



Nymi Configuration Specifications

Nymi Enterprise Edition

3.3

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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

Nymi Enterprise Edition 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.

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

Nymi Enterprise Edition Overview

Nymi Enterprise Edition is an authentication solution that minimizes the impact of compliance and security requirements on manufacturing workflows. It combines a wearable component, the Nymi Band, with enterprise software, creating a secure authentication solution.

Nymi Enterprise Edition solution contains three elements: device hardware, infrastructure and solution. The device hardware refers to the Nymi Band and firmware. Infrastructure consists of software, such as SDK, Nymi Enterprise Server and Nymi Band Application, that runs on terminals and servers.

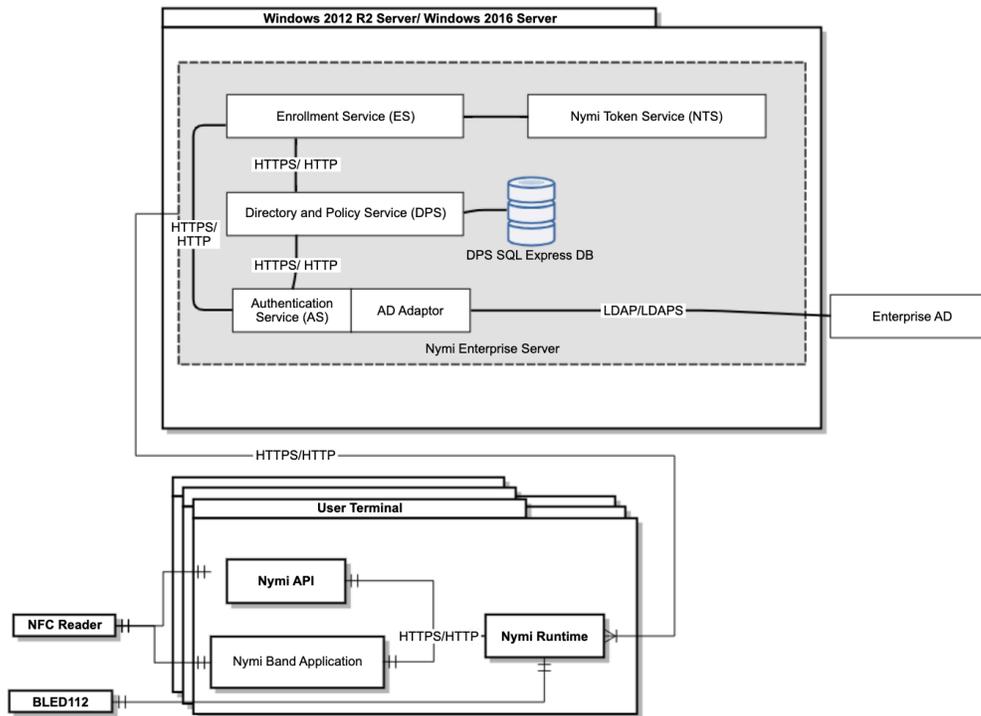


Figure 1: Nymi Enterprise Edition Architecture

Configurations

A Nymi Enterprise Edition 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 2012 R2, Windows Server 2016)	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 Enterprise Edition Deployment Guide.
URS-003	FS-CFG-03	Nymi Enterprise Edition 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.

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-027	FS-SAF-005	NES maintains an audit log of Nymi Band user assignments	CS-SAF-005	NES stores Nymi Band user assignment audit logs in the NES's SQL server database. By default, access to the SQL database is limited to the user account that installed the NES software.
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 #	FS #	Functional Specification	CS #	Configuration Specification
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	Nymi Enterprise Edition solution ensures that the Nymi Band user is valid in Active Directory. Usernames and passwords are not stored by NES.	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. As error is reported and logged.
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	MES applications make use of the intent notification and assert_identity request to implement this functionality.

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 .

Nymi Enterprise Edition Deployment in Citrix Environment

The following figure provides an overview of the Nymi Enterprise Edition components that are installed in a Citrix environment.

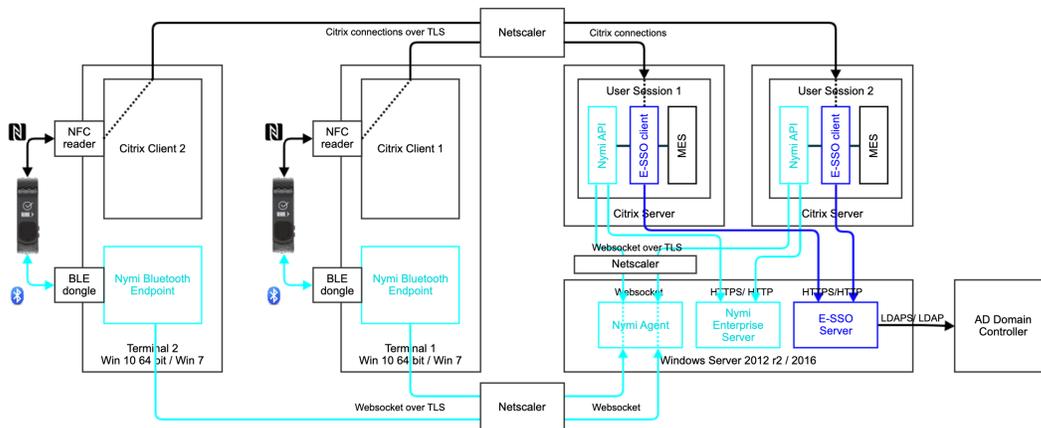


Figure 2: Nymi Enterprise Edition components in a Citrix environment

This figure shows the following configuration:

- The Nymi Bluetooth Endpoint is installed on each Citrix client. The Nymi Bluetooth Endpoint service on each Citrix 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 Citrix client, and is configured with the location of the Nymi Agent.
- An NEA runs on the Citrix server and includes the *nymi_api* for communicating with Nymi Bands.

