



Nymi Configuration Specifications

Connected Worker Platform

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Introduction

Based upon the type of system (e.g., configurable or custom), configuration and design specifications provide a detailed, technical expansion of the Functional Specification (FS) (see Appendix D2).

The specifications outlined in this document explain how the system will do what is defined in the FS. This information provides the basis for subsequent configuration management.

This document is the Configuration Specifications (CS) for a solution in which user authentication for login and electronic signatures is based on biometrics instead of usernames and passwords.

Software Design

Connected Worker Platform is a Category 4 product under GAMP and defined as a configured product. Software Design specifications are required for custom applications. This is not normally required for configurable products, where software design is normally reviewed or evaluated as part of supplier assessment.

Nymis software is developed and validated based on internal processes, outlined in *10014 - Software Development Life Cycle and 10009-Verification and Validation*.

Configurations

A Connected Worker Platform environment requires a minimum of two computer systems, a Windows server on which the NES software is installed and a Windows network terminal on which to install the Nymi Band Application.

The following table summarizes the configuration specifications and related user specifications for configuration requirements.

Table 1: Configuration specifications for configurations

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-001	FS-CFG-01	The server-side components can be installed on bare metal within the customer's environment (Supported Operating Systems: Windows Server Windows Server 2016, Windows 2019)	n/a	n/a
URS-029	FS-CFG-02	Create a document that describes the steps to deploy Nymi Agent so that it can achieve 99.9% availability	CS-CFG-02	This information is covered in the Nymi Connected Worker Platform—Deployment Guide.
URS-003	FS-CFG-03	Connected Worker Platform shall be deployable in a way that allows a user's Nymi Band to be enrolled once and able to authenticate to systems in multiple domains.	CS-CFG-03	During NES deployment on the Enterprise window, there exists the option to specify multiple domains on which an which a user can use an authenticated Nymi Band.
URS-003	FS-CFG-04	NES shall require only one AD account for all domains for which there are trust relationships (requires two way trust between domains).	CS-CFG-04	The user account that is specified during NES deployment on the Enterprise window, in the Domain table must be a member of one of the domains in the trust.

Configurations

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-002	FS-CFG-010	NES and the Nymi Agent are installable on a virtual machine that has connectivity with required components, such as a Domain Controller and AD server. The NES server and Nymi Agent must also have connectivity and access to the user terminals. The Nymi Agent can qualify as a server side component and you can deploy Nymi Agent on a VM.	CS-CFG-010	This functionality is qualified as part of the Product verification and validation testing performed by Nymi.
URS-011	FS-DAT-002	Backup and restore procedures for database protection follow corporate policies.	CS-DAT-002	Configure SQL backups in accordance to corporate policies

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-027	FS-SAF-005	<p>The solution maintains an audit log of Nymi Band user assignments that:</p> <ul style="list-style-type: none"> • Maintains a record of each change (create, update, delete) that is made to a system record, including the date and operator ID. • Is accessible to the enterprise that deployed the Connected Worker Platform solution, without support from Nymi. • Is stored in an intelligible, well-defined format, and be available at any time for review, even past the lifetime of NES. • Supports the addition of fields that you can add to the log later without affecting existing records (e.g. a "reason for change" field could be added later). • Provides the existence of the audit log and a procedure for viewing its administrator. • Ensures that nothing in the Nymi system allows a user to change audit log records after the record has been generated. • Allows MES application to gather key information about the Nymi Band and the username to support the creation of an authentication audit trail. 	CS-SAF-005	<p>NES stores Nymi Banduser assignment audit logs in the NES SQL server database.</p> <p>By default, access to the SQL database is limited to the user account that installed the NES software.</p>

