

ISO 24571:2022-06 (E)

Traditional Chinese medicine - General requirements for the basic safety and essential performance of electro-acupuncture stimulators

Contents	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	2
4.1 General.....	2
5 General requirements for testing EA stimulators	2
6 Classification of EA stimulators in medical electrical (ME) equipment and ME systems	2
6.1 General.....	2
6.2 Protection against electric shock.....	2
6.3 Mode of operation.....	2
7 Identification, marking and documents of EA stimulators	2
7.1 General.....	2
7.2 Electrical input power from the supply mains.....	3
7.3 Instructions for use.....	3
7.3.1 General.....	3
7.3.2 Additional information.....	3
8 Protection against electrical hazards from EA stimulators	3
8.1 General.....	3
8.2 Classification of applied parts.....	3
9 Protection against mechanical hazards of EA stimulators	3
9.1 General.....	3
9.2 Disconnection prevention.....	4
10 Protection against unwanted and excessive radiation hazards	4
11 Protection against excessive temperatures and other hazards	4
12 Accuracy of controls and instruments and protection against hazardous outputs	4
12.1 Accuracy of controls and instruments.....	4
12.1.1 General.....	4
12.1.2 Output amplitude.....	4
12.1.3 Pulse parameters.....	4
12.1.4 Independent control of multiple output channels.....	4
12.2 Usability of ME equipment.....	5
12.3 Alarm systems.....	5
12.4 Protection against hazardous output.....	5
12.4.1 General.....	5
12.4.2 Supply voltage fluctuations.....	5
12.4.3 Output interlock.....	5
12.4.4 Output indicator.....	5
12.4.5 Limitation of output parameters.....	5
13 Hazardous situations and fault conditions	6
14 Programmable electrical medical systems (PEMS)	6

15	Construction of ME equipment	6
15.1	General.....	6
15.2	Needle clips and leads.....	6
16	ME systems	6
17	Electromagnetic compatibility of ME equipment and ME system	6
18	Electromagnetic compatibility - requirements and tests	6
18.1	General.....	6
18.2	Emissions tests.....	6
18.2.1	General.....	6
18.2.2	Patient lead.....	6
18.3	Immunity.....	6
18.3.1	General.....	6
18.3.2	EA stimulator with acupuncture needle.....	7
Annex A	(informative) Configuration of EA stimulator system	8
Annex B	(normative) Test methods for EA stimulator	9
Annex C	(informative) The safety issue of excessive total current per session	10
Annex D	(informative) Test methods for EA stimulator for various impedance conditions	11
Bibliography	12