UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. PHILIPS NORTH AMERICA LLC d/b/a PHILIPS MEDICAL SYSTEMS and PHILIPS HEALTHCARE, a limited liability company, and CARLA KRIWET and OJAS A. BUCH, individuals, Defendants.	Civil Action No. 17-cv-11955 CONSENT DECREE FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction against Philips North America LLC ("PNA") doing business as Philips Medical Systems ("PMS") and Philips Healthcare, and individuals Carla Kriwet and Ojas A. Buch (collectively, "Defendants"), and Defendants, without admitting or denying the allegations in the complaint, having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED AS FOLLOWS:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c).

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301 et. seq.

3. For purposes of this Decree, the following definitions shall apply:

A. "Defendants' Facilities" refers to: (i) 3000 Minuteman Road, Andover, Massachusetts ("Andover facility"), (ii) 22100 Bothell Everett Highway, Bothell, Washington

("Bothell facility"), and (iii) any additional facility that, on the date of entry of this Decree or any subsequent date, is or becomes a manufacturer of any PCMS Device that, on the date of entry of this Decree or any subsequent date, is manufactured, held, and/or distributed by Defendants at the Andover or Bothell facilities.

B. "PCMS Device" refers to any device, as defined by 21 U.S.C. § 321(h), that, on the date of entry of this Decree or any subsequent date, is manufactured, held, and/or distributed by Defendants' Patient Care and Monitoring Solutions ("PCMS") business group (or a successor) at any of Defendants' Facilities. "PCMS Device" includes, but is not limited to: (i) all ECR Devices as defined in paragraph 3.C; and (ii) all devices listed in Attachment 1 of this Decree even if manufacture of the device is transferred to another PNA, PMS, or Philips Healthcare business group (or successor).

C. "ECR Device" refers to any device, as defined by 21 U.S.C. § 321(h) that, on the date of entry of this Decree or any subsequent date, is manufactured, held, or distributed by Defendants' Emergency Care & Resuscitation ("ECR") business unit (or a successor) within PCMS (or a successor) at any of Defendants' Facilities. "ECR Device" includes, but is not limited to, all devices listed in Attachment 2 of this Decree even if manufacture of the device is transferred to another PNA, PMS, or Philips Healthcare business group (or successor).

D. "Other PCMS Business Units" refers to the Value Segment Solutions ("VSS"), Patient Monitoring ("PM"), and Medical Consumables and Sensors ("MCS") business units (or a successor) within PCMS (or a successor) on the date of entry of this Decree or any subsequent date.

E. "Manufacture" or "Manufacturing" refers to designing, manufacturing, fabricating, packing, assembling, processing, contract sterilizing, installing, labeling, relabeling, remanufacturing, repacking, and/or specification development.

4. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into

interstate commerce, articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice ("CGMP") requirements set forth in 21 C.F.R. Part 820.

5. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of device to become adulterated within the meaning of 21 U.S.C. § 351(h), as described in paragraph 4 above, while such devices are held for sale after shipment of one or more of their components in interstate commerce.

6. Upon entry of this Decree, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), subject to the conditions identified in paragraph 7, from directly or indirectly manufacturing, holding, and/or distributing any ECR Device at any of Defendants' Facilities, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, hold, and distribute ECR Devices are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System ("QS") regulation, 21 C.F.R. Part 820;

B. Defendants select and retain at their expense an independent person or persons (the "Expert"), to conduct inspections of Defendants' Facilities related to ECR Devices and to review Defendants' procedures and methods for manufacturing, holding, and distributing ECR Devices, to determine whether their methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Decree. The Expert shall be qualified by

education, training, and experience to conduct such inspections, have specific expertise in evaluating compliance with the CGMP requirements for devices as set forth in the QS regulation, 21 C.F.R. Part 820, and be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their families. Defendants shall notify the FDA in writing of the identity of the Expert within ten (10) calendar days of retaining such Expert;

C. The Expert develops a plan to inspect Defendants' Facilities with respect to manufacturing, holding, and distributing ECR Devices and submits the plan to FDA for its review and written approval;

D. Within twenty (20) business days of receipt of the plan identified in subparagraph C., FDA shall inform in writing the Expert and Defendants of its determination regarding the approval status of the plan. After receiving FDA's written approval, the Expert performs a comprehensive inspection of Defendants' Facilities and certifies in writing to FDA: (i) that the Expert has inspected Defendants' Facilities, processes, and controls; (ii) whether Defendants have adequately corrected all observations set forth in FDA's lists of inspectional observations ("Forms FDA 483") from all prior FDA inspections of Defendants' Facilities since January 1, 2013; and (iii) whether, based upon this comprehensive inspection, Defendants' Facilities, processes, and controls related to ECR Devices are operated in conformity with the Act, its implementing regulations, and this Decree. The Expert shall submit the Expert's report(s) to FDA at the addresses specified in paragraph 23, and the Expert's report shall include, but not be limited to, an evaluation of the following:

(i.) Defendants' compliance with 21 U.S.C. § 351(h) and 21 C.F.R. Part 820;

(ii.) Defendants' processing of all Corrective and Preventive Actions ("CAPAs") since January 1, 2013 and Defendants' procedures for its CAPA system including, but not limited to: analyzing quality data to identify existing and potential causes of nonconforming product and other quality problems; investigating the causes of nonconformities relating to product, processes,

and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; verifying or validating corrective and preventive actions to ensure such actions are effective and do not adversely affect the finished device; implementing and recording changes in methods and procedures as needed to correct and prevent quality problems; conducting and documenting adequate failure investigations; and implementing an effective complaint handling system;

(iii.) Defendants' design control system, including, but not limited to the design change control process, design development and planning, design input, design output, design review, design verification, design validation, and the design history file;

(iv.) Defendants' actions to ensure that Defendants' current designs have been properly validated and transferred into appropriate product specifications;

(v.) Defendants' procedures to adequately control received, purchased, or manufactured products to verify conformance to product specifications;

(vi.) Defendants' records maintenance system; and

(vii.) Defendants' complaint system;

E. Defendants report to FDA in writing the actions that they have taken to: (i) address all observations brought to Defendants' attention by the Expert and all observations set forth in FDA's Forms FDA 483 for Defendants' Facilities from all prior FDA inspections since January 1, 2013; and (ii) ensure that the methods used in, and the facilities and controls used for manufacturing, holding, and distributing the ECR Devices are operated and administered and will be continuously operated and administered in conformity with the Act, its implementing regulations, and this Decree. Defendants shall include with their report a copy of a written certification from the Expert that Defendants are in compliance with the Act, its implementing regulations, and this Decree;

F. Defendants recall in the form of a notification, at Defendants' sole expense, all

external defibrillators manufactured with the R92 resistor supplied by International Resistive Company, and all Q-CPR meters. The recall notifications set forth in Attachments 3 and 4 shall be distributed, respectively, to consignees and purchasers of each such device, and Defendants shall submit a 21 C.F.R. Part 806 report to the FDA following each such notification;

G. FDA, as and when it deems necessary, inspects Defendants' operations to determine whether the requirements of this paragraph have been met, including whether Defendants' Facilities are operated in conformity with CGMP, as required under the Act and its implementing regulations;

H. Defendants pay all costs of expenses incurred under paragraph 6 for FDA inspections, investigations, supervision, reviews, examinations, and analyses, at the rates set forth in paragraph 18 of this Decree; and

I. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 6.A.-F., and H. of this Decree. In no circumstances shall FDA's silence be construed as a substitute for written notification. FDA will notify defendants whether such facilities appear to comply with the above-identified paragraphs of this Decree within forty-five (45) calendar days from the later of FDA concluding its inspection of the Defendants' Facilities or receipt of the Defendants' response to the inspectional findings.

