。 是□ 否□

您的更换产品是否出现过不良事件？ 是□ 否□

如果是，您是否通知了 Philips？ 是□ 否□

如果是，请填写 Philips 事件号_____和详细情况：

详细情况：

此处填写当地处理情况：

PHILIPS
Respiratory Ventilation

20 April 2017
FSN 86600037A

URGENT - Field Safety Notice
Medical Device Correction
V60 VENTILATORS MANUFACTURED BEFORE 15 SEPTEMBER 2015
INTERNAL CABLE REPLACEMENT

Dear Customer,

Our records show that you purchased a Philips V60 Ventilator in the past.

Respironics California, LLC ("Respironics") is voluntarily initiating a Correction for all Philips V60 Noninvasive Ventilators (NIV) manufactured before 15 September 2015, which involves replacing an internal cable within the ventilator.

Respironics began distributing V60 Ventilators in 2009. All V60s with date of manufacture before 15 September 2015 are subject to this correction.

V60 Ventilators manufactured on or after 15 September 2015 incorporate a different internal cable and, therefore, are not included in this Correction and no action is required for them.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

The date of manufacture is visible on the back of the V60 ventilators, so it is unnecessary to pause or discontinue the use of the ventilator to check it.

Please refer to the instructions attached to this letter to determine the date of manufacture of your V60 ventilators.

This notice has been reported to the appropriate Regulatory Agencies. Philips apologizes for any inconveniences caused by this problem.

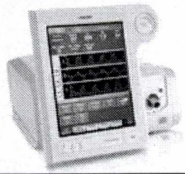
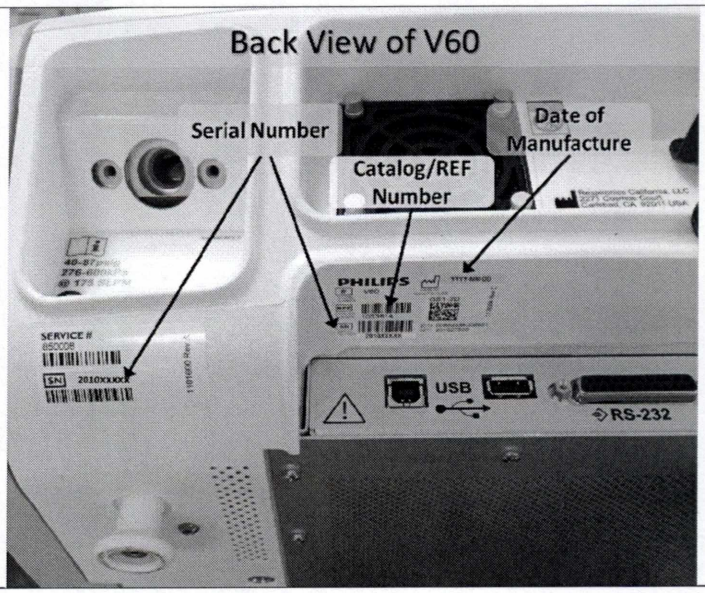
Sincerely,

Donald J. Sherratt
Head of Quality and Regulatory, Hospital Respiratory Care

PHILIPS
Respiratory Ventilation

20 April 2017
FSN 86600037A

URGENT - Field Safety Notice
Medical Device Correction
PHILIPS V60 VENTILATORS MANUFACTURED BEFORE 15 SEPTEMBER 2015 – INTERNAL CABLE REPLACEMENT

AFFECTED PRODUCTS	All V60 Ventilators with a date of manufacture before15 September 2015. 
PROBLEM DESCRIPTION	Over time, low-frequency vibrations can cause the pins within the female connectors on the internal Motor Controller to Data Acquisition Board ribbon cable to become partially displaced, which causes momentary high resistance that interferes with data transfer. This may cause the ventilator to fail Power on Self Testing (POST) or cause Continuous Built in Test (CBIT) to detect a fault and lead to a ventilator shut down with alarm during use or during intra-hospital transport. If the V60 shuts down for any Vent Inop condition and is operating on battery power, an audible high-priority alarm will sound continuously for at least 2 minutes. If the V60 is connected to AC power (mains supply), the alarm will continue to sound until an operator intervenes. If the V60 is connected to a remote alarm system, the alarm system will be activated until action is taken by the operator. The device may display an error code 100A, 1006, 1007, or 1008 on the screen. Displaying one of these error codes indicates that the ventilator has had a communication failure that may be caused by the cable.
HAZARD INVOLVED	If a Vent Inop event occurs when a patient is connected, pressure support and O_2 delivery will cease. Such cessation may cause the patient's SpO_2 to drop and, if the alarm is not attended to promptly, may lead to Hypoxemia or Hypercarbia.
HOW TO FIND THE DATE OF MANUFACTURE OF A V60 VENTILATOR	

