

URGENT - Field Safety Notice IPX1 Rating Symbol Label Issue

IPX1 Rating Symbol Printed on various Coil Labels

Dear Customer,

An inaccuracy on a coil label has been detected on a number of Philips Shoulder and Neurovascular Coils; specifically, the labels have been mistakenly printed with an IPX1 rating symbol. IPX ratings relate to protections that products have from water ingress. This type of rating is not a requirement for the affected coils and does not affect the performance of the equipment. This Field Safety Notice is intended to inform you of the following:

- What the problem is
- The actions that should be taken by the customer, if any
- The actions planned by Philips to correct the problem.

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

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

Please retain a copy with the equipment Instruction for Use.

To summarize this notification, the labeling on the affected coils listed on Page 2 of this notice incorrectly contains a printed symbol: IPX1 (see Figure 1 for an example). The product requirements for these coils does not require this type of rating. Unfortunately, an error occurred that allowed the inclusion of this symbol on the product label. The inclusion of this rating symbol does not affect form, fit, or function of these coils and poses no risk to user or patient safety.

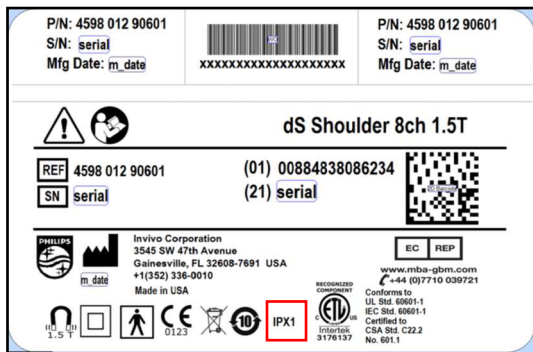


Figure 1. Example label showing IPX1 symbol (red box)

If you need any further information or support concerning this issue, please contact your local Philips representative:

0800 80 3000

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Q&R Director

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IPX1 Rating Symbol inappropriately on various Coil Labels

AFFECTED PRODUCTS	The products with the following part have been identified to be in scope of this field action:			
	P/N on box or coil label	Description	P/N on box or coil label	Description
	4522-150-40202	SENSE SHOULDER COIL 1.5T	4598-012-91131	1.5T 16CH SHOULDER, COIL
	4522-150-40362	FRU, ST SENSE WRIST COIL	4598-012-95481	16CH WRIST 1.5T, COIL
	4535-300-54581	ELECTRICAL ASSY, ST SENSE WRIST COIL	4598-012-95531	16CH WRIST 3.0T, COIL
	4535-300-71071	ASSM, BASEPLATE, PMS 1.5T QSC	4598-013-12411	3.0T 16CH SHOULDER, COIL
	4535-300-71271	ASSM, FINAL, PMS SMALL 1.5T QS	4598-014-99951	FOK FRU, DS HEAD COIL 1.5T
	4535-300-71281	Electro/Mech Assy , Lg Shoulder, 1.5T, P	4598-014-99971	FOK FRU, DS HEADNECK COIL 1.5T
	4535-302-77861	FRU, ASM, QSC LARGE, 1.5T	4598-014-99991	FOK FRU, DS BASE COIL 1.5T
	4535-302-77871	FRU, ASM, QSC SMALL, 1.5T	4598-015-00031	FOK FRU, DS HEAD COIL 3.0T
	4535-302-77891	FRU, ASM, BASEPLATE, 1.5T	4598-015-00051	FOK FRU, DS HEADNECK COIL 3.0T
	4535-302-94611	FRU, COIL ASSY, PHC 1.5T 8CH HRK	4598-015-00071	FOK FRU, DS BASE COIL 3.0T
	4535-302-94612	FRU, COIL ASSY, PHC 1.5T 8CH HRK	9896-030-13432	SENSE Shoulder Coil 1.5T 4Ch
	4535-302-94613	FRU, COIL ASSY, PHC 1.5T 8CH HRK	9896-030-13972	ST SENSE WRIST COIL
	4535-302-94621	FRU, COIL ASSY, PHC 3.0T 8CH HRK	9896-030-24282	DS HEADNECKSPINE PACK 1.5T
	4535-302-94623	FRU, COIL ASSY, PHC 3.0T 8CH HRK	9896-030-24402	DS HEADNECKSPINE PACK 3.0T
	4535-303-59931	FRU, DS BASE COIL 1.5T	9896-032-00441	PMS OBELIX 1.5T SENSE KNEE COIL, 8CH.
	4535-303-59951	FRU, DS HEAD COIL 1.5T	9896-032-00442	PMS OBELIX 1.5T SENSE KNEE COIL, 8CH.
	4535-303-59953	FRU, DS HEAD COIL 1.5T	9896-032-00443	PMS OBELIX 1.5T SENSE KNEE COIL, 8CH.
	4535-303-59971	FRU, DS HEADNECK COIL 1.5T	9896-032-00451	PMS OBELIX 3.0T SENSE KNEE COIL, 8CH
	4535-303-59973	FRU, DS HEADNECK COIL 1.5T	9896-032-00453	PMS OBELIX 3.0T SENSE KNEE COIL, 8CH
	4535-303-60031	FRU, DS BASE COIL 3.0T	9896-032-08011	dS BASE 3.0T
	4535-303-60033	FRU, DS BASE COIL 3.0T	9896-032-08021	dS Head 3.0T
	4535-303-60051	FRU, DS HEAD COIL 3.0T	9896-032-08031	dS HeadNeck 3.0T
	4535-303-60053	FRU, DS HEAD COIL 3.0T	9896-032-08051	dS Base 1.5T
	4535-303-60071	FRU, DS HEADNECK COIL 3.0T	9896-032-08061	dS Head 1.5T
	4535-303-60073	FRU, DS HEADNECK COIL 3.0T	9896-032-08071	dS HeadNeck 1.5T
	4535-303-60751	FRU, HEADNECKSPINE COIL 1.5T	9896-032-15621	dS SHOULDER 8CH 1.5T – NEW ID
	4535-303-60771	FRU, HEADNECKSPINE COIL 3.0T	9896-032-15671	dS Base 1.5T
	4598-000-97974	DS BASE COIL 3.0T	9896-032-15681	dS Head 1.5T
	4598-000-97984	DS HEAD COIL 3.0T	9896-032-15682	dS Head 1.5T
	4598-000-97994	DS HEADNECK COIL 3.0T	9896-032-15691	dS HeadNeck 1.5T
	4598-012-90041	dS HEAD 1.5T, COIL	9896-032-15692	dS HeadNeck 1.5T
	4598-012-90042	dS HEAD 1.5T, COIL	9896-032-15731	dS Shoulder 16ch 1.5T - NID
	4598-012-90051	dS BASE 1.5T, COIL	9896-032-15741	Ingenia 1.5T 16ch Hand/Wrist
	4598-012-90061	dS HEADNECK 1.5T, COIL	9896-032-15751	dS KNEE 1.5T 8CH