7. A. Paragraph 6 shall not apply to the following:

(i.) Defendants' manufacturing, processing, packaging, holding for sale, or introducing into interstate commerce Defendants' ECR Devices, including any component, part, or accessory of such devices, that are intended solely for export from the United States, provided that:
(a) Defendants identify all devices to be exported with a specific code, number, or identifier along with the serial and lot numbers that readily identify the devices as intended solely for export;
(b) Defendants establish controls and documentation for all devices to be exported to assist with the

monitoring and tracking of the exported products and to prevent their reimportation into the United States, except for the purpose of a failure investigation by Defendants to investigate a complaint; (c) Defendants provide FDA with an action plan Defendants intend to implement in the event that Defendants become aware of a customer or supplier that has attempted to import, or has reimported, into the United States a device that was intended for export only; and (d) the requirements of 21 U.S.C. §§ 381(e) or 21 U.S.C. § 382 have been satisfied and documented with respect to any such device;

(ii.) Defendants' manufacturing, processing, packing, holding, or distributing Defendants' ECR Devices, and any components, parts, or accessories thereof, solely for the purpose of: (a) conducting clinical investigations in accordance with 21 C.F.R. Part 812, for devices that are subject to an Investigational Device Exemption ("IDE"); or (b) exporting devices necessary to permit the continuation of ongoing clinical investigations outside of the United States that were commenced prior to entry of this Decree, provided that, Defendants:

(1.) Notify FDA in writing of any ongoing clinical investigation that falls within this subparagraph and any planned clinical investigation that falls within this subparagraph prior to initiation;

(2.) Maintain and make available to FDA upon request records identifying the clinical trials for which devices have been distributed under this subparagraph, the recipients of such devices, the type and number of devices distributed to each recipient, and the dates of each such distribution; and

(3.) Comply with all applicable laws and regulations relating to the manufacture, distribution, and export of investigational devices, including 21 U.S.C. § 382;

(iii.) Defendants' manufacturing, processing, or distributing to testing laboratories of Defendants' ECR Devices, including any components, parts, or accessories, solely for

the purpose of development, testing, verification, validation, or qualification activities necessary to complete (a) designs and design changes or modifications in accordance with 21 C.F.R. Part 820 or comparable international standards, (b) changes to production and process controls, (c) changes to manufacturing procedures, (d) corrective and preventive actions, (e) changes to components, parts, or suppliers, or (f) preparing or supporting a premarket approval application ("PMA"), premarket notification submitted under 21 U.S.C. § 360(k), or supplement thereto;

(iv.) Defendants' distributing ECR Devices, including any components, parts, or accessories, for a period not to exceed one year following the date of entry of this Decree, solely for the purpose of responding to a documented request or written order to: (a) perform service or maintenance on Defendants' ECR Devices that are in the possession of customers of Defendants; or (b) for automated external defibrillators, provide a replacement automated external defibrillator as a necessary service response to minimize the loss of use of the defibrillator, provided that:

(1.) Defendants shall send to each customer a copy of all relevant notification letters applicable to the customer's device upon providing a replacement component, part, accessory, or device; and

(2.) Defendants shall maintain records, and allow FDA access to such records upon request, of all such requests or orders and "ship to" records, which shall contain the following information: a detailed description of the request, including a description of the issue that gave rise to the request; the date of the request; the date of service or maintenance; the names, addresses, and telephone numbers of the persons/entities making the request; the identification of the devices needing service or maintenance by means of a specific code, number, or identifier along with the serial and model numbers that readily identify the devices at issue; and the description of the automated external defibrillators and the ECR device components, parts, and/or accessories provided under this paragraph;

(v.) Defendants' distribution of software for the Defendants' MRx and FR3 defibrillators, after such devices receive approval under 21 U.S.C. § 360e, in response to customer requests for modifications or conversions of their existing devices in order to comply with the 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (Nov. 3, 2015) or comparable international standards, provided that: (a) any such modification or conversion of an existing Philips defibrillator under this subparagraph be limited to installing software upgrades that are necessary to implement AHA Guideline recommendations or to comply with comparable international standards, and (b) Defendants maintain records with adequate information and provide such records to FDA within ten (10) business days upon request, regarding each modification or conversion request made by a customer, including but not limited to, device identification information, software version (along with FDA approved supplement number, when applicable), and whether any software upgrades have occurred;

(vi.) Defendants' distribution of Defendants' ECR Devices for use in product demonstrations, workshops, market research, and research laboratories or for use with animals, provided that Defendants' Devices are labeled "For Demonstration/Research/Animal Use Only – Not for Human Use," and they are demonstrated or used in a manner that does not involve use on human beings;

(vii.) Defendants' manufacturing, processing, packing, selling, or distribution of any component, part, or accessory of Defendants' ECR Devices the manufacture, processing, packing, sale, or distribution of which has been requested by Defendants in writing pursuant to this subparagraph, provided that: (a) Defendants submit to FDA the documentation and justification for such request that FDA deems necessary; and (b) the Defendant's request has been authorized by FDA in writing;

(viii.) Defendants' manufacturing, processing, reprocessing, packaging,

installing, servicing, and distributing consumables and accessories identified in Attachment 5 of this Decree, provided that neither the Expert nor FDA informs the Defendants in writing that a consumable or accessory is not in compliance with the Act, its implementing regulations, and/or this Decree;

(ix.) Defendants' manufacturing, processing, packaging, labeling, holding, or distributing ECR Devices, including any component, part, or accessory, solely for the purposes of implementing a specified correction or removal to reduce, mitigate, or eliminate an unreasonable risk to health, provided that Defendants (a) shall notify FDA within five (5) business days of initiating such correction or removal under 21 C.F.R. Part 806, and (b) shall cease the removal or correction, and/or the manufacturing, processing, packaging, labeling, holding, and/or distribution of such ECR devices, including any component, part or accessory, if FDA so instructs;

(x.) Defendants' manufacturing, processing, packing, labeling, and holding (but not distributing) Defendants' ECR Devices in anticipation of FDA's approval of a premarket approval application submitted under 21 U.S.C. § 360e, clearance of a premarket notification submitted under 21 U.S.C. § 360(k), or a supplement thereto. Defendants understand and agree that any devices manufactured under this paragraph shall be destroyed, at Defendants' sole expense, in the event FDA does not approve such application or determines that the devices are not substantially equivalent, unless FDA, in writing, waives destruction of such devices to permit a resubmission by the Defendants to achieve such approval or clearance;