PHILIPS
Respiratory Ventilation

20 April 2017
FSN 86600037A

URGENT - Field Safety Notice
Medical Device Correction

PHILIPS V60 VENTILATORS MANUFACTURED BEFORE 15 SEPTEMBER 2015 – INTERNAL CABLE REPLACEMENT

ACTION TO BE TAKEN BY CUSTOMER / USER	If you have checked the date of manufacture and your V60 ventilator is subject to this correction: 1. Continue using the V60. The incidence of failure is low. 2. To minimize risks of illness or injury, operate the V60 as directed or recommended in the operator's manual, including by a. Promptly attending to all alarms presented by the V60 Ventilator. b. Using an external O_2 monitor/analyzer and setting the alarm thresholds appropriately. c. Ensuring the correct circuits and masks identified in the operator's manual are used with the V60. d. Wherever possible, connecting the V60 to a remote call system. 3. If the V60 Shuts down, alarms, and displays any of the error codes 100A, 1006, 1007, or 1008, then (i) turn the V60 off, (ii) discontinue use of the V60, and (iii) use an alternate ventilator. Call your local customer service contact and report the failure. Please reference FCO86600037A. ***4. You must acknowledge receiving this notification by either:*** : **INSERT INFO HERE FOR THE APPROPRIATE MARKET**

PHILIPS
Respiratory Ventilation

20 April 2017
FSN 86600037A

URGENT - Field Safety Notice
Medical Device Correction
PHILIPS V60 VENTILATORS MANUFACTURED BEFORE 15 SEPTEMBER 2015 – INTERNAL CABLE REPLACEMENT

ACTIONS PLANNED BY PHILIPS	Philips will arrange for a Philips Field Service Engineer or Approved Service Provider to install new cables in affected V60 ventilators at no cost to the customer. Philips will contact each consignee to schedule an appointment for this service.
FURTHER INFORMATION AND SUPPORT	**Contact information:** Monday through Friday between 8:00am and 5:00 pm US Pacific Time **Firm responsible for FSN:** Respironics California, LLC 2271 Cosmos Court Carlsbad, CA 92011 **Local Contact** Enter local contact info here

PHILIPS

Effective 20 April 2016

FSN 86600037A

MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE PHILIPS V60 MANUFACTURED BEFORE 15 SEPTEMBER 2015 – MC-DA CABLE REPLACEMENT

Acknowledgement and Receipt Form

Response is Required

Customer Information:

Customer Name:							
Street Address:							
City:		State:		Zip Code:		Country:	
Contact Person:		Telephone Number:			E-mail:		

I have read and understand the recall instructions provided in the notification letter. Yes ☐ No ☐

Have any adverse events associated with recalled product occurred at your site? Yes ☐ No ☐

If yes, have you informed Philips of the event? Yes ☐ No ☐

If yes, please provide Philips Case Number_____ and details:

Details:

Add local response info here

中华人民共和国医疗器械注册证

注册证编号：国械注进20163545139

注册人名称	Respironics California, Inc.
注册人住所	2271 Cosmos Court, Carlsbad, California, 92011 USA
生产地址	2271 Cosmos Court, Carlsbad, California, 92011 USA
代理人名称	飞利浦（中国）投资有限公司
代理人住所	上海市天目西路218号1602-1605
产品名称	呼吸机 Ventilator
型号、规格	V60
结构及组成	产品由主机、落地台车、电池、电源线、呼吸管路、过滤器组成。工作模式：CPAP、S/T、PCV、AVAPS（可选）、PPV（可选）。
适用范围	带成比例压力通气和Auto-Trak+软件选项的V60呼吸机是一种辅助呼吸机，用于加强患者呼吸，预期用于需要机械通气的自主呼吸患者：医院或其他机构中医师指导下的呼吸衰竭、慢性呼吸功能不全、阻塞性睡眠呼吸暂停患者。该呼吸机预定支持体重大于20千克的儿科患者及成年患者，也适用于与无创应用选择标准相同的气管插管患者。应由合格的医疗专业人员如医师、护士和呼吸治疗师使用，且只能与各种Respironics推荐的患者回路、界面（面罩）、加湿器组件和其他附件一起使用。
附件	产品技术要求
其他内容	/
备注	

