



# VivoSense®

## User Manual - BioRadio Import Module

VivoSense® BioRadio Import Version 3.1

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**Cautions and disclaimer**

VivoSense® software is not a medical diagnostic tool and is intended for research and investigational purposes only. VivoSense® is not intended to be, or to replace, medical advice or review by a physician.

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# Table of Contents

|       |   |    |
|-------|---|----|
| 1.    | Introduction.....                               | 4  |
| 1.1.  | VivoSense® for BioRadio .....                   | 4  |
| 1.2.  | System Requirements.....                        | 4  |
| 2.    | Importing Data .....                            | 5  |
| 2.1.  | .bcrx File.....                                 | 5  |
| 2.2.  | BioCapture .....                                | 8  |
| 3.    | Processing Data Channels .....                  | 10 |
| 3.1.  | Accelerometer Data Channels .....               | 10 |
| 3.2.  | Electrocardiogram (ECG) Data Channels.....      | 10 |
| 3.3.  | Respiration Data Channels .....                 | 12 |
| 3.4.  | Electroencephalogram (EEG) Channels.....        | 12 |
| 3.5.  | Electromyogram (EMG) Channels .....             | 13 |
| 3.6.  | Pulse Oximeter Data Channels.....               | 14 |
| 3.7.  | Galvanic Skin Response (GSR) Data Channels..... | 14 |
| 3.8.  | Spirometer Data Channels.....                   | 14 |
| 3.9.  | Temperature Data Channels.....                  | 15 |
| 3.10. | Generic Data Channels .....                     | 16 |
| 4.    | BioRadio Layouts .....                          | 18 |

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# 1. Introduction

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## 1.1. VivoSense® for BioRadio

This manual describes the use of the BioRadio import module for VivoSense® software and its ability to import and analyze data collected with BioRadio series sensor system. The BioRadio import module is generally included as part of the core version of VivoSense®.

For more information about available data and capabilities of the BioRadio, please refer to the BioRadio user manuals.

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## 1.2. System Requirements

The BioRadio import module is an add-on module to VivoSense®. In addition to VivoSense® requirements, the BioRadio import module has the following system requirements:

- BioRadio wireless receiver – to receive data wirelessly from the BioRadio and transfer it to a PC.
- BioRadio accessories – specific to the type of data desired (e.g respiration band, ECG electrodes, etc)
- BioCapture software – visualizes and records real-time data from the BioRadio.