(xi.) Defendants' importing components, parts, and accessories necessary to manufacture Defendants' ECR Devices in support of any part of this Decree;

(xii.) Defendants' distribution, for a time period not to exceed one year after date of entry of this Decree, of Defendants' FR3 automated external defibrillators to existing customers to respond to such customers' specific and immediate need for additional defibrillators;

provided that such customers: (a) describe the nature and immediacy of their need for Defendants' defibrillators in a detailed written request to Defendants, and (b) certify that (1) their facilities have previously standardized on Defendants' defibrillators and (2) they need such devices to provide adequate care to patients. However, the number of defibrillators distributed under this subparagraph shall not exceed 10% of the average annual number of Defendants' FR3 defibrillators sold in the United States from October 1, 2014 to September 30, 2016. Defendants shall maintain records evidencing Defendants' compliance with this subparagraph for two years following each such distribution; and

(xiii.) Defendants' distribution of HS1 automated external defibrillators with the R92 resistor manufactured by Riedon Inc. This exception to paragraph 6 may be withdrawn by FDA at any time in the agency's sole discretion.

B. In recognition of the Court's inherent equitable authority to grant equitable disgorgement for the distribution of devices pursuant to subparagraphs 7.A.(vii), 7.A.(ix), 7.A.(xii), and 7.A.(xiii) prior to the issuance of the notice pursuant to paragraph 6.I. that the government alleges are not manufactured in compliance with the Quality System Regulation—but without admitting that allegation or any violation of law—Defendants agree to pay to the United States Treasury an amount equal to 30% of net revenue (*i.e.*, gross revenue after all rebates and price discounts) from the sale of the devices identified in 7.A.(vii), 7.A.(ix), 7.A.(xii), and 7.A.(xiii). Defendants' obligation to pay shall continue to accrue from the date of entry of this Decree until the date that FDA issues the notification specified in paragraph 6.I. Defendants shall make such payments every ninety (90) days. The amounts paid under this paragraph shall be determined by a qualified financial auditor, who shall be paid by Defendants, acceptable to Defendants and FDA, and without former or current personal or financial ties to the Defendants or their immediate families. Defendants shall cooperate fully with the financial auditor and provide

all records reasonably requested by the financial auditor to make the determination described in this paragraph. Defendants and the auditor further agree, upon written request by the government, to make all documents reviewed and prepared by the financial auditor available to the government. The parties acknowledge and agree that any payment(s) made under this Decree is (are) not a fine, penalty, forfeiture, or payment in lieu thereof for any purpose, and that such payment(s) is (are) an equitable remedy and not punitive.

8. With respect to any of Defendants' ECR Devices distributed pursuant to paragraphs 7.A.(i), 7.A.(ii), 7.A.(iv), 7.A.(vii), 7.A.(ix), 7.A.(x), 7.A.(xii), and 7.A.(xiii), Philips shall provide to each receiving customer a written notice that contains the following statement: "This product is distributed pursuant to an exception to the Consent Decree of Permanent Injunction, filed in United States v. Philips North America LLC, *et al.*, Civ. Action No. xxxxxxx (D. Mass. [2017]). The restrictions on the sale or distribution of Philips' devices pursuant to the Decree will remain in effect until Philips has satisfied FDA that its facilities, methods, processes, and controls related to the manufacture and quality of the product are in conformity with the Quality System Regulation, 21 C.F.R. Part 820 and the terms of the Consent Decree." Defendants shall maintain records evidencing Defendants' compliance with the terms and conditions of this paragraph with respect to each of Defendants' ECR Devices distributed pursuant to this paragraph for two years following each distribution.

9. Defendant's Other PCMS' Business Units at the Andover and Bothell facilities shall be subject to the following requirements:

A. Within twenty (20) business days of entry of this Decree, Defendants shall retain at their expense an independent person or persons (the "Expert Consultant"), to inspect each of the Other PCMS Business Units. The qualifications of the Expert Consultant shall be the same as those set forth in paragraph 6.B. The Expert Consultant may, if Defendants choose, be the same person or

persons described as the Expert identified in Paragraph 6.B. The Expert Consultant retained by one of the Other PCMS' Business Units may be the same Expert Consultant retained by another or all of the Other PCMS' Business Units. Defendants shall notify FDA in writing of the identity and qualifications of the Expert Consultant as soon as they retain such person or persons. In the event Defendants have a need to replace the retained Expert Consultant, Defendants shall notify FDA in writing of any such successor within ten (10) business days after such replacement.

B. Defendants shall cause the Expert Consultant to begin comprehensive inspections of the Other PCMS' Business Units to ensure that the methods, facilities, and controls used to manufacture, process, pack, hold, and distribute Defendants' PCMS Devices comply with the Act, its implementing regulations, and this Decree. In preparation for these inspections, the Expert Consultant shall review all Form FDA 483s issued to Defendants regarding the Defendants' Facilities since January 2013, and Defendants' actions taken in response thereto, pertaining to the business unit subject to the audit. These inspections of all of the Other PCMS Business Units shall be completed no later than six (6) months after the date of entry of this Decree.

C. Within thirty (30) days of the completion of each inspection of one of the Other PCMS Business Units, the Expert Consultant shall prepare a detailed written report of the Expert Consultant's inspection that certifies to FDA: (i) that the Expert Consultant has inspected the PCMS business unit; and (ii) whether that PCMS business unit is in compliance with the Act, its implementing regulations, and this Decree. The Expert Consultant shall submit the inspection report concurrently to Defendants and FDA.

D. Within thirty (30) days of receipt of the Expert Consultant's report on each Other PCMS Business Unit inspection, Defendants shall submit a written report to FDA that details the specific corrective actions Defendants will take and a timetable to address any deficiencies identified by the Expert Consultant. The timetable shall be subject to FDA approval. Defendants shall ensure the

implementation of the corrective actions detailed in the report.

E. As the corrective actions detailed in the report described in subparagraph D are completed, Defendants shall notify the Expert Consultant. The Expert Consultant shall promptly inspect and verify whether those actions have been completed to the Expert Consultant's satisfaction and in accordance with the timetable approved by FDA. If the Expert Consultant determines that an action has not been completed to the Expert Consultant's satisfaction, the Expert Consultant promptly will so notify Defendants. Upon FDA approval of the timetable under subparagraph D, and thereafter on the first day of each month, the Expert Consultant shall submit to FDA a table that succinctly summarizes the Expert Consultant's findings regarding whether the actions have been completed to the Expert Consultant's satisfaction and in accordance with the timetable approved by FDA. FDA may, in its discretion and without prior notice, periodically inspect the Other PCMS Business Units and undertake such additional examinations, reviews, and analyses to verify whether the actions reported to have been completed have in fact been completed in a satisfactory manner. In the event that FDA determines that an action that has been reported to be completed is inadequate, FDA will notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable that is subject to approval by FDA.

