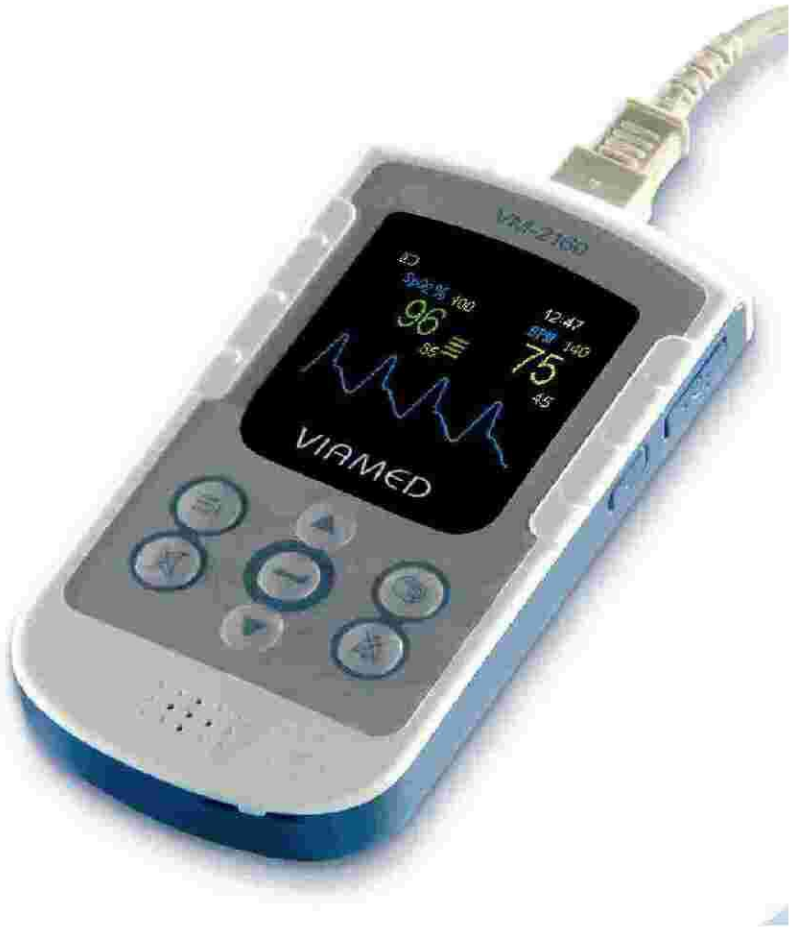

Viamed 2160 Spot Check Pulse Oximeter

Technical manual

V1.00 07/23/08

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Contents

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Introduction

Warning

This instrument uses static susceptible devices. Anti static precautions should be taken at all times anyone attempting to open and/or repair the unit

The pcb's use surface mounted technology.

Only qualified engineers trained in surface mounting techniques and anti static prevention techniques should attempt a repair.

There are no readily available user changeable components.

Read the full user manual to fully understand all the functions of this instrument

1. Intended Use & Warnings

Intended Use

The VM 2160 handheld pulse oximeter is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric and newborn patients in hospital, hospital type facilities, transport, emergency care and mobile environments; as well as in the home care environment.

⚠ Warnings

Warnings are identified by the WARNING symbol shown above. Warnings alert the user to potential serious outcomes, such as death, injury, or adverse events to the patient or user.

⚠ Do not make any clinical judgments based solely on the VM 2160. The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. The interpretation of the measurement values should be done only by trained health care professionals.

⚠ Explosion hazard. Do not use VM 2160 in the presence of flammable anaesthetics mixture with air, oxygen, or nitrous oxide.

⚠ Routinely monitor the patient to ensure that the VM 2160 is functioning and that the sensor is correctly placed.

⚠ Pulse oximetry measurements and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.

⚠ If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then ensure that the VM 2160 is functioning correctly.

⚠ The use of accessories, sensors, and cables other than those specified may result in increased emission and/or create invalid readings of the VM 2160.

⚠ Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

⚠ Do not silence the audible alarm function or decrease the audible alarm volume if patient safety could be compromised.