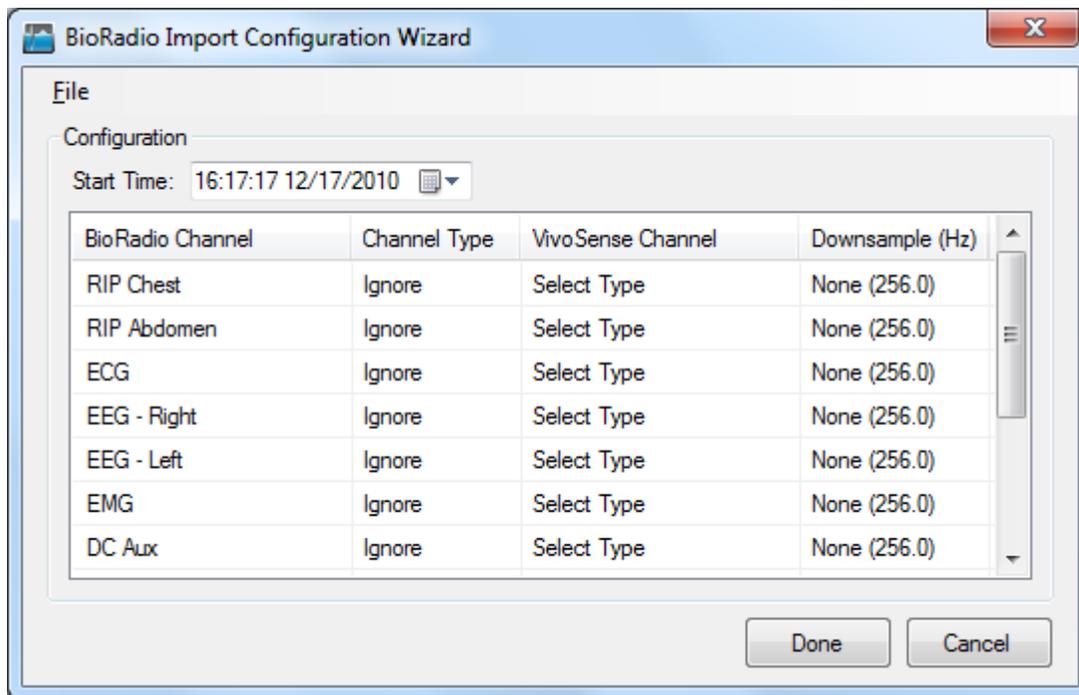
## 2. Importing Data

Ambulatory physiological data from the BioRadio system is recorded through Cleveland Medical's BioCapture software and stored as a .bcr/.bcrx file on the PC.

The .bcr/.bcrx file and BioCapture are discussed in the following two sections.

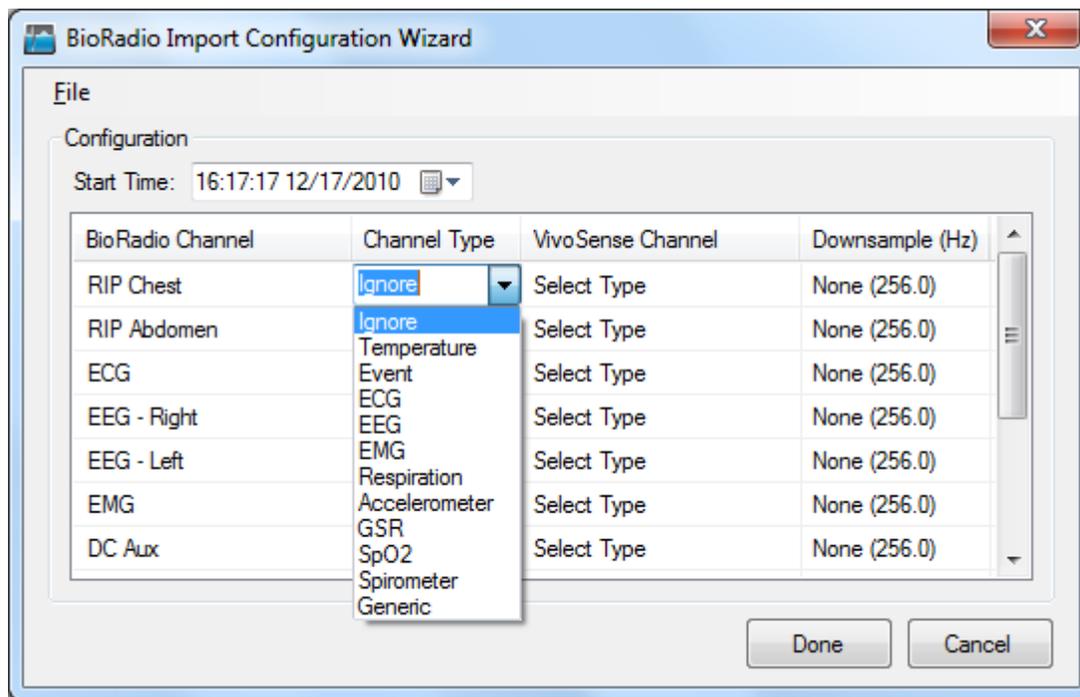
### 2.1. .bcrx File

VivoSense® can import .bcrx files saved from BioCapture. The BioRadio import option is available from the File -> Import Hardware File menu. Upon selecting a .bcrx file, VivoSense® will open the file and look for all available data channels. These channels will then be presented along with a mapping of channels that VivoSense® can import in the Import Configuration Wizard. See Figure 1.



**Figure 1. BioRadio Import Configuration Wizard**

At this point, a user can select all or a subset of the channels that they would like to analyze in VivoSense®. To do this, find the row of the desired channel and then click once on the Channel Type entry. A drop down box will appear with the possible options. Upon choosing the desired type, a corresponding VivoSense® channel name will automatically be selected for you. See Figure 2.



