

BioDashboard[™] Instructions for Use

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Intended Use

- BioDashboard (the Device) is intended to display and visualize physiological and medical data and log assessments.
- The Device displays data and notifies healthcare professionals when physiological data fall outside clinician specified parameters.
- The data from the Device are intended as an aid to diagnosis, diseases management, and treatment.
- Healthcare professionals are the intended operators of this device.
- The Device is intended for use on patients who are 18 years of age or older.
- The Device is not intended for critical care.
- The Device has the ability to allow the clinician to configure the parameters for notifications.



IN CASE OF EMERGENCY, CALL 911 IMMEDIATELY

Our support line is not for medical emergencies. If you believe you have an emergency, call 911.

Warnings and Precautions

- Recommendations provided by BioDashboard are adjunctive (supporting). Do not solely or primarily rely on the BioDashboard to prevent, diagnose, or treat a disease or condition.
- Do not use accessories, detachable parts or materials other than those described.

Use Instructions

LOGIN

1. To begin using the BioDashboard proceed to **https//biodashboard.net** which will display the following login screen.

8 BioDashboard
Email Password Log In Forgot Password
Sign in with Auth0 For any issues, <u>contact support</u>
© 2024 BioIntelliSense, Inc. All rights reserved. BioIntelliSense, BioButton, BioSticker, and the BioSticker device shape are trademarks/trade dress of BioIntelliSense, Inc.

IFU-BDB-10598 Ver.4 | February 2025

LOGIN (CONTINUED)

- 2. Enter your username and password to login to BioDashboard. The following options are available:
 - **Email:** Provide your email/username for your BioDashboard account.
 - **Password:** Provide your password for your BioDashboard account.
 - Log In Button: After entering your username and password, click this button to login.
 - Forgot Password Button: If you have forgotten your password, you can click this button to reset your password.
 - Sign in with Auth0: Click this button to use Auth0 to log in.

BioDashboard Enter Search Te

Unit 18 items selected

Email Password Log In Forgot Password Sign in with AuthO For any issues, <u>contact support</u>

BioDashboard Login Form

BioDashboard

MULTI-PATIENT VIEW

0

1. Once logged into BioDashboard, the Multi-Patient View is displayed similar to that shown below. Click the Census Button in the banner on the left side of the screen to access the Multi-Patient View at any time:

New Location (1) (New Location (0) (ABC (0) Off Unit (0)

 Image: Strain and Strain an

ts 🖬

ina (0) (

2. The Multi-Patient View displays summary information for all patients within the selected unit(s). The following options are available:

PATIENT CELL

View summary information for an individual patient. Click a patient cell to display the Patient Detail View (described below) for that patient.

- Patient room number.
- Patient name.
- Last data. Displays the time since the last data was received by a BioIntelliSense wearable monitoring device.
- **Patient Heart Rate.** Displays the most current resting heart rate for the patient from the BioIntelliSense wearable monitoring device. Yellow highlight indicates abnormally high level or low level. See Color Limits Tab in Help Menu for definitions.
- **Patient Respiratory Rate.** Displays the most current resting respiratory rate for the patient from the BioIntelliSense wearable monitoring device. Yellow highlight indicates abnormally high level or low level. See Color Limits Tab in Help Menu for definitions. See Color Limits Tab in Help Menu for definitions.





ICON	MEANING
Notes Button	Click this button to access the Notes screen to view patient specific notifications that need review, enter tower notes, and view notification history, as well as add new issues for assessment (described below). IMPORTANT NOTE: Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this icon.
Patient Graphs Button	Click this button to access detailed vital sign graphs for the specific patient.
🔧 Wrench Icon	Indicates notification settings have been changed for the specific patient.
Active Clinical Notification Button	Indicates an active clinical notification. Click this button to view the Notes screen.
• Active Non-Clinical Notification Button	Indicates an active non-clinical notification. Click this button to view the Notes screen.
Clinical Notification Review Button	Indicates a clinical notification for a specific patient that needs review. Click this button to view and enter an assessment for any notifications that need review. IMPORTANT NOTE: Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this icon.
Non-Clinical Notification Review Button	Indicates a non-clinical notification for a specific patient that needs review. Click this button to view and enter an assessment for any notifications that need review. IMPORTANT NOTE: Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this icon.
Ove Patient Button	Click this button to access a dropdown menu to categorize the selected patient by location and color within a care unit in the Multi-Patient View, based on the configuration of the user. The default options are Not Set, Monitor, Telemetry, Floor, Home, and SNF.

ADD PATIENT BUTTON

Click this button to access the Patient Registration Form (described below) to add a new patient to the current Unit.

IMPORTANT NOTE: PHI display must be enabled in the Multi-Patient View Settings to view this button, and it will only be available if configured for your organization.



Select All Button

Apply Button

UNIT DROPDOWN MENU

Select the care unit(s) to display by selecting the corresponding checkbox(es). Click the "Apply" Button to show the selected censuses. Click the "Select All" Button to select all censuses. Click the "Clear" Button to clear selections.

Clear Button

SORT BY DROPDOWN MENU

Choose to sort patients by notifications, patient last name,BioID, length of stay, patient age, room number, and patient ID/MRN. **IMPORTANT NOTE:** Patients with active notifications and notifications that need review are always displayed at the top of multi-patient view. PHI display must be enabled in the Multi-Patient View Settings to sort by notifications that need review.

FILTER DROPDOWN MENU

Select to display devices that have displayed data in the last 24 hours or 7 days, have notifications that need review, have modified alert settings, recently viewed patients (i.e. last 20 patients recently viewed), have active notificationicons, and/or have tower notes.