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-030 URS-039	FS-APP-001	The Nymi Band Application is a graphical user interface that allows users to enroll a Nymi Band and authenticate their Nymi Band using corporate credentials.	DS-APP-001	After a user logs in to the Nymi Band Application with a valid AD username and password, the application provides users with step-by-step instructions to enroll their Nymi Band. After users have enrolled their Nymi Band, they can use the Nymi Band Application to authenticate the Nymi Band by their Active Directory username and password if active policy on NES is configured to support corporate credential authentication.
URS-019 URS-024	FS-APP-002	The NES Administrator Console is a web-based application that allows administrators to manage NES policies, users and their Nymi Bands.	CS-APP-002	The NES Administrator Console is a secure web interface into NES that an NES Administrator accesses from any computer on the network, to manage policies, Nymi Band users and certificates. The NES Administrator Console is used to delete Nymi Band assignments.
URS-013	FS-NB-016	Connected Worker Platform solution ensures that the Nymi Band user is valid in Active Directory. Passwords are not stored in the NES database.	CS-NB-016	NES can be configured to check a user's AD user status with every action that they perform with the Nymi Band. If the user is inactive in AD, the user cannot log into the terminal, MES application or perform an e-signature with their Nymi Band. An error is reported and logged.

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-014 URS-023	FS-MES-001	The Active Directory user status is queried for every user authentication provided by a Nymi Band to Windows and MES login.	CS-MES-001	NES provides an option to check the Active Directory Status of users. There is an option to cache the User Status to cache user status in NES for a specified period, the default is 15 minutes. Only users who are members of the NES Admin group can access administrator settings in NES.
URS-004 URS-015	FS-MES-006	Integrate the Nymi API into an MES to support the use of a Nymi Band for login.	CS-MES-006	To implement this functionality, the MES applications make use one of three authentication workflows: Tap and Authenticate, Authenticated Tap, or Tap and Lookup.

Remote application support via Citrix and RDP

Allows users to access multi-user applications running on a remote RDP-based and Citrix-based environment solution and have multiple user sessions running on it by using an authenticated Nymi Band .

Components in a Centralized Nymi Agent Configuration

A Connected Worker Platform deployment in an environment that uses MES applications that are hosted on an RDP /Citrix server contain the same components as a Connected Worker Platform deployment in a local environment, but some components are configured differently.

The following figure provides an overview of the Connected Worker Platform components in a centralized Nymi Agent environment.