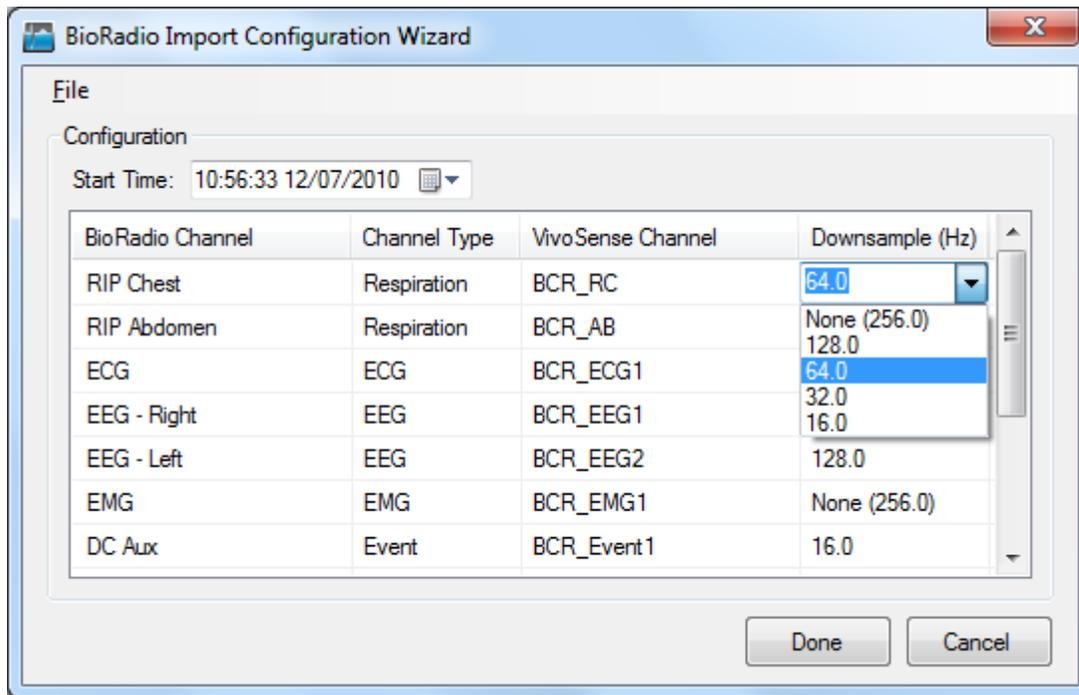
**Figure 2. BioRadio Import Configuration Wizard - Selecting a channel type**

If you would like to modify the VivoSense® channel name, simply click on it and another drop down box will appear with alternative possibilities. A VivoSense® channel name can only be used once. This will result in an error message after selecting the 'Done' button if multiple BioRadio channel names have been assigned to a single VivoSense® channel.

VivoSense® will automatically down sample BioRadio channels to the minimum appropriate sampling frequency possible for the selected channel type. Down sampling reduces unnecessary file size and noise in the data caused by over sampling a channel. For example, an accelerometer channel sampled at 256 Hz alongside an ECG channel, will be automatically down sampled to 64 Hz, while the ECG channel will remain sampled at the appropriate rate of 256 Hz.

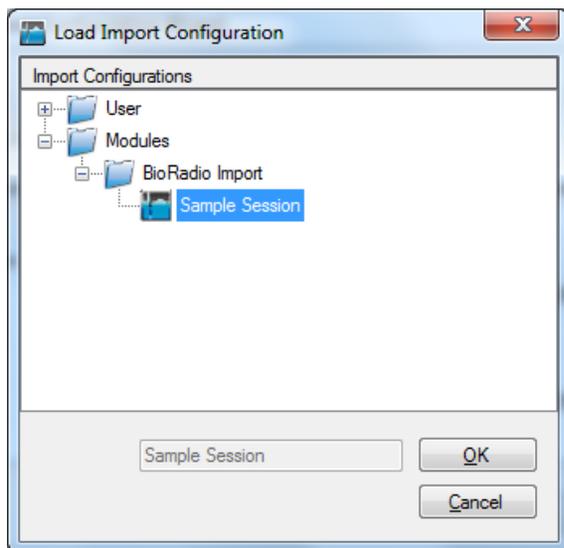
VivoSense® will down sample appropriate channels in factors of 2. A 256 Hz channel will be down sampled to 128 Hz > 64 Hz > 32 Hz and so on.

