

Known Anomalies for Clinicians – Project BFG

Rev A

Relevant IFU(s)	ID	Description	Impact on Safety and Efficacy	Mitigation
WIFU	CPMAE-126	<p>QRS detection algorithm returning non-unique QRS locations.</p> <p>This bug potentially leads that non-diastolic heart sounds strength can't be computed because QRS complex locations are used to segment the 1st and 2nd heart sounds.</p> <p>Occurrence of this anomaly is extremely low.</p>	2-Minor Risk	None. Clinician gets no information instead of inaccurate information.
WIFU	15991	<p>On Customer administration application, there is a field for setting patient's specific time zone.</p> <p>The dropdown list for this time zone field needs to be shortened to only include time zones applicable to the patients from the countries this product will be offered</p> <p>The list already includes the list of countries.</p>	1-Negligible Risk	None

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WIFU	16128	<p>On Customer management application – while adding/editing a patient the autocomplete feature is enabled which provides the user an option from previously saved details.</p> <p>If there are multiple patients to load a user error can cause incorrectly adding patient details</p>	2-Minor Risk	None
WIFU	16133	<p>On the customer admin application, when a user tries to Edit a patient, an error occurs when the alternate contact is changed</p> <p>A user can enter valid alternate contact information</p>	1-Negligible Risk	None Needed
WIFU	3965	<p>Logistics UI : Login button is displayed after user signed in.</p> <p>This UI is rarely used by the manufacturer administrator The user may disregard the log-in button.</p>	2- Minor Risk	None. Minor inconvenience to the user.

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WIFU	8600	Customer admin network outage error message is not displayed if the user opens the Program Details page without an internet connection.	1-Negligible Risk	None. Minor inconvenience. The software is not usable during a loss of internet connectivity, irrespective of the error message. The user may briefly be confused before realizing via other means that their internet connection has dropped.
WIFU	12158	On Customer Admin, the "Last updated" date is not updated immediately after making changes on Care Setting. It can take a few seconds.	1 – Negligible Risk	Minor inconvenience. SSO users do not use this flow. Non-SSO users should check to make sure they are inputting their correct email address when initiating the "forgot password" workflow.
WIFU	12218	On Customer Admin, the "Last updated" date is not updated immediately after making changes on Care Setting. It can take a few seconds.	1 – Negligible Risk	None Needed. The feature is working as intended User can refresh the page or see the updates after couple of seconds
WIFU	12252	No "Cancel Modal" window pops up when the user cancels the "add patient" action in the Customer Administration UI.	1 – Negligible Risk	None. Users are trained to use the Add Patient feature

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WIFU	16901	An incorrect message is displayed to a user if they enter their code manually and use a keyboard enter action	1 – Negligible Risk	None. A user can continue verifying the multifactor authentication code using the verify code action button on the login user interface
WIFU	20697	Inactive users can reset their passwords using Forgot Your Password feature	1 – Negligible Risk	None. The password can be reset however the user is blocked from login since account status is inactive
WIFU	21556	When a user attempts to navigate to an invalid patient, an error message is displayed along with a loading indicator.	1 – Negligible Risk	None. A descriptive error message is shown to the user.
WIFU	21694	List of Programs are displayed after applying a filter, even when the search results show "No programs" for the previous search. Additionally, the search text remains in the search bar.	1- Negligible Risk	Functionality is not affected, and user can still search for programs
WIFU	21927	Clicking on the browser's back button is navigating users back to the Terms of Use page and prompting them to review and accept, even if they had already completed that.	1 - Negligible Risk	Minor inconvenience. User should refresh and proceed to login again.

