	Form Number: **SOP-LI-03-65**	
nuraleve	Product Incident Report Form / Customer	
	Effective Date: **14/04/2014**	Revision: **A**

THIS REPORT

Reference Number: (PIR-YYYYMM-nnnn)	**PIR -**	Date (YYYY/MM/DD)	
Purpose of the report	☐ Incident ☐ Notification (evaluated as not an incident)		
AE Report Type *(please select one)*	☐ Initial ☐ Follow-up ☐ Final		

WHO IS REPORTING

Business Name (Full legal name)	
Contact Person *(Name & Designation)*	
Name of the Doctor in charged during the incident	
Date of Doctor awareness	
Address	
Tel no.	
Fax no.	
E-mail address	

INFORMATION ABOUT THE PRODUCT

Product Type	☐ SmartStim ☐ SmartStim Accessories ☐ Other		
Product Brand and Name		Model Number	
Batch/Lot Number		Serial Number	
Product description			

INFORMATION ABOUT THE INCIDENT				
Seriousness of the event *(please select one)*	☐ Product Defect ☐ Death ☐ Recall ☐ Incorrect/insufficient information ☐ Injury ☐ Serious Injury ☐ Incident, No Injury ☐ Others			
Severity of the event	☐ Minimal ☐ Moderate ☐ Severe ☐ Life-threatening			
Date of the incident		Number of people affected		
Describe the incident (Injury type, Treatment, Body part).				
In your opinion, are corrective measures required?	☐ Yes ☐ No			
Enter explanation of why corrective measures are not required OR enter details of corrective measures				
Other documents and pictures added to this report				

Regulatory/Competent Authority/Other that this report was also sent

Person reporting the Incident		
(name)	(signature)	(yyyy/mm/dd)

Product incident reports and inquiries are to be directed to:

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Email: info@nuraleve.com