⚠ The VM 2160 is a prescription device to be operated only by trained personnel. The monitor is for attended monitoring only.

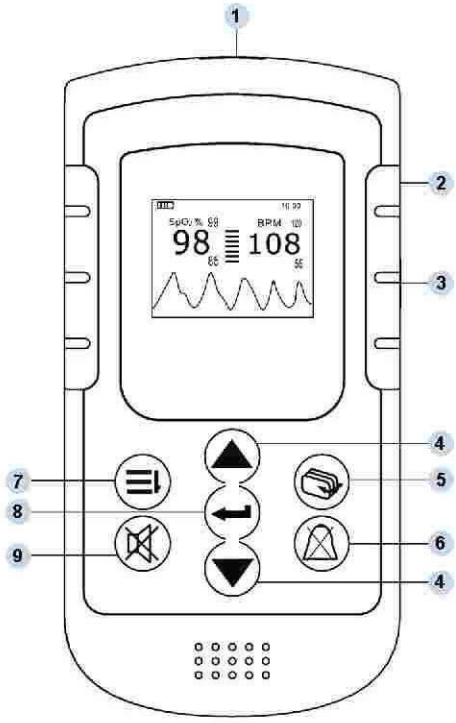
⚠ The VM 2160 is not defibrillator-proof. However, it may remain attached to the patient throughout defibrillation or while an electrosurgical unit is in use. The measurements may be inaccurate throughout the defibrillation, or use of an electrosurgical unit, and shortly thereafter. To avoid shock, the caregiver should not hold the VM 2160 while using a defibrillator on a patient.

⚠ Disconnect the VM 2160 and sensor from the patient throughout magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.

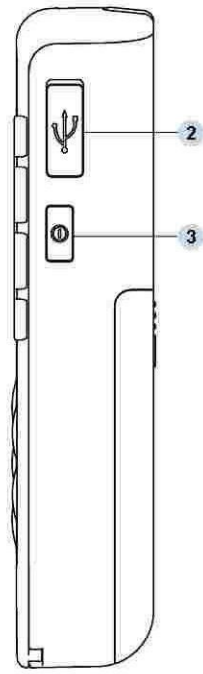
⚠ Do not use sensors where optical components are exposed.

⚠ Ensure that the speaker is clear of any obstruction and that the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.

Controls & Symbols



Front view



Side view

No.	Symbol	Feature/Button	Function
1		Sensor Port	Port for the SpO_2 sensor
2		USB	USB 2.0 interface
3		On/Off	To turn on the device: press and hold power button briefly. To turn off the device: press and hold power button for approx. 3 seconds.
4		Arrow Buttons (up/down)	Multifunction buttons used for 1. scrolling through menu items and 2. increasing/decreasing parameters. 3. From monitoring display modes: can be used as shortcuts to volume/brightness control
5		Display Mode	Toggles between various display modes
6		Alarm On/Off	Silences alarm for max. 2 minutes or reactivates silenced alarm.
7		Menu	Menu selection
8		ENTER button	Confirms selection
9		Pulse Tone	Turns pulse tone on/off

No.	Symbols/Indicators	Definition
1		Battery level indicator. The three segments represent the battery charge level. The symbol flashes red when the battery capacity is low.
2	10:07	Current time, displayed in 12h or 24h format
3		Alarm silenced indicator. The audible alarm can be silenced for a maximum period of two minutes.
4		Pulse tone off
5		The colour of the bar graph is an indicator for signal quality. - Green: good signal quality, very accurate measurement. - Yellow: average signal quality, measurement may be inaccurate. - Red: poor signal quality, unreliable measurement.
6		Memory symbol The device's memory for measurement data is full. No new data can be stored. Old data can be erased or overwritten.