F. When the Expert Consultant determines that all of the corrective actions identified in the timetable approved by FDA pursuant to subparagraph D have been completed to the Expert Consultant's satisfaction, the Expert Consultant shall provide Defendants with a written certification that all of the actions have been completed and that the respective PCMS business unit, based on the inspection conducted under paragraph 9.B. and on the satisfactory completion of the actions identified under paragraph 9.D., is in conformity with the Act, its implementing regulations, and this Decree. Once the certification has been issued, Defendants shall promptly submit the expert consultant's certification to FDA.

G. Within forty-five (45) days of receipt of the certification, FDA may, in its discretion and without prior notice, commence an inspection of the Other PCMS Business Units and undertake such additional examinations, reviews, and analyses as the Agency deems appropriate to determine whether the Other PCMS Business Units are in conformity with the Act, its implementing regulations, and this Decree. If FDA determines that any of the Other PCMS Business Units are not operating in conformity with the Act, its implementing regulations, and this Decree, FDA will notify Defendants of the deficiencies it observed and take such other action, if any, as the Agency deems appropriate.

H. Within thirty (30) days of receiving the notification from FDA under subparagraph G, Defendants shall submit to FDA a plan of actions Defendants propose to take and a timetable for correcting the deficiencies. The timetable shall be subject to FDA approval. Defendants shall promptly correct all deficiencies noted by FDA in accordance with the FDA- approved timetable, and cause the Expert Consultant to reinspect and either (i) certify that the deficiencies have been corrected to assure that the manufacturing facility is in conformity with the Act, its implementing regulations, and this Decree, or (ii) notify Defendants that the one or more deficiencies remain uncorrected. If one or more deficiencies have not been corrected, Defendants and the Expert Consultant shall notify FDA in writing, and after Defendants have addressed those deficiencies, the Expert Consultant shall determine whether he/she may make the certification. Defendants shall then submit the certification to FDA. Within forty-five (45) days of FDA's receipt of the certification, FDA may re-inspect as it deems necessary.

10. In the event that Defendants fail, as determined either by the Expert Consultant or FDA, to satisfactorily complete one or more actions in the timetable approved by FDA pursuant to paragraph 9.D., under paragraph 24, Defendants shall be subject to pay to the United States Treasury as liquidated damages the sum of $15,000 per action, per business day, until the action is fully

implemented and completed to FDA's satisfaction.

11. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, are permanently enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, (i) any ECR Device that is adulterated within the meaning of 21 U.S.C. § 351(h), or (ii) any PCMS Device that has previously been subject to an order under subparagraph 13.A. and that is adulterated within the meaning of 21 U.S.C. § 351(h); and/or;

B. Violates 21 U.S.C. § 331(k), by (i) causing any ECR Device, including any component or part of any ECR Device, to become adulterated within the meaning of 21 U.S.C 351(h), or (ii) causing any PCMS Device that has previously been subject to an order under subparagraph 13.A., including any component or part of any such PCMS Device, to become adulterated within the meaning of 21 U.S.C. § 351(h), while such devices are held for sale after shipment of one or more of its components in interstate commerce.

12. After Defendants have complied with paragraphs 6(A)-(F) and (H) and FDA has notified Defendants in writing pursuant to paragraph 6(I), Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' operations applicable to ECR Devices at each of Defendants' Facilities not less than once within the period of twelve (12) months after entry of this Decree and not less than once every twelve (12) months for a period of four (4) years thereafter, for a total of five (5) years. The Auditor shall be

qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to Defendants' officers or employees or their families. The Auditor may be the same person or persons described as the Expert in paragraph 6(B).

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' operations are operated and administered in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than twenty (20) calendar days after the date the audit inspections are completed. If any Audit Report identifies any deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at Defendants' Facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. Defendants shall complete their corrections within thirty (30) calendar days, unless

FDA approves in writing the Correction Schedule, in which case Defendants shall complete all corrections according to the approved Correction Schedule. Within thirty (30) calendar days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within five (5) calendar days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected, and an assessment of the risks of the uncorrected items and recommended corrective actions.

13. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analysis of samples, a report or data prepared or submitted by Defendants, the Expert, the Expert Consultant, or the Auditor pursuant to this Decree, or any other information, that Defendants have violated the Act or its implementing regulations or have failed to comply with any provision of this Decree, or that additional corrective actions are necessary to achieve compliance with the Act, its implementing regulations, or this Decree, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions. Such actions related to Defendants' PCMS Devices may include, but are not limited to, the following:

A. Cease manufacturing, holding, distributing, storing, and/or servicing devices;

B. Revise, modify, or expand any report(s) prepared pursuant to the Decree;

C. Submit additional notifications, reports, or any other materials or information to FDA;

D. Recall, repair, refund, or replace, at Defendants' sole expense, adulterated ECR Devices, accessories, or components manufactured, distributed, and/or sold by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;

E. Issue a safety alert, public health advisory, and/or press release; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with the Act, its implementing regulations, and this Decree.

14. Paragraph 13.A. shall not apply to the manufacturing, processing, packaging, holding for sale, or introducing or delivering for introduction into interstate commerce any PCMS device, including the components, parts or accessories of any such device, that is intended solely for export from the United States, provided that: (A) Defendants identify all devices to be exported with a specific code, number, or identifier along with the serial and lot numbers that readily identifies the device as intended solely for export; (B) Defendants establish controls and documentation for all devices to be exported to assist with the monitoring and tracking of the exported products and to prevent their reimportation into the United States, except for the purpose of a failure investigation by Defendants to investigate a complaint; (C) Defendants provide FDA with an action plan Defendants intend to implement in the event that Defendants become aware of a customer or supplier that has attempted to import, or has reimported, into the United States a device that was intended for export only; and (D) the requirements of 21 U.S.C. 381(e)(1) or 382 have been satisfied and documented with respect to any such device.

15. The following process and procedures apply when FDA issues an order under paragraph 13, except as provided in subparagraph D. below:

A. Unless a different timeframe is specified by FDA in its order, within ten (10) calendar days after receiving an order under paragraph 13, Defendants shall notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific actions taken or to be taken and the proposed schedule for completing the actions; or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in detail and in writing the basis for their disagreement; in doing so, Defendants also may propose specific alternative actions and specific

timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. This written notification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable). Defendants shall continue to diligently implement FDA's order while the matter is before the Court and unless and until the Court reverses, stays, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 26.

D. The process and procedures set forth in paragraphs 15.A.-C. shall not apply to any order issued under paragraph 13 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief.

16. Any cessation of operations described in paragraph 13 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 13 shall be borne by Defendants at the rates specified in paragraph 18.

17. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' Facilities, or other facilities that manufacture, process, hold, and distribute Defendants' PCMS Devices in the future, and take any other measures necessary to monitor and to ensure continuing compliance with the terms of this Decree. During such

inspections, FDA representatives shall be permitted: access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' materials and products, containers, and labeling; and to examine and copy all records relating to the design, manufacture, processing, packing, labeling, holding, and distribution of any and all devices. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

18. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $93.26 per hour and fraction thereof per representative for inspection work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

19. Within ten (10) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree in the employee common areas at the Andover and Bothell facilities where Defendants' employees are located and on Defendants' intranet website in such a manner to ensure that it will be viewed by such employees. Defendants shall ensure that the Decree remains posted in its employee common areas and on its intranet website for as long as the Decree remains in effect.