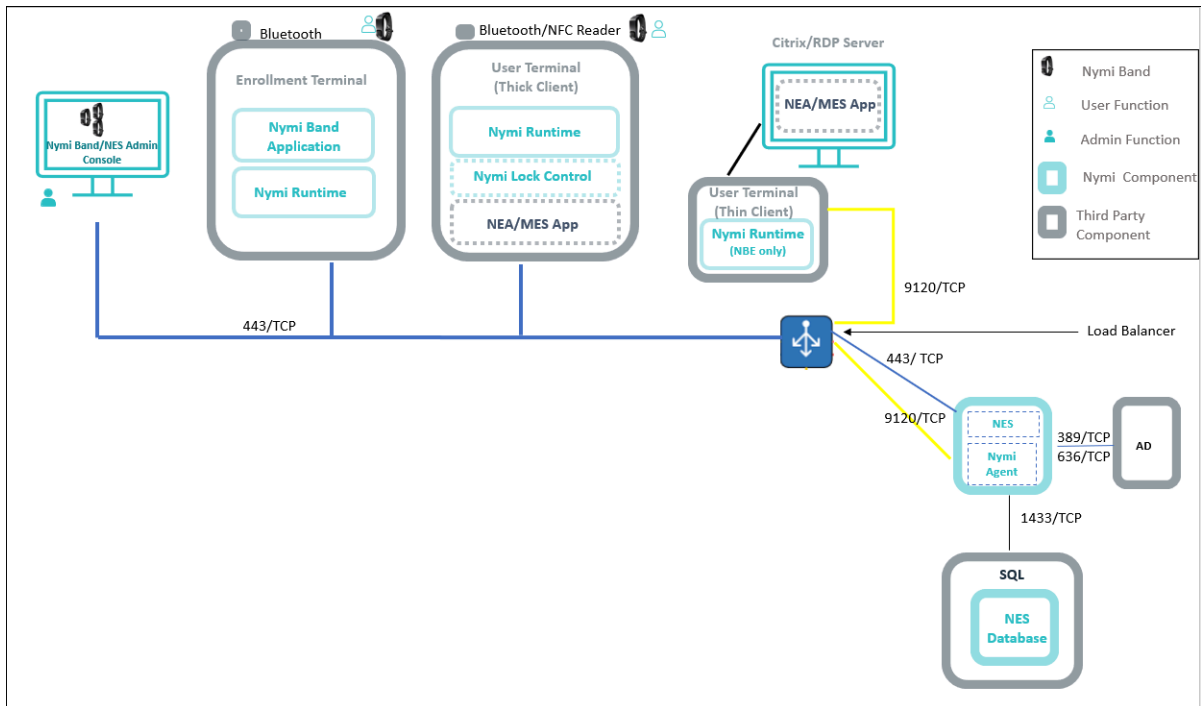


Figure 1: Connected Worker Platform components in a Citrix/RDP environment

The following table summarizes how the component configurations differ in a remote environment. For general information about the Connected Worker Platform components, see the section *Connected Worker Platform Components in a Local Environment*.

Note: While not displayed, it is assumed that NES, Nymi Agent, and the CWP Backend components are clustered.

Table 2: Connected Worker Platform Components

Component	Description
Enrollment Terminal	Windows 10 endpoint that users access to enroll their Nymi Band. Nymi recommends that you use a thick client for the enrollment terminal.
User Terminal (thick client)	<p>A Windows 10 endpoint that users use to:</p> <ul style="list-style-type: none"> Access a remote session host and launch an NEA that is installed on a remote session host. Use Nymi Lock Control to lock and unlock the desktop. <p>When you install Nymi Runtime on the user terminal, only install the Nymi Bluetooth Endpoint component. The <i>nbe.toml</i> file defines the location of the centralized Nymi Agent. The Nymi Bluetooth Endpoint service communicates with the Nymi Agent service over websocket port 9120.</p>

Component	Description
User Terminal (thin client)	<p>An endpoint that users use to:</p> <ul style="list-style-type: none"> • Access a remote session host and launch an NEA that is installed on a remote session host. • Use Nymi Lock Control to lock and unlock the remote or virtual desktop. <p>When you install Nymi Runtime on the user terminal, only install the Nymi Bluetooth Endpoint component. The <i>nbe.toml</i> file defines the location of the centralized Nymi Agent. The Nymi Bluetooth Endpoint service communicates with the Nymi Agent service over websocket port 9120.</p>
User Terminal (iOS Device)	<p>An iPad endpoint that users use to:</p> <ul style="list-style-type: none"> • Perform authentication tasks in a web-based Nymi-enabled Application(NEA). • Perform authentication tasks in a native iOS NEA. <p>When you install Nymi Runtime on the user terminal, only install the Nymi Bluetooth Endpoint component. Configuration settings defines the location of the centralized Nymi Agent. The Nymi Bluetooth Endpoint service communicates with the Nymi Agent service over websocket port 9120.</p> <p>For web-based and native iOS NEAs that are accessed by an iOS device, the NEA defines the Nymi Agent host and communication port number. The <i>Nymi SDK Developer Guide—Webapi(Windows)</i> provides more information.</p>
Nymi Application	<p>Required on the iOS devices to perform authentication tasks. Nymi Application is a Nymi-supplied native iOS application that:</p> <ul style="list-style-type: none"> • Embeds the Nymi Bluetooth Endpoint application, which provides an interface between the native Bluetooth Adapter (BLE) and the Nymi Agent. • Detects an intent to perform an authentication task with a Nymi Band (a tap) and passes the request to the NEA.
Citrix/RDP server	<p>Remote session host. In Citrix and RDP environments, the user uses a thin client to connect to a remote session host and then launches an NEA that is installed on a remote session host. Different user sessions run their own NEA instance.</p>

Component	Description
Centralized Nymi Agent	Nymi Runtime component that you install in a central location on a single machine or a cluster of two or more machines that is accessible to all user terminals, for example on the server with the NES application. Provides BLE management, manages operations and message routing. Facilitates communication between NEAs and the Nymi Band, and maintains knowledge of the Nymi Band presence and authenticated states.

Connected Worker Platform Deployment in RDP Environment

The Connected Worker Platform support deployments in RDP Environments.

The following figure provides an overview of the Connected Worker Platform components that are installed in an RDP environment.