Typical Error messages

Message	Cause	Cure
"No sensor!"	The sensor is not connected properly to the device.	Check sensor connection.
"Probe off!"	The sensor has been removed from the monitoring site.	Check that the sensor is properly attached to the patient.
"Low battery!"	battery symbol blinking red The battery is almost completely discharged	Replace batteries immediately
Sensor fault	The connected sensor compatible with the device	check sensor
Device defective	Resulting from improper handling, such as use with computed tomography	The device must be sent in to the Service Department.
"Too much ambient light!"	High ambient light sources near the sensor, e.g. surgical lights.	Shield sensor more effectively from external light.
"Bad signal quality"	Poor-quality pulse signal, for example as a result of low perfusion.	Move the sensor to a different site on the patient or provide more effective monitoring conditions.

Possible causes of Failure

Problem	Cause
There is no response to the Power button,	Ensure that the Power button is filly depressed. The batteries may be mis- sing, discharged. or oriented incorrectly. Install new batteries.
No pulse signal found	Check the patient. Check the sensor directions for use to determine if an appropriate sensor is being used and if it is applied properly. Check sensor and extension cable connections. Test the sensor on another subject. Try another sensor or extension cable. Perfusion may be too low for the monitor to track the pulse. Check the patient. Test the monitor on yourself Change the sensor site. Try another sensor. Interference due to patient activity may be preventing the monitor from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied and replace it i ±necessary. Change the sensor site. The sensor may be too tight, there may be interference due to ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary. Electromagnetic interference may be preventing the monitor from tracking the pulse. Remove the source of interference.
After a valid measurement the pulse signal can not be found anymore	Check the patient Check the sensor directions for use to determine if an appropriate sensor is being used and if it is applied properly. Check sensor and extension cable connections. Test the sensor on another subject Try another sensor or extension cable. Perfusion may be too low for the monitor to track the pulse. Check the patient. Test the monitor on yourself Change the sensor site. Try another sensor. Interference due to patient activity may be preventing the monitor from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site. The sensor may be too tight, there may be interference due to ambient light, or the sensor may be on an extremity with a