20. Within twenty (20) calendar days after the entry of this Decree, Defendants shall

provide a copy of this Decree, by email (with affirmative acknowledgment of review and receipt), personal service or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, PCMS employees at Defendants' Facilities, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities) with responsibility for the design, manufacture and/or distribution of Defendants' PCMS Devices (hereinafter, collectively referred to as "Associated Persons"). Within twenty (20) calendar days of the entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who have received a copy of this Decree pursuant to this paragraph, and attaching copies of the executed certified mail return receipts or email with affirmative acknowledgment of review and receipt.

21. In the event that Defendants become associated, at any time after the entry of this Decree, with new Associated Person(s), Defendants shall within ten (10) calendar days of the commencement of such association: (a) provide a copy of this Decree to each such Associated Person(s) by personal service or certified mail (restricted delivery, return receipt requested); and provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who received a copy of this Decree pursuant to this paragraph, and attaching copies of the executed certified mail return receipts.

22. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of partnerships, subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the

corporate structure of Defendant Philips North America LLC, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

23. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be sent via electronic mail to the Program Division Director, FDA, Office of Medical Device & Radiological Health, Division 1, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180 at oradevices1firmresponse@fda.hhs.gov, and via electronic and hard copy mail to the Program Division Director, FDA, Office of Medical Device & Radiological Health, Division 3, 19701 Fairchild, Irvine, CA 92612 and oradevices3firmresponse@fda.hhs.gov. All responses should reference the case name and civil action number.

24. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on written notice of the United States of America in this proceeding, Defendants shall pay to the United States of America the sum of fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues, an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree, and an additional sum in liquidated damages equal to twice the retail value of each shipment of devices that are adulterated or otherwise in violation of the Act, its implementing regulations, and/or this Decree. The annual total amount of such liquidated damages shall not exceed twenty million dollars ($20,000,000.00) in any calendar year. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not in any way limit the ability of the United States of America to seek, or the Court to

impose, additional civil and criminal contempt penalties based on conduct that may also form the basis for the payment of liquidated damages.

25. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States of America for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

26. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. When contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

27. No sooner than five (5) years after Defendants receive notification from FDA pursuant to paragraph 6(I), Defendants may petition this Court for relief from this Decree. If Defendants have maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations during the five (5) years preceding Defendants' petition, Plaintiff will not oppose such petition.

28. The obligations under this Decree of each individual named herein (or any Substitute Individual Defendant as defined below) shall apply only to the extent of the individual's authorities, responsibilities, and/or conduct at Philips. If, and for so long as, an individual Defendant or an employee of Philips ceases to be employed by or act on behalf of Philips or any of its subsidiaries, affiliates, and/or "doing business as" entities (the "Defendant Entities"), then that Defendant or employee shall be liable for such individual Defendant's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by or to act on behalf of the Defendant Entities.

An individual Defendant shall notify FDA within twenty (20) days after said Defendant ceases to be employed or otherwise act for all of the Defendant Entities. Within thirty (30) days of the separation of the individual Defendant from Defendant PMS, PMS shall designate an individual of similar position and responsibilities to be substituted as an individual Defendant ("Substitute Individual Defendant") and notify FDA of the identity and nature of employment of the Substitute Individual Defendant. FDA and PMS shall submit a stipulation to the Court identifying the Substitute Individual Defendant and requesting that the Court effect the substitution by order. The Substitute Individual Defendant added to this Decree shall be bound by the Decree in the same manner as the Defendants originally named in the Decree.

29. Defendants may petition FDA in writing to extend any deadline or timeframe provided herein, and FDA may grant such extension without seeking leave of Court. However, any such petitions shall not become effective or stay the imposition of any payments under this Decree unless granted by FDA in writing.

30. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

This 31st day of October, 2017

UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree:

For the Defendants:

CARLA KRIWET
Individually and on behalf of Philips North America LLC

OJAS A. BUCH
Individually

KRISTIN R. DAVENPORT
Goodwin Procter LLP
Counsel for Philips North America LLC

For the United States:

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Office of the General Counsel
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ATTACHMENT 1

PCMS DEVICES

	Product Identifier	Product Description	510(k) File Number(s)
	MCS		
1	Expression (MR200, MR400, IP5)	Patient Monitor for MRI environment (including wireless ECG and SpO2 modules)	K090785, K124061, K131382, K132359, K152330
2	Non-Invasive Blood Pressure cuffs, hoses, connectors*	Consumables	K810838, K884421, K903379, K905101, K071885, K101600, K131913, K151812, K152363
3	ECG Cables & Electrodes, temperature probes, and SpO2 sensors*	Consumables	K813639, K883793, K962070, K103646, K111114, K120366, K133961, K151761; K864730, K893643, K913516, K973437, K000794, K010451, K030973, K032755, K032949, K042306, K052377, K062455, K062605, K101600, K113125, K120366, K131913, K133961, K151812; ECG Electrodes are 510(k) exempt per 21 CFR § 870.2360
4	Transesophogeal Transducer Sheath	Consumables	K843262
5	Single use warmers (heel, mattress) & Positioning aids (pads, Gel)	Newborn Solutions	K936084, K040044; other devices are 510(k) exempt per 21 CFR § 880.6450
6	WeeSpecs, transilluminators, Nasal aspirators, indicators, belts	Newborn Solutions	K023931; other devices are 510(k) exempt per 21 CFR §§ 880.2200, 880.5270, 880.6470, 886.1945
7	BiliChek (Bilirubin spot check)	Newborn Solutions	K983071, K010052
8	Xper Flex Cardio	Hemodynamic patient monitor	K101571
	Patient Monitoring		
9	IntelliVue Information Center (PIIC)	Connected Monitoring System	K081983
10	IntelliVue Information Center iX (PIIC iX)	Connected Monitoring System	K102495, K143057, K153702, K163584

* Certain of the devices within this Attachment 1 **Product Identifier** are neither manufactured, distributed nor held by or at the Defendants' Andover or Bothell facilities. Although bearing the Philips name, these products are manufactured by third-party private labelers, and they are not PCMS Devices as defined in Consent Decree paragraph 3.B. 510(k) numbers for the third-party private-labeled devices may not be included in this Attachment. Other than ECR devices, no PCMS device is manufactured, distributed or held at the Bothell facility.