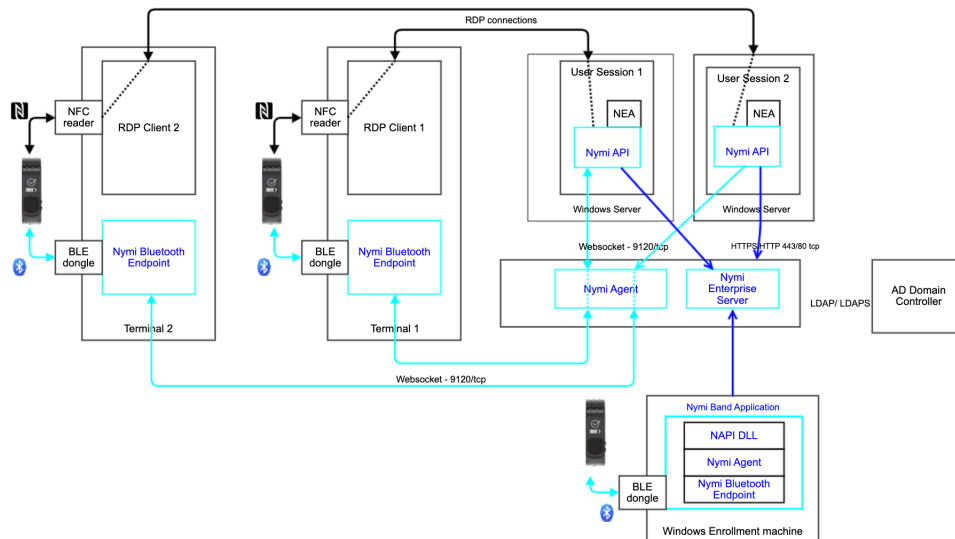


Figure 2: Connected Worker Platform components in a RDP environment

In RDP environments, the user launches an NEA that is installed on a remote session host. Different user sessions run their own NEA instance. In this configuration the NEA communicates with a centralized Nymi Agent, which is installed on a single machine or a cluster of two or more machines in the environment.

This figure shows the following configuration:

- The Nymi Bluetooth Endpoint is installed on each RDP client. The Nymi Bluetooth Endpoint service on each RDP client communicates with the Nymi Agent service, which is installed on a separate host, on websocket port 9120.
- The Nymi Agent is installed in a central location that is accessible to all user terminals, for example on the NES server.
- An *nbe.toml* file is installed on the RDP client, and is configured with the location of the Nymi Agent.
- An NEA runs on the RDP server and includes the *nymi_api* for communicating with Nymi Bands.

Citrix and RDP specifications

The following table summarizes the configuration specifications and related user specifications for remote application support requirements.

Table 3: Configuration specifications for remote application support

URS #	FS #	Functional Specification	CS #	Design / Configuration Specification
URS-021 URS-022	FS-RDP-005	Administrators can install NEAs on Windows 10 thin clients running Citrix (compatibility requirement).	CS-RDP-005	NEAs installed on the thin client require the <i>nymi_api.dll</i> file. The <i>nymi_api.dll</i> must be compatible with Windows 10 64-bit.

Hardware Design

Nymi Band 3.0

The Nymi Band wearable is a biometric device used by companies to increase security and improve workflows.

Nymi Band Physical Features

The following figures show the front and back of the Nymi Band.