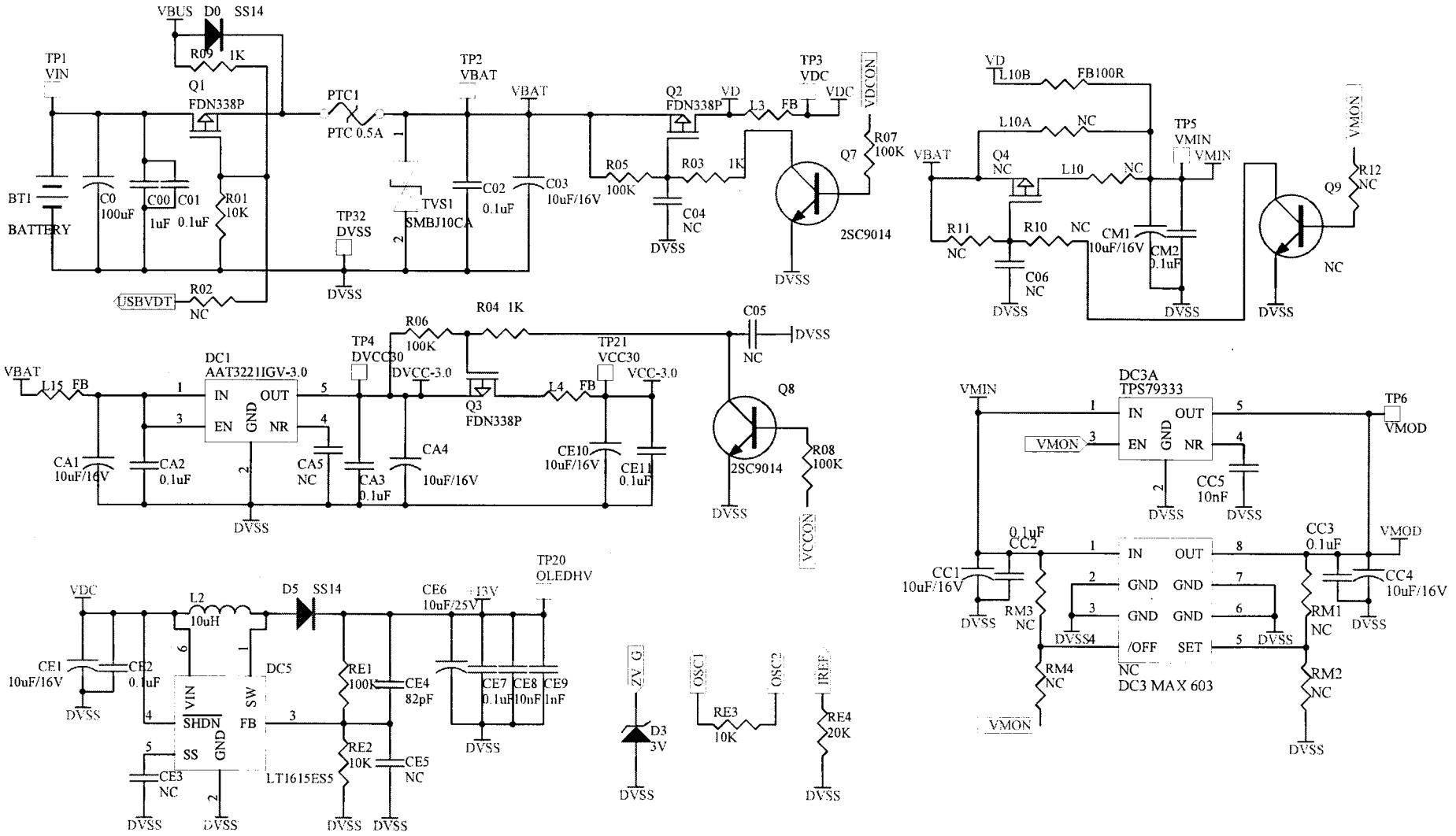
	blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary. Electromagnetic interference may be preventing the monitor from tracking the pulse. Remove the source of interference.
No pulse tone	Continue to listen for the pulse beep tone as the monitor is used. If it does not sound with each pulse it indicates one of the following: Pulse beep volume is off. - Switch volume on Speaker/audio has malfunctioned. Signal is corrupted. VM 2160 has stopped functioning.
EMI (Electromagnetic Interference)	This device has been tested and found to comply with the limits for medical devices according to EN 60601-1-2, (second edition), and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. Due to the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments, it is possible that high levels of such interference due to close proximity, or strength of a source, may result in disruption of performance of this device. Examples of noise sources in health care environments that could cause electromagnetic interference are: Electrosurgical. units Cellular phones Mobile two-way radios Electrical appliances High-definition televisions (HDTV's) The monitor is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly Disruption may be evidenced by erratic reading cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of disruption, and the following actions taken to eliminate the source: * Turn equipment in the vicinity off and on to isolate the offending equipment. * Reorient or relocate the interfering equipment * Increase the distance between the interfering equipment and this equipment The monitor generates uses, and radiates radio frequency energy. If it is not installed and used in accordance with these instructions, the monitor may cause harmful interference with other devices in the vicinity.

