

PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)**Device Info**

Device Name: **Anzai Medical Respiratory Gating System AZ-733VI** [Anzai Medical Co., Ltd.]

Description: Respiratory Gating System AZ-733VI is intended to be used with diagnostic X-ray or radiation therapy systems to gate these devices on and off when target points of the patient's respiratory cycle are within preset limits. When an organ with respiratory movement is targeted by the external device synchronizing its irradiation with the respiratory information, that is respiratory-gated irradiation, improved accuracy of diagnostic image or radiation therapy can be attained. Intended operators are those who understand the operation of the system and the effectiveness of respiratory gating systems. To help you understand them effectively, we are providing training based on this manual. Intended patients are those who are to undergo image diagnosis or radiation therapy, able to obey the operators and able to keep stable respiration.

Medical Specialty Area: Radiology / Imaging

Medical Device Class: Class C medical device

Device Registration No: DE0505026

Registration Date: 12/10/2020

Change Notification Approval Date: Not Applicable

Product Owner

1. [Anzai Medical Co., Ltd.](#) [Anzai Medical Co., Ltd.] 3-9-15, Nishi-Shinagawa, Shinagawa-ku, Tokyo, 141-0033, JAPAN

Registrant

1. [EMERGO SINGAPORE CONSULTING PRIVATE LIMITED](#) 1 FUSIONOPOLIS WALK, SOLARIS South Tower, #10-01, SINGAPORE 138628

Models

No.	Model Name	Identifier
1	Sensor Port	400322-1
2	Relay Box	400322-2
3	Gate Disable Switch	400322-3
4	Personal computer	400322-4
5	Load Cell Standard	400322-5
6	Load Cell Deep	400322-6
7	Load Cell Fixing Belt (S,M,L,LL)	400073-36, 6, 7, 8
8	Load Cell Calibrator	400073-9
9	SP-RB I/O Cable	400322-18
10	Gate Disable Switch Cable	400322-19
11	Sensor Cable	400322-20
12	USB Cable	400322-21
13	EXT.I/O Cable	400322-38
14	AC Power Cable (For USA, 3m)	400073-43
15	AC Power Cable (For EU, 3m)	400073-14
16	Screwdriver Set	400073-22
17	Laser Sensor (85mm)	400322-11
18	Laser Sensor (120mm)	400322-12
19	Laser Sensor (250mm)	400322-49
20	Laser Sensor Fixture (Type A)	400074-1
21	Laser Sensor Fixture (Type M)	400074-13
22	Laser Sensor Fixture (Type T)	400074-4
23	IRP Sensor Main Unit	400322-51
24	IRP Sensor Fixture	400322-54
25	Tablet set	400409-1
26	Patient Exclusive Goggle	400409-2
27	ABLE(Anzai Breath Learning Equipment)	ABLE
28	Tablet Fixture (Stand type)	400409-3
29	Wave Monitor	400322-14
30	ECG Board	400322-15
31	Interface Board 1	400322-16
32	Interface Board 2	400322-17
33	Wave Monitor Cable	400322-27
34	ECG Cable	400322-39
35	RS232C Cable	400322-40
36	Reflector	400322-52
37	Tablet Fixture(Mount type)	400409-4
38	Bluetooth Transceiver	400409-5
39	USB Cable	400409-6
40	AC Adapter	400409-7
41	Respiratory Gating System AZ-733VI	AZ-733VI

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