批准日期：二〇一六年十二月二十八日

有效期至：二〇二一年十二月二十七日

审批部门：国家食品药品监督管理总局

国家食品药品监督管理总局 进口医疗器械 注册专用章

RESPIRONICS®

Health Hazard Evaluation Form

Step I. Identification of the Issue/Problem:

Philips Business Unit Reference Number:	HRC-CA-2017-02
Date HHE Initiated:	March 28, 2017
Respironics CAPA Control #: (if applicable)	PR 2983139, 3252793, 3875169
- Product Data -	
Product Code:	MNT
Model:	V60
Device Name:	V60 Respiratory Ventilator
Lot/Serial Numbers:	All V60 ventilators manufactured prior to the following serial numbers: • 100157239 (100XXXXXX series S/N's) • 201015191 (200XXXXXX series S/N's) Exceptions include any ventilators built under Temporary Process Monitors TPM0904 TPM0907 or serviced in accordance with FCO86600026.
Marketing Status (Include 510(k)Number, Specify if Class I Exempt from 510(k)):	Cleared in the U.S. under 510(k) #K082660
Manufacturer Address:	Respironics California, LLC 2271 Cosmos Court Carlsbad, CA 92011
Product Description (Include Intended Use From Labeling):	Instructions for Use: V60 Ventilator User Manual (Part Number: 1047358) The Respironics V60 Ventilator is an assist ventilator and is intended to augment patient breathing. It is intended for spontaneously breathing individuals who require mechanical ventilation: patients with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional settings under the direction of a physician. The ventilator is intended to support pediatric patients weighing 20 kg (44 lb.) or greater to adult patients. It is also intended for intubated patients meeting the same selection criteria as the noninvasive applications. The ventilator is intended to be used by qualified medical professionals, such as physicians, nurses, and respiratory therapists. The ventilator is intended to be used only with various combinations of Respironics-recommended patient circuits, interfaces (masks), humidifiers, and other accessories.
Brief description of the issue/problem and how it was identified:	Customer complaints referenced in CAPA's 2983139, 3252793, and/or 3875169 are often related to losing data communications within the ventilator resulting in a vent inop condition (shutdown). While this issue was previously identified in HHE HRC-C-2015-3, complaint trending in February 2017 has indicated the complaint rate and adverse event rate determined for that HHE do not represent the modern trending between September 2015 – January 2017. Therefore, this HHE is being generated to reassess the risk-to-benefit relationship of ventilators with the old DA-MC cable remaining in the field.

Affected Patient/User Population:	Any patient undergoing ventilation on the V60. Most vulnerable population - Severe Hypoxemic respiratory failure patients such as a patient in acute pulmonary edema.
HHE Owner (Name/Function):	Donald J. Sherratt *Head of Q&R, HRC*
HHE Contributors (Name/Function):	Elizabeth Hurley *Product Manager 5* David Rogers *Principal Electrical Engineer* Adam Seiver, MD, PhD *Chief Medical Officer, Hospital Respiratory Care* Zoran Pscnicnik *Sr. Manager QA Engineering* Ian Thorson *Sr. Quality Engineer*

Step II. Analyze Post Release Health Risk Associated with Affected Units:

Note: Assess the risk as if no corrective action will be taken and all affected devices will remain in the marketplace.