Technical specification

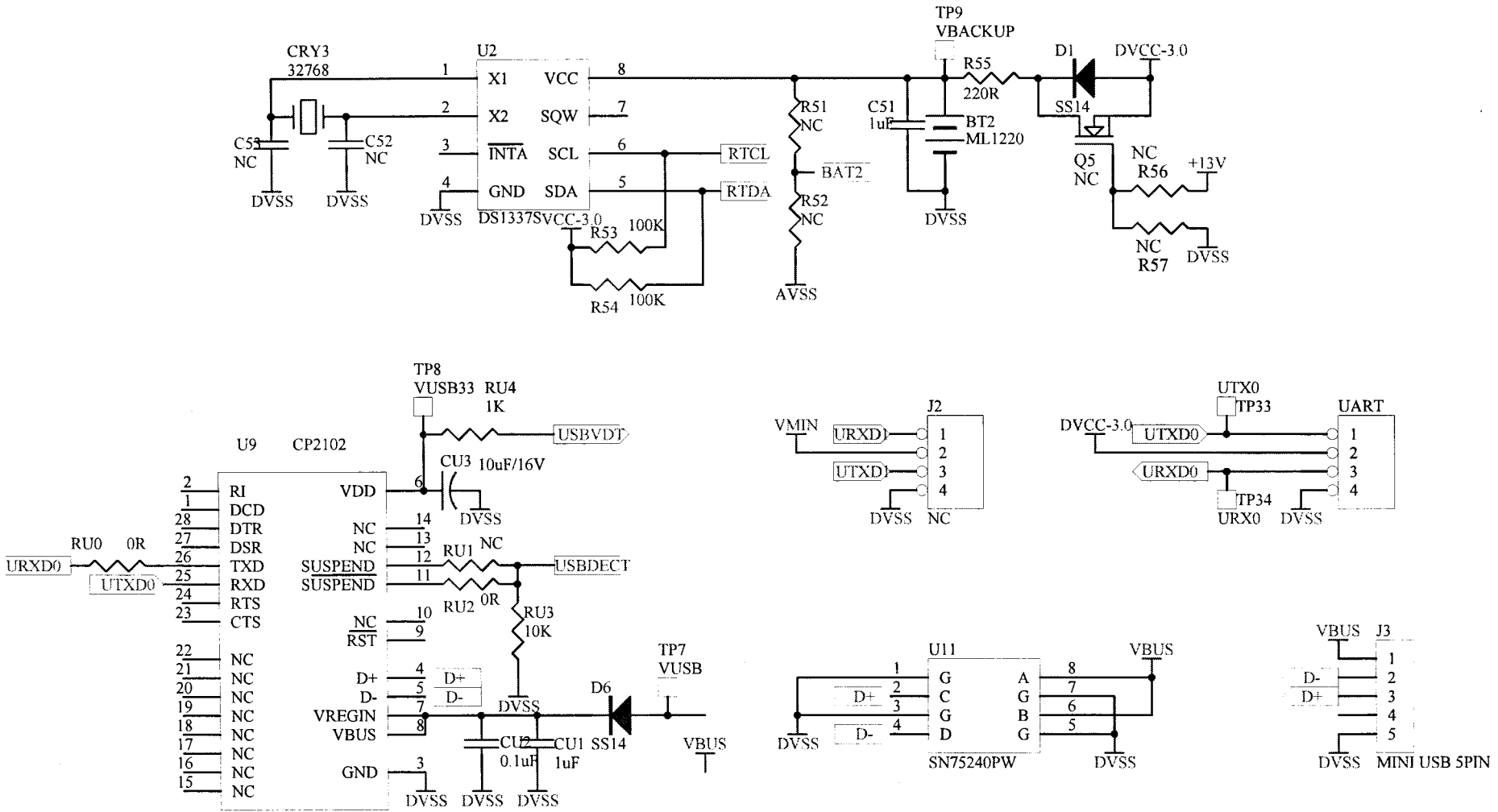
Measurement Range:
Sp02: 45 to 100%
Pulse Rate: 20 to 300 beats per minute (bpm)
Accuracy:
$SpO_{2,}$: +/- 2% (70 to 100%)
Pulse Rate: -Fl- 1 digit («= 100 bpm);
-Fl- 1% (> 100 bpm)
Display:
* OLED colour graphic display, 262,000 colours, 128 x 160 pixels
* Data displayed: oxygen saturation, pulse rate, plethysmogram, bar graph, short-term and long-term trends
* Indicators: signal quality, pulse amplitude, battery status, alarm silenced, sensor detection, sensor disconnection
Trend Information:
* Long-term Trends: up to 48 hours
* Short-term Trends: 15 mm / 30 mm / 4 Irs
Environmental Conditions:
* Operating conditions: 0 to 50°C; 15 to 95% RI-I; 600to l300hPa
* Storage conditions: -20 to 70°C: 10 to 95% RH 600 to 1500 hPa
Other:
* Class JIb Product
* Water-resistant construction
- `Type BF
* Dimensions (lxwxh): 11.8 cms. 6 cms. 2.5 cm
* Weight: approx. 160 g (with batteries, without sensor)
* Power Supply: 3 batteries (1.5 volt, AA)
* Battery Lift: > 2 days of continuous operation. or approx. 5 days in power-save mode

