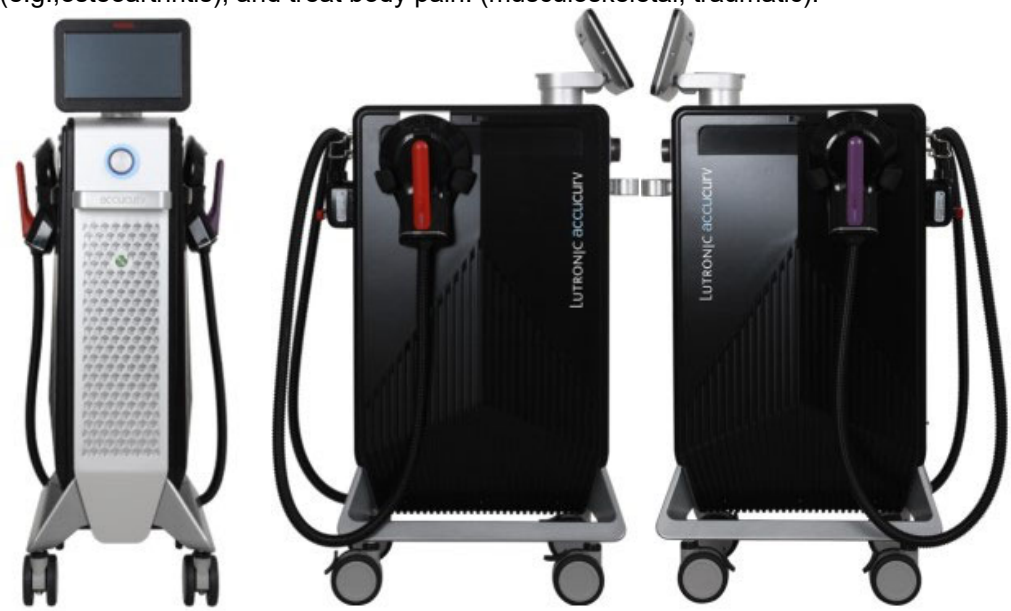
Date: 04.JUL.2023

Field Safety Notice
accucurv

For Attention of*: LUTRONIC's Customer

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Field Safety Notice (FSN)
accucurv
Thermal deformation of equipment

1. Information on Affected Devices	
1.	1. Device Type(s)
	accucurv is an Electromagnetic Stimulator delivering magnetic field energy with its applicators. The applicator generates a magneticfield through the electrical energy delivered from the system and delivers it to the treatment location. accucurv Electromagnetic stimulator is indicated for patients with musculoskeletal and neurological painful disorder to treat musculoskeletal disorders (e.g.,osteoarthritis); and treat body pain. (musculoskeletal, traumatic). 
1.	2. Commercial name(s)
	accucurv
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)
	accucurv system is intended to be used by a trained physician as treatment of the following: Gonarthrosis / Periarthritis / Coxarthrosis / Acute lumbar discopathy / Low back pain (e.g. vertebrogenic algic syndrome) / Sciatic syndrome / Post-traumatic nerve injuries of lower and upper limbs (grade ofaffection of the respective muscle nerve: 1 and 2)
1.	5. Device Model/Catalogue/part number(s)
	accucurv(1101000200)
1.	6. Software version
	GUI Software : Rev 1.03 / System Control Firmware : Rev 1.03 / Power Control Firmware : Rev 1.00
1.	7. Affected serial or lot number range
	MS122K001, MS123B006, MS122H006, MS122H007, MS122K002, MS122K003, MS122K004, MS122L005, MS122L006, MS122L007, MS122J001, MS122M002, MS123B001, MS123B004, MS122L001