A. Identification of the Individual Hazard(s):

Hazard Category:	Excess level of carbon dioxide in the blood resulting in hypercarbia or abnormally low levels of oxygen in the blood resulting in hypoxemia.
Hazard Cause:	Disruption of the communications between or within the Data Acquisition (DA) to Motor Controller (MC) or DA to Central Processing Unit (CPU) Printed Circuit Board Assembly (PCBA) due to interface between systems.
Hazardous Situation:	Ventilator support may not be available or a loss of ventilator support could occur, as follows: 1. Failure to power on into ventilator mode accompanied by a high priority alarm and 1 or more error codes displayed and/or logged into the diagnostic memory. a. Unable to initiate ventilation support for patient. 2. The ventilator may enter into an inop state during operation accompanied by a high priority alarm accompanied by 1 or more error codes displayed and/or logged into the diagnostic memory. a. Patient loses ventilation support. b. Patient is not capable of adequate CO2 excretion without ventilation support. c. Patient cannot maintain normal O2 saturation without FiO2 > 0.21 or without positive expiratory pressure.

B. Estimation of Severity:

Description of reported and/or potential harm:	The potential harm is hypercarbia and/or hypoxemia leading to hypoxia. Hypoxia can cause brain and other major organ injury. There have been two (2) reported deaths and nine (9) reports of harm/injury.	
Estimation of Severity of Harm:	**Check Applicable Severity Level**	**Examples**
	_____4	Directly results in death
	__X__3	Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment
	_____2	Results in moderate injury: temporary impairment, or self-limiting illness
	_____1	Results in less than moderate or no injury
Comments about severity of harm rationale: Severity = 3; Ventilator shuts down, with alarm, resulting in increased risk of hypoxia. Clinical intervention would be required to limit the severity.		

C. Estimation of Probability of Harm Resulting from Affected Units:

Estimated quantity of affected devices (# in field, # in factory, # in distribution centers, etc.):	An estimated quantity of ~30,000 ventilators in the field utilize a down revision DA-MC cable. The improved cable was implemented into V60 manufacturing on September 15, 2015. All ventilators utilizing a down revision DA-MC cable are susceptible to incurring vent inop conditions relating to disruption of SPI Bus communication.
Adverse Event Query:	The following Query Criteria was used to generate a spreadsheet containing all Adverse Events within TrackWise. • "Symptom Code 1" ***is any of*** "V60" • "Type of Reported Complaint" ***is any of*** "Serious Injury", "Death" Each complaint was individually reviewed by QE to determine if the cause of the complaint was related to SPI Bus communication link failure.
Number and type of injuries/number of deaths attributed to the problem with the device (if any):	Between September 01, 2015 – January 31, 2017, there have been ~1370 complaints associated with V60 ventilators shutting down due to failure of the SPI Bus. Within these complaints, there have been two (2) reported patient deaths and nine (9) reports of injury/harm. The first reported death (PR 5991147) occurred following failure of the SPI Bus during intra-hospital transport; complaint notes allege the patient was initially stabilized but expired thereafter. The FSE later confirmed with the customer that the death was not directly caused by the ventilator failure. The second death occurred in China (PR 6283589). The error log indicated that failure was due to a SPI Bus communication failure. The patient was diagnosed with Diffuse Large B-Cell Lymphoma and relatives had refused intubation of the patient, resulting in the use of non-invasive ventilation on the V60. In the nine (9) events alleging injury/harm, nearly all reported "no patient harm", however, all events required medical intervention to prevent injury. In compliance with regulations and internal procedures, these complaints have been identified as Adverse Events.

