FCC ID Labeling Scheme

Per 47 CFR 2.926 (e),

> "Where it is shown that a permanently affixed nameplate is not desirable or is not feasible, an alternative method of positively identifying the equipment may be used if approved by the Commission. The proposed alternative method of identification and the justification for its use must be included with the application for equipment authorization.
>
> Note: As an example, a device intended to be implanted within the body of a test animal or person would probably require an alternate method of identification."

Since the EUT is implanted in the human body, the FCC ID will not be applied to outside of the device. Instead, the applicant is proposing the following alternate method of applying the FCC ID number to two locations:

1. The FCC ID, along with the disclosure statement required by 95.1215(a), is in the User Manual (page 165 – see excerpt below).

2. The FCC ID also appears on the package label (see below), which is affixed to outside of the shipping box for the EUT.

CYLOS DRT

DUAL CHAMBER,
RATE ADAPTIVE PACEMAKER
IS-1, UNI/BIPOLAR
ISO 5841-3:1992(E)
DDDR Uncoated

BIOTRONIK

Order No.: *** ***
Serial No.: ********
Use Before: **/**/****
Rate: 60 ppm
Pulse: (A) 3.6 V; 0.4 ms
(V) 3.6 V; 0.4 ms

Description: One dual chamber pacemaker (two IS-1 Receptacles) with rate adaptive pacing provided by Closed Loop Stimulation (CLS) or a motion sensor.

NOTE: This unit is designed for use with two (2) Unipolar or Bipolar IS-1 leads meeting the International Standard ISO 5841-3:1992(E).

Mode	DDD*
Lower Rate	60 ppm
Home Monitoring	OFF
Hysteresis	OFF
Upper Tracking Rate	130 ppm
Dynamic AV Delay	LOW
Safety AV Delay	100 ms
Ventricular Blanking Period	10 ms
Magnet Rate	Auto
Pulse Amplitude	(A) 3.6 V; (V) 3.6 V
Pulse Width	(A) 0.4 ms; (V) 0.4 ms
Sensitivity	(A) 1.0 mV; (V) 2.5 mV
Refractory Period	(A) 425 ms; (V) 250 ms
Polarity Sense	Unipolar
Polarity Pace	Unipolar

*See enclosed Technical Manual for programmable values.

STERILE: Pacemaker as identified and accessories

NON-STERILE: Package Inserts

STERILIZATION: This unit has been gas sterilized with ethylene oxide. Sterility cannot be guaranteed if the package has been damaged during transportation. Please examine the package carefully before opening. If it shows any evidence of damage or mishandling, it should be returned immediately to BIOTRONIK. Once the box seal has been broken, title passes to the hospital and a purchase order is required.

CAUTION: Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and the VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

CAUTION: Recommended Storage Temperature: 5° C - 55° C (41° F - 131° F).

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

FCC Statement: (FCC I.D# PG6CYLOS) CYLOS DR-T is equipped with an RF transmitter for wireless communications. This device must not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Satellite or Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Made in Germany TBD

Manufactured by:

BIOTRONIK GmbH & Co. KG
Woermannkehre 1
D-12359 Berlin
Germany

Distributed by:

BIOTRONIK Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800)547-0395

BIOTRONIK

Device / No.:	CYLOS DR-T / *** ***	Device / No.:	CYLOS DR-T / *** ***
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004
Device / No.:	CYLOS DR-T / *** ***	Device / No.:	CYLOS DR-T / *** ***
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004
Device / No.:	CYLOS DR-T / *** ***	Device / No.:	CYLOS DR-T / *** ***
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004
Device / No.:	CYLOS DR-T / *** ***	Device / No.:	CYLOS DR-T / *** ***
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004
Device / No.:	CYLOS DR-T / *** ***	Device / No.:	CYLOS DR-T / *** ***
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004

Federal Communications Commission Disclosure

The CYLOS DR-T pacemaker is equipped with an RF transmitter for wireless communications. This transmitter is authorized by rule under the Medical Implant Communications Service (47 CFR Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

The FCC ID number for this device is: PG6CYLOS.

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