

Medical Precision B.V. Comfort Marker 2.0

TECHNICAL DATA SHEET



PRODUCT NAME	Comfort Marker 2.0
PRODUCT NUMBER	MPCM2010 Medical Precision Comfort Marker 2.0 System, Qty 1 MPCM4022 Medical Precision Patient Marking Set. Includes: Safety Needle (Qty 50), Ink Cup (Qty 50), Black RadSafe Pigment (Qty 50)
GENERAL DESCRIPTION	The Comfort Marker 2.0 allows the user to place accurate reference points on patients enabling radiotherapy. It consists of a Pen module which drives the Safety needle. Different depth settings can be chosen to accommodate for different skin types. When the reference point has been placed, the Control Unit can be stored and charged in the Docking station.
INDICATIONS FOR USE	Placement of markings on human skin at a controlled depth to enable effective radiotherapy.
MR STATUS	Not intended for use in MRI (magnetic resonance imaging) room
FDA CLEARANCE	Yes, De Novo and 510(k) cleared
OTHER COUNTRY REGISTRATIONS	Available upon request
COUNTRY OF MANUFACTURE	The Netherlands

TECHNICAL DETAILS

COMPONENT	MPCM2010 Comfort Marker 2.0 System
PRIMARY MATERIALS	Lithium polymer battery, Electronics, Metal and Plastics
WEIGHT (APPROX)	0.7 kg (1.7 lb)
DIMENSIONS (MM)	24.9 cm x 18.5 cm x 5.4 cm (9.8" x 7.3" x 2.1")
UNIT/BOX	One

TECHNICAL DRAWING

CHARGING/DOCKING STATION



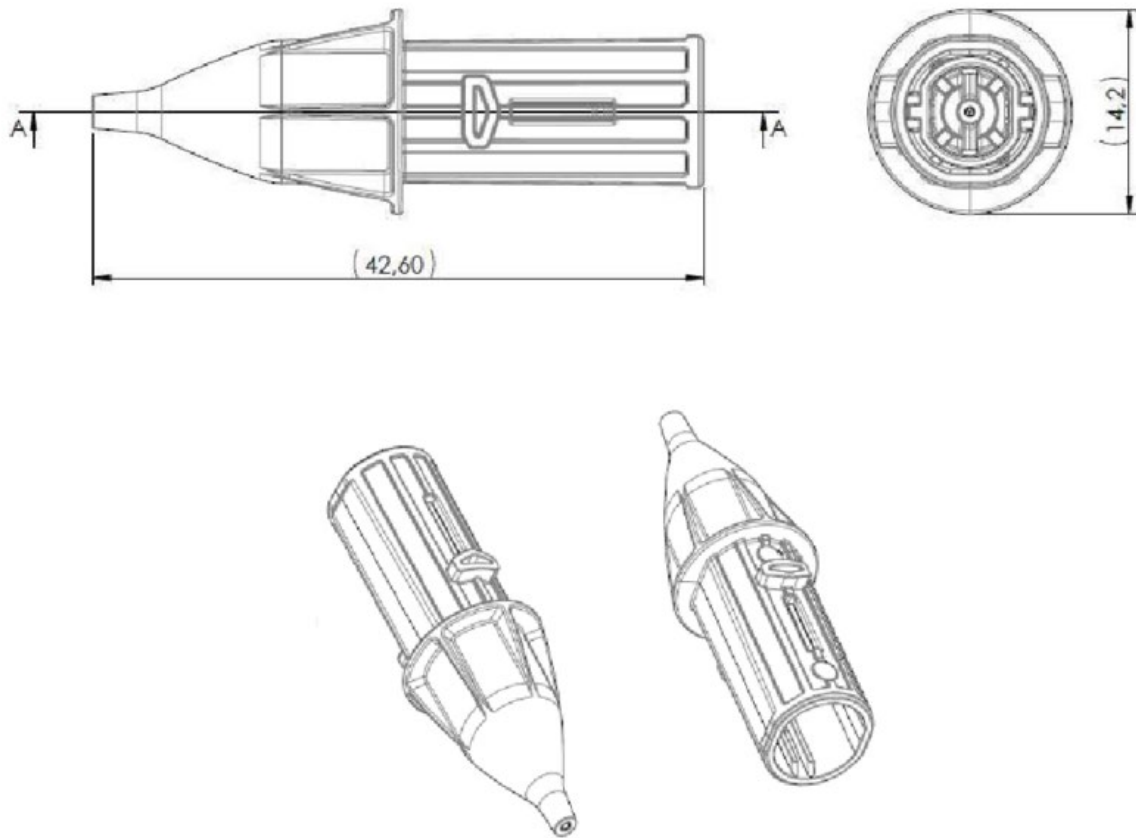
CONTROL UNIT AND PEN




TECHNICAL DETAILS

COMPONENT	Safety Needle
PRIMARY MATERIALS	Zylar co-polymer (Housing); Stainless Steel (Spring/Needle)
WEIGHT (APPROX)	1.19 g (0.0026 lb)
DIMENSIONS (MM)	4.4 cm x 1.4 cm (1.7" x 0.5")
QUANTITY	Qty 50 (2 boxes of 25 individual pouches per box)
SHELF LIFE	Sterile, 2 years

TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	Black Ink
MANUFACTURER	Biotic Phocea Laboratoires
COMPOSITION	Mixture of pigments dispersed in the liquid phase. Synthetic pigments with controlled conformity on analysis bulletins, referenced to the color index Mineral Pigments. Iron oxides (CI 77499) Organic Pigments: CI 77266. No pigment contains or is likely to release aromatic amines or can be considered CRM (Carcinogenic, Reprotoxic or Mutagenic).
DISPERSANT	Propane-1,3-diol 100% natural origin
ADDITIVES	pH modifiers (sodium hydroxide or lactic acid)
SECURITY	The device contains no latex, paraphenylenediamine (PPD), nitrosamines, and cadmium oxide. Guaranteed without water, preservatives and products of human or bovine origin.
WEIGHT (APPROX)	3 g (0.006 lb)
DIMENSIONS (MM)	4.6 cm x 1.4 cm x 0.5 cm (1.8" x 0.5" x 0.2")
QUANTITY	Pack of 50
SHELF LIFE	Sterile, 5 years
TECHNICAL DRAWING	
	

TECHNICAL DETAILS

COMPONENT	Ink Cup
PRIMARY MATERIALS	Polystyrene
WEIGHT (APPROX)	1 gram
DIMENSIONS (MM)	1.6 cm x 1.3 cm (0.6" x 0.5")
QUANTITY	Pack of 50
SHELF LIFE	Sterile, 3 years

TECHNICAL DRAWING



PACKAGING

WARRANTY	See website for Product Warranty Statement
LAUNCH DATE	December 10, 2021