SEARCH TEXT BOX

Search for specific text to find patients.

CENSUS BUTTON

Click this button in the banner on the left side of the screen to access the Multi-Patient View.

SETTINGS BUTTON

Click this button in the banner on the left side of the screen to access the Multi-Patient View Settings Menu (described below).

ABOUT MENU BUTTON

Click this button in the banner on the left side of the screen to display the BioDashboard version number and other software identification information, as well as provides access to the BioDashboard Instruction for Use.

HELP MENU BUTTON

Click this button in the banner on the left side of the screen to access the Help Menu (described below).

LOGOUT BUTTONS

Click either of these buttons to logout.

GROUP BY LOCATION SLIDER

Slide this toggle to turn location features on or off. Individual patients can be categorized by location in the Patient Detail View Settings Menu (described below).

LOAD DISCHARGED PATIENTS SLIDER

Slide this toggle to show or hide discharged patients in the Muti-Patient View.







Settings Menu Option





Help Menu Option



LOG OUT

Email Address



Group by location slider



Load Discharged Patients slider

LOCATION BUTTONS

Click a location button at the bottom of the screen to only show patients within that specific location. The default options are Not Set, Monitor, Telemetry, Floor, Home, and SNF.

PATIENT DETAIL VIEW

1. When an individual patient cell is clicked in Multi-Patient View, the Patient Detail View is displayed similar to that shown below:

(<u></u>	BioDashboard Enter	Search Term 🗸	Last Login: 2025.0115 206PM MST LOG OUT
> :	CENSUS		(12h) 24h 3d 7d 30d Custom Export BioReport
			Heart Rate at Rest
		Sin trap Jane 2 Jane 2 Jane 2	00- 00- 00-
	Active Notifications (2) Heart Rate Threshold		00 Борам борам 700ам ворам 100ам 100ам 100ам 1200ам 100ам 200ам 300ам 400ам 600а
	Notification 60 minute median Heart Rate (118.1 bpm) is above threshold. 1 hr, 29 mins ago	Hit at Best 120 bpm 7 minir ago	Respiratory Rate at Rest
	Low Signal Quality Notification Heart rate at rest unavailable due to low signal quality. 2 hrs, 59 mins ago		30 20 หารไป ที่มีประกับชื่อได้เขาเปลี่ยนหาร์ ไม่ เม่าสำนั้งหมู่สูงรู้ประวัยหาร์แห่ง เร็าเรื่องที่สามาร์ได้มี 20 500M 800M 700M 800M 900M 1000M 1000M 1000M 1000M 200M 200M 20
	Patient Details 🥕		
_	Census: Thomas Census Z		38
0	Room:		36
9 ~	Patient ID / MRN: 663290872		»
€→	Bio ID: 857970736s		ал 30 500ли 600ли 700ли вооли вооли 100ли 100ли 1200ги 200ги 300ги 400ги 600ги 600г

2. The Patient Detail View displays detailed information for an individual patient. The following options are available:

PATIENT HEART AND LUNG ICONS

The organs displayed in the image move at the rate of the patient's most current vital signs from BioIntelliSense wearable monitoring device. Green color indicates normal level and yellow indicates abnormally low or high level. Blue color indicates no data are available. See Color Limits Tab in Help Menu for definitions.

THERMOMETER ICON

The thermometer icon displays the current skin temperature for a specific patient. Green color indicates normal level and yellow indicates abnormally low or high level. Blue color indicates no data are available. See Color Limits Tab in Help Menu for definitions.

PATIENT VITAL SIGNS AND BIOMETRIC GRAPHS

Click a timescale button to display the following graphs over different timescales. The options are 12HR, 24HR, 3D, 7D, 30D, and Custom.

- Heart Rate at Rest. Line graph of resting heart rate over time in bpm.
- Respiratory Rate at Rest. Line graph of resting respiratory rate over time in bpm.

- Skin Temperature. Line graph of skin temperature over time in degrees C.
- Sleep. Bar graph of sleep over time in minutes per hour.
- Activity. Bar graph of physical activity levels over time in minutes per hour, summarized as low, medium, and high activity.
- **Degree of Incline While Sleeping.** Bar graph showing the average degree of incline angle while sleeping each day.
- **Body Position.** Bar graph of time in different body positions in minutes per hour, summarized as supine, prone, upright, lying right, lying left, and unknown.
- Steps. Bar graph of steps over time, summarized as steps per hour.
- Step Symmetry. Dot plot of step symmetry over time, summarized each hour.
- Step Strength. Dot plot of step strength of right and left feet over time, summarized each hour.
- On/Off Body. Bar graph of time wearing BioIntelliSense wearable monitoring device in minutes per hour.

IMPORTANT NOTE: Some of the graphs listed above may not be displayed depending on your configuration.

EXPORT BUTTON

Click this button to generate a PDF report of the currently selected patient's vital signs and biometrics. Click "Save" in your web browser to download the report when prompted.

CENSUS BACK BUTTON

Click this button above the patient name to stop monitoring the patient for billing and navigate back to the Multi-Patient View.

SETTINGS BUTTON

Click this button to the left of the patient to access the Patient Detail View Settings Menu (described below).

WRENCH ICON

Indicates notification settings have been changed for the specific patient.

NOTES BUTTON

Click this button under the patient name to view the Notes screen and enter tower notes for the specific patient. **IMPORTANT NOTE:** Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this button.





