

Compatibility Statement

NordicNeuroLab, Møllendalsveien 1, N-5009 Bergen, Norway, markets the devices listed below (hereinafter referred to as "Product").

Philips Medical Systems Nederland B.V. has performed compatibility tests utilizing a limited number of samples of Product in February 2021. The scope of this compatibility statement is strictly limited to the below listed Philips MRI systems (hereinafter "MRI System") and Product.


Philips MRI System		NordicNeuroLab fMRI solutions	
Product	Product number	Product	Product number
Ingenia 1.5T	781341	InroomViewingDevice (Display)	LCD 3.1
		LCD Power supply	LPS 3.1
Ingenia 1.5T S	781347		
Ingenia 1.5T CX	781262		
Ingenia Ambition S	781359		
Ingenia Ambition X	781356		
Ingenia 3.0T	781342		
Ingenia 3.0T CX	781271		
Ingenia Elition S	781357		
Ingenia Elition X	781358		

Through the basic compatibility testing with the Product, Philips found the MRI System performed as intended and specified, with no detrimental degradation of MRI System efficacy or safety when used per the conditions as stated in their Instructions for Use. This testing indicates compatibility of the Product with MRI System.

Safety and efficacy of the Product is the sole responsibility NordicNeuroLab. All issues related to the use of Product shall be referred to NordicNeuroLab. This compatibility statement does not guarantee assurance that compatibility will be maintained with future changes to Product, including incorporated software releases, modifications, and upgrades.

Compatibility testing reference files: D000798324

Philips Medical Systems Nederland B.V.


(signature)

Text

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