The down sample rate can be modified by using the drop down menu in the File Import Configuration. The down sample rate can be set back to the original sample rate by selecting a down sample rate of "None". See Figure 3.



**Figure 3. BioRadio Import Configuration Wizard - Downsample**

Once you have created the desired mapping of BioRadio channels to VivoSense® channels, press the 'Done' button. If this is a new configuration, you will be prompted to save your configuration for later use. This can significantly speed up subsequent imports of files with the same configurations by allowing VivoSense® to automatically perform the mapping process for you. Figure 4 displays how on the second import of a file with the same channels, a configuration can be loaded that automatically selects the previously saved VivoSense® channels.



**Figure 4. BioRadio Import Configuration Wizard – Loading a Configuration**

If the time is not automatically imported, the start time of the recording can be set within the Import Configuration Wizard. Click on any number within the Start Time Box to change it to the desired value. The format is HH:mm:ss dd/MM/yyyy. Clicking on the Start Time Box's document icon will cause a calendar to appear that allows for quick selection of the recording date. This start time will be saved and applied along with the channel mappings when a configuration is used in later imports.

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## 2.2. BioCapture

The BioCapture software allows configuration and data recording from a single BioRadio. A brief overview of the recording process is provided here and a more detailed explanation can be found in Cleveland Medical's BioCapture documentation.

To set up BioCapture for a recording, first start the program and search for nearby devices. Your BioRadio must be turned on and close by for this to work. Once discovered, your BioRadio can be configured to start recording. Users create channel configurations that include the name of the signal to be recorded as well as any scaling that should be applied before the data are saved. See Figure 5.

It is important to note that the names given to the data channels at this point will be read in by VivoSense® at the time of import. Using descriptive channel names is highly recommended as this will make the import process much easier.

After your BioRadio series device has been configured, press the record button to begin saving real-time data. After finishing your recording, press the stop button and then save the .bcrx file when prompted. The data file may now be imported into VivoSense® as described in section 2.1.

Please note that BioRadio data may be susceptible to radio loss if the subject moves out of range. Dropped data will appear in VivoSense® as blank spaces in the data plots. VivoSense® will perform calculations around these losses and all VivoSense® statistics and algorithms will refer only to the available data.

Configure Device
— □ ×

Configuration Name 
Bandwidth : 16 Kbps Wireless Memory

Programmable Channels  Single-Ended  Differential
Sample Rate:  Hz

| Ch.                                 | Name                                 | Type                        | Resolution                        | Input Range |
|-------------------------------------|--------------------------------------|-----------------------------|-----------------------------------|-------------|
| <input checked="" type="checkbox"/> | <input type="text" value="CHEST"/>   | RIP <input type="text"/>    | <input type="text" value="1 μV"/> | +/- 0.187 V |
| <input checked="" type="checkbox"/> | <input type="text" value="ABDOMEN"/> | RIP <input type="text"/>    | <input type="text" value="1 μV"/> | +/- 0.187 V |
| <input type="checkbox"/>            | <input type="text" value="Ch3"/>     | Custom <input type="text"/> | <input type="text" value="1 μV"/> | +/- 0.187 V |
| <input type="checkbox"/>            | <input type="text" value="Ch4"/>     | Custom <input type="text"/> | <input type="text" value="1 μV"/> | +/- 0.187 V |

Sensor Pods

Motion Sensors

All Sensors

Program
Cancel

Figure 5. BioCapture – BioRadio Device Configuration

## 3. Processing Data Channels

Available data channels from BioRadio devices may be divided into 2 categories: Raw data channels from the device and derived channels – as calculated by VivoSense®.

The raw data channels from BioRadio are located in the Data Explorer under the “Raw” node. They include Waveforms, Measures and Information channels, as described in the following sections. All Raw channels are prefixed with BCR\_. For complete information regarding the data in each of these channels, please consult the hardware documentation for the specific BioRadio unit.

The core VivoSense® manual contains a general description of the derived channels. Only the derived channels that are particular to the BioRadio product are described here.