Census Back Button









PATIENT DETAIL VIEW (CONTINUED)

REVIEW BUTTON

This button indicates that one or more notification(s) require review. Click this button to view the Notes screen and review any notification(s) that require review. See Notifications and Icons Tab in Help Menu for definitions. Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this button.

ACTIVE NOTIFICATIONS

Active notifications are listed. Clinical notifications are indicated by yellow icon and listed in yellow text. Non-clinical notifications are indicated by black icon and listed in black text.

PATIENT DETAILS

Displays the following details associated with the selected patient. Important Note: Some details may not be listed or different depending on your configuration.

- Census. The census the patient is located in.
- **Room.** The room the patient is located in.
- Patient ID/MRN. Patient specific identifier.
- BioID. BioIntelliSense Device ID.
- Date of Birth (Age). Patient date of birth and age.
- Date of Activation. Date of BioIntelliSense Device activation.
- Diagnosis. Patient diagnosis.
- Procedure. Patient procedures.

EDIT PATIENT BUTTON

Click this button to access the access the Edit Patient Registration Form (described below) to edit patient details. This form can be used to enter a new BioID to use a new BioButton with the selected patient and/or update other patient details. PHI display must be enabled in the Multi-Patient View Settings to view this button, and it will only be available if configured for your organization.

END MONITORING

Click this button to discontinue patient monitoring and move the patient to the Discharged Section. PHI display must be enabled in the Multi-Patient View Settings to view this button, and it will only be available if configured for your organization.



Patient ID / MRN: 112384293

Bio ID: 1234-567-890

Sex:

Female

DOB (Age) 1990-1-21 (34)

Date of Activation 2024-02-12

Diagnosis: None

Procedure: None



Edit Patient Button



End Monitoring Button

PATIENT DETAIL VIEW (CONTINUED)

PATIENT ENCOUNTERS

Displays date(s) of patient visit(s) and associated BioIDs for each visit.

- In Facility Icon indicates In Facility patient visit.
- At Home Icon indicates At Home patient visit.

CONFIGURATION MENUS

 Multi-Patient View Settings Menu: Clicking the Settings Button in the banner on the left side of the screen allows configuration of various options that apply to all patients in the Multi-Patient View and displays the settings menu shown below. The following options are available:



- Theme Mode: Choose to toggle "Dark mode" or "Light mode" display modes.
- Temperature Unit: Choose to toggle temperature display as Celsius or Fahrenheit.
- Date Format Dropdown Menu: Select the Date format from the dropdown menu.
- Day/Month Format Dropdown Menu: Select the Day/Month format from the dropdown menu.
- Time Format Dropdown Menu: Select the time format from the dropdown menu.
- **Refresh Rate in Seconds:** Use the arrows or type in the box to change the screen refresh rate.
- Show PHI Slider: Slide this toggle to turn PHI display on or off.
- Show Notes and Notification Review Slider: Slide this toggle to allow access to the Notes View, which enables Notification Review, Enter Issue, Tower Notes, and Notes History features (described below).





CONFIGURATION MENUS (CONTINUED)

- 2. Patient Detail View Settings Menu: Clicking the Settings Button in patient name in Patient Detail View allows configuration of various options that apply only to an individual patient and displays a settings menu similar to that shown below. The following options are available:
 - Patient Location Dropdown Menu. Use this dropdown menu to categorize the selected patient by location and color within a care unit in the Multi-Patient View, based on the configuration of the user. The default options are Not Set, Monitor, Telemetry, Floor, Home, and SNF. PHI must be enabled to use this feature.
 - Skin Temperature Slider. Use the left slider and/or box to set the low limit and the right slider and/or box to set the high limit for skin temperature in degrees C for the selected patient before a notification is sent. On the slider, the green range indicates normal values and yellow ranges indicate abnormal values. Default values are indicated with an asterisk* (Low Default = 31°C) (High Default = 37 °C).
 - Heart Rate Slider. Use the left slider and/or box to set the low limit and the right slider and/or box to set the high limit for resting heart rate in bpm for the selected patient before a notification is sent. On the slider, the green range indicates normal values and yellow ranges indicate abnormal values. Default values are indicated with an asterisk* (Low Default = 50 bpm) (High Default = 115 bpm).

Patient Settings	×
Patient Location	
Not Set ←	
Notification Limits / Color Limits	
Skin Temperature, Normal Range (Fahrenheit, °F)	
Heart Rate, Normal Range (bpm)	
Respiratory Rate, Normal Range (rpm)	
These range sliders allow you to define the normal range for the specified attribute. The slider represents the normal range where values are displayed in green. Values outside this range are displayed in yellow and will trigger a notification. If the value is set to the lower and/or upper limit(s), the high and/or low notification(s) is(are) disabled.	
RESET TO DEFAULT SAVE)

- Respiratory Rate Slider. Use the left slider and/or box to set the low limit and the right slider and/or box to set the high limit for resting respiratory rate in bpm for the selected patient before a notification is sent. On the slider, the green range indicates normal values and yellow ranges indicate abnormal values. Default values are indicated with an asterisk* (Low Default = 8 bpm) (High Default = 28 bpm).
- **Reset to Default Button.** Click this button to reset all notification limits to their default.
- Save Settings Button. Click this button to save current notification limit settings.



NOTES VIEW

IMPORTANT NOTE: Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to access these features.

