FDA

Class 2 Device Recall eCare Coordinator

See Related Information[22]

Date Initiated by Firm	March 02, 2017
Create Date	April 04, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1708-2017
Recall Event ID	76660[23]
510(K)Number	K141706[24]
Product Classification	Transmitters and receivers, physiological signal, radiofrequency[25] - **Product Code** DRG[26]
Product	*eCare Coordinator* Product Usage: is software intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. eCare Coordinator does not send any real time alarms and is not intended to provide automated treatment decisions. This software is an informational tool only and is not to be used as a substitute for professional judgment of healthcare providers in diagnosing and treating patients.
Code Information	*453564506091 , eCareCoordinator.*
Recalling Firm/ *Manufacturer*	Philips Visicu *217 E Redwood St Ste 1900* Baltimore MD 21202-3315
***Manufacturer Reason* for Recall**	*eCareCoordinator (eCC) is intended for use in data aggregation, patient interaction* facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The *software is intended to provide patient information from the patient location through* networking technology to a remote care team. A software defect was discovered in the Philips eCareCoordinator (eCC) Clinical User Interface that can at times cause missing or redundant *data to be saved without notification to the user.*
FDA Determined Cause [2]	Software Manufacturing/Software Deployment
Action	Field Safety Notice (FSN) will be sent to all customers using eCareCoordinator all Versions. The FSN describes the problem and circumstances in which the design defects occurs and the action planned by Philips to correct the problem. The FSN will also detail the functionality change in detail. A software correction will be made and released.by the vendor. Customers will have this correction applied to their current version when made available by Vendor in order to fix this correction.
Quantity in Commerce	26
Distribution	Worldwide Distribution-US Nationwide

565479	محمود	محمد	سعود	حليمه	6825512	61	2186	564560	6825512	61	2186
648781	تغريد	ملحم	مظلوم	زينب	0	43	401	565296	0	43	375
810830	مارينا	علي	جعفر	ريما	525485/03			565303	441813/03	46	586
[illegible]02027	هبه	علي	المصري	جمال	76/674329	43	375	566007	.	43	387
[illegible]04611	نجاة	[illegible]	فاضل	[illegible]	03/523674	56	1252	[illegible]	70/950536	56	1252
1151750	هلا	[illegible]	ناصر	زينب	0	59	1327	[illegible]	0		
569354	هلا	[illegible]	ناصر	زينب	0			567458	0		
1121204	مريم	علي	كرنبي	[illegible]	0	43	405	[illegible]	102981/03	43	405
1027205	علا	حسين	نصار	[illegible]	7855419	58	[illegible]	[illegible]	0	58	1221
709354	هدى	[illegible]	القطب	افتخار	0			568952	3528292	60	1449
783831	ماري	جرجس	شاكر	ميلاد	09/212769			569731	0		
688983	ماري	جرجس	شاكر	ميلاده	09/212769			569731	0		
587427	ماري	جرجس	شاكر	ميلاده	09/212769			[illegible]	0		
551561	فاطمة	عبد الله	حسين	[illegible]	0			[illegible]	0		
1317140	سهيل	رضى	عبود	[illegible]	0	58	1182	569738	0		
1192230	سهيل	رضى	عبود	[illegible]	0	58	1182	[illegible]	0		
530746	سهيل	رضى	عبود	[illegible]	0			[illegible]	0		
934854	انصاف	وديع	القري	حبوبه	3943088	54	[illegible]	570446	9926793		
562928	عبد الامير	السيد موسى	فضل الله	فاطمة	0			571155	0		
[illegible]62108	علي	حسين	سعيد	مريم	0	50	1090	571157	0		
[illegible]96011	مريم	مصطفى	ويراني	زينب	70/844579	59	1373	[illegible]	0		
[illegible]22640	مريم	مصطفى	ويراني	[illegible]	0			[illegible]	0		
667077	[illegible]	ابراهيم	زبية	[illegible]	0			571179	0		
[illegible]13344	فاطمة	محمد	غملوش	[illegible]	0			560222	0		
[illegible]46851	[illegible]	حسين	قوصان	[illegible]	0	59	1303	[illegible]	0		
[illegible]39372	[illegible]	[illegible]	عواضة	زينب	0			561709	0		
[illegible]70200	ملاح	علي	سلمان	امنة	0			561715	0		
[illegible]63106	ملاح	علي	سلمان	امنة	0			561715	0		
1164536	زينب	احمد	قانصوه	مناهل	0	48	914	563885	0		
781811	زينب	احمد	قانصوه	مناهل	0			[illegible]	0		
1052186	[illegible]	مصطفى	ندى	[illegible]	[illegible]04	60	[illegible]	[illegible]	649504	60	1468
441847	حسين	محمد	حيدر	[illegible]	0			564588	163461/03	43	420
758293	فاطمة	محمد	الحجيري	عطرشان	912729/03	43	405	[illegible]	3930232	43	405
1218248	خليل	[illegible]	بوركلي	كاملة	0	58	1216	[illegible]	0		
689348	حسين	صادق	سلوم	علية	0			564625	0		
699046	حسين	صادق	سلوم	علية	0			564625	0		
700522	حسين	صادق	سلوم	علية	0			564625	0		
721811	حسين	صادق	سلوم	علية	0			564625	0		
1016949	ايمان	[illegible]	الجمال	[illegible]	[illegible]0201/71	43	[illegible]	565306	0	43	2582
795651	محسن	[illegible]	غريب	زينب	[illegible]/03	47	[illegible]	[illegible]	03/711949	47	595
[illegible]86751	عبد الله	رشيد	ناجي	[illegible]	0	48	779	[illegible]	0		
[illegible]41871	مريم	حسن	حمود	خديجه	0	59	1300	566083	0	59	1300
[illegible]74498	مريم	حسن	حمود	خديجه	0	59	[illegible]	566083	0	59	1300
[illegible]4383	مريم	هزاع	ملحم	فاطمه	0	59	[illegible]	566790	0	59	1373
[illegible]50843	مريم	هزاع	ملحم	فاطمه	0			566790	0	59	1373
[illegible]71392	[illegible]	[illegible]	حاريلا	تميمه	0	48	825	566805	0	48	825
[illegible]73419	[illegible]	[illegible]	ريشي	[illegible]	8800322	42	148	569753	8800322	42	148
733120	فياض	اسعد	قرباني	[illegible]	0			569770	0		
[illegible]99486	فياض	[illegible]	قرباني	[illegible]	0			[illegible]	0		
[illegible]84989	فاطمة	[illegible]	عمار	خديجة	0			569779	0		
902555	وفاء	حسين	عوالا	تمام	0			571193	0		
747901	وفاء	حسين	عوالا	تمام	0			571193	0		
1296711	زهرة	السيد علي	محمد	نعيمة	0	59	1305	571199	0		
1078307	حسين	عباس	مصطفى	جميله	0	59	1300	571215	0	59	1300