

INTENSIA VR 124

The document titled 'cover letter FCC for question 8' indicates that model VR 124 and VR 9250 are similar devices, with the major difference being the radiated header.

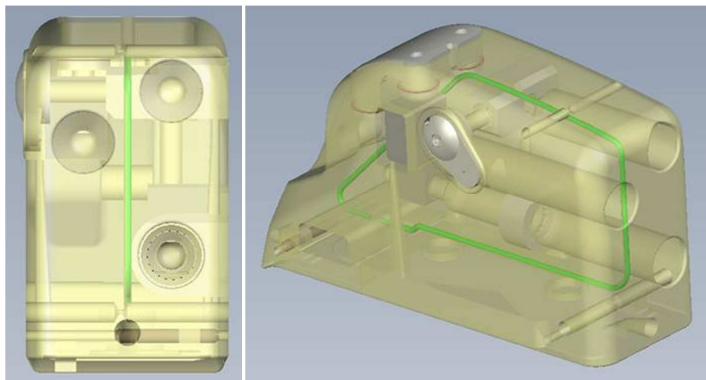
The 2 devices share the same electronics, battery, shock capacitors, main and RF feedthroughs and titanium cases. The only differences are the wire routing inside the headers, as the connector blocks do not have the same location in the Tecothane moulded headers, and the radiated headers and the silicone caps glued on the headers. The aim of the new header is to propose DF-4 connection to the physicians and the patients, which allow lowering the connection time of the leads during implantation (1 port vs 3).

Paradym RF VR 9250 has 3 ports: IS-1, DF-1.

INTENSIA VR 124 has 1 port: DF-4.

Paradym RF VR 9550 (header with IS-1 & DF-1 lead cavities):

The DF-1 RF antenna plane is flat and located in the middle of the radiated header (highlighted in green in below 3D pictures), as the 3 lead cavities have roughly the same diameters 3,7 mm and located both sides of the 11,5 mm width header.



Intensia VR 124 (header with DF-4 lead cavity):

The DF-4 cavity diameter being bigger (6,35 mm), we had to route RF antenna wire around the DF-4 cavity. The VR header has only 1 DF-4 lead cavity, so we have designed a header which is lower in height & volume than the other 3 models DR, CRT-D and SonR CRT-D). This header of lower volume & lower height is more comfortable to the patient. Please refer to the 2 pictures below (RF antenna highlighted in green in below 3D pictures).