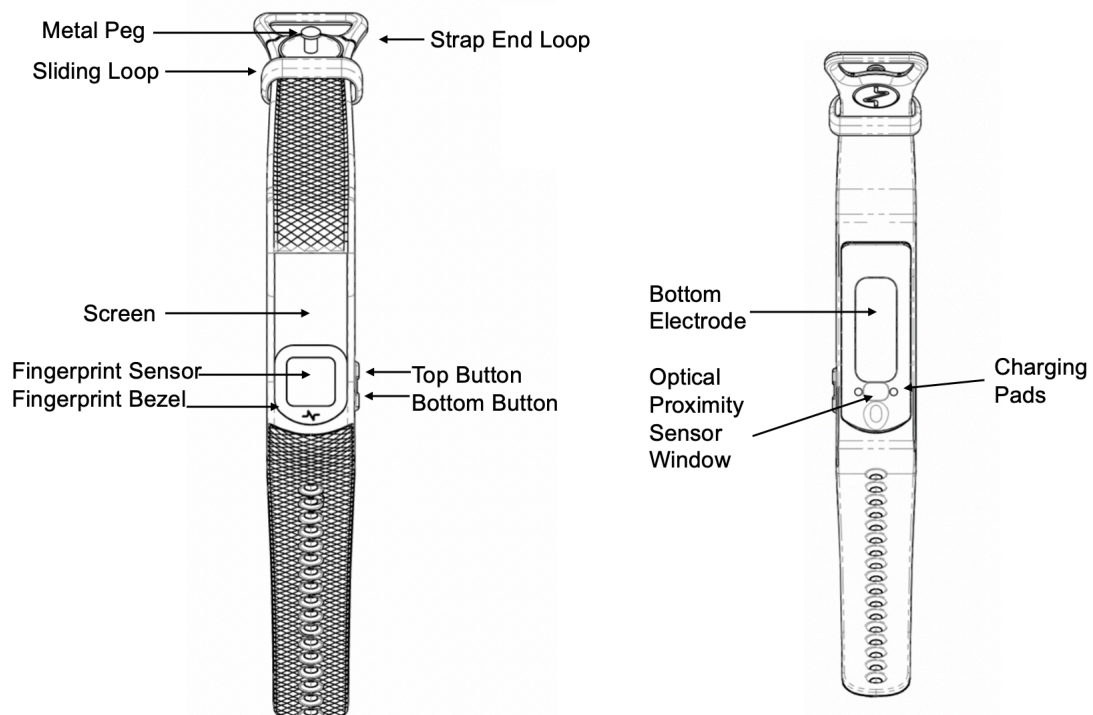


Figure 3: Nymi Band front and back

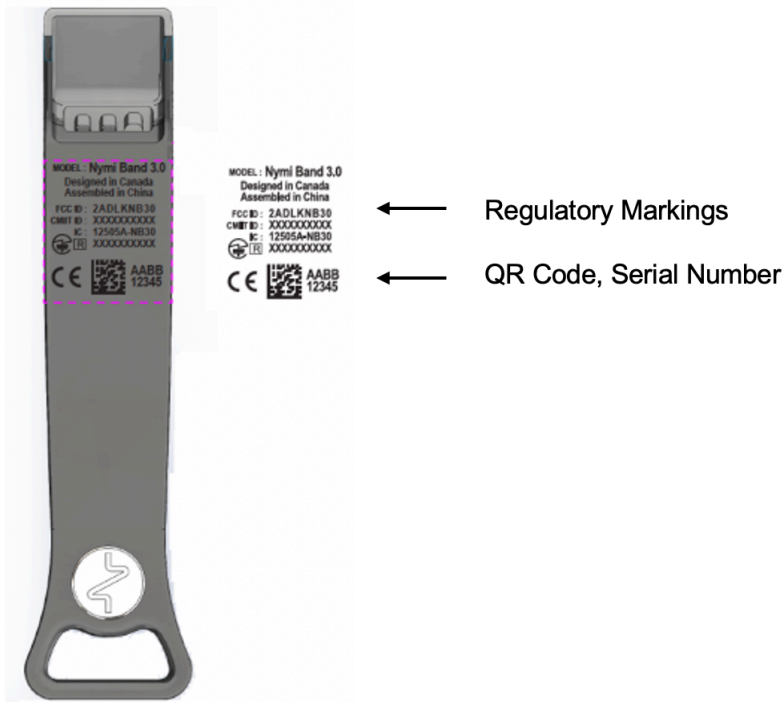


Figure 4: Nymi Band Strap

The Nymi Band is made up of the following main components:

- Screen—Visual interface on the face of the Nymi Band.
- Fingerprint Sensor—Fingerprint detection pad on the face of the Nymi Band.
- Fingerprint Bezel— Electrode that is used to capture the electrocardiogram (ECG) signal during authentication.
- Top and Bottom Buttons—Turns on the Nymi Band and allows users to navigate through screens. The buttons are also used to access administrative functions while the Nymi Band is charging.
- Charging Pads—Makes contact with the pins of the charger.
- Optical Proximity Sensor Window—Sensor that detects if the Nymi Band is on the wrist of the user.
- Bottom Electrode—Electrode that is used to capture the ECG signal during authentication. Also used to capacitively sense that the Nymi Band is on the user's wrist.
- Metal Peg—Peg that is used to secure the Nymi Band strap while it is on the wrist of the user.
- Sliding Loop—Loop used to keep any excess Nymi Band strap in place while it is on the wrist of the user.
- Strap End Loop—The loop integrated into the strap that helps the user get a good fit on their wrist. The wearer uses the strap loop in the same way that they would use a watch buckle.