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### 3.1. Accelerometer Data Channels

The BioRadio accelerometer measures acceleration along 3 axes denoted by BCR\_AccX, BCR\_AccY and BCR\_AccZ (Lateral, Longitudinal and Vertical respectively). The raw data is measured in computer units (cu) with an arbitrary offset. The conversion to physical units in the derivation of Core Channels (AccX, AccY and AccZ) is obtained by scaling the raw data with a constant gain provided by the manufacturer and by shifting the offset by an amount specific to the individual hardware. This calibration is done automatically upon import. See the VivoSense® core manual for additional information regarding axis definitions.

#### ***Raw Accelerometer Waveforms***

##### BCR\_AccX

Acceleration, measured along the X axis

##### BCR\_AccY

Acceleration, measured along the Y axis

##### BCR\_AccZ

Acceleration, measured along the Z axis

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### 3.2. Electrocardiogram (ECG) Data Channels

VivoSense® provides the ability to import up to two ECG signals for analysis. These are denoted as BCR\_ECG1 and BCR\_ECG2. VivoSense® will process both channels and perform QRS detection on both to generate two sets of R-wave markings.

VivoSense® further provides options to select one of the ECG channels as the primary source ECG for further analysis (i.e. derived measures such as RR and HR). This selection may be performed by navigating to the Properties of the RR channel and selecting either RR1 or RR2 from the Source Channel dropdown menu.

If only one ECG is recorded, it will not be necessary to select the source channel.

## ***Raw Electrocardiogram Waveforms***

### **BCR\_ECG1**

Primary ECG raw signal

### **BCR\_ECG2**

Secondary ECG raw signal

## ***Electrocardiogram Waveforms***

### **Ecg1**

Filtered BCR\_ecg1.

### **Ecg2**

Filtered BCR\_ecg2.

## ***Electrocardiogram Markings***

### **Rwave1**

This channel identifies the peak of the R-wave on the corresponding Ecg1 waveform. These markings are provided as a result of the QRS detection algorithm implemented in VivoSense®.

### **Rwave2**

This channel identifies the peak of the R-wave on the corresponding Ecg2 waveform. These markings are provided as a result of the QRS detection algorithm implemented in VivoSense®.

## ***Electrocardiogram Measures***

### **RR**

RR is a duplicate of either RR1 or RR2 depending on the selection for the 'Source Channel' property of RR and represents the time interval between two consecutive R-waves in seconds. All subsequent derived measures, for example heart rate, heart rate trends, or heart rate variability calculations, are derived from the primary selected RR channel. A secondary Ecg signal allows the user to choose the optimum source channel based on data quality and accuracy of R-wave markings.

### **RR1**

This channel represents the time interval between two consecutive R-waves in seconds as marked by Rwave1. This channel may be further used to adjust specific parameters of the QRS detection algorithm for Ecg1.

### **RR2**

This channel represents the time interval between two consecutive R-waves in seconds as marked by Rwave2. This channel may be further used to adjust specific parameters of the QRS detection algorithm for Ecg1.

### 3.3. Respiration Data Channels

VivoSense® allows for the import of up to four respiratory signals within a single .bcrx file. These signals can come from any combination of the following: One or two Respiratory Inductive Plethysmography (RIP) bands, located on either the abdomen or ribcage of the subject, and one or two Strain Gauge bands, located on either the abdomen or ribcage of the subject.

All respiratory measurements in VivoSense® are divided into two categories, RIP and Strain, depending on the source of the data. If both abdominal and thoracic signals are available for a particular respiratory band type, then all measurements will be derived by summing the two signals and performing the normal sequence of calculations (see Core manual). If only one signal is available for either the RIP or Strain type, then in some instances volumetric measurement may not be accurate due to contributions to the breathing cycle from two compartments (thoracic and abdominal) when only a single breathing compartment is being measured.

#### ***Raw Respiration Waveforms***

##### *BCR\_RC*

This is the raw respiration waveform recorded from the BioRadio. Thoracic excursions are measured in non-physical computer units. The tidal Volume waveform, RIP Vt, is derived from BCR\_RC by summing it with BCR\_RipAB (if available) and then scaling with a gain factor obtained from a calibration procedure performed automatically on import. This calibration factor is determined by scaling the estimated average peak to trough excursions to 400 ml.