Order Number:
0012160

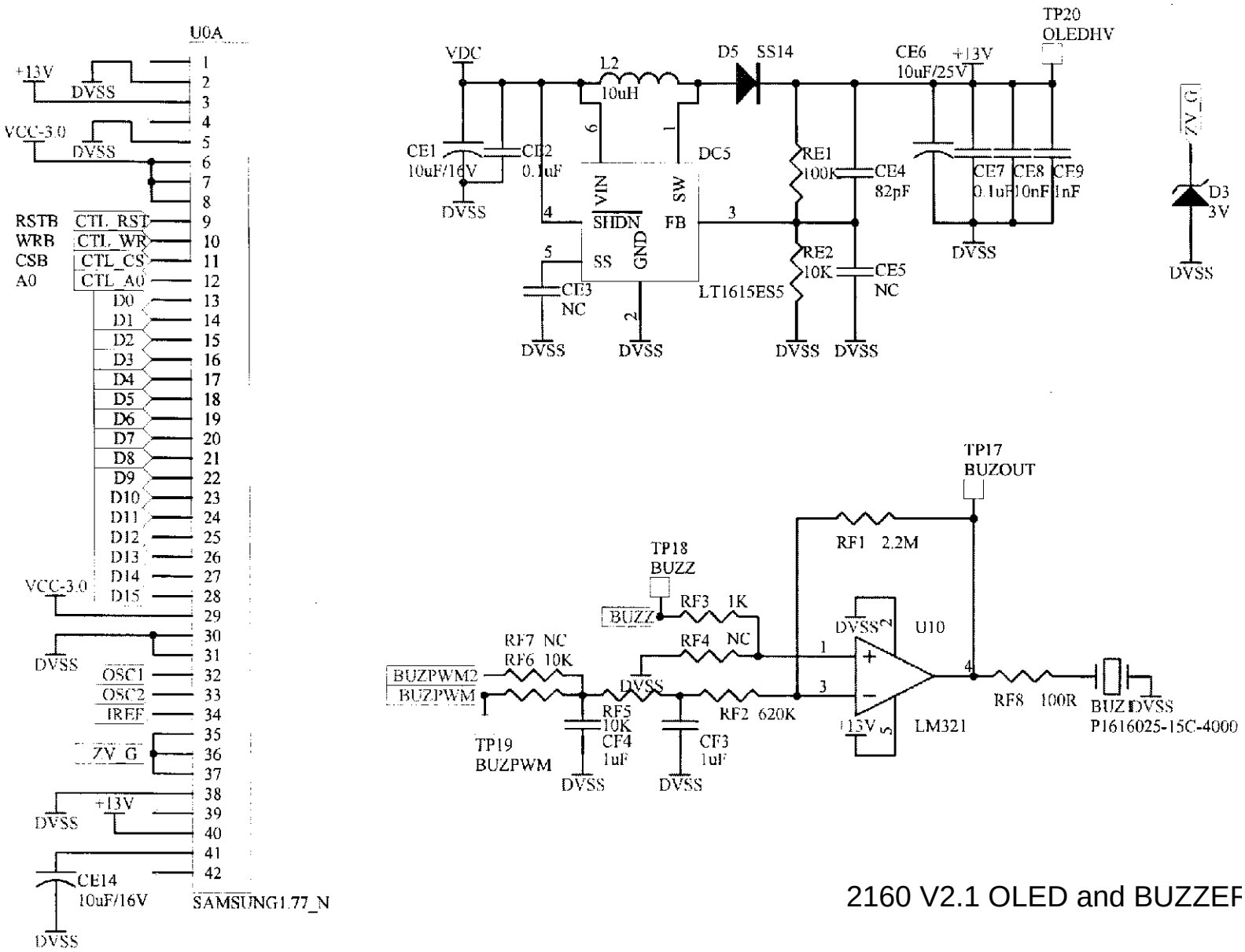
Applied Standards:
EN 60601-1, EN 865, ISO 9919:2005