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WIFU	22022	User is either navigated to a different page or an error is displayed up on clicking on the "Cancel" button from the forgot password screen.	1 – Negligible Risk	User should refresh if an error is displayed or click on the "Go back to Login" button if they are redirected to a different page.
WIFU	22124	User is getting an error message" you don't have the required permission to perform this action. " While switching from one institute to the other even though the user has the correct permission and still able to perform all actions.	1 - Negligible Risk	None. User is still able to perform the required action despite the error message.
WIFU	22182, 22183	A generic error message is displayed when user refreshes while they are on the send verification step/page after initiating a login process.	1 - Negligible Risk	None. User can refresh the page and are navigated to login page.
WIFU	22188	An unclear error message is displayed to a user when the Internet connection is lost while creating a patient.	1 - Negligible Risk	Functionality is not affected as the user can continue creating a patient once Internet connection is restored

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WIFU	26500	During the authentication flow, an incorrect error message is displayed to a user even after they have completed the verify code action and completed the verification successfully.	1 - Negligible Risk	Inconvenience. The error message does not prevent a user login and therefore any actions within the application that they are authorized to carry out.
WIFU	29191	During the Kit activation flow, some requests failed with errors when the load reached approximately 100 concurrent requests.	1 – Negligible Risk	None.
WIFU	30526	A Program's state remains new instead of updating to active, after an active patient is linked to the program.	2 - Minor Risk	None Needed. Program Status indicators are not used to manage patient's status
WIFU	30913	When a user refreshes while viewing a specific institution, they are redirected to the first institution listed in the Institution menu, rather than staying on the same page.	1 - Negligible Risk	User can select the institution again from the Institutions dropdown menu to continue viewing.

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WIFU	31814	When accessing program settings without an internet connection, the user encounters an infinite loader instead of a 'No internet connection' warning message.	1 – Negligible Risk	User can continue navigating the program setting page once Internet connection is restored.
WIFU	3145	CPM system is affected by AWS Lambda cold start. Loading data is slow if you haven't used the system in a while.	2-Minor Risk	Minor inconvenience.
WIFU	3781	During a Forgot password user flow, a error message from a previous user action is not cleared when a authenticated user moves to the next form/page even after addressing the actual error.	1- Negligible Risk	Inconvenience. The error message does not prevent a user to complete their password reset flow and login to the application.
WIFU	4891	If the user clicks "log-in" without entering a password, there's a minor layout error that causes the on-screen error "Please enter your password" and "Forgot your password?" to overlap slightly with the password field.	1- Negligible Risk	Minor inconvenience. The feature can be used as intended.

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WIFU	7904	The 'Select/Load/View' option in the ECG display on the web application is being overridden by the 'Include Data in Trend Chart' in the web application. This will require the clinician to reload the web page to view the desired ECG display. 'Include data in Trend Chart' is overriding 'Select load / view' option regarding ECG display	1 – Negligible Risk	Minor inconvenience. Reload the selected view by refreshing the web page.
WIFU	7935	The ECG can be "pinched and dragged" but at the very end of the ECG strip, the pinch+drag function fails and the last .5 seconds of the ECG strip is not visible.	1 – Negligible Risk	Minor inconvenience. The user can drag the graph to the end using the slide bar below the ECG graph, making the entire ECG strip visible.
WIFU	7936	If the user moves the ECG graph to the last 2 seconds of the ECG strip, then zooms in significantly, and then clicks autoscale, the ECG disappears and the whole graph area becomes white.	1 – Negligible Risk	The feature works as expected at typical resolution. The user can zoom back out one click to restore the visual graph.

Relevant IFU(s)	ID	Description	Impact on Safety and Efficacy	Mitigation
WIFU	96, 933, 329	'In the Manage Reading & Select Baseline modal interface, the "slider button" (that allows the user to select individual readings for which data should be included in the trend chart) unselects itself if the user moves between multiple pages of historical readings without saving their selection first.	1 – Negligible Risk	Minor inconvenience. Users should be trained to save their selections per-page of results before moving on to view another page of results.
WIFU	9725	A reading that is still being processed or that has failed to process can be selected as a patient's baseline.	1 – Negligible Risk	Minor inconvenience. Users should always review a reading before using it as the baseline, and should only select representative readings (relative to a given patient) to use as a baseline.
WIFU	10678	There is a grammatical error in the footer text. The word "diagnostic" is used, rather than "diagnosis".	1 – Negligible Risk	None. The feature can be used as intended.
WIFU	16178	When patient id is in lower case letters CPM UI fails to fetch Patient Details.	1 – Negligible Risk	While searching a patient, a user can select the offered suggestion and complete their search. It redirects and loads all data properly. Alternatively, a user can replace the patient id completely in the URL and reload.