The Nymi Band strap contains regulatory markings, a QR code, and the Nymi Band serial number. When scanned, the QR code displays the serial number.

Note: The Nymi Band is shipped with a protective film on the optical sensor and bottom electrode. Remove the protective film before use.

Nymi Band Functionality

Configuration specifications outlining setting, parameters, tools or methods that are used to set required options, any dependencies or impacts on other systems, infrastructure items such as operating systems and layered software, and any security settings.

Table 4: Configuration specifications for the computer system

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-010 URS-012	FS-NB-012	The biometric information that is stored on the Nymi Band consists of a fingerprint template, which is securely stored locally on the micro-controller unit (MCU). The biometric information is permanently deleted when the user perform a delete user data operation on their Nymi Band. No biometric information is stored in the server and the fingerprint template never leaves the Nymi Band.	CS-NB-012	The Nymi Band uses an FPC 1321 fingerprint sensor FPC 2050 drive IC. The FPC 1321 is a capacitive fingerprint sensor that uses arrays of tiny capacitor circuits to capture the fingerprint. It has a scratch-resistant coating and is made by Fingerprints Cards AB (1). Physical communication lines (USB, serial) are disabled on the MCU. If the MCU were physically removed from the Nymi Band, physical communication lines remain disabled ensuring no access to MCU memory by design.
URS-009	FS-BAT-005	Nymi Band contains a rechargeable battery and Nymi performs standard benchmark battery life tests that can be used to provide estimations to customers and compare battery life between different firmware releases.	CS-NB-013	The Nymi Band features a rechargeable 48 mAh lithium polymer battery that is charged by using a Nymi-provided charging cradle. The battery life is continually monitored and benchmarked in every subsequent release to meet the requirement.

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-007	FS-BAT-001	The Nymi Band supports a 3-day battery life, assuming 10-hour shifts, 900 taps total (300 per shift) with one shift per day.	CS-BAT-001	The Nymi Band supports a 3-day battery life, assuming 10-hour shifts, 900 taps total (300 per shift) with one shift per day.
URS-026	FS-PHY-007	The Nymi Band has a display which provides information to the user.	CS-PHY-007	Display information such as battery life, band label, and authentication status (authenticated/deauthenticated).

Inputs and Outputs

Input and output format may include digital and/or analog signals. External equipment should consider accuracy, isolation, range of current and voltage, type and numbers of interface cards and timing.

Table 5: Configuration specifications for inputs and outputs

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-030	FS-NB-015	Connected Worker Platform allows authentication to the Nymi Band by biometrics or an external authenticator, such as Active Directory.	CS-NB-015	NES Administrator can configure the default policy to allow an External Authenticator for authentication.

Environment

The operating environments for hardware shall be defined to include use, temperature, humidity, external interface, physical security, shielding against radio frequency, electro-magnetic or US interfaces, hardening against physical hazards such as dust or vibration.

Table 6: Configuration specifications for the environment

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-005	FS-ENV-001	The Nymi Band maintains biocompatibility and chemical resistance.	CS-SAF-001	n/a

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-005	FS-ENV-002	<ul style="list-style-type: none"> The Nymi Band is certified by: <ul style="list-style-type: none"> FCC (United States) CE (Europe) IC (Canada) The Nymi Band is made of hypoallergenic material. 	CS-SAF-002	n/a
URS-008	FS-ENV-003	The Nymi Band can be sanitized with an alcohol wipe or spray and hydrogen peroxide.	CS-SAF-003	The external surface of the Nymi Band shall be cleanable daily by soap and brush cleaning, hydrogen peroxide, 70% isopropanol wipe or 70% isopropanol submersion without any negative impact on reliability or functionality over a 3-year span. The external surface of the Nymi Band shall be durable to daily cleaning by soap and brush, 70% isopropanol wipe or 70% isopropanol submersion without any objectionable degradation in surface finish over a 3-year span.
URS-006 URS-017	FS-NB-019	<p>The Nymi Band:</p> <ul style="list-style-type: none"> NFC antennae supports a read-range that allows detection by an NFC reader through protective clothing and plexiglass coverings. Bluetooth antennae supports a read-range that allows detection by the Bluegiga Bluetooth adapter through protective clothing. 	CS-NB-001	This functionality is qualified as part of the QA and user acceptance testing process for the Connected Worker Platform solution.

