PRESSUREWIRE X

Wireless FFR Measurement System



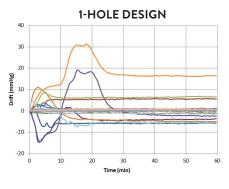
THE WORLD'S ONLY WIRELESS PRESSURE GUIDEWIRE¹⁻⁵

NOW MORE ACCURATE WITH AN IMPROVED DESIGN

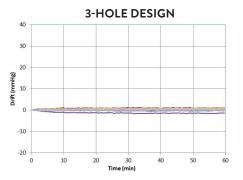
- The innovative PressureWire X guidewire is the world's only wireless pressure guidewire for coronary physiology assessment with metrics such as fractional flow reserve (FFR).¹⁻⁵
- This wire now has a new design for the jacket surrounding the pressure sensor, which improves the clinical decisions made using measurements from the wire.
- The soft tip design and hydrophilic coating help navigate tortuous anatomy, enable smoother stent delivery, and improve overall maneuverability. ⁶⁻⁸

ACCURATE AND RELIABLE

The new design of the jacket surrounding the pressure sensor improves the accuracy of pressure measurements by reducing acute drift of >2 mmHg by 84%.¹⁰









Updated Sensor Jacket with multiple, larger "windows"

WIRELESS CORONARY PHYSIOLOGY

 The PressureWire X guidewire (wireless configuration) is the world's only wireless pressure guidewire for FFR assessment.¹⁻⁵

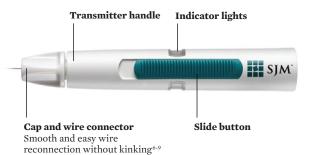
Abbott data on file. Report 90328885. *Bench testing data designed to simulate the cath lab environment.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force.



HIGH LEVEL OF HANDLING PERFORMANCE

- Improved shapeability and reshapeability for improved navigation.⁹
- Better shape retention for performance in complex anatomy and for multiple pull-backs.⁹
- More durable⁶ soft tip designed to protect the vessel in tortuous anatomy⁷ without compromising steerability/trackability.⁹



ORDERING INFORMATION

| REORDER NUMBER | DESCRIPTION | |
|----------------|---|--|
| C12059 | PressureWire X Wireless FFR Guidewire, 175 cm | |
| C12009 | PressureWire X Cabled FFR Guidewire, 175 cm | |

- 1. Volcano Corp. Verrata[†] guidewire and PrimeWire Prestige[‡] Plus guidewire IFUs.
- 2. Opsens Inc. OptoWire[‡] guidewire and OptoWire[‡] II guidewire IFUs.
- 3. ACIST Medical Systems. Navvus[‡] Microcatheter IFU.
- 4. Boston Scientific Corporation. Comet⁺ guidewire IFU.
- 5. Abbott. PressureWire[™] X guidewire IFU.
- 6. Abbott data on file. Report 90205458.
- 7. Abbott data on file. Report 90205274.
- 8. Abbott data on file. Report R2542-01.
- 9. Compared to the previous generation (PressureWire 8 Guidewire); Abbott data on file. Report 90239691.
- 10. Abbott data on file. Report 90328885.

Caution: These products are intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at *eifu.abbottvascular.com* or at *Manuals.sjm.com* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. **Information contained herein for DISTRIBUTION outside of the U.S. ONLY**. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

Tests performed by and data on file at Abbott. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott International BVBA

Park Lane, Culliganlaan 2B, 1831 Diegem, Belgium, Tel: 32.2.714.14.11

[™] Indicates a trademark of the Abbott group of companies. ‡ Indicates a third party trademark, which is property of its respective owner. www.Vascular.Abbott

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EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. Issued To: CE 623075 St. Jude Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA

In respect of:

PressureWire Diagnostic Guidewire

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary C Stade

Gary E Slack, Senior Vice President Medical Devices

First Issued: 2014-12-18

Date: 2019-04-04

Expiry Date: 2024-04-13

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284. A member of BSI Group of Companies.





EC Design-Examination Certificate

Supplementary Information to CE 623075

Issued To:

St. Jude Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA

Product: PressureWire Certus, PressureWire Aeris

| Model Number | Product Name | | |
|--------------|--|--|--|
| C12008 | PressureWire Certus, Agile Tip, 175 cm | | |
| C12308 | PressureWire Certus Agile Tip, 300 cm | | |
| C12058 | PressureWire Aeris Agile Tip, 175 cm | | |
| C12358 | PressureWire Aeris Agile Tip, 300 cm | | |

Product: PressureWire X

| Model Number | Product Name | |
|-----------------|---|--|
| PWX175C, C12009 | PressureWire X, 175 cm, cabled connection | |
| PWX300C, C12309 | PressureWire X, 300 cm, cabled connection | |
| PWX175W, C12059 | PressureWire X, 175 cm, wireless connection | |
| PWX300W, C12359 | PressureWire X, 300 cm, wireless connection | |

First Issued: 2014-12-18

Date: 2019-04-04

Expiry Date: **2024-04-13** ...making excellence a habit.[™]

Page 2 of 3

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EC Design-Examination Certificate

Supplementary Information to CE 623075

Issued To:

