

Edwards

URGENT MEDICAL DEVICE CORRECTION – FCA-137

Product: EV1000 Clinical Platform NI

Model Numbers: EV1000NI

Serial Numbers: Refer to Appendix A

Sep 18, 2019

<Customer #>

<Contact name or Dept.>

<Firm Name>

<Attention: RISK MANAGEMENT>

cc: Chairman Medical Board and relevant Head of Departments

<Address>

<City/state/zip>

Dear Valued Customer:

As part of our strong commitment to quality, we continuously monitor our products throughout their life cycle to quickly identify and correct any potential issues. We recently became aware that certain EV1000 NI units were shipped with incorrect information for the Applied Part designation in the Operator's Manual. Please note, we are not recalling any product.

This notice should be provided to all users of the EV1000 Clinical Platform NI system within your organization. If you have any questions or concerns regarding this Medical Device Information Letter, please contact Edwards Tech Support at **+65 9658 4570**.

Description of Issue:

This non-conformance involves an EV1000NI system with incorrect information for the Applied Part designation in the Operator's Manual. Applied Part type refers to the electrical contact that the product has with the patient.

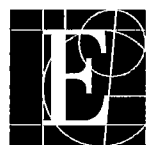
The correct information should be "Type BF Applied Part". (Type BF: Electrically connected to Patient but not directly to heart.)

The current Operator's Manuals in Latvian, German, and Hungarian state "Type CF Applied Part" (Type CF: Electrically connected to the heart of the Patient).

The Swedish manual currently states, "Type B Applied Part" (Type B: No electrical contact with Patient and may be earthed).

The corresponding symbology in all manuals is correct. The Operator's Manual for EV1000NI has a description of the monitoring system, in which it is described as non-invasive. This is a labeling issue that does not affect the function of this product.


As the symbology is correct in all Operator's Manuals, there is no risk to the patient or the user, associated with this labeling issue.



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Examples:

Correct English Version:

	Type BF applied part
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Incorrect Versions:


German Version:

	Anwender teil Typ CF
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Hungarian Version:

	CF-típusú alkalmazott rész
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Latvian Version:

	CF tipa lietotā daļa
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Swedish Version:

	Patientanslutningen del typ B
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Description and indication of product:

The EV1000 Clinical Platform NI monitors key hemodynamic parameters derived from continuous noninvasive measurement of the arterial pressure waveform. The EV1000 Clinical Platform NI assists the clinician in assessing the patient's physiologic status and supports clinical decisions related to hemodynamic optimization.

If you have any questions, please contact **Edwards Tech Support at +65 9658 4570.**