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WIFU	20375	Patient search is unresponsive when non-Latin characters are typed in the input fields.	1 – Negligible Risk	A user can still continue using patient search feature for valid patient ID and Patient Names.
WIFU	20761	The unit of measurement displayed on the Y-axis of the trends graph does not update correctly when the user toggles between Celsius or Fahrenheit while viewing a patient with no recoded readings.	1 – Negligible Risk	This does not impact functionality, as no data is available to display for patient without readings. The graph displays correctly when viewing information of patient with existing readings.
WIFU	20790	In the Vital records section, users are able to choose any future date to input vital records of a patient without triggering any error which allows entry of false information.	2 – Minor Risk	Today Vitals feature in the CPM web is not used that frequently as part of monitoring. When it's used, users are trained to select valid dates to record vital information
WIFU	21310	A user is prompted to accept an updated version of the Terms of Use, but the modal does not have a clear explanation that these terms have been revised. This can lead to confusion, as the user may think they are being asked to accept the same terms they previously agreed to.	1 – Negligible Risk	The Terms of Use feature is working as expected. Users can still accept the Terms of Use and continue to login into the application.

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WIFU	22084	A user with read-only permissions can attempt to add new vitals but is unable to save the details, and an appropriate error message is not displayed.	1 – Negligible Risk	None Needed. The user is not able to save the vital records even though they are able to create a new one, this is acceptable as their role should only allow for reviewing existing records and not creating new ones. User is able to review the details as expected
WIFU	22086	A user is unable to open the Terms of Use contents when attempting the link in a new window; Instead, the patient's detail page is displayed.	1 – Negligible Risk	The user should open and review the Terms of Use from the main page instead of launching it in a new window.
WIFU	22185	A user signing in with SSO account is getting an error while they refresh their page which has the “Send Verification Code” feature	1 – Negligible Risk	None. There is a message on the form which informs the user not to refresh the page before completing the verification flow.

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WIFU	27008	The system represents the decreased trended values with both a negative sign and also with a downward arrow icon next to the numeric value.	2 – Minor Risk	No workaround. The actual value is not inaccurately represented. There are 2 indicators which indicate the downward trend for the measurement parameters
WIFU	28113	The year indicated in the copyright information is outdated.	2 – Minor Risk	None. The feature can be used as intended
WIFU	28149	The user is unable to log out if they have previously canceled a logout request; they must refresh the page and try again to successfully log out.	1 – Negligible Risk	The user should refresh the page and attempt to logout again.
WIFU	28861	An active patient’s data is not displayed on the CPM web’s Patient’s Detail page when their kit is deactivated. However, when a patient’s kit is reactivated (with a new device) and the patient uploads new measurements, it details accurately	2- Minor Risk	No workaround. Users have to be trained to use the application to view patient’s measurements when the patient has a kit that is activated.
WIFU	29827	The search history is not cleared after removing the patient ID or name form the search box	1 – Negligible Risk	No workaround The feature can be used as intended

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WIFU	30918	On pressing the browser's back button from the patient detail page, a user is navigated back to Terms of Use page even if they had accepted them before.	2 – Minor Risk	None needed. Users can accept the terms of use and navigate back to the patient search page to continue with monitoring patient
WIFU	31332	A clear error message does not appear when a user refreshes the page during the login process after entering their username	1 – Negligible Risk	None needed. Once the internet connection is restored, the user can refresh the page and proceed to log in again.
WIFU	31340	The date format in the Delta Z section of the parameter details chart appears incorrectly when certain parameters are filtered.	1 – Negligible Risk	This issue does not impact functionality, as the correct date is still displayed to the user, although in a different format. Additionally, users can obtain the necessary information from the graph.
WIFU	31406	The "clear breach notification" button inside the Trends and EGG section is not displayed while viewing patients who don't have threshold breaches.	1 – Negligible Risk	Minor inconvenience. The button is not displayed only for patients who don't have threshold breaches, so it doesn't affect the functionality