11	IntelliVue Clinical Network (PSCN/CSCN)	Connected Monitoring System	K081983
12	IntelliBridge System (IBS)	Connected Monitoring System	Originally K093177; subsequently 510(k) exempt per 21 CFR § 880.6310
13	IntelliBridge Enterprise (IBE)	Connected Monitoring System	510(k) exempt per 21 CFR § 880.6310
14	IntelliSpace Event Management (IEM)	Mobility Solution	K102974
15	CareEvent	Mobility Solution	K142935, K161164
16	IntelliSpace Critical Care and Anesthesia (ICCA)	Informed Decisions	K100272, K151366
17	IntelliSpace Perinatal (OBTraceVue)	Informed Decisions	K100420
18	IntelliSpace Console Critical Care	Informed Decisions	K151366
19	IntelliVue MX40	Clinical Telemetry	K103646, K113125
20	Telemetry Network	Clinical Telemetry	K041741
	VSS		
21	PageWriter TC Series (TC 20, TC 30 TC 50, TC70)	Electrocardiographs	K113144
22	Philips Holter Monitor System 1810 and 2010 software	Holter Monitoring Solutions	K010949
23	Digitrak XT Holter Recorder	Holter Monitoring Solutions	K071733
24	ST80i Stress Test System	Stress Test Systems	K121638
25	IntelliSpace ECG	Electrocardiograph Management Systems	K120885

26	Suresigns VM Series (VM4, VM6, VM8)	Patient Monitors	K123900
27	SureSigns VS Series (VS4, VS2+, Vsi)	Vital Sign Monitors	K111114, K112652
28	SureSigns Central	Central Monitoring Station	K131032
			Unless indicated otherwise below, all ECR medical devices listed hereunder are subject to a PMA order under 21 USC § 360e(b) and are included in a pending PMA application
	ECR		
29	HeartStart MRx	Batteries, paddles, cables and service parts only for HeartStart MRx Monitor/Defibrillator (both hospital and pre-hospital configurations). Manufacture and distribution of the defibrillator/monitor itself has ceased	Batteries, paddles, cables and service parts are included in a pending PMA application
30	HeartStart XL+	HeartStart XL+ Monitor/Defibrillator, including batteries, paddles, cables and service parts	Unapproved device not subject to a pending PMA application; manufactured for export only. Batteries, paddles, cables and service parts are included in a pending PMA application
31	QCPR Meter	QCPR measurement and feedback tool for MRx	
32	QCPR Meter	QCPR measurement and feedback tool for FR3	
33	Wireless Link	Wireless Link for MRx (radio module for transmitting data from Monitor/Defibrillator)	
34	IntelliVue Telemetry	IntelliVue Telemetry for MRx (Hardware module to connect MRx and Philips Intellivue Clinical Monitoring Network)	
35	HeartStart FR3	HeartStart FR3 AED	
36	HeartStart FR2	Batteries and cables for HeartStart FR2 AED only	Batteries and cables are included in a pending PMA application

		(manufacture and distribution of this AED has ceased)	
37	HeartStart Onsite	HeartStart Onsite AED (HS1)	
38	HeartStart Home	HeartStart Home AED sold OTC (HS1)	
39	HeartStart FRx	HeartStart FRx AED	
40	HeartStart FR3 Trainer	HeartStart AED Training Unit for FR3 (not for diagnostic or therapeutic use)	
41	HeartStart HS1 Trainer	HeartStart AED Training Pads for HS1 (Onsite and Home) (not for diagnostic or therapeutic use)	
42	HeartStart FRx Trainer	HeartStart AED Training Pads for FRx (not for diagnostic or therapeutic use)	
43	HeartStart Configure	HeartStart Configure Software (PC software to configure HeartStart AED)	
44	HeartStart Telemedicine System	HeartStart Telemedicine System (Patient Data Management Software)	
45	Philips HeartStart 12 Lead Transfer Station	HeartStart 12 Lead Transfer Station (PC software to facilitate display and management of 12-lead ECG acquired by MRx)	
46	HeartStart XL	Batteries, paddles, cables and service parts only for HeartStart XL Monitor/Defibrillator (manufacture and distribution of this monitor/defibrillator has ceased)	Batteries, paddles, cables and service parts are included in a pending PMA application
47	Defibrillation Pads and Pad Cartridges	Defibrillation and Multifunction Pads and Pads Cartridges for all Philips AEDs and Monitor/Defibrillators	

ATTACHMENT 2

ECR DEVICES

	Product Identifier	Product Description
1	HeartStart MRx	Batteries, paddles, cables and service parts only for HeartStart MRx Monitor/Defibrillator (both hospital and pre-hospital configurations). Manufacture and distribution of the defibrillator/monitor itself has ceased
2	HeartStart XL+	HeartStart XL+ Monitor/Defibrillator, including batteries, paddles, cables and service parts
3	QCPR Meter	QCPR measurement and feedback tool for MRx
4	QCPR Meter	QCPR measurement and feedback tool for FR3
5	Wireless Link	Wireless Link for MRx (radio module for transmitting data from Monitor/Defibrillator)
6	IntelliVue Telemetry	IntelliVue Telemetry for MRx (Hardware module to connect MRx and Philips Intellivue Clinical Monitoring Network)
7	HeartStart FR3	HeartStart FR3 AED
8	HeartStart Onsite	HeartStart Onsite AED (HS1)
9	HeartStart FR2	Batteries and cables for HeartStart FR2 AED only (manufacture and distribution of this AED has ceased)
10	HeartStart Home	HeartStart Home AED sold OTC (HS1)
11	HeartStart FRx	HeartStart FRx AED
12	HeartStart FR3 Trainer	HeartStart AED Training Unit for FR3 (not for diagnostic or therapeutic use)
13	HeartStart HS1 Trainer	HeartStart AED Training Pads for HS1 (Onsite and Home) (not for diagnostic or therapeutic use)
14	HeartStart FRx Trainer	HeartStart AED Training Pads for FRx (not for diagnostic or therapeutic use)
15	HeartStart Configure	HeartStart Configure Software (PC software to configure HeartStart AED)
16	HeartStart Telemedicine System	HeartStart Telemedicine System (Patient Data Management Software)

17	Philips HeartStart 12 Lead Transfer Station	HeartStart 12 Lead Transfer Station (PC software to facilitate display and management of 12-lead ECG acquired by MRx)
18	HeartStart XL	Batteries, paddles, cables and service parts only for HeartStart XL Monitor/Defibrillator (manufacture and distribution of this monitor/defibrillator has ceased)
19	Defibrillation Pads and Pad Cartridges	Defibrillation and Multifunction Pads and Pads Cartridges for all Philips AEDs and Monitor/Defibrillators

ATTACHMENT 3

Form of Recall Notification for External Defibrillators Manufactured with the R92 Resistor Supplied by International Resistive Company

PHILIPS

Month, Day, 2017
FSNXXXXXXX

Medical Device Recall/Notification
HeartStart FRx, HeartStart Home, and Heartstart OnSite AEDs

Dear HeartStart AED Owner,

We are contacting you because our records show you are the owner of one or more Philips HeartStart FRx, HeartStart OnSite, or HeartStart Home automated external defibrillators (AEDs) manufactured between 2005 and 2012. Philips is voluntarily issuing this recall notification due to awareness of isolated failures with one of the device's electrical components (a resistor).

1. Reason for This Recall Notification:

Your Philips AED is used to treat ventricular fibrillation (VF), a common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs). These Philips AEDs have a low failure rate of less than ½ % per year.