	4598-012-90062	dS HEADNECK 1.5T, COIL	9896-032-15821	dS HEAD 32 CH 3.0T
	4598-012-90091	dS BASE 3.0T, COIL	9896-032-15822	dS HEAD 32 CH 3.0T
	4598-012-90101	dS HEAD 3.0T, COIL	9896-032-16021	dS BASE 3.0T
	4598-012-90102	dS HEAD 3.0T, COIL	9896-032-16031	dS Head 3.0T
	4598-012-90121	dS HEADNECK 3.0T, COIL	9896-032-16032	dS Head 3.0T
	4598-012-90122	dS HEADNECK 3.0T, COIL	9896-032-16041	dS HeadNeck 3.0T
	4598-012-90261	dS KNEE 1.5T 8CH, COIL	9896-032-16042	dS HeadNeck 3.0T
	4598-012-90601	dS SHOULDER 8CH 1.5T, COIL – NEW ID	9896-032-16091	dS KNEE 3.0T 8CH
	4598-012-90631	dS KNEE 3.0T 8CH, COIL	9896-032-16161	dS SHOULDER 8CH 3.0T- NEW ID
	4598-012-90831	dS SHOULDER 8CH 3.0T, COIL – NEW ID	9896-032-16301	dS Shoulder 16ch 3.0T - NID
	4598-012-90891	dS HEAD 32 CH 3.0T, COIL	9896-032-16321	Ingenia 3.0T 16ch Hand/Wrist
	4598-012-90892	dS HEAD 32 CH 3.0T, COIL		
PROBLEM DESCRIPTION	Product labels are incorrectly printed with IPX1 rating symbol. During development of the label printing specification the IPX1 symbol was incorrectly included during the document approval process. The symbol was introduced in November 2016.			
HAZARD INVOLVED	The labeling non-conformance is not a potential hazard to Users or Patients.			
HOW TO IDENTIFY AFFECTED PRODUCTS	Products manufactured from November 2016 contain this easily identifiable symbol on its label (see Figure 1) and are in the scope of this field action.			
ACTION TO BE TAKEN BY CUSTOMER / USER	Although the symbol on the label should not be have been included, the device poses no risk to users of these devices nor patients. Customers need take no action other than the following: <ul style="list-style-type: none"> Notify all members of your staff who need to be aware of the contents of this communication. 			
ACTIONS PLANNED BY PHILIPS	Corrective and Preventative Actions are being implemented to ensure this type of non-conformance does not occur in the future. Immediate corrections are taking place to remove IPX1 symbols from labels for future use. This notice is being distributed to Customers who have affected products installed at their sites.			
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: 0800 80 3000			