Sincerely,



Sunita Das
Director | Quality Assurance
Edwards Lifesciences

Appendix A: List of Impacted Serial Numbers

Region	Country	Item	Serial No	Bill to No	Ship to No	Account Name ST	Ship to Type	ST Description	Location	Install base Last Update Date	Qty
Europe	Germany	EVMPM	600153000154	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	12/11/2018	1
Europe	Germany	EVMPM	600153000749	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	3/29/2018	1
Europe	Germany	EVMPM	600153001904	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/25/2019	1
Europe	Germany	EVMPM	600153003071	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/17/2018	1
Europe	Germany	EVMPM	600153003079	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	10/23/2018	1
Europe	Germany	EVMPM	600153010011	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	10/24/2018	1
Europe	Germany	EVMPM	600153010085	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	2/21/2018	1
Europe	Germany	EVMPM	600153012648	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	9/14/2018	1
Europe	Germany	EVMPM	600153014520	45	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/1/2019	1
Europe	Germany	EVMPM	600153001180	70	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/30/2019	1
Europe	Germany	EVMPM	600153000485	523732	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	1/10/2019	1
Europe	Germany	EVMPM	600153002077	523732	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/26/2019	1
Europe	Germany	EVMPM	600153012181	523732	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	5/8/2019	1
Europe	Germany	EVMPM	600153000889	523732	560517	EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	5/9/2019	1
Europe	Germany	EVMPM	600153000890	523732	560517	EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	5/9/2019	1
Europe	Germany	EVMPM	600153002559	523732	560517	EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	5/9/2019	1
Europe	Germany	EVMPM	600153002869	523732	560517	EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	5/9/2019	1
Europe	Germany	EVMPM	600153003059	523732	560517	EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	5/9/2019	1
Europe	Germany	EVMPM	600153003608	523732	560517	EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	5/9/2019	1
Europe	Germany	EVMPM	600153003617	523732	560517	EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	5/9/2019	1
Europe	Germany	EVMPM	600153013282	523732	560517	EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	5/9/2019	1
Europe	Germany	EVMPM	600153000130	668478	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	10/5/2016	1
Europe	Germany	EVMPM	600153013103	725113	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	3/15/2019	1
Europe	Germany	EVMPM	600153011645	788840	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	1/9/2019	1
Europe	Germany	EVMPM	600153000714	1179323	1179390	Hettstedt, Helios KI, Versorgungssyste	ST	SHIP-TO ADDRESS	CUSTOMER	1/4/2017	1
Europe	Germany	EVMPM	600153013102	1377152	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/16/2019	1
Europe	Germany	EVMPM	600153000325	46296109	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/12/2019	1
Europe	Germany	EVMPM	600153013106	46302068	742718	Berlin,Charite,Z-Lager,CC	ST	SHIP-TO ADDRESS	CUSTOMER	3/1/2018	1
Europe	Germany	EVMPM	600153014860	46302068	742718	Berlin,Charite,Z-Lager,CC	ST	SHIP-TO ADDRESS	CUSTOMER	2/28/2019	1
Europe	Germany	EVMPM	600153001624	46302091	62442708	Bonn Uni,Zent. Waren.	ST	SHIP-TO ADDRESS	CUSTOMER	2/26/2018	1
Europe	Germany	EVMPM	600153014815	46302091	62442710	Bonn, Uni. Lager Versorgungskn.Funktion	ST	SHIP-TO ADDRESS	CUSTOMER	12/27/2018	1
Europe	Germany	EVMPM	600153000824	46302113	629094	Freiburg,UniAnästhesie/Intensivst. I	ST	SHIP-TO ADDRESS	CUSTOMER	5/25/2018	1
Europe	Germany	EVMPM	600153003634	46302116	62443857	Freiburg, Uni, Techni-Ersatzleilzentrum	ST	SHIP-TO ADDRESS	CUSTOMER	6/6/2016	1