To help ensure your AED will perform in the event of an emergency, Philips AEDs include self-tests that run automatically when the AED is not being used. Various tests occur at daily, weekly, and monthly intervals. These self-tests have been effective at catching over 99% of critical performance issues and alerting users through a series of audible chirps. However, isolated failures can occur that are not detected by these self-tests, and occur during use, putting patients at risk of not receiving adequate therapy for their VF or VT, potentially resulting in serious injury, or even death.

Philips has become aware of a specific issue with one of the electric components (a resistor) in approximately 650,000 AEDs that were manufactured between 2005-2012. Virtually all of these resistor-related failures were detected through the device's automatic self-testing, alerting the user by issuing audible chirps. The in-use reliability of these AEDs is greater than 99.9% when the AED determines a cardiac arrest victim is in need of shock therapy.

However, in rare instances, self-tests might not identify a problem and the device might not deliver a shock when needed. To date, Philips is aware of more than 7 instances in which this component failed during treatment, out of more than 45,000 uses in which shock therapy was delivered. In all these instances, the device delivered at least one shock before failure. Among the cases for which the patient outcome is known, 5 patients died and 2 patients were successfully resuscitated and survived. Importantly, when AEDs are used on patients suffering sudden cardiac arrest, not all patients survive. In published studies of public access defibrillation to treat sudden cardiac arrest, the typical indicated survival rates are approximately 25% when an AED is used by a bystander versus 10% if an AED is not used.

2. Risk to Health

Philips is sending this letter to remind customers about the nature and meaning of audible chirps, and to notify customers what to do ***in the extremely rare circumstances the automated tests fail to detect the AED's inability to function normally, and fail to deliver a shock when one is needed.***

3. Actions To Be Taken By Customer/User

Understanding Audible Chirps from Your AED:

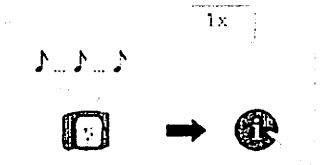
Your Philips AED tests itself at regular intervals to ensure it is ready for use. Issues identified during self-tests result in the sounding of audible single chirps or triple chirps. When an error is detected, the AED continues to chirp until the error is cleared. To help you better understand the difference between single and triple chirps, please view the instructional video on our website at:

www.philips.com/aedaudiblechirps

As stated in your HeartStart manual:

If your AED emits a series of single chirps (♪... ♪... ♪...):

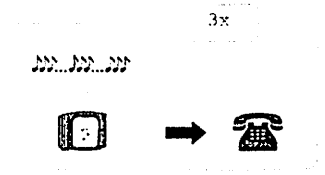
Press the flashing blue i-button for information. Your AED will tell you what actions to take (such as replacing expired battery or pads).



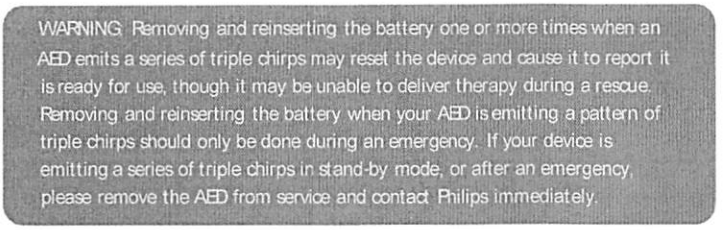
If your AED emits a series of triple-chirps (♪♪♪... ♪♪♪... ♪♪♪...), this could mean that a potentially serious problem was detected during self-test that could prevent your AED from delivering therapy in an emergency.

If you ever hear your AED emit a series of triple chirps:

During Stand-By Mode: ***Please call Philips immediately*** for technical support including delivery of a replacement unit and receipt of a Return Authorization (RA) number.



During an Emergency Rescue: Press the flashing blue i-button and follow the voice prompts. Removing and reinserting the battery can clear some errors, and equip the device to deliver therapy in a rescue. ***The battery removal and reinsertion procedure should only be done in an emergency situation. Once the emergency is over, call Philips immediately*** for technical support including delivery of a replacement unit and receipt of a Return Authorization (RA) number.



In the rare event that an AED fails during use and is unable to deliver shock therapy, you should:

- ***Ensure that 911 has been called.***
- ***Continue CPR while waiting for Emergency Medical Services to arrive.***
- ***If an additional bystander is available, send him/her to locate another nearby AED.***

4. Specific Products Covered by This Notification

Philips AED Models: HeartStart FRx, HeartStart Home, and HeartStart OnSite AEDs manufactured from 2005 through November 2012 are included within the scope of this notification. The year of manufacture can be identified by the 2nd and 3rd characters in the serial number on the back of the AED in the range:

Home/Onsite: A05A-xxxxx *through* A12K-xxxxx
FRx: B05A-xxxxx *through* B12K-xxxxx

Examples:

Serial number A07C-01002 was manufactured in 2007. It falls within this range and ***is*** covered by this notification.

Serial number A13B-00773 was manufactured in 2013. It does ***not*** fall within this range and ***is not*** covered by this notification because it does not contain the resistor associated with this recall notification.

Exception:

If your device was manufactured in 2012 and the 4th digit is the letter "L" it is not covered by this recall. For example, A12L-02375 is not covered by this recall because it does not contain the resistor associated with this recall notification.

5. Action Taken by Philips

Philips began notifying owners of this potential hazard in September 2012. With this mailing, we are providing additional information and have created an instructional video available at www.philips.com/aedaudiblechirps.

Philips carefully monitors the reliability of our AED products. If you experience an issue with your AED or if it is emitting triple chirps, please contact Technical Support (refer to following section).

5. For Technical Support

As noted above, and in your HeartStart AED owner's manual, if your Philips AED has ever emitted or begins to emit a pattern of triple chirps, please contact Philips for technical support at 1-800-263-3342. Live support is available Monday-Friday, 7:00AM-5:00PM PST. This number is available 24 hours a day, seven days a week for customer messages that will be promptly returned the next business day.

Adverse reactions or quality problems experienced during use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

6. Replacement or Rebate Opportunity

Your continued satisfaction with Philips AEDs is very important to us and we want to ensure your confidence in the reliability of our products. If your device is covered by this notification and is still under warranty, you are entitled to receive a refurbished exchange unit at no cost, in accordance with our standard warranty terms. If your device is no longer under warranty or if you desire to purchase a newer model replacement for your present AED, as an owner of a Philips HeartStart FRx, HS1 OnSite, and HS1 Home AED manufactured prior to 2013, you may be eligible for a trade-in rebate. Philips is offering trade-in rebates ranging from $50 to $625, depending on the age and model of your AED.

To request a warranty exchange unit or a trade-in rebate, or to obtain additional information, please contact your local Philips representative or contact Philips directly at 1-800-263-3342.