##### *BCR\_AB*

This is the raw respiration waveform recorded from the BioRadio. Abdominal excursions are measured in non-physical computer units. The tidal Volume waveform, RIP Vt, is derived from BCR\_AB by summing it with BCR\_RipRC (if available) and then scaling with a gain factor obtained from a calibration procedure performed automatically on import. This calibration factor is determined by scaling the estimated average peak to trough excursions to 400 ml.

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### 3.4. Electroencephalogram (EEG) Channels

The BioRadio system allows for the connection of an up to eight EEG sensors.

#### ***Raw Electroencephalogram Waveforms***

##### *BCR\_EEG1*

This is the first raw EEG signal.

##### *BCR\_EEG2*

This is the second raw EEG signal.

##### *BCR\_EEG3*

This is the third raw EEG signal.

**BCR\_EEG4**

This is the fourth raw EEG signal.

**BCR\_EEG5**

This is the fifth raw EEG signal.

**BCR\_EEG6**

This is the sixth raw EEG signal.

**BCR\_EEG7**

This is the seventh raw EEG signal.

**BCR\_EEG8**

This is the eighth raw EEG signal.

---

## **3.5. Electromyogram (EMG) Channels**

The BioRadio system allows for the connection of an up to eight EMG sensors.

### ***Raw Electromyogram Waveforms***

**BCR\_EMG1**

This is the first raw EMG signal.

**BCR\_EMG2**

This is the second raw EMG signal.

**BCR\_EMG3**

This is the third raw EMG signal.

**BCR\_EMG4**

This is the fourth raw EMG signal.

**BCR\_EMG5**

This is the fifth raw EMG signal.

**BCR\_EMG6**

This is the sixth raw EMG signal.

**BCR\_EMG7**

This is the seventh raw EMG signal.

**BCR\_EMG8**

This is the eighth raw EMG signal.

---

## 3.6. Pulse Oximeter Data Channels

The BioRadio can connect to an optional Nonin pulse oximeter that calculates oxygen saturation and pulse rate.

### ***Raw Pulse Oximeter Measures***

#### *BCR\_SpO2*

This raw measurement is calculated internally on the pulse oximeter, and provides an indication of percent oxygen saturation.

#### *BCR\_PulseRate*

This raw measurement is calculated internally on the pulse oximeter, and provides heart rate in beats per minute. These measurements are averaged to a one second interval.

---

## 3.7. Galvanic Skin Response (GSR) Data Channels

The BioRadio system allows for the connection of an optional sensor for measuring Galvanic Skin Response (GSR).

### ***Raw Galvanic Skin Response Waveforms***

#### *BCR\_GSR*

This is the raw GSR waveform recorded from the optional sensor.

---

## 3.8. Spirometer Data Channels

The BioRadio system allows for the connection of an optional spirometer sensor for measuring air flow.

### ***Raw Spirometer Waveforms***

#### *BCR\_Spirometer*

This is the raw waveform recorded from the spirometer. VivoSense® expects this to be in millivolts.

### ***Spirometer Waveforms***

#### *Flow (Calibrated)*

This is the filtered and calibrated air flow waveform, which was derived from the raw BCR\_Spirometer waveform by applying a gain and offset, and then low pass filtering the signal. The gain is from hardware specifications. By default, the offset is set to the mean of the data.

## 3.9. Temperature Data Channels

VivoSense® allows the import of up to eight temperature waveforms from the BioRadio.

### ***Raw Temperature Waveforms***

#### *BCR Temp1*

This channel provides the raw temperature waveform from an optional external temperature sensor.

#### *BCR Temp2*

This channel provides the raw temperature waveform from an optional external temperature sensor.

#### *BCR Temp3*

This channel provides the raw temperature waveform from an optional external temperature sensor.

#### *BCR Temp4*

This channel provides the raw temperature waveform from an optional external temperature sensor.

#### *BCR Temp5*

This channel provides the raw temperature waveform from an optional external temperature sensor.

#### *BCR Temp6*

This channel provides the raw temperature waveform from an optional external temperature sensor.

#### *BCR Temp7*

This channel provides the raw temperature waveform from an optional external temperature sensor.

#### *BCR Temp8*

This channel provides the raw temperature waveform from an optional external temperature sensor.