Describe the factor(s) that need to occur to create the hazardous situation (reasonably foreseeable sequence or combination of events):	• Patient is being ventilated. • Internal ventilator conditions occur resulting in a breakdown of the SPI Bus communication link. • Ventilator enters a Ventilator Inoperative (Vent Inop) state and ceases ventilation of the patient. Simultaneously, the ventilator will initialize a high priority alarm that will remain active indefinitely until the unit is powered off. o If the ventilator is operating on a fully charged battery, the unit will continue to alarm for ~6 hours until battery depletion. • A clinician does not see, hear, or quickly respond to the Vent Inop alarm denoting the ventilator is inoperable. This priority alarm will remain active indefinitely on A/C power unless reset by clinician. This priority alarm will remain active for ~6 hours on battery until battery depletion, provided battery was fully charged beforehand. • If ventilator is being used remotely and is properly connected to a remote alarm / nurse call, a clinician does not notice or quickly respond to the alert of a priority alarm denoting the ventilator is inoperative. This alarm will remain active indefinitely unless reset by clinician. • The clinician does not hear or quickly respond to the alarm from the physiologic and/or SpO_2 monitoring notifying that the patient's condition has changed and/or O_2 saturation is below the minimum threshold set by the clinician. • The clinician does not hear or quickly respond to the alarm from any FiO_2 monitoring equipment notifying the O_2 delivery to the patient is below the minimum threshold set by the clinician. • If the ventilator is used during transport of a patient, alternative methods of respiratory care, such as bagging, oxygen cannulas, or alternate non-invasive ventilatory support, are immediately unavailable and/or cannot be utilized to properly stabilize patient oxygen saturation levels mid-transport.
Factors that might mitigate risk (e.g., safety mechanisms present in the design, instructions for use, current label warnings, etc.):	• The ventilator will initiate a Vent Inop priority alarm when breakdown of the SPI Bus communication link occurs. The ventilator will indefinitely sound an auditory alarm at maximum volume every ~5 seconds until reset by clinician if running on A/C. The ventilator will sound an auditory alarm at maximum volume every ~5 seconds for ~6 hours until reset by clinician if running on battery, provided battery was fully charged beforehand. • The ventilator display will change to present a Vent Inop alarm message indicating its inoperative state. This display state will remain visible indefinitely if operating on A/C power and for ~6 hours if operating on battery power, provided battery was fully charged beforehand. • There is an LED indicator on the front of the ventilator that flashes during a priority alarm condition. • The ventilator can be connected to a central monitoring station or a remote nurse alarm. If properly connected, the remote alarm / nurse call will sound an alarm indefinitely unless reset by clinician. • A warning in the clinical user manual advises the clinician to monitor FiO_2 using an external O_2 analyzer/ monitor with properly set low O_2 concentration alarm. Upon initiation of the Vent Inop condition, the set FiO_2 would no longer be delivered and the O_2 monitor would alarm once the delivered FiO_2 degraded and crossed the O_2 monitor's lower O_2 concentration threshold, assuming desired oxygen delivery is >21%. • In accordance with the V60 indications for use, typical spontaneously breathing patients should be able to remove their ventilator mask. In

	addition, approved masks feature air entrainment valves to allow patients to breathe room air should the patient be unable to remove their mask. • If the failure occurs during Power On Self Test (POST), the operator would detect the hazardous condition and the ventilator would not be placed on a patient, therefore preventing any risk to the patient.
Would a user detect the hazardous situation prior to occurrence of harm? If so, describe how:	Yes When best practices for noninvasive ventilation are applied, the caregivers will be notified of a change in patient condition through adequate monitoring. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3042435/pdf/1830293.pdf). As stated in the cited article, "Early detection of failed noninvasive ventilation requires careful monitoring of the patient's vital signs and blood gas levels." Best practices teach that: • Respiratory therapists and clinicians should have training to promptly recognize and treat hypoventilation, hypercarbia, hypoxemia, and hypoxia. • Clinical personnel should be available and alert to changes in patient physiological status as indicated by direct examination and by physiological monitors, such as SpO_2 monitors that alarm to signal hypoxemia. • If the patient deteriorates, immediate alternative ventilator support should be provided, such as resuscitation with a bag/mask resuscitator & oxygen and/or endotracheal intubation and invasive mechanical ventilation.

Considering the factors above, assess the probability that use of, or exposure to, the affected devices will cause future harm during the product's lifetime. Consider segments of the population most at risk (e.g. infants, elderly, pregnant women, critically ill patients, etc.).

Check Applicable Level	Example of Probability of Harm
_____ 4	Occurs every time*.
4K 3	Good chance to occur; considerable certainty to occur; or reasonable probability*.
_____ 2	Expected to occur from time to time (e.g., no clear trend), rarely occurring, or remote*.
_____ 1	Not expected to occur.
_____ 0	Inconceivable, not possible.

* Corresponds with probability levels set forth in FDA's CDRH HHE Form Version 3-1 01/12/2007.

Note: If harm has already occurred as a result of the issue under review, then:

Probability level zero (0) and one (1) can only be used if the investigation shows the harm was the result of an isolated incident and no other units are likely to be affected; a detailed rationale for why harm is not likely to occur again must be provided.