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WIFU	31429	The error message displayed during the loss of Internet connection while searching for a patient is not detailed.	1 – Negligible Risk	The error message displayed still indicates that something has went wrong even if it's not precise. User can continue to search once Internet connection is restored.
WIFU	30919	No error message is shown to the user when the internet connection is lost while attempting to accept the Terms of Use.	1 – Negligible Risk	The user can still continue to review and accept the Terms of User when the Internet connection is restored.
CIFU	3237	Correct device battery percentage is not displaying in mobile app	1-Negligible risk	Disconnect the wearable and reconnect to get a battery level.
CIFU	4147	Mobile app: Systolic, Diastolic bp and weight fields behavior should be same across the Mobile and Web applications	1-Negligible risk	The feature can be used as intended. Users must be attentive to manually entered values. Users can check values in the CPM Web UI, where validations are working properly.
CIFU	6080	Time zone drop-down - A user views a list of all the global time zones in the dropdown list and must scroll through the entire list to locate the US time zones, currently not prioritized in the list.	1-Negligible risk	No workaround - the feature can be used as intended. A user can scroll through the list and select applicable US time zones while onboarding the patients with the clinician mobile app

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CIFU	6676	Forgot password field is overlapping in password field	1-Negligible risk	No workaround - the feature can be used as intended.
CIFU	6734	During measurement, step out of App for a minute and come back, Mobile App remains in a spinning loop.	1-Negligible risk	No workaround. Users are trained to remain in the application during the reading until they have confirmation that the baseline reading is complete.
CIFU	6976	Mobile App - Authorization failure message is confusing	1-Negligible risk	The user is instructed to contact an administrator when any access issue occurs. The administrator can resolve this issue with some quick investigation.
CIFU	7592	Unhelpful error message when trying to save patient details at baseline reading	1-Negligible risk	No workaround - feature can be used as intended.
CIFU	8465	"Steroid" is misspelled in the Mobile App "warnings and precautions" page	1-Negligible risk	No Workaround. Feature works as intended
CIFU	8466	Inconsistency in Error Dialog - Scenario: Bluetooth Turned Off in Mobile	1-Negligible risk	No Workaround. Can be used as intended.
CIFU	8467	Inconsistency in Error Dialog - Scenario: Device connected to Base Station during active Bluetooth communication	1-Negligible risk	No workaround. Can be used as intended.

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CIFU	16173	Patient-ID is overlapping in the patient details page	1-Negligible risk	Minor inconvenience. No workaround, feature can be used as intended
CIFU	21896	Location prompt not appearing again after selecting "Only this time" setting for select android versions.	1-Negligible risk	No workaround, feature can be used as intended. This is an android level constraint. User can continue taking the reading as the location permission was set up the first time.
CIFU	24172	Not able to discover the CPM Wearable over BLE, when tried frequently.	1-Negligible risk	Wait for 30 seconds and retry.
CIFU	24299	Getting 'Patient Data Failure' error though internet connectivity present after successful reading	1-Negligible risk	Check mobile internet connectivity and try again
CIFU	26265	Lean Forward Tilt error message is not coming in Position 2 reading page	1-Negligible risk	User can try correcting the body posture or they can skip this error modal

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CIFU	31921	Mobile app unable to delete the measurement files when the file size is reached maximum in wearable	1-Negligible risk	Minor inconvenience, to free up space on your wearable device, connect it to the base station. The base station will upload the measurement files to the cloud and then delete the files from the wearable device.
CIFU	32032	Intermittent issues in the threshold and medical details page	1-Negligible risk	No workaround - feature can be used as intended.
CIFU	29488	Wearable Device communication stuck at device handshake with base station.	1-Negligible risk	Need to unplug and re plug the magnetic cable
CIFU	29489	In very rare occasions the base Station is entering into reprovisioning state when kept for overnight.	1-Negligible risk	Contact the technical support line in the event of inability to take a measurement. Base station may have to be replaced.