	BioDashboo	Enter Search Term		~		ast Login: 2025.01.28 6:47PM MST LOG OUT
> #	CENSUS Name: Bi Sandy Parker 12 Room:	io ID: Patient ID/MRN: DOB (Ago): 8284928s 43554209	CLOSE NOTIFIC	ATION REVIEW	TowarNote A	Save Note Cancel
	Filters: View Type Notification	BODY PANEL (HISTOR All Details (MIST) Heart Rost Threshold Modification 60 manufa median theart that (10.0 Spin) is a dove Threshold	Assessment Assessment: N/A Actions: N/A	User Details (MST) Displayed at: 2025 02 03 310AM MST Reviewed at: 2025 02 03	Notification Review (30) A Kespiration Rate Threshold Notification Rode (13 pm) is above threshold. 2015 02:03 7:50AM MST Not a problem	Add New Entry Add New Entry elefect Reaction elefect Reaction teaction Details Save Assessment
• @ \$	Monitoring Status Update Notification	2025/02/03 7:54AM MBT Device: (28/26/2016; registerned to Rotterit tid: 43536/42/03 in Cansus: Action particirmed by User: System 2025 01/03 8:02AM MBT Device: Activation Hotification: Device activated.	Reactions: N/A	Iz 00PM MST Reviewed by User: System Dote: 2025 0130 8:02AM MST Displayed et: 7025 0130 8:03AM MST Reviewed et: N/A Reviewed by: N/A	TZh 24 h 3 d 7 d 30 d Custom Heart Rate at Rest 10 10 10 10 10 70 100000 20000 200000 200000 200000 200000 20000 200000 200000 20000 20000 2000000	Export BioReport

PATIENT INFORMATION

The Patient Name, BioID, Gender, ID/MRN, Date of Birth, and Age are displayed in the top left corner of the screen to facilitate review.

BODY PANEL/HISTORY TOGGLE BUTTONS

Click Body Panel Button to display patient health data. Click History Button to display the History List (described below).

HISTORY LIST

The History List displays the patient history log. The following options are available to display from the Filters Dropdown.

BODY PANEL	HISTORY
Body Pane Toggle E	l/History Button

Filters Dropdown

- View All. Select from the dropdown to view all items in the History List.
- Tower Note Updates. Select from the dropdown to view Tower Notes Updates in the History List.
- Notifications. Select from the dropdown to view Notifications in the History List.
- Entries. Select from the dropdown to view manual user entries in the History List.
- **Monitoring Status Updates.** Select from the dropdown to view Monitoring Status Updates in the History List.

CENSUS BACK BUTTON

Click this button above the patient name to stop monitoring the patient for billing and navigate back to the Multi-Patient View.

CLOSE NOTIFICATION REVIEW BUTTON

Click this button to close the Notes View and go back to the Patient Detail View.

TOWER NOTE TEXT BOX

Enter a tower note for the patient by entering text in the box and clicking the Save Note Button. This will also enter the tower note information in the History List on the right side of the screen. Click the Cancel Button **Cancel** to discard the current Tower Note.

NOTIFICATION REVIEW

Use the arrows $\langle n \rangle$ to select a notification that requires review. The following options are available:

- Assessment Dropdown. Select an option from the dropdown menu to log the assessment for the current notification.
- Assessment Details Text Box. Add additional details about the assessment for the current notification.
- Action Dropdown. Select an option from the dropdown menu to log the action for the current notification.
- Action Details Text Box. Add additional details about actions for the current notification.
- **Reaction Dropdown.** Select an option from the dropdown menu to log the reaction for the current notification.
- Reaction Details Text Box. Add additional details about reactions for the current notification.
- Save Assessment Button. Click this button to save the current assessment for the notification review. This will also log the assessment in the History List on the left side of the screen and will remove the notification from the Notification Review, remove the Review Button Review / Review in Patient Detail View, and remove the Notification Review Icon / from the Multi-Patient View, unless other current notifications still require review.
- Not a Problem Button . Click this button to indicate that the current notification is not a problem. This will also log the assessment in the History List on the left side of the screen and will remove the notification from the Notification Review, remove the Review Button
 REVIEW
 / PREVIEW
 in Patient Detail View, and remove the Notification Review Icon
 Notification Review Icon
 / Provide from the Multi-Patient View, unless other current notifications still require review.













ADD NEW ENTRY BUTTON

Click this button to view the New Entry Screen shown below. This option allows a user to enter a new, unlisted entry in the History List. The following options are available:

- New Entry Details Text Box. Add details about the new entry in the text box.
- Select Entry Category Dropdown. Select an option from dropdown menu to categorize the new entry.
- Flag Patient for Retrospective Case Review. Check this box to create a retrospective case review.
- Continue Button. Click this Button to save the new entry. This will log the new entry in the History List on the left side of the screen.
- Close Button. Click this button to close the New Entry Screen and go back to the Notification Review Screen.
- Select Reaction/Patient Response. Select the appropriate checkboxes and/or enter text to indicate the patient's reaction for the new issue.
- **Cancel Button**. Click this button to cancel the current assessment for the new issue.
- Save Assessment Button. Click this button to save the current assessment for the new issue. This will also enter the new issue in the History List on the right side of the screen.

ΡΔΤΙΕΝΤ VΙΤΔΙ	SIGNS AND	BIOMETRIC	GRAPHS
FAIILINI VIIAL	JIGHJAND	DIOMETRIC	GRAFIIS.

w Entry

New Entry Details

Select Entry Category

Patient Vital Signs and Biometric Graphs are available to view in the lower right corner of the screen to facilitate notification review. Click a timescale button to display the following graphs over different timescales. The options are 12HR, 24HR, 3D, 7D, 30D, and Custom. Scroll up and down to view various graphs.

