Health

Next Generation Connected Health from Lamprey Networks

Personal Health Gateway – 1000 *Low-Cost Cellular Enabled Gateway*

- Open standards connectivity for both data collection and uploading. Supports all Continua and Bluetooth Low Energy Med devices. Uploads to FHIR servers, or HL7 V.2
- Supports the LPWA Cellular IoT protocols Cat.M1 and Cat,NB for low cost connectivity on a global basis
- Meets clinical requirements for patient identity, timestamping and measurement representation.
- Transparent to user – no user facing interface to learn
- Diagnostic tooling to resolve common user issues, including remote Bluetooth pairing
- Security framework built on dual certificate SSL, BTLE encryption, OAuth, and SAML
- Operates without requiring Personal Health Information nor storing any data in transit
- Support for enterprise scale provisioning
- Cost-effective for population health monitoring
- Available off the shelf, as a white-labeled product or part of a turnkey Health@Home program

The first standards-based, multi-user on-premises medical device gateway addressing patient identity, correctness of time and measurement representation for clinical-grade remote health monitoring with Cellular and Wi-Fi connectivity.

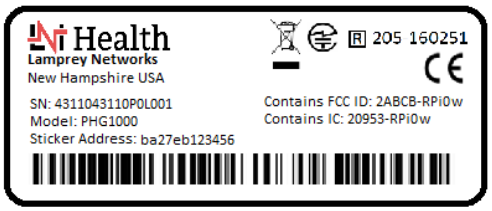
Low-cost cellular enabled Cat M and Cat NB

Easy-to-provision and pre-pair devices

Regulatory Approval

The PHG1000 has achieved the following regulatory approval:

- United States FCC (Contains FCC ID: 2ABCB-RPI32)
- Canada IC (Contains IC: 20953-RPI32)
- European Union: CE Mark
- Japan Radio Law Conformity Mark: 205-160251
- FDA - Classification is as a Medical Device Data System which is not classified as a Medical Device
- European Union - The PHG1000 is not considered to be a medical device (93/42/EEC)



The label displays the serial number, model, and the sticker address used in configuring the hub (can also be scanned using the bar code)
US FCC ID, Canada IC ID, CE mark, Japan Radio compliance

Power Supply

The typical Health@Home PHG1000 operates with a power draw of about 305 - 340 mA without external USB devices while plugged into standard electric. Peak power consumption is about 400 mA.

When being used with a USB battery source, LNI recommends using a power supply that can provide 2.5 Amps of USB power.

The PHG1000 is powered using the micro-USB connector (right). The PHG1000 also supports a display using the HDMI connector shown in this view (left).

Network Connectivity

Supported network connectivity options include:

- IEEE 802.11 with support for 2.4 GHZ and 5 GHZ
- IEEE 802.3 (Ethernet – optional)
- Cellular Technologies - *worldwide*
    - IoT
        - Cat.NB
        - Cat.M1

IoT Cellular offers a significant reduction in monthly cost and operational complexity

Cellular management is built into the LNI Health@Home Exchange management platform allowing single source of enterprise hub management.

Single Enterprise System

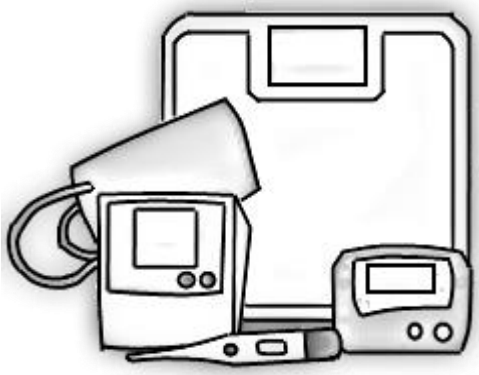
All hubs run the same HubOS allowing for a common implementation experience and same device support. Exchange provides a consistent Management interface across all hub types. This allows for common profiles and simplified management tools.

Supported Devices

The PHG1000 supports open standards. This includes all devices that use the IEEE 11073-20601 protocol, and devices supporting the Bluetooth and Bluetooth Low Energy Medical Device profiles.

Additionally, a collection of non-standard devices is supported. See https://www.lnihealth.com/device-category for the current list.

LNI offers additional device inclusion for customers on an as-identified basis. LNI's experienced team can assist in incorporating new custom sensor devices into the Health@Home ecosystem.



