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April 30, 2019

**Northern Digital Inc.**

103 Randall Drive

Waterloo, Ontario

Canada, N2V 1C5

**Attn.: Joseph De Croos**

**Subject: Verification Testing in accordance with CISPR 11/EN55011 and EN 60601-1-2: 2014 4<sup>th</sup> Edition** - Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests

**Product: Polaris Vega**  
**Models: Vega 1.2 with Ethernet and Lemo Port**  
**Vega 1.2 with Ethernet Port only and VCU**

Dear Joseph De Croos,

The product sample has been tested in accordance with **CISPR 11/EN55011 and EN 60601-1-2: 2014 4<sup>th</sup> Edition** – Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests and the results and observation were recorded in the engineering report, Our File No.: 19NDI153\_EN60601-1-2.

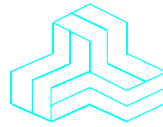
Enclosed you will find a copy of the engineering report. If you have any queries, please do not hesitate to contact us.

Yours truly,

Tri Minh Luu  
Vice President - Engineering

Encl.

# VERIFICATION CERTIFICATE



## NOT TRANSFERABLE

This Verification Certificate is hereby issued to the named GRANTEE and is VALID ONLY for the equipment identified hereon for use under the rules and regulations listed below:

**GRANTEE:**

Address: Northern Digital Inc.  
103 Randall Drive  
Waterloo, Ontario  
Canada, N2V 1C5

Contact Person: Joseph De Croos  
Tel. No.: 519-884-5142 x298 or x331  
Fax No.: 519-884-5184  
Email Address: [jdecroos@ndigital.com](mailto:jdecroos@ndigital.com) or [ian@avnan.com](mailto:ian@avnan.com)

**Equipment Type:****Product Name:****Models:**

Medical Electrical/Electronic Equipment  
Polaris Vega  
Vega 1.2 with Ethernet and Lemo Port  
Vega 1.2 with Ethernet Port only and VCU

The above product was  
tested by UltraTech  
Engineering Labs Inc. and  
found to comply with:

- **CISPR 11:2009+A1:2010 / EN 55011:2009+A1:2010, Class A, Group 1**
- **IEC 61000-3-2 / EN61000-3-2:** Harmonic Current Emissions
- **IEC 61000-3-3 / EN61000-3-3:** Voltage Fluctuation and Flicker in Low-Voltage Supplies
- **EN 60601-1-2: 2014 / IEC 60601-1-2: 4<sup>th</sup> Edition-** Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests

**Note(s):** See attached report, UltraTech's File No.: 19NDI153\_EN60601-1-2 dated April 30, 2019 for details and conditions of Verification Compliance.

**Approved by: Tri M. Luu**  
**V.P. – Engineering**

## UltraTech

3000 Bristol Circle, Oakville, Ontario, Canada, L6H 6G4  
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# DECLARATION OF CONFORMITY

**APPLICATION OF COUNCIL DIRECTIVE(S):** 93/42/EEC - The Medical Device Directive

**APPLICANT:** Northern Digital Inc.

**Equipment Type:** Medical Electrical/Electronic Equipment  
**Product Name:** Polaris Vega  
**Models:** Vega 1.2 with Ethernet and Lemo Port  
Vega 1.2 with Ethernet Port only and VCU

*I, the undersigned, hereby, declare that the above device has been tested and found to comply with the following standard(s):*

**STANDARD(S) TO WHICH CONFORMITY IS DECLARED:**

- **CISPR 11:2009+A1:2010 / EN 55011:2009+A1:2010, Class A, Group 1**
- **IEC 61000-3-2 / EN61000-3-2:** Harmonic Current Emissions
- **IEC 61000-3-3 / EN61000-3-3:** Voltage Fluctuation and Flicker in Low-Voltage Supplies
- **EN 60601-1-2: 2014 /IEC 60601-1-2: 4<sup>th</sup> Edition** - Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests

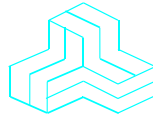
**TEST LABORATORIES:** UltraTech Group of Labs Inc.  
3000 Bristol Circle  
Oakville, Ontario  
Canada, L6H 6G4

**Applicant:**

**Legal Representative in Europe:**

Signature:	_____	Signature:	_____
Full Name:	_____	Full Name:	_____
Title:	_____	Title:	_____
Full Address:	_____	Full Address:	_____
Phone No.:	_____	Phone No.:	_____
Email Address:	_____	Email Address:	_____

# ENGINEERING TEST REPORT



## **Polaris Vega** **Models: Vega 1.2 with Ethernet and Lemo Port** **Vega 1.2 with Ethernet Port only and VCU**

**Applicant:** Northern Digital Inc.  
103 Randall Drive  
Waterloo, Ontario  
Canada, N2V 1C5

**In Accordance With**

**IEC 60601-1-2: 2014 (4<sup>th</sup> Edition)**  
**Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests**

**UltraTech's File No.: 19NDI153\_EN60601-1-2**

This Test report is Issued under the Authority of  
Tri M. Luu  
Vice President of Engineering  
UltraTech Group of Labs

Date: April 30, 2019

Report Prepared by: Channele Luu

Tested by: William Truong, Hien Luu & Tim Quan

Issued Date: April 30, 2019

Test Dates: April 3 – 27, 2019

- The results in this Test Report apply only to the sample(s) tested, and the sample tested is randomly selected.
- This report must not be used by the client to claim product endorsement by any agency of the US Government.
- This test report shall not be reproduced, except in full, without a written approval from UltraTech.

## UltraTech

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