□ Flag patient for retrospective case review ()

Export BioReport Button. Click this button to generate a PDF report of the currently selected patient's vital signs and biometrics. Click "Save" in your web browser to download the report when prompted

2. Notification List: Notifications and their associated icons that can appear on the Multi-Patient View, Patient Detail View, and/or Notes View are shown below:



Close Button





Save Assessment Button

CLOSE

CONTINUE





Add New Entry Button





NOTIFICATION TITLE	ICON	DESCRIPTION	
Low Battery Notification		Low battery detected	
Device Last Seen Notification	•	Most recent timestamp the device connected to a gateway	
Off Body Notification	0	Sensor not attached for longer than X hours (configurable)	
Low Signal Quality Notification	0	Heart rate at rest unavailable due to Low Signal Quality	
Low Motion Notification	•	Potential device off body	
Body Orientation Notification	!	Patient turn is overdue, with a potential indication of a turn being undone.	
Heart Rate Threshold	!	High Heart Rate Threshold: 60 minute median Heart Rate (X bpm) is above threshold. [Default Threshold: 115 bpm]. Configurable for each patient in BioDashboard. Contact your BioIntelliSense Client Implementation Manager to configure globally by census, facility, and/or organization.	
Notification	!	Low Heart Rate Threshold: 60 minute median Heart Rate (X bpm) is below threshold. [Default Threshold: 50 bpm]. Configurable for each patient in BioDashboard. Contact your BioIntelliSense Client Implementation Manager to configure globally by census, facility, and/or organization.	
	!	Heart Rate Increase Trending 30 min/2 h: Heart rate at rest increased X % to X bpm. 30 minute notification after 2 hour baseline.	
Heart Rate Trending Notification	!	Heart Rate Decrease Trending 30 min/2 h: Heart rate at rest decreased X % to X bpm. 30 minute notification after 2 hour baseline.	
	!	Heart Rate Increase Trending 1/4 h: Heart rate at rest increased X % to X bpm. 1 hour notification after 4 hour baseline.	

NOTIFICATION TITLE	ICON	DESCRIPTION	
	!	Heart Rate Decrease Trending 1/4 h: Heart rate at rest decreased X % to X bpm. 1 hour notification after 4 hour baseline.	
	!	Heart Rate Increase Trending 2/4 h: Heart rate at rest increased X % to X bpm. 2 hour notification after 4 hour baseline.	
	!	Heart Rate Decrease Trending 2/4 h: Heart rate at rest decreased X % to X bpm. 2 hour notification after 4 hour baseline.	
Heart Rate Trending Notification	!	Heart Rate Increase Trending 4/24 h: Heart rate at rest increased X % to X bpm. 4 hour notification after 24 hour baseline.	
	!	Heart Rate Decrease Trending 4/24 h: Heart rate at rest decreased X % to X bpm. 4 hour notification after 24 hour baseline.	
	!	Heart Rate Increase Trending 24/72 h: Heart rate at rest increased X % to X bpm. 24 hour notification after 72 hour baseline.	
	!	Heart Rate Decrease Trending 24/72h: Heart rate at rest decreased X % to X bpm. 24 hour notification after 72 hour baseline.	
		High Respiratory Rate Threshold: 60 minute median Respiratory Rate (X rpm) is above threshold. [Default Threshold: 28 bpm].	
Respiratory	!	Configurable for each patient in BioDashboard. Contact your BioIntelliSense Client Implementation Manager to configure globally by census, facility, and/or organization.	
Notification		Low Respiratory Rate Threshold: 60 minute median Respiratory Rate (X rpm) is below threshold. [Default Threshold: 8 bpm].	
	!	Configurable for each patient in BioDashboard. Contact your BioIntelliSense Client Implementation Manager to configure globally by census, facility, and/or organization.	
	!	Respiratory Rate Increase Trending 30 min/2 h: Respiratory rate at rest increased X % to X rpm. 30 minute notification after 2 hour baseline.	
Respiratory Rate Trending Notification	!	Respiratory Rate Decrease Trending 30 min/2 h: Respiratory rate at rest decreased X % to X rpm. 30 minute notification after 2 hour baseline.	
	!	Respiratory Rate Increase Trending 1/4 h: Respiratory rate at rest increased X % to X rpm. 1 hour notification after 4 hour baseline.	

