

INFORMATION FOR LIMITED DISTRIBUTION



Mallinckrodt[™]
Pharmaceuticals

Technical Bulletin

Ref: **TB- 16007-ENG**

Issue date: **August 2016**

Product: INOmax DS_{IR}[®], INOmax DS_{IR}[®] Plus and
INOmax DS_{IR}[®] Plus MRI

Priority: Low

Affected parts: Accessories/Disposables/Labeling Classification: Information for Limited Distribution

Subject: **Part Number Changes for Accessories, Disposables and Labeling in Canada**

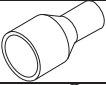
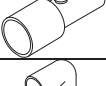
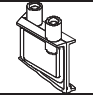
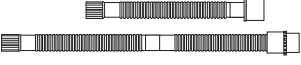
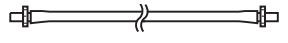
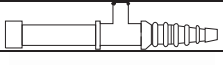
As part of the Mallinckrodt rebranding initiative, the following part numbers for accessories, disposables and labeling have changed.

When ordering new accessories, disposables or labeling, please refer to the tables listed below:

Accessories

Description	Previous Part Number	New Part Number
Calibration Tubing Kit	50107	50239
Injector Module Cable	1605-3057-000	90838
Injector Module Cable, MR Conditional	90623	90850
INOcal Calibration Gas, NO, 45 ppm	BOM-COM-0150	BOM-COM-0159
INOcal Calibration Gas, NO ₂ , 10 ppm	BOM-COM-0162	BOM-COM-0167
INOcal Regulator Kit	10036	10090
Sensor, NO	6050-0004-318	90844
Sensor, NO ₂	6050-0004-319	90845

Disposables

Image	Description	Previous Pack of Five (Part Number)	New Pack of Five (Part Number)
	Adapter, 15M Fits 4.5mm ID Tubing	50079	50244
	Adapter, 22F X 15M	50080	50243
	Adapter, 22M/15F X 22M/15F	50081	50242
	Adapter, Cuff, 22mm ID X 22mm ID	50082	50253
	Adapter, Gas Sample Tee	50083	50241
	Adapter, 90 Degree Sample Port	50084	50252
	Bunnell Life Pulse Disposable Adapters Convenience Pack	50085	50249
	Patient Sample Gas Line Disk Filter, 1.0 micron, glass fiber	50172	50258
	Water Separator Cartridge, INOmax DS _{IR}	50087	50247
	Neonatal Tubing, 10mm (2 pieces)	50089	50255
	NO/N ₂ Injector Tube	50090	50240
	MR Conditional NO/N ₂ Injector Tube	50191	50260
	One-Way Valve, 22F X 22M	50091	50245
	Patient Gas Sample Line with (Nafion)	50136	50257
	MR Conditional Patient Gas Sample Line with (Nafion)	50190	50261
	Pediatric Extension, 15 mm, 6 inches	50093	50254
	Sample Tee, O ₂ Tubing	50094	50246
	Sensormedics 3100A/B Filtered Circuit Disposable Adapters Convenience Pack	50095	50251

Labeling

Description	Previous Part Number	New Part Number
INOmax DSIR Plus		
INOmax DSIR Plus Operation Manual (English)	20530	20717
French-Canadian	20569	20867
INOmax DSIR Plus Pocket Guide (English)	20540	20751
French-Canadian	20571	20868
INOmax DSIR Plus Pre-Use Card (English)	20570	20753
French-Canadian	20572	20869
INOmax DSIR Plus MRI		
INOmax DSIR Plus MRI Operation Manual (English)	20691	20765
French-Canadian	20686	20870
INOmax DSIR Plus MRI Pre-Use Card (English)	20679	20764
French-Canadian	20687	20871
Technical Bulletins		
TB-08007, Ventilator Compatibility List (English)	20093	20721
French-Canadian	20231	20874
TB-12004, INOmax DSIR Software Version 2.1.0 and 2.1.1 (English)	20249	20741
French-Canadian	20250	20881
TB-12012, INOmax DS-DSIR INOblender Breathing Device Applications (English)	20374	20748
French-Canadian	20463	20885
TB-13006, INOcal Tubing Assembly Change (English)	20532	20750
French-Canadian	20545	20887
TB-14001, INOmax DSIR Hamilton Ventilator Testing (English)	20585	20756
French-Canadian	20618	20888
TB-14006, Injector Module Part Number Change (English)	20609	20760
French-Canadian	20637	20889
TB-14007, 50mm, 1.0 micron Nebulizer Disk Filter (English)	20610	20761
French-Canadian	20654	20890
TB-15001, INOmax DSIR-INOblender UDI Labeling (English)	20677	20763
TB-16001-ENG, INOmax DSIR Plus MRI Updates (English)	20712	21083
French-Canadian	20716	21084

If you have further questions, please contact Customer Support at 1-877-566-9466 (North America) or your local representative.

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Signature Manifest

Document Number: 21079**Revision:** 1**Title:** TB-16007-ENG Part Number Changes for Accessories, Disposables and Labeling in Canada

All dates and times are in Eastern Standard Time.

TB-16007-ENG PN Change Canada

DCC Review

Name/Signature	Title	Date	Meaning/Reason
David Jameson (JAMESOD)	Engineering Quality Manger	22 Jul 2016, 09:43:55 AM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Susan Hansey (HANSEYS)			
Jeff Griebel (GRIEBELJ)	Clinical Specialist	25 Jul 2016, 04:11:13 PM	Complete
Bill McGuire (MCGUIRB)	Mgr Inventory Control Process	26 Jul 2016, 09:32:52 PM	Complete
Brian Paap (PAAPB)		27 Jul 2016, 12:22:10 PM	Complete
Paul Heric (HERICPW)	Dir Device Technical Service	27 Jul 2016, 01:09:27 PM	Complete
John Kottke (KOTTKEJ)	Service Support Tech	28 Jul 2016, 03:14:46 AM	Complete
David Trueblood (TRUEBLD)	Dir. Devices Global RA	28 Jul 2016, 10:43:24 AM	Complete
Jeffrey Schmidt (SCHMIDTJ)	Manager Delivery Devices	28 Jul 2016, 12:54:43 PM	Complete

Doc Control Review

Name/Signature	Title	Date	Meaning/Reason
Daria Cooney (COONEYD)			
Christopher Gilbert (GILBERC)			
Kimberly Valente (KIMBERLY.VALENTE)	Client Service Coordinator	28 Jul 2016, 02:24:10 PM	Complete

Approvals

Name/Signature	Title	Date	Meaning/Reason
Jeff Griebel (GRIEBELJ)	Clinical Specialist	28 Jul 2016, 03:01:07 PM	Approved
David Jameson (JAMESOD)	Engineering Quality Manger	28 Jul 2016, 03:39:15 PM	Approved
Brian Paap (PAAPB)		28 Jul 2016, 04:22:48 PM	Approved
Jeffrey Schmidt (SCHMIDTJ)	Manager Delivery Devices	28 Jul 2016, 04:50:51 PM	Approved
John Stanton (STANTOJ)	Sustaining Engineering	28 Jul 2016, 07:11:13 PM	Approved
David Trueblood (TRUEBLD)	Dir. Devices Global RA	29 Jul 2016, 08:10:54 PM	Approved
Susan Hansey (HANSEYS)		02 Aug 2016, 02:04:01 PM	Approved