Additionally, to help you get the most out of your AED and to help you ensure it is ready for use if needed, please refer to the online instructional video on AED pads and batteries:

www.philips.com/padsandbatteries

ATTACHMENT 4

Form of Recall Labeling Correction for HeartStart MRx and FR3 Monitor/Defibrillators With Q-CPR Meter or CPR Sensor Revised Instructions for Use

PHILIPS

Month, Day, 2017
FSNXXXXX
XX

Medical Device Recall / Labeling Correction

Philips HeartStart MRx and FR3 Monitor/Defibrillator
And HeartStart FR3 AED Used With
Q-CPR Meter or CPR Sensor

Dear HeartStart MRx Owner,

1. Reason for This Voluntary Action:

- Philips is sending this letter as a formal notice of a Medical Device Labeling Correction
  - to ensure HeartStart MRx customers have access to the *HeartStart MRx Addendum* as a supplement to the MRx Instructions for Use (IFU)
  - to ensure Heartstart FR3 customers whose Q-CPR Meters are used on an MRx are aware that certain information contained in the FR3 AED Instructions for Administrators (IFA) and the FR3 Q-CPR Meter Instructions for Use (IFU) also applies to use of the Q-CPR Meters with the MRx.

2. Product Information:

The Q-CPR meter can be used with the following devices:

Device	Device Model #	Q-CPR Model #
HeartStart FR3	861388 and 861389	989803149941
HeartStart MRx	M3535A and M3536A	453564145481, 453564257691, 989803162401 and M4761A

When attached to the bare chest of a suspected victim of Sudden Cardiac Arrest (SCA), the Q-CPR meter provides real-time feedback on the depth and frequency of CPR compressions in accordance with current CPR guidelines. These devices are intended for use by persons professionally trained in CPR, to assure proper use and the delivery of optimal CPR to the victim.

The disposable adhesive pad must be present and properly positioned when the Q-CPR Meter is used.

3. Action Taken by Philips:

- In August, 2015, Philips distributed a Q-CPR Addendum to the MRx Instructions for Use (IFU). This information was already available in the HeartStart FR3 Instructions for Administrators (IFA) and the FR3 Q-CPR Instructions for Use (IFU)
- The addendum for the MRx addressed feedback received from customers about two specific issues:
  - Correct placement of the disposable adhesive pad on the Q-CPR meter
    - Philips provided an in-color graphic with instructions to clarify the positioning of the adhesive pad
  - Types of injuries associated with the proper performance of CPR
    - Philips included a WARNING in the Addendum, calling out the types of injuries that may result from properly performed CPR.

4. Risk to Health:

- Tissue damage, bone breakage, etc. are well-known complications of CPR and are seen when CPR is correctly administered with or without the use of the Q-CPR Meter and CPR Sensor. The Q-CPR Meter and CPR Sensor when used as directed facilitate the administration of CPR and resulting tissue damage may still occur.

5. Action to be Taken by Customer:

- For MRx Customers, ensure that your copy of the MRx IFU contains the Addendum.
- For FR3 Customers, ensure that the IFU for any MRx with which your Q-CPR Meter may be used contains the Addendum
- Inform all staff who may use the Q-CPR Meter with an MRx of the information in the Addendum, regardless of whether the Q-CPR Meter was originally sold for use with an FR3 or MRx
- Immediately return the attached reply card indicating whether your firm continues to possess an MRx or FR3, which is used with the Q-CPR Meter or CPR Sensor.

6. Technical Support:

Call 1-800-722-9377, Option 8 for technical support

Philips is committed to providing products and services of the highest quality. If you require further information or support regarding this notice, please contact your local Philips representative.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

ENGLISH

HeartStart Q-CPR Adhesive Pads

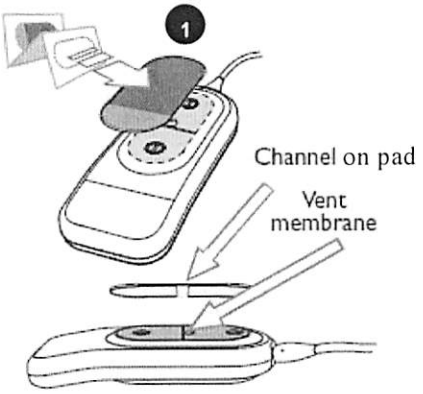
This document clarifies the section in your *HeartStart MRx Instructions for Use* related to attaching the adhesive pad to the CPR meter. It also replaces the HeartStart IFU Addendum dealing with Q-CPR Adhesive pad (Part number 4535645288861). Keep this addendum with your *Instructions for Use*.

When using the CPR meter (or the earlier generation CPR sensor) for CPR feedback during an event, you must properly attach an adhesive pad to the rear cover of the device before using.

To attach the adhesive pad:

1. Open the package of adhesive pads. Peel one pad off the strip, exposing the adhesive surface on the underside. Align the bottom of the adhesive pad with the yellow patient-adhesive mount area of the rear cover of the CPR meter, making sure the channel on the adhesive pad is directly over the vent membrane. Press into place. See 1
2. Do not peel off the green and yellow liner from the front of the pad until you are ready to apply the device to a patient.

For more information on the CPR meter or sensor and its adhesive ads, see the *Q-CPR and Data Capture* chapter in the *HeartStart MRx Instructions for Use*.



WARNING: Properly performed CPR can result in the fracturing of a patient's ribs or other chest injuries, including external chest wall bruising or abrasion.* If patient rib or chest integrity has been compromised, continue to provide CPR in accordance with your local protocol.

CAUTION: As directed in the instructions, the CPR meter must be used with the adhesive pad in place and properly positioned.

**Black CJ (1), Busuttil, A, Robertson C. Chest wall injuries following cardiopulmonary resuscitation, Resuscitation. 2004: 63:339-343*

ATTACHMENT 5

Consumables and Accessories for Philips AEDs and Monitor/Defibrillators for Purposes of Paragraph 7.A.(viii)*

1. Carrying Cases
2. Power Supplies including Batteries, AC Power Modules, DC Power Modules and associated cables and chargers
3. Defibrillation Pads, Pad Cartridges and Cables
4. Defibrillation Paddles (internal and external)
5. Infant / Child keys
6. Fast Response Kit
7. Data Management Software & Accessories
8. Training Materials & Instructions
9. Pads Adapters
10. Three-lead ECG Assessment Module (for FR3 only)
11. Networking and Data Cards

*The following consumables and accessories that may be used with Philips AEDs or Monitor/Defibrillators and other devices, are not ECR Devices as defined in Paragraph 3. Because they are not ECR Devices, their manufacture and distribution is neither subject to the paragraph 6 injunction, nor the paragraph 7.A.(viii) exception. A list of these consumables and accessories is provided below to avoid confusion.

A. ECG Cables (3-lead, 5-lead and 12-lead)
B. SPO_2 Sensors and Cables
C. CO_2 and O_2 Air Tubes
D. Temperature Probes & extension cables
E. Non-invasive Blood Pressure Tubes and cuffs
F. Invasive Blood Pressure kits, sensors, domes, catheters, cables and adapters
G. Cabinets, Cases, Bed Mounts & Wall Mounts

H. Wall Signs, Awareness Placards & Posters

I. Thermal paper