NOTIFICATION TITLE	ICON	DESCRIPTION		
	!	Respiratory Rate Decrease Trending 1/4 h: Respiratory rate at rest decreased X % to X rpm. 1 hour notification after 4 hour baseline.		
	!	Respiratory Rate Increase Trending 2/4 h: Respiratory rate at rest increased X % to X rpm. 2 hour notification after 4 hour baseline.		
	!	Respiratory Rate Decrease Trending 2/4 h: Respiratory rate at rest decreased X % to X rpm. 2 hour notification after 4 hour baseline.		
Respiratory Rate Trending Notification	!	Respiratory Rate Increase Trending 4/24 h: Respiratory rate at rest increased X % to X rpm. 4 hour notification after 24 hour baseline.		
	!	Respiratory Rate Decrease Trending 4/24 h: Respiratory rate at rest decreased X % to X rpm. 4 hour notification after 24 hour baseline.		
	!	Respiratory Rate Increase Trending 24/72 h: Respiratory rate at rest increased X % to X rpm. 24 hour notification after 72 hour baseline.		
	!	Respiratory Rate Decrease Trending 24/72 h: Respiratory rate at rest decreased X % to X rpm. 24 hour notification after 72 hour baseline.		
Temperature	!	High Skin Temperature Threshold: 60 minute median Skin Temperature (X deg.) is above threshold. [Default Threshold: 37 deg.]. Configurable for each patient in BioDashboard. Contact your BioIntelliSense Client Implementation Manager to configure globally by census, facility, and/or organization.		
Threshold Notification	!	Low Skin Temperature Threshold: 60 minute median Skin Temperature (X deg.) is above threshold. [Default Threshold: 31 deg.]. Configurable for each patient in BioDashboard. Contact your BioIntelliSense Client Implementation Manager to configure globally by census, facility, and/or organization.		
Temperature Trending Notification	!	The mean temperature for a 4 hour period was out of range compared to the previous 24 hour period.		
Double High Threshold Notification	!	60 minute median Heart Rate (X bpm) and Respiratory Rate (X bpm) are above double-high thresholds [Default Thresholds: HR = 100 bpm, RR = 24 bpm].		
Triple High Threshold Notification	!	Triple High Threshold: 60 minute median Heart Rate (X bpm), Respiratory Rate (X bpm), and Skin Temperature (X deg.) are above triple-high thresholds [Default Thresholds: HR = 100 bpm, RR = 24 bpm, Temp = 36 deg.].		

NOTIFICATION TITLE	ICON	DESCRIPTION
N/A		All Tower Notes and Issues
N/A	= /	Clinical Notification Review Button (Multi-Patient View): Clinical case needs review. Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this icon.
N/A		Non-Clinical Notification Review Button (Multi-Patient View): Non-clinical case needs review. Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this icon.
N/A	Review	Clinical Notification Review Button (Patient Detail View): Clinical case needs review. Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this button.
N/A	Review	Non-Clinical Notification Required Button (Patient Detail View): Non-clinical case needs review. Notes and Notification Reviews must be enabled in the Multi-Patient View Settings to view this button.
N/A	2	Patient configurations have been altered

4. Notification Calculations: The calculations for notifications are explained below: IMPORTANT NOTE: BioDashboard software does not calculate notifications directly.

NON-CLINICAL TECHNICAL NOTIFICATIONS

- Low Battery Technical Notification. The Low Battery Technical Notification generates a notification when a BioIntelliSense wearable monitoring device falls below 10% battery power remaining. The purpose of this notification is to allow clinicians to identify patients who need to recharge their BioIntelliSense wearable monitoring device battery.
- Device Last Seen Technical Notification. The Device Last Seen Technical Notification notifies clinicians
 of patients who may be having technical issues with their BioIntelliSense wearable monitoring device.
 A notification is triggered when a BioIntelliSense wearable monitoring device has not synchronized
 data to Bio Cloud for at least X hours (Default 4 h).

- Low Signal Quality Technical Notification. In certain situations, BioIntelliSense wearable monitoring device firmware may not be able to capture heart rate readings despite being worn on a patient's body and the patient being at rest. This occurs when the quality of the signal obtained from the accelerometer is not high enough to distinguish heartbeat pulses. The Low Signal Quality Notification identifies situations when all of the following criteria are met during an hour of a patient wearing BioIntelliSense wearable monitoring device and triggers a notification:
 - The patient was resting, as evidenced by low motion readings; and
 - No heart readings were obtained during the hour.
- Off-Body Technical Notification. The outputs of the Off-Body Determination Algorithm are used to produce a technical notification to notify a clinician when a patient has not worn the BioIntelliSense wearable monitoring device for a configurable minimum length of (consecutive) time. By default, the notification is triggered when the device has been off-body for at least four (4) consecutive hours. A Random-Forest machine learning algorithm uses BioIntelliSense wearable monitoring device data to determine if the device is off body at any given minute.

BODY ORIENTATION TRACKER CLINICAL NOTIFICATION

The Body Orientation Tracker (BOT, or the device) monitors the orientation and movements of bedridden patients. The device takes input from compatible Food and Drug Administration (FDA)-cleared medical devices and calculates the time since patient's last rotation as outputs. The device provides notifications when characteristics of a patient's position deviate from preset parameters. The notification is triggered when either of the following conditions are true:

- **Rotation Overdue Notification:** The patient has not been rotated at least X degrees (Default = 30 degrees) in X minutes (Default = 150 minutes) (i.e. the patient requires rotation).
- Rotation Undone Notification: The patient has reverted at least 20 degrees back to their original position within Y minutes (Default = 15 minutes) of being rotated (i.e. the patient reverted to their original position too quickly after being rotated). The user will receive a notification to rotate the patient for this condition only if the patient has also not been rotated in X minutes (Default = 150 minutes) as is configured above.

LOW MOTION NOTIFICATION

The Low Motion Notification is intended to provide insight about a potentially concerning stop in a patient's physiological activity to a clinician or command center technician responsible for monitoring a patient remotely. Specifically, the feature will notify if an extended period of time has passed (Default = 150 min) during which ALL of the following criteria are met:

- The BioButton reads as on-body.
- No valid heart rate or respiratory rate readings are measured.
- The AC Motion remains below a very low threshold (Default = 25,000).

PERSONALIZED TRENDING CLINICAL NOTIFICATIONS

These clinical notifications are triggered when a clinically and statistically meaningful increase or decrease in a single vital sign (heart rate or respiratory rate) occurs over a defined period of time. The following criteria outlined in the description and table below must be met for each notification to be triggered.