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-025	FS-BAT-006	Users can accurately tell whether their Nymi Band's battery is Low, Medium, or High from the battery indicator on the screen.	CS-BAT-006	The Nymi Band hardware utilizes a fuel gauge chip which tracks the state of charge of the battery to a roughly 1% accuracy. This state of charge is read in firmware and mapped out to a battery charge indicator on the band's screen, which shows 4 levels of charge (4 bars, plus empty battery).
URS-040	FS-ENV-005	The solution provides a configurable option to disable haptic feedback on Nymi Bands to maintain compliance with the ANSI 12.12.03.2011 standard.	CS-ENV-005	An option exists in NES Policies to disable haptic feedback. By default the Haptic Feedback option is enabled. When you disable haptic feedback, and enroll a user, the Nymi Band does not provide haptic feedback after enrollment completes and does not signal to the user the deauthentication of the Nymi Band.

NES enrollment

NES supports uses Nymi Token Service (NTS) to manage certificates during enrollment.

The following table summarizes the design and configuration specifications and related user specifications for enrollment requirements.

Table 7: Design and configuration specifications for enrollment

URS #	FS #	Functional Specification	CS #	Design / Configuration Specification
URS-042	FS-ENR-009	The enrollment process provides the user with a statement of usage and consent, and the enroll cannot proceed until the user acknowledges the statement.	CS-ENR-015	This is an unconfigurable option in the Nymi Band Application and occurs for every enrollment.
URS-043	FS-APP-004	The solution provides configurable options to a user to use the Nymi Band Application to enroll to another Nymi Band when a Nymi Band to user association already exists in the Nymi Enterprise Server.	CS-APP-005	NES policies include options that allow users to re-enroll their own Nymi Band or any active Nymi Band without the need for a CWP Administrator to log in to the NES Administrator Console and delete the Nymi Band association with the user.

Nymi SDK - WebAPI support

The following table summarizes the design and configuration specifications and related user specifications for the Nymi SDK WebAPI support requirements.

Table 8: Design and configuration specifications for for Nymi SDK Web API

URS #	FS #	Functional Specification	CS #	Design / Configuration Specification
URS-041	FS-WEB-010	Nymi WebAPI works with Linux, iOS and Windows clients.	CS-WEB-010	Nymi WebAPI is implemented in the Nymi Agent and provides support for Nymi-enabled Applications (NEAs) that are accessed by iGel, Windows 10 and iOS clients. The Nymi SDK package includes iOS components. For iOS devices that access web-based NEAs, the solution provides the Nymi Application, which you install on the iOS device, which interfaces with the Nymi Band and the web-based NEA.

Interfaces

Nymi interfaces include application interfaces, FIDO2 support, NFC reader support, and remote application support.

Application Interfaces

Table 9: Design and configuration specifications for enrollment

URS #	FS #	Functional Specification	CS #	Design / Configuration Specification
URS-039	FS-APP-003	The solution provides the Nymi Band Application to assign a single user to a Nymi Band.	DS-APP-001	Nymi provides the Nymi Band Application, which facilitates enrollment for Evidian and Nymi-direct integration environments during one enrollment. The Nymi Band Application will use appropriate Evidian WGSS API methods to populate the both Evidian database and NES with the Nymi Band Application and user data.

Glossary

Definitions/acronyms used throughout this document are defined below.

Table 10: Glossary

Acronym	Definition
AD	Active Directory. Directory service for domain networks.
MES	Manufacturing Execution System
CWP	Connected Worker Platform
Class A	Class A clean rooms are for high-risk operations (eg. filling zone, stopper bowls, open ampoules and vials and, making aseptic connections). Class A environments are sterile environments
Class B	Class B Clean rooms provide the background environment for grade A zone items needing aseptic preparation and filling.
Class D	Environments for less critical tasks in the manufacturing process.
21 CFR Part 11	Part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration regulations on electronic records and electronic signatures.

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