Europe	Germany	EVMPM	600153010073	46302185	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/18/2019	1
Europe	Germany	EVMPM	600153010429	46302200	62444269	München, Rechts d. Isar, Zentrallager	ST	SHIP-TO ADDRESS	CUSTOMER	7/22/2016	1
Europe	Germany	EVMPM	600153010430	46302200	62444269	München, Rechts d. Isar, Zentrallager	ST	SHIP-TO ADDRESS	CUSTOMER	7/22/2016	1
Europe	Germany	EVMPM	600153001207	46302217	62512459	Minden, Klinikum,Med-Technik,	ST	SHIP-TO ADDRESS	CUSTOMER	1/29/2016	1
Europe	Germany	EVMPM	600153014119	46302438	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/4/2019	1
Europe	Germany	EVMPM	600153000760	46302503	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/30/2019	1
Europe	Germany	EVMPM	600153000522	46302546	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	2/19/2019	1
Europe	Germany	EVMPM	600153000246	46302664	62444638	Korbach, Stadtkrankenhaus, Enser Str. 19	ST	SHIP-TO ADDRESS	CUSTOMER	2/16/2018	1
Europe	Germany	EVMPM	600153014120	46302721	62444825	Ebersberg, KKH, Interne Intensiv	ST	SHIP-TO ADDRESS	CUSTOMER	10/25/2018	1
Europe	Germany	EVMPM	600153001196	46302802	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	5/2/2019	1
Europe	Germany	EVMPM	600153014116	46302958	62444782	Rostock, Univ., Z-lager, Schillingallee	ST	SHIP-TO ADDRESS	CUSTOMER	9/11/2018	1
Europe	Germany	EVMPM	600153014117	46302958	62444782	Rostock, Univ., Z-lager, Schillingallee	ST	SHIP-TO ADDRESS	CUSTOMER	9/11/2018	1
Europe	Germany	EVMPM	600153014554	46303007	954093	Lübeck, Drägerwerk, WarenanMLZ,Novgorods.	ST	SHIP-TO ADDRESS	CUSTOMER	12/27/2018	1
Europe	Germany	EVMPM	600153014646	46303007	954093	Lübeck, Drägerwerk, WarenanMLZ,Novgorods.	ST	SHIP-TO ADDRESS	CUSTOMER	12/27/2018	1
Europe	Germany	EVMPM	600153001670	46303007	62444930	Lübeck, Dräger AG & Co.KGaA	ST	SHIP-TO ADDRESS	CUSTOMER	11/15/2016	1
Europe	Germany	EVMPM	600153002237	46303007	62444930	Lübeck, Dräger AG & Co.KGaA	ST	SHIP-TO ADDRESS	CUSTOMER	11/20/2015	1
Europe	Germany	EVMPM	600153013828	46303051	62445048	Halle, KH, Martha- Maria, HKL	ST	SHIP-TO ADDRESS	CUSTOMER	8/21/2018	1
Europe	Germany	EVMPM	600153000719	46303134	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	11/13/2017	1
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Europe	Germany	EVMPM	600153001671	46306297	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	5/7/2019	1
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Europe	Germany	EVMPM	600153003080	46306297	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	5/2/2019	1
Europe	Germany	EVMPM	600153003136	46306297	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	3/14/2019	1
Europe	Germany	EVMPM	600153010047	46306297	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	5/2/2019	1
Europe	Germany	EVMPM	600153014121	46306297	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	9/12/2018	1
Europe	Germany	EVMPM	600153014122	46306297	45	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	1/2/2019	1
Europe	Germany	EVMPM	600153000565	46306297	1171679	Klaffki, Sven, ship to	ST	SHIP-TO ADDRESS	CUSTOMER	5/8/2019	1
Europe	Germany	EVMPM	600153001612	46306297	1171679	Klaffki, Sven, ship to	ST	SHIP-TO ADDRESS	CUSTOMER	5/8/2019	1
Europe	Germany	EVMPM	600153003551	46306297	1279530	Lübeck, Brigitte Morof-Windhorst	ST	SHIP-TO ADDRESS	CUSTOMER	2/7/2018	1
Europe	Germany	EVMPM	600153002897	46306297	1283190	München, Björn Petersen	ST	SHIP-TO ADDRESS	CUSTOMER	3/1/2018	1
Europe	Germany	EVMPM	600153000557	46306297	1289043	Berlin, Pavel Cojocar	ST	SHIP-TO ADDRESS	CUSTOMER	1/15/2019	1
Europe	Germany	EVMPM	600153001902	46306297	1289043	Berlin, Pavel Cojocar	ST	SHIP-TO ADDRESS	CUSTOMER	4/23/2019	1
Europe	Germany	EVMPM	600153002545	46306297	1289043	Berlin, Pavel Cojocar	ST	SHIP-TO ADDRESS	CUSTOMER	4/15/2019	1
Europe	Germany	EVMPM	600153003072	46306297	1289043	Berlin, Pavel Cojocar	ST	SHIP-TO ADDRESS	CUSTOMER	4/18/2019	1
Europe	Germany	EVMPM	600153001321	46306297	1297380	Frankfurt, Laura Mack	ST	SHIP-TO ADDRESS	CUSTOMER	4/26/2018	1