Comments about probability of harm rationale:

Probability of harm considers both hardware reliability, safety mechanisms incorporated into the ventilator to prevent harm including operator warnings, and hospital practice in detecting and preventing failures from concluding in a harmful condition.

Based on a review of the failure mode, mitigations present, and resulting residual risk, we have done further analysis of the probability for harm. For the failure and the hazardous situation to culminate in patient harm, the following mitigating factors would also need to fail:

- Warning in operator manual to use a separate O_2 concentration monitor.
- Warning to use the Nurse Call functionality as a backup to the ventilator's primary alarm when ventilating an at-risk patient failure.
- Standard practice of physiological monitoring SpO_2.
- Ventilator used in a life-sustaining situation rather than as assist ventilator intended to augment patient breathing or on patients who are at risk of transitioning into compromised ventilation state.
- Close clinical observation of patient physiological condition.
- Timely clinical response to provide alternative support.

Still given these mitigations, a ventilator inoperative state leading to death by hypoxia is estimated to affect 15 or more patients over the next 10 years*.

*See associated spreadsheet, "SPI Bus Review Decision Tree Analysis – Final Draft.xlsx" for supporting analysis

Step III. Health Risk Assessment Conclusion:

Probability	Severity			
	1	2	3	4
4	Unacceptable	Unacceptable	Unacceptable	Unacceptable
3	Acceptable	Unacceptable	Unacceptable	Unacceptable
2	Acceptable	Further Analysis Required *	Unacceptable	Unacceptable
1	Acceptable	Acceptable	Further Analysis Required *	Unacceptable
0	Acceptable	Acceptable	Acceptable	Acceptable

* If the results of a risk evaluation fall into one of these two cells (3x1 or 2x2), then a risk/benefit analysis and/or appropriate justification must be documented in section C below.

Note: The original premarket risk/benefit analysis may be used, if still applicable, to justify the risk as acceptable.

Note: The above Risk Table helps assess whether the risk is acceptable or not; however, the reviewer/approvers of this document make the final determination.

A. Document the results of the Health Hazard Evaluation for each hazardous situation under review:

Severity: 3 / Probability: 3 = Unacceptable

B. If the risk of the individual hazardous situation is acceptable, review the Risk Management Summary (RMS) and consider combined impact of all the individual risks to evaluate whether overall residual risk of the device is still acceptable. Is the summary of all the risks acceptable or not acceptable?

Enter Acceptable or Not Acceptable: Not Acceptable

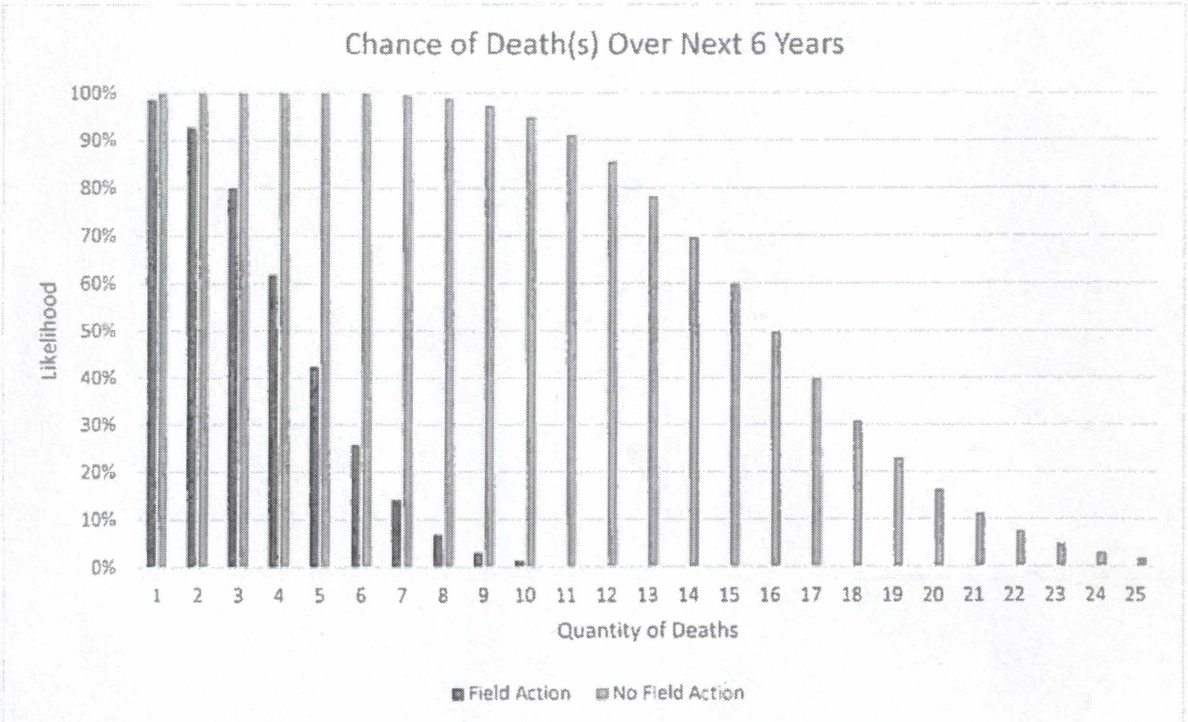
C. Any additional information (if applicable):