- Increase Notification is Triggered When Both Below Are True:
 - Percentage Change >= Percentage Change Threshold
 - Cohen's D Threshold >= Cohen's D Threshold
- Decrease Notification is Triggered When Both Below Are True:
 - Percentage Change <= (-Percentage Change Threshold)
 - Cohen's D Threshold <= (-Cohen's D Threshold)

IMPORTANT NOTE: Cohen's D thresholding is not used for the 30 min vs. 2 h and 1 h vs. 4 h notifications.

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The table below lists the associated Percentage Change and Cohen's D Thresholds for each Personalized Trending Notification:

				COHEN'S D THRESHOLD		
VITAL SIGN	NOTIFICATION TYPE	MODE	% CHANGE THRESHOLD	Q10 (BIOBUTTON - BBN)	Q2	Q3
	Increase	30 min vs. 2 h	30%	N/A	N/A	N/A
		1 h vs. 4 h	30%	N/A	N/A	N/A
		2 h vs. 4 h	30%	N/A	N/A	N/A
Resting Heart Rate		4 h vs. 24 h	30%	3.2	3.2	3.2
		24 h vs. 72 h	20%	2.0	2.0	2.0
	Decrease	30 min vs. 2 h	30%	N/A	N/A	N/A
		1 h vs. 4 h	30%	N/A	N/A	N/A
		2 h vs. 4 h	25%	N/A	N/A	N/A
		4 h vs. 24 h	25%	1.6	2.2	2.2
		24 h vs. 72 h	15%	1.0	1.3	1.3



	NOTIFICATION TYPE	MODE	% CHANGE THRESHOLD	COHEN'S D THRESHOLD			
VITAL SIGN				Q10 (BIOBUTTON - BBN)	Q2	Q3	
	Increase	30 min vs. 2 h	65%	N/A	N/A	N/A	
		1 h vs. 4 h	65%	N/A	N/A	N/A	
		2 h vs. 4 h	30%	N/A	N/A	N/A	
Resting Respiratory Rate		4 h vs. 24 h	30%	2.4	2.8	2.6	
		24 h vs. 72 h	20%	1.0	1.6	1.6	
	Decrease	30 min vs. 2 h	65%	N/A	N/A	N/A	
		1 h vs. 4 h	65%	N/A	N/A	N/A	
		2 h vs. 4 h	25%	N/A	N/A	N/A	
		4 h vs. 24 h	25%	1.6	1.2	1.2	
		24 h vs. 72 h	15%	1.2	1.4	1.4	

THRESHOLD CLINICAL NOTIFICATIONS

- **High Heart Rate Threshold:** Heart rate 60 minute median is above 115 bpm for in facility patients and above 105 bpm for at home patients (configurable by patient).
- Low Heart Rate Threshold: Heart rate 60 minute median is below 50 bpm (configurable by patient).

- **High Respiratory Rate Threshold:** Respiratory rate 60 minute median is above 28 bpm for in facility patients and above 26 bpm for at home patients (configurable by patient).
- Low Respiratory Rate Threshold: Respiratory rate 60 minute median is below 8 bpm (configurable by patient).
- **High Skin Temperature Threshold:** Temperature 60 minute median is above 37°C (98.6°F) (configurable by patient).
- Low Skin Temperature Threshold: Temperature 60 minute median is below 31°C (87.8°F) (configurable by patient).
- **Double High:** 60 minute median heart rate is above 100 bpm, and 60 minute median respiratory rate is above 24 bpm.
- **Triple High:** 60 minute median heart rate is above 100 bpm, and 60 minute median respiratory rate is above 24 bpm, and 60 minute median skin temp is above 36°C (96.8°F).
- 5. Notification Delays: The display of notifications in the user interface will be delayed by the processing of their signals. A summary of the delays associated with each signal processing step is shown in the table below:

SIGNAL PROCESSING STEP	DURATION OF DELAY
Vital Sign Calculation	60 seconds
Data Offloaded from BioIntelliSense wearable monitoring device to Gateway to BioCloud	20 minutes (average)
Data Received in BioCloud to Data Fully Decrypted and Processed	0.631 seconds (average)
Data Fully Processed to Algorithm Output Calculation	67.7 seconds (average personalized heart rate/ respiratory rate notifications), 61.7 seconds (average personalized skin temperature notifications), and 68.7 seconds (average threshold notifications)
Notification Output Determination to Notification Delivery from BioCloud to Internal Messaging Service (i.e. Confluent)	0.52 seconds (average)
BioDashboard Receiving a New Notification Message from Internal Messaging Service (i.e. Confluent) to Displaying Notification Icon in User Interface	69.2 seconds (average)
Total Processing Time	23.3 minutes

PATIENT REGISTRATION

 BioDashboard Registration: When the Add Patient Button is clicked in Multi-Patient View (described above), the following registration form is displayed. Enter the registration information for the new patient and click the "+Add Patient" button to register the patient. A BioID must be entered to begin collecting data with a BioIntelliSense device. A new patient cell will appear in the Multi-Patient View for this patient in a few moments.