2 **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	The connection between the applicator and body may become loose due to external vibration, shock or other factors. This loosening may cause heat generation.
2.	2. Hazard giving rise to the FSCA
	The degree of heat may vary depending on the level of contact instability of the connector. This instability could potentially lead to a rapid rise in temperature, causing a melt to the plastic cover. This may cause malfunction of the device or component failure.
2.	3. Probability of problem arising
	Rare occurrence
2.	4. Predicted risk to patient/users
	If a problem were to occur, it is unlikely that patient injury would occur because the user would immediately recognize the abnormality. Also, if users are careful in their use, they should not encounter any problems.
2.	5. Further information to help characterise the problem
	If an abnormality is found in the applicator connection, stop using it and contact the manufacturer immediately.
2.	6. Other information relevant to FSCA
	We plan to upgrade and add additional parts to the lever, which will secure the junctions to be appropriately placed, to prevent the loosening of connectors in all events and outside factors

3. Type of Action to mitigate the risk

3. 1. Action To Be Taken by the User

☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

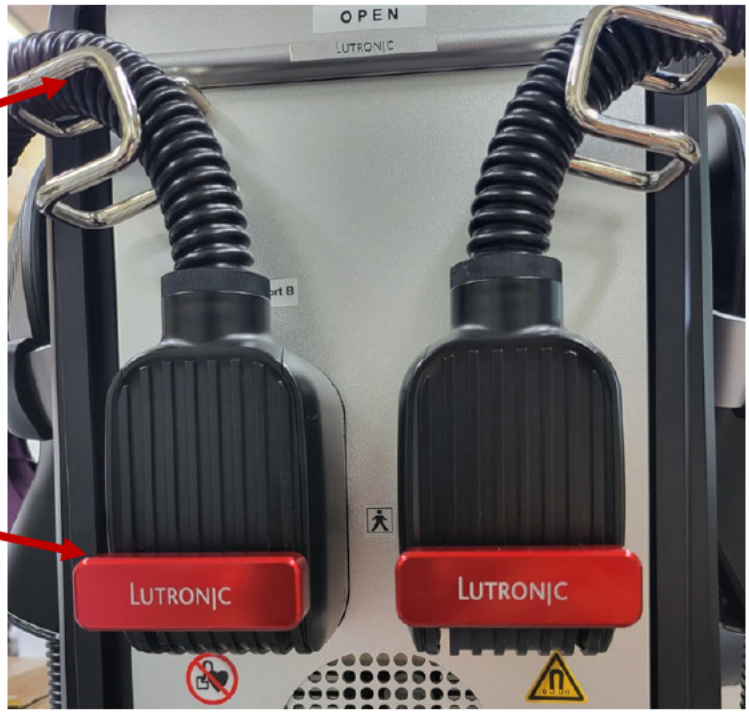
☐ Follow patient management recommendations

☒ Take note of amendment/reinforcement of Instructions For Use (IFU)

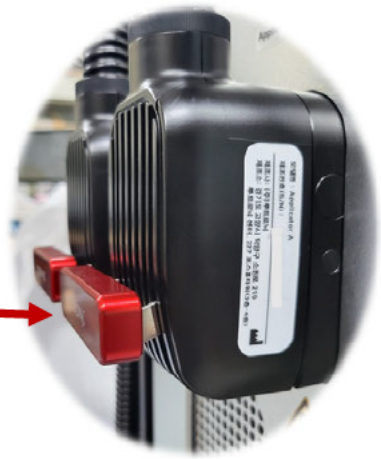
☐ Other ☐ None

We highly recommend that user check the lever before use to ensure that it is properly positioned, as stated in below Exhibit, so that the junctions are stable. Also, when the device is not being used, please make sure that the device is turned off and the power is not on. These instructions are temporary.

The applicator should be used by mounting it on the cable holder



Both levers should be raised to the top (normal engagement)



Both levers should be raised to the top (normal engagement)

3.	2. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**3. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Thus, we plan to upgrade and add additional parts to the lever, which will secure the junctions to be appropriately placed, to prevent the loosening of connectors in all events and outside factors	
3	4. By when should the action be completed?	If user pay attention, it's not urgent. All actions are expected to be completed by December 31, 2023.

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Lutronic Corporation**
	b. Address	**219 Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Republic of Korea (10534)**
	c. Website address	**https://www.lutronic-europe.com/**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.