Please refer to the conclusion below for a complete qualitative and quantitative assessment.

Health Hazard Evaluation Conclusion:

The response to the hazard identified within this HHE must account for both the potential reduction in adverse clinical consequences by correcting the hazard and any adverse clinical consequences that may be introduced. Any intervention that may be undertaken has the potential to deprive a patient of access to noninvasive ventilation by taking a V60 ventilator out of service. When used in the appropriate indications, noninvasive ventilation is superior to invasive ventilation such that for every 10 patients (or less) treated with noninvasive ventilation, an average of one life is saved (see Landoni G, Comis M, Conte M, et al. Mortality in Multicenter Critical Care Trials: An Analysis of Interventions With a Significant Effect. Crit Care Med. 2015;43:1559-1568).

However, due to the occurrence rate of breakdown of the SPI Bus communication link in clinical settings, some hospital personnel have opted to request FCO86600026 for entire fleets of V60 ventilators. The Decision Tree analysis titled, "SPI Bus Review Decision Tree Analysis – Final Draft.xlsx" derives the number of related events which may occur in the field and assesses the risk of harm associated its occurrence in comparison with the risk of harm associated with field action. Decision Tree analysis determines the following correlation of patient deaths from field action vs. patient deaths from no field action:



Although the rate of patient harm associated with an individual inoperable ventilator state is low, the frequency of occurrence of ventilator inoperative conditions associated with SPI Bus communication link breakdown results in unacceptable patient risk. The results of the risk assessment have concluded the risk associated with these vent inop conditions exceed the risk associated with field action. The remediation strategy should focus attention on identifying ventilators susceptible to SPI Bus communication link breakdown and performing FCO86600026 to remediate the associated risks. As shown in the graph above, the risks associated with SPI Bus communication link breakdown outweigh the benefits of no field action..

RESPIRONICS®

Health Hazard Evaluation Form

Step IV. Outcome approved by the following individuals:

Prepared By:

Ian Thorson 04APR2017

Signature Date

Ian Thorson, Sr. Quality Engineer

Approved by Quality Engineering:

04APR 2017

Signature Date

Zoran Psenicnik, Sr. Manager, QA Engineering

Approved by Site Q&R Lead:

7 APR 2017

Signature Date

Donald J. Sherratt, Head of Q&R (HRC)

Approved by Engineering:

I.T. 04APR17 (1)

David J Rogers 04 APR 2017

Signature Date

David Rogers, Principal Electrical Engineer

Approved by Clinical:

4/4/2017

Signature Date

Adam Seiver, MD, Chief Medical Officer (HRC)

Approved by Product Manager:

Elizabeth Hurley 4/4/2017

Signature Date

Elizabeth Hurley, Product Manager

Q&R Functional Vice President for the Business:

05 APR 2017

Signature Date

Ojas A. Buch, Head of Q&R, PCMS

- *Upon obtaining all signatures, scan completed HHE form and vault in the electronic CAPA Record.*

(1) DISREGARD LINED-OUT MARKING, THIS WAS MADE IN ERROR. THE SIGNATURE MADE IN BLACK INK IS CORRECT. I.T. 04APR2017