Europe	Germany	EVPMP	600153014123	46306297	1297380 Frankfurt, Laura Mack	ST	SHIP-TO ADDRESS	CUSTOMER	4/25/2019	1
Europe	Germany	EVPMP	600153014922	46306297	1297380 Frankfurt, Laura Mack	ST	SHIP-TO ADDRESS	CUSTOMER	4/29/2019	1
Europe	Germany	EVPMP	600153000698	46306297	62442803 Unterschleißheim, CC ,	ST	SHIP-TO ADDRESS	CUSTOMER	9/1/2014	1
Europe	Germany	EVPMP	600153000741	46306297	62509417 Berlin,Volker Haag,	ST	SHIP-TO ADDRESS	CUSTOMER	12/4/2018	1
Europe	Germany	EVPMP	600153001191	46306297	62509417 Berlin,Volker Haag,	ST	SHIP-TO ADDRESS	CUSTOMER	3/1/2018	1
Europe	Germany	EVPMP	600153000724	46338965	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	3/7/2018	1
Europe	Germany	EVPMP	600153000217	46341753	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	8/23/2018	1
Europe	Germany	EVPMP	600153010049	46341753	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	1/14/2019	1
Europe	Germany	EVPMP	600153001185	46362769	62476771 Althengstett, Philips Wichtig AG- DE9 A	ST	SHIP-TO ADDRESS	CUSTOMER	2/17/2017	1
Europe	Germany	EVPMP	600153000188	46377035	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/24/2019	1
Europe	Germany	EVPMP	600153000932	46377035	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/12/2019	1
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Europe	Germany	EVPMP	600153002909	46377035	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/16/2019	1
Europe	Germany	EVPMP	600153010436	46377035	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	2/18/2019	1
Europe	Germany	EVPMP	600153000715	46377035	62443619 EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	4/9/2019	1
Europe	Germany	EVPMP	600153002227	46377035	62443619 EDWARDS LIFESCIENCES GMBH	ST	SHIP-TO ADDRESS	CUSTOMER	9/18/2018	1
Europe	Germany	EVPMP	600153012127	62455788	45 RETURN EQUIPMENT IN STOCK - DE SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	5/3/2019	1
Europe	Germany	EVPMP	600153013568	62471747	62470686 Landstuhl-Kirchberg, Meditrade, Regional	ST	SHIP-TO ADDRESS	CUSTOMER	6/19/2018	1
Europe	Germany	EVPMP	600153013576	62471747	62470686 Landstuhl-Kirchberg, Meditrade, Regional	ST	SHIP-TO ADDRESS	CUSTOMER	6/19/2018	1
Europe	Germany	EVPMP	600153013579	62471747	62470686 Landstuhl-Kirchberg, Meditrade, Regional	ST	SHIP-TO ADDRESS	CUSTOMER	6/19/2018	1
Europe	Germany	EVPMP	600153000302	62475220	62475221 Weimar, Sophien-und Hufeland,Zentrall	ST	SHIP-TO ADDRESS	CUSTOMER	9/15/2018	1
Europe	Germany	EVPMP	600153002217	62479357	62479358 Tauberbischofsheim, Kreiskrankenhaus,Frei	ST	SHIP-TO ADDRESS	CUSTOMER	11/15/2017	1
Europe	Hungary	EVPMP	600153000242	62466329	62466327 VARIOMEDIC KFT.	ST	SHIP-TO ADDRESS	CUSTOMER	5/22/2014	1
Europe	Lithuania	EVPMP	600153002565	46420727	62478115 MEDIQ LIETUVA UAB	SI	SHIP-TO INACTIVE	CUSTOMER	1/22/2016	1
Europe	Sweden	EVPMP	600153000193	47	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	3/24/2017	1
Europe	Sweden	EVPMP	600153000195	47	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	10/20/2015	1
Europe	Sweden	EVPMP	600153000569	47	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	3/24/2017	1
Europe	Sweden	EVPMP	600153001225	47	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	2/8/2016	1
Europe	Sweden	EVPMP	600153001458	47	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	5/7/2018	1
Europe	Sweden	EVPMP	600153001909	47	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	10/30/2015	1
Europe	Sweden	EVPMP	600153002572	47	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	3/24/2017	1
Europe	Sweden	EVPMP	600153003554	47	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	3/24/2017	1
Europe	Sweden	EVPMP	600153010058	47	874195 FALU LASARETT	ST	SHIP-TO ADDRESS	CUSTOMER	9/25/2018	1
Europe	Sweden	EVPMP	600153000087	47	62473308 SÖDERSJUKHUSET	ST	SHIP-TO ADDRESS	CUSTOMER	10/12/2017	1
Europe	Sweden	EVPMP	600153000568	725113	745044 SÖDERTÄLJE SJUKHUS	ST	SHIP-TO ADDRESS	CUSTOMER	2/26/2019	1
Europe	Sweden	EVPMP	600153001418	725113	745044 SÖDERTÄLJE SJUKHUS	ST	SHIP-TO ADDRESS	CUSTOMER	3/1/2018	1
Europe	Sweden	EVPMP	600153012145	725113	745044 SÖDERTÄLJE SJUKHUS	ST	SHIP-TO ADDRESS	CUSTOMER	1/25/2019	1
Europe	Sweden	EVPMP	600153001668	893141	893143 INFINITI MEDICAL AB	ST	SHIP-TO ADDRESS	CUSTOMER	6/26/2015	1
Europe	Sweden	EVPMP	600153014286	46410220	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/18/2019	1
Europe	Sweden	EVPMP	600153000189	62455336	866042 MERIKE ÖDMARK	ST	SHIP-TO ADDRESS	CUSTOMER	1/9/2017	1
Europe	Sweden	EVPMP	600153000190	62455788	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	2/19/2018	1
Europe	Sweden	EVPMP	600153000567	62455788	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	2/9/2017	1
Europe	Sweden	EVPMP	600153012128	62455788	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	2/19/2018	1
Europe	Sweden	EVPMP	600153010052	62483136	47 RETURN EQUIPMENT IN STOCK - ND SERVICES	ST	SHIP-TO ADDRESS	CUSTOMER	4/15/2019	1