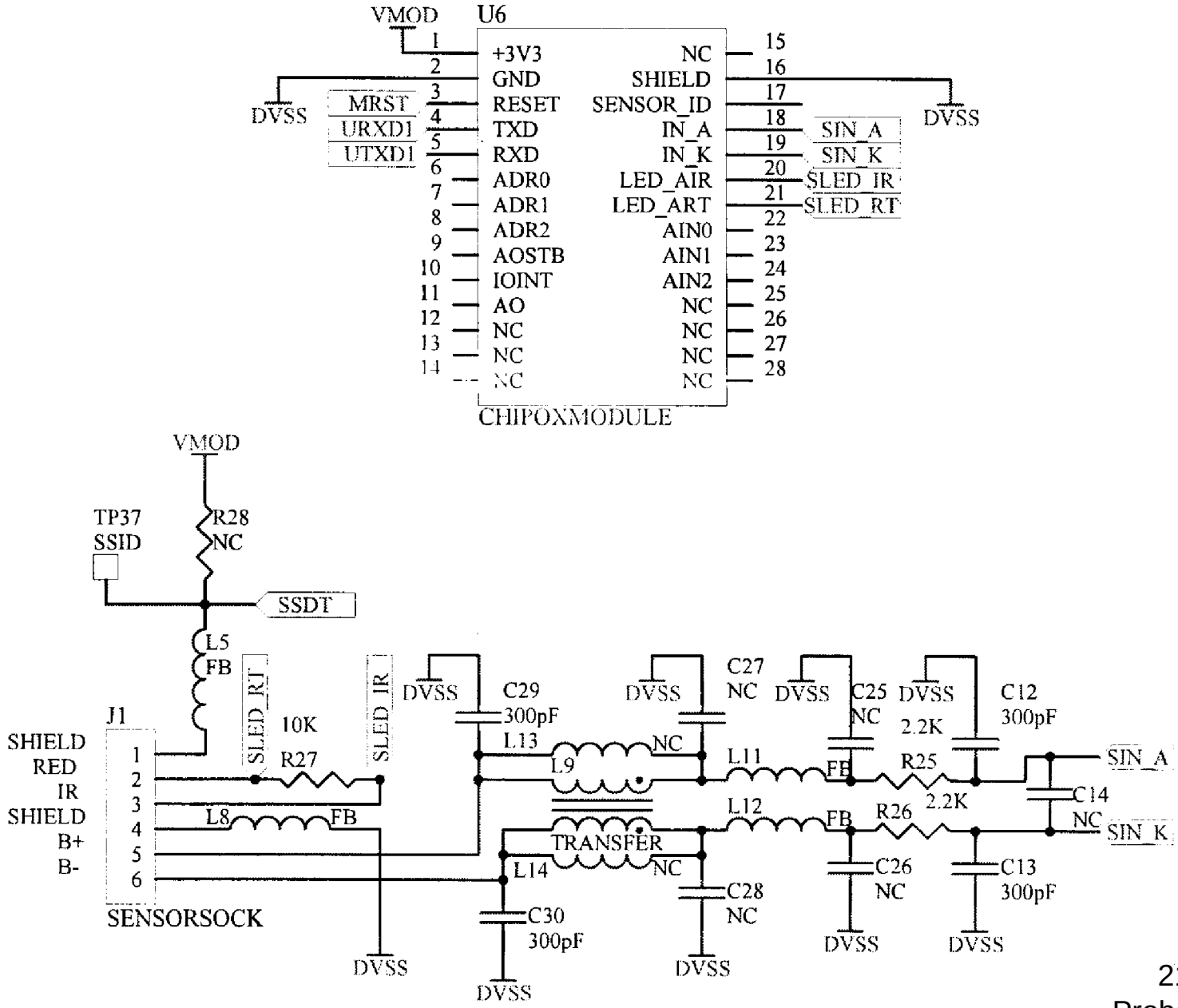
2160 V2.1 Power