Patient				
Patient ID/MRN*	First Name*	Last Name*	Sex*	
			○ M ○ F ○ U	
Date of Birth*	Height(cm)	Weight(kg)	Admission Date*	
25/06/2024			25/06/2024	
Zone shift in charge phone number	Arabic Interpreter*	Patient Phone Number		
Device				
Wearable ID*	Date Applied*			
	25/06/2024			
tiolatallisopse Care Coordinator				
BioIntelliSense Coordinate First Name*	BioIntelliSense Coordinator Last Name*	Bio Coordinator Phone*		
lext of Kin				
Next of Kin First Name*	Next of Kin Last Name*	Next of Kin Contact Number*		
Diagnosis				
Diagnosis	Procedure	Procedure Date		
		25/06/2024		

IMPORTANT NOTE: Display PHI must be enabled in the Multi-Patient View Settings to access these features. Some of the fields shown above may not be displayed or may be different depending on your configuration.

PATIENT REGISTRATION (CONTINUED)

2. BioDashboard Edit Patient Registration: When the Edit Patient Button is clicked in the Patient Detail View (described above), the following registration form is displayed. Enter the updated information for the new patient and click the "Save" button to update the patient information. A new BiolD may be entered to begin collecting data with a new BiolntelliSense device. The updated patient information will appear in the corresponding patient cell in the Multi-Patient View and Patient Detail View for this patient in a few moments after editing.

IMPORTANT NOTE: Display PHI must be enabled in the Multi-Patient View Settings to access these features.

Some information is unable to be updated with the update patient registration form and will appear in gray. Some of the fields shown above also may not be displayed or may be different depending on your configuration.

Detiont			
atient ID/MRN*	First Name*	Last Name*	Sex*
Date of Birth*	Height(cm)	Weight(kg)	Admission Date*
25/06/2024			25/06/2024
Zone shift in charge phone number	Arabic Interpreter*	Patient Phone Number	
evice			
Wearable ID*	Date Applied* 25/06/2024		
ioIntellisense Care Coordinator BioIntelliSense Coordinate First Name*	BioIntelliSense Coordinator Last Name*	Bio Coordinator Phone*	1
lext of Kin			
Next of Kin First Name*	Next of Kin Last Name*	Next of Kin Contact Number*]
iagnosis			-
Diagnosis	Procedure	Procedure Date 25/06/2024	

3. Electronic Medical Record Patient Registration: Patients can also be registered, transferred, or discharged through the electronic medical record (EMR), if applicable. Contact your hospital administrator for more information.



HELP MENU

1. When the Help Menu Icon is clicked in Multi-Patient View (described above), the following help menu is displayed. The following options are available:



- **Help:** Click tab to display the Help Pages. This lists the help options that are available and the BioIntelliSense Technical Support Email Address.
- **Color Limits:** Click this tab to display definitions of colors for vital signs in the Multi-Patient View and for body organs and other biometrics in the Patient Detail View.
- **Icons and Notifications:** Click this tab to display definitions of notifications and their associated icons.
- Selected Census Dropdown: Click this dropdown to view the different census configurations for color limits and notifications, based on the configuration available.

HELP COLOR LIMITS ICONS & NOTIFICATIONS
Welcome to BioDashboard,
Select the tabs above to get more information about:
Color Limits - A breakdown of the color levels for the organs, labs and elements
Icons & Notifications - List of notifications and associated icons
Please contact support@biointellisense.com for any questions or further assistance

ABOUT MENU

Clicking the About Button in the banner on the left side of the screen displays the BioDashboard version number and other software identification information, as well as provides access to the BioDashboard Instructions for Use.



(Q)(O)	BioDashboard Enter Search Term
>	
*	BioIntelliSense, Inc. About BioDashboard
	This Platform and Product is operated by BioIntelliSense, Inc. All other feedback, comments, requests for technical support and other communications relating to the Platform and Product should be directed to support@biointellisense.com
	For detailed instructions, reference the BioDashboard Instructions for Use document.
	Model Number: SW-BDB Part Number: SW-BDB-0002 UDI: (01) 00800005949466 (4326) 2025-02-12 (8012) 2.3
	► System Debug Information
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Troubleshooting and FAQs

If additional support is required, please call 888.908.8804 (US) or email support@biointellisense.com.

Safety and Regulatory Information

Version Number: 0002 Model Number: SW-BDB Product Name: BioDashboard V2 Part Number (PN): SW-BDB-0002 GTIN: 00850005949466

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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RESPONSIBLE PARTY: BioIntelliSense, Inc.

570 El Camino Real #200 Redwood City, CA 94063

TERMS OF USE STATEMENT

NOTICE: Use of the BioIntelliSense Product(s) is subject to our:

- Website and Product User Terms of Use at www.biointellisense.com/website-and-product-userterms-of-use
- Website and Product Privacy Policy at www.biointellisense.com/legal/privacy-policy

By using the Product(s), you indicate you have read these terms and policies and that you agree to them, including the limitations and disclaimers of liability. In particular, you understand and consent that use of the Product(s) measures and records personal information about you, including vital sign and other physiologic measurements. That information may include respiratory rate, heart rate, temperature, activity level, sleep duration, body position, step count, gait analysis, coughing, and other symptomatic or biometric data. You understand that the Product(s) do not render medical advice or diagnose or prevent any specific disease, including any communicable disease or virus. If you have any concerns about your health, including whether you have been exposed to or have contracted any disease or virus, immediately contact your healthcare provider.

SYMBOL LIBRARY



Medical device

RONLY For prescription use only

Caution Consult Instructions for use i

Technical Specifications

Product Name Version Number BioDashboard V2 0002

COMMUNICATIONS

Security

AES 128 bit encryption/TLS 1.2 for data transfer AES 256 bit encryption for data at rest

Contact Us

For non-urgent support or questions about our product, please call 888.908.8804 (US) or email support@biointellisense.com

MANUFACTURED BY

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