Supported Transports

11073 Device Specializations (USB PHDC and Bluetooth HDP)	All Continua Defined Device Specializations are supported. The following commonly used specializations have been tested against products in the marketplace: • Blood Pressure Cuff • Blood Glucose • Weight Scale, including Body composition analyzer • Pulse Oximeter • Activity Monitor
BTLE Medical Device Profiles (Bluetooth LE)	All Continua defined BTLE Personal Health Devices, which includes: • Heart Rate • Blood Glucose • Blood Pressure • Blood Oxygen (pulse ox) • Thermometer • Weight Scale

Bluetooth Capabilities

- white listing
- auto-pair
- Ability to connect with non-pairing Bluetooth random address devices
- Bluetooth Encryption
- Additional advanced options for managing specific Bluetooth compatibility issues

Storage Medium

The PHG1000 application uses a 16 GB class 10 Micro SD card for persistent storage of onboard OS and diagnostics. No external access is available to the end user. All updates can be performed over-the-air and only require small packet signatures. Updating can be scheduled and completed at controlled release times. …*No User data is stored on device…*

Management Interface

Management of the PHG1000 can be accomplished via Health@Home Exchange or by connecting to the local http server on the device.

Patient Identity	When multiple patients are using the PHG1000 to upload health data, patient identity can be established by setting a default user on the Exchange portal to be assigned to all measurements
Provisioning and Operational Management	The PHG1000 can be fully provisioned remotely, allowing "plug in and go" deployments. Additional real-time white-listings are available either via the Health@Home Exchange portal or service API
Diagnostic and Logging	The following log capability exists: • Audit log for all received, sent, and dropped observations • Connectivity management, including cellular signal integrity • Bluetooth device pairing and transfers • Changes in configuration
Remote Provisioning	The PHG1000 can be remotely provisioned such that the device simply needs to be plugged in when on-premise in order to be ready to take measurement.
Companion Application	Android based application allows the PHG1000 to be attached to a Wi-Fi network during initial deployment. Simple enough to be used by nonprofessional care provider

Capabilities

- Localization capabilities (Language - English, German, Wi-Fi Regulatory domain, time zone)
- Selectable value for MQTT keep alive (manages cellular bandwidth utilized for management)
- Ability to set contact and location information for PHG1000 (manual)
- Ability to setup Emergency account to allow login when password is lost
- Support for RADIUS server with enterprise Wi-Fi configurations
- Use UAC segment in PCD-01 messages to pass method of patient identification
- Configurable setting to enable deleting of stored observations
- Configurable setting to support devices that provide streamed or spot observations (Pulse Oximeter)

Measurement Upload Capabilities

Feature	Description of Feature	Notes
Exchange Support	• Uploads observations to Exchange • Implements H.812.3 Capability Exchange – allowing for automated discovery and configuration of services • Automated first boot – Allows PHG1000L to startup without user action in home deployment • Remote operational control in real time • Software updating. Remote pairing, cellular status, device battery management	
Security Framework	• Transport Security for IP - TLS 1.1 • Authorization - OAuth 2.0 (H.812.5, Capability Exchange), SAML 2.0 (H.812.1), Two way TLS authorization (boot server) • Bluetooth - Encryption and pairing required	
Measurement Upload	• Upload of observation using Continua H.812.1 SOAP upload (IHE PCD-01/HL7 v2.6 payload with SOAP header and body) • Upload of observation using Continua H.812.5 (will work with both FHIR observation server, and FHIR observation reporting server)	

Technical Details

Antenna

Band#3 F_Start (MHz) 3000

Band#1 F_End (MHz) 960

Band#1 F_Start (MHz) 600

Band#2 F_End (MHz) 3000

Band#2 F_Start (MHz) 1000

Band#3 F_End (MHz) 6000

An Experienced Partner in Connected Health

Lamprey Networks (LNI) is a leading provider of interoperability solutions for remote monitoring in healthcare and life sciences. We are passionate devotees of technical standards that facilitate end-to-end, plug-and-play solutions, and designing solutions that are easy to use, manage and customize.

In addition to its solutions, LNI is widely recognized for its engineering services related to interoperability and compliance for emerging technical standards. We have been providing industry solutions to large commercial customers since 2008.

Remote Monitoring, Your Way - Turnkey, by Component or White Label

Health@Home

Health@Home is LNI's flagship remote monitoring solution for next-generation connected health in long term care and rehabilitation, chronic disease management, remote physician visits and clinical research. Designed for usability, scalability and customization, Health@Home is the most comprehensive standards-based, end-to-end, plug-and-play remote monitoring suite in the market today—comprising hardware and software hubs, cloud solution, servers and remote monitoring management services. Reflecting LNI's commitment to 'right size' partnership, Health@Home is available as a complete turnkey solution; or, its components can be purchased by integrators and developers to supplement existing resources, capabilities or equipment. This enables LNI's partners to invest incrementally in open, standards-based plug-and-play remote health monitoring. Health@Home offers attractive economies of scale along with reduced OS complexities and can be white labeled for seamless integration into a branded remote monitoring program or solution.

LNI Health

We're dedicated to 'right size' partnerships in next generation connected health. For more information about LNI's turnkey Health@Home Remote Monitoring Solution, customized or white label orders, or LNI's specialized Engineering Services, please contact:

Chuck Parker

781-724-8872

chuckparker@lnihealth.com