

Medical Precision B.V. Comfort Marker 2.0

CIVCO RT 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.	
MRI Compatible	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

Primary Materials	Lithium polymer battery, Electronics, Metal and Plastics
Weight (approx)	0.7 kg (1.7 lb)
Dimensions	24.9 cm x 18.5 cm x 5.4 cm (9.8" x 7.3" x 2.1")
Unit/Box	One
Photo (MPCM2010)	



Charging/Docking Station

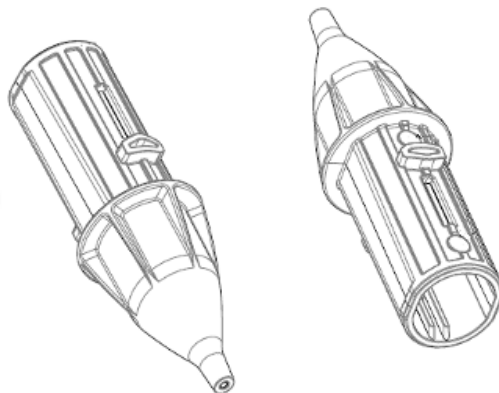
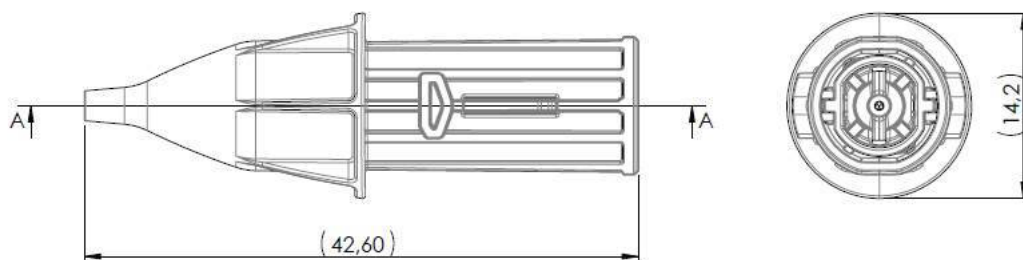


Control Unit and Pen

Technical Details

Primary Materials	Zylar co-polymer (Housing); Stainless Steel (Spring/Needle)
Weight (approx)	1.19 g (0.0026 lb)
Dimensions	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 (Safety Needle)



Technical Details

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	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 (Black Ink)



Technical Details

Primary Materials	Polystyrene
Weight (approx)	1 gram
Dimensions	1.6 cm x 1.3 cm (0.6" x 0.5")
Quantity	Pack of 50
Shelf Life	Sterile, 3 years

Technical Drawing (Ink Cup)



Warranty

Warranty	See CIVCO RT website for Product Warranty Statement
Launch Date	February 2022

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