Nymi Enterprise Edition Deployment in RDP Environment

Nymi Enterprise Edition support deployments in RDP Environments.

The following figure provides an overview of the Nymi Enterprise Edition components that are installed in an RDP environment.

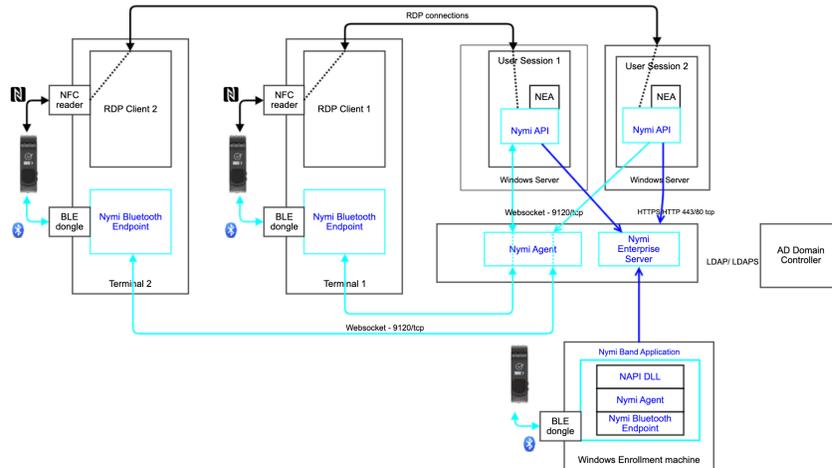


Figure 3: Nymi Enterprise Edition components in a RDP environment

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 2: 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 7 32-bit and 64-bit, and 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.

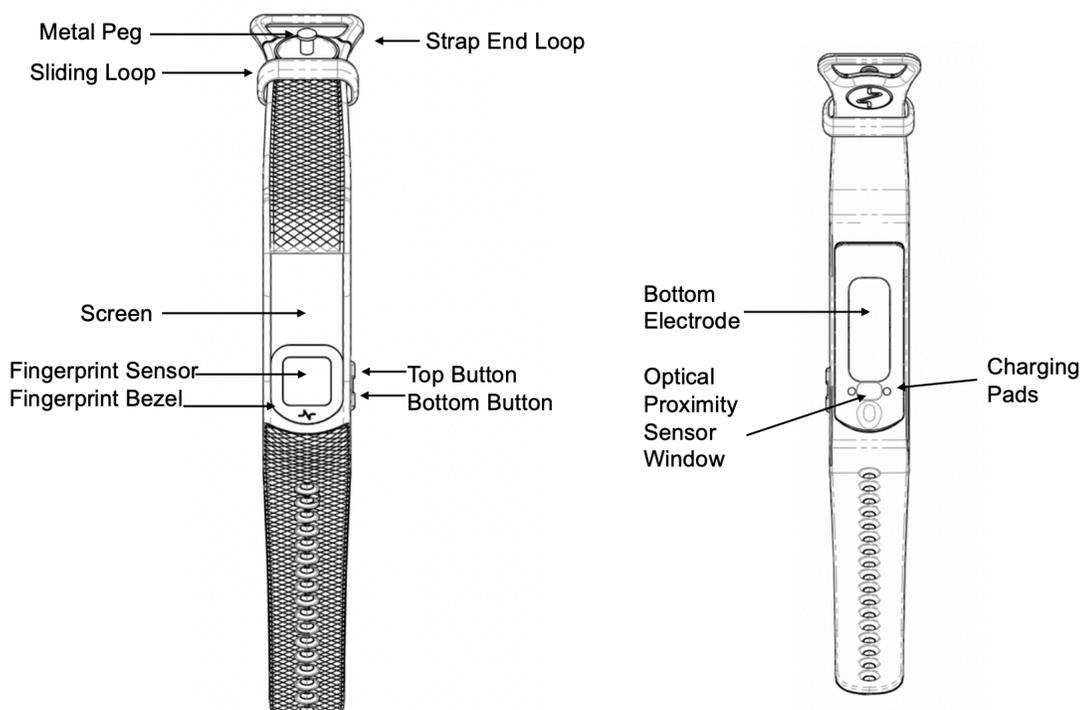


Figure 4: Nymi Band front and back



Figure 5: 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 3: 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 Nymi Band is security wiped. 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-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 4: Configuration specifications for inputs and outputs

URS #	FS #	Functional Specification	CS #	Configuration Specification
URS-030	FS-NB-015	Nymi Enterprise Edition 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 5: 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-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 #	FS #	Functional Specification	CS #	Configuration Specification
URS-008	FS-ENV-003	The Nymi Band can be sanitized with an alcohol wipe or spray.	CS-SAF-003	The external surface of the Nymi Band shall be cleanable daily by soap and brush cleaning, 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	The Nymi Band NFC antennae supports a read-range that allows detection by an NFC reader through protective clothing and plexiglass coverings.	CS-NB-01	This functionality is qualified as part of the QA and user acceptance testing process for the Nymi Enterprise Edition solution.
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 (3 bars, plus empty battery).

Definitions/acronyms used throughout this document are defined below.

Table 6: Glossary

Acronym	Definition
AD	Active Directory. Directory service for domain networks.
MES	Manufacturing Execution System
NEE	Nymi Enterprise Edition
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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