### ***Temperature Waveforms***

#### *Temp1*

This is the calibrated temperature in degrees Celsius.

#### *Temp2*

This is the calibrated temperature in degrees Celsius.

#### *Temp3*

This is the calibrated temperature in degrees Celsius.

#### *Temp4*

This is the calibrated temperature in degrees Celsius.

Temp5

This is the calibrated temperature in degrees Celsius.

Temp6

This is the calibrated temperature in degrees Celsius.

Temp7

This is the calibrated temperature in degrees Celsius.

Temp8

This is the calibrated temperature in degrees Celsius.

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## **3.10. Generic Data Channels**

VivoSense® allows for the import of other raw data signals that may not yet be sold by Cleveland Medical, or are not yet fully supported.

### ***Raw Generic Waveforms***

BCR\_Generic1

This is the raw waveform for generic signal 1.

BCR\_Generic2

This is the raw waveform for generic signal 2.

BCR\_Generic3

This is the raw waveform for generic signal 3.

BCR\_Generic4

This is the raw waveform for generic signal 4.

BCR\_Generic5

This is the raw waveform for generic signal 5.

BCR\_Generic6

This is the raw waveform for generic signal 6.

BCR\_Generic7

This is the raw waveform for generic signal 7.

BCR\_Generic8

This is the raw waveform for generic signal 8.

## **Generic Trends**

### **Trend Generic1**

This is a computed trend of the raw generic waveform BCR\_Generic1. The default is comprised of the medians from five-minute windows.

### **Trend Generic2**

This is a computed trend of the raw generic waveform BCR\_Generic2. The default is comprised of the medians from five-minute windows.

### **Trend Generic3**

This is a computed trend of the raw generic waveform BCR\_Generic3. The default is comprised of the medians from five-minute windows.

### **Trend Generic4**

This is a computed trend of the raw generic waveform BCR\_Generic4. The default is comprised of the medians from five-minute windows.

### **Trend Generic5**

This is a computed trend of the raw generic waveform BCR\_Generic5. The default is comprised of the medians from five-minute windows.

### **Trend Generic6**

This is a computed trend of the raw generic waveform BCR\_Generic6. The default is comprised of the medians from five-minute windows.

### **Trend Generic7**

This is a computed trend of the raw generic waveform BCR\_Generic7. The default is comprised of the medians from five-minute windows.

### **Trend Generic8**

This is a computed trend of the raw generic waveform BCR\_Generic8. The default is comprised of the medians from five-minute windows.

## 4. BioRadio Layouts

VivoSense® contains a collection of Layouts specific to the BioRadio Import module. The following layouts are provided with the BioRadio Import module.

### Actigraphy

This is a set of Charts suitable for evaluating the motion or activity of a subject. This layout contains channels for each calibrated accelerometer axis as well as derived posture and motion measures.

### Breath Detection & Calibration

This is a specific set of Charts designed for adjusting the breath detection settings and calibrating the Vt waveform. All of the charts necessary for the examination of changes in breath detection are available. This layout also provides easy access to the Breath Detection channel (for adjusting breath detection settings) as well as the Calibration Volume channel (for performing a fixed volume calibration). Changing the Breath Detection settings will result in changes in RIP respiratory measures and their corresponding trends.

### Cardiac

This is a set of Charts suitable for use when evaluating cardiac information from an electrocardiogram sensor. This layout contains one filtered Ecg waveform, results of QRS detection and subsequent derived R-R intervals. A trend of the heart rate is included along with accelerometer waveforms to be used for context interpretation and identification of artifact. If necessary, this layout should be used for making changes to the R-wave picker settings.

### Quality Control

This set of Charts is the most general and is suitable for evaluating the quality of recorded data. It contains waveforms and measures from the respiration, electrocardiogram and accelerometer data channels. It is not however a complete set of measurements from all channels.

### Respiration

This is a set of Charts suitable for evaluating respiratory data and contains several key respiratory measures and trends. The Vt waveform with breath detection markings, as well as respiration trend channels.

### Sleep

This is a set of Charts suitable for use when evaluating sleep data and contains respiratory waveforms and measures, motion and posture data, as well as oxygen saturation data.