St. Jude Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA

Certificate History

| Date | Reference Number | Action | | |
|------------------|---------------------|--|--|--|
| 18 December 2014 | 10152648 | First Issue. Mirror certificate to CE 620481. | | |
| 25 August 2015 | 10156926 | DuPont Tyvek Medical Transition Project update. | | |
| 15 April 2016 | 10162099 | Addition of PressureWire X models. | | |
| 03 May 2016 | 10163009 | Correction of typographical error in product table. | | |
| 02 August 2016 | 10164104 | Changes for PressureWire X products: Shelf life extension to 2 years, addition of hydrophilic PEG coating over sensor, changes to labeling and IFU, addition of alternate model numbers. | | |
| 13 August 2018 | 8899153 | Change to Pressurewire X products: addition of 2 extra windows around pressure sensor to improve fluid flow and reduce drift | | |
| 05 March 2019 | 8250541 | Traceable to NB 0086. | | |
| Current | 9686240 | Certificate Renewal. | | |

First Issued: 2014-12-18

Date: 2019-04-04

Expiry Date: **2024-04-13** ...making excellence a habit.[™]

Page 3 of 3

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SJM Declaration of Conformity PressureWire

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

| any declaration issued previously for the same pro- | duct(s). | | |
|---|--|--|--|
| Manufacturer Address: | St. Jude Medical 5050 Nathan Lane North Plymouth, Minnesota 55442 USA | | |
| European Representative: | St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium | | |
| Product Type: | Guidewire mounted sensor | | |
| Product Name(s): | PressureWire Diagnostic Guidewire | | |
| Model Number(s): | See Attachment 1. | | |
| Classification: | Class III per Annex IX, Rule 7 | | |
| GMDN Code(s): | 15071 Catheter-tip transducer, pressure 35094 Cardiac catheter guidewire, single use | | |
| Original CE Mark Date: | See Attachment 1. | | |
| Certificate No and expiration date: | Certificate No: CE 597699 – Annex II.3 (FQA) Expiration Date: 15 May 2023 | | |
| | Certificate No: CE 623075 – Annex II.4 (DE) Expiration Date: 13 April 2019 | | |
| Applicable Quality System Standards: | ISO 13485 and EN ISO 13485:2012 | | |
| Notified Body: | BSI Kitemark Court Davy Avenue Knowlhill, Milton Keynes MK5 8PP UK | | |
| Notified Body Number: | 0086 | | |
| Manufacturing Facilities: | St. Jude Medical Costa Rica LTDA Zona Franca Coyol S.A. Edifico #44B, Calle 0, Avenida 2, Coyol Alajuela Costa Rica | | |
| Signature: | ಲ್ಲಿಲ್ಡ್ ಪ್ರಶಸ್ತಿ ಪ್ರಶಸ್ತಿ ಪ್ರಶಸ್ತಿ ಬಿಡುವನ್ನ | | |
| Marlano Pataroon | 16 May 2018 | | |

Issue Date

86480 SJM Declaration of Conformity Template Rev C

Marlene Peterson

Regulatory Affairs Manager

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SJM Declaration of Conformity PressureWire

Attachment 1. PressureWire Model Numbers

| Product Description | Model Number | Original CE Mark Date |
|--|-----------------|--------------------------|
| PressureWire Certus, Agile Tip, 175cm | C12008 | 18 December 2014* |
| PressureWire Certus, Agile Tip, 300cm | C12308 | 18 December 2014* |
| PressureWire Aeris, Agile Tip, 175cm | C12058 | 18 December 2014* |
| PressureWire Aeris, Agile Tip, 300cm | C12358 | 18 December 2014* |
| PressureWire X, 175cm, cabled connection | PWX175C | 15 April 2016 |
| PressureWire X, 300cm, cabled connection | PWX300C | 15 April 2016 |
| PressureWire X, 175cm, wireless connection | PWX175W | 15 April 2016 |
| PressureWire X, 300cm, wireless connection | PWX300W | 15 April 2016 |
| PressureWire X, 175cm, cabled connection | C12009 | 2 August 2016 |
| PressureWire X, 300cm, cabled connection | C12309 | 2 August 2016 |
| PressureWire X, 175cm, wireless connection | C12059 | 2 August 2016 |
| PressureWire X, 300cm, wireless connection | C12359 | 2 August 2016 |

*Date reflects original CE Mark through BSI, as denoted on Annex II.4 certificate, CE 62305. Previously CE marking was through Intertek (Certus and Aeris only) in 2009, and through Dekra (for Certus only) in 2006.

Signature:

Ve man Marlene Peterson

Regulatory Affairs Manager

16 May 2010 Issue Date

86480 SJM Declaration of Conformity Template Rev C





Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Medical 4 Robbins Road Westford Massachusetts 01886 USA

Holds Certificate No:

FM 701294

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture, and servicing of Optical Coherent Tomography Imaging Systems, including embedded software and sterile Imaging Catheters. The distribution of syringes, sterile bags, inflation devices and accessories. Design of Diagnostic Guidewire, Computer, Signal Transmission and Diagnostic software and accessories.

For and on behalf of BSI:

Original Registration Date: 2018-10-01 Latest Revision Date: 2018-10-01





tomas Carlos Pitanga, Chief Operating Office

icer Assurance – Americas

Effective Date: 2018-10-01 Expiry Date: 2021-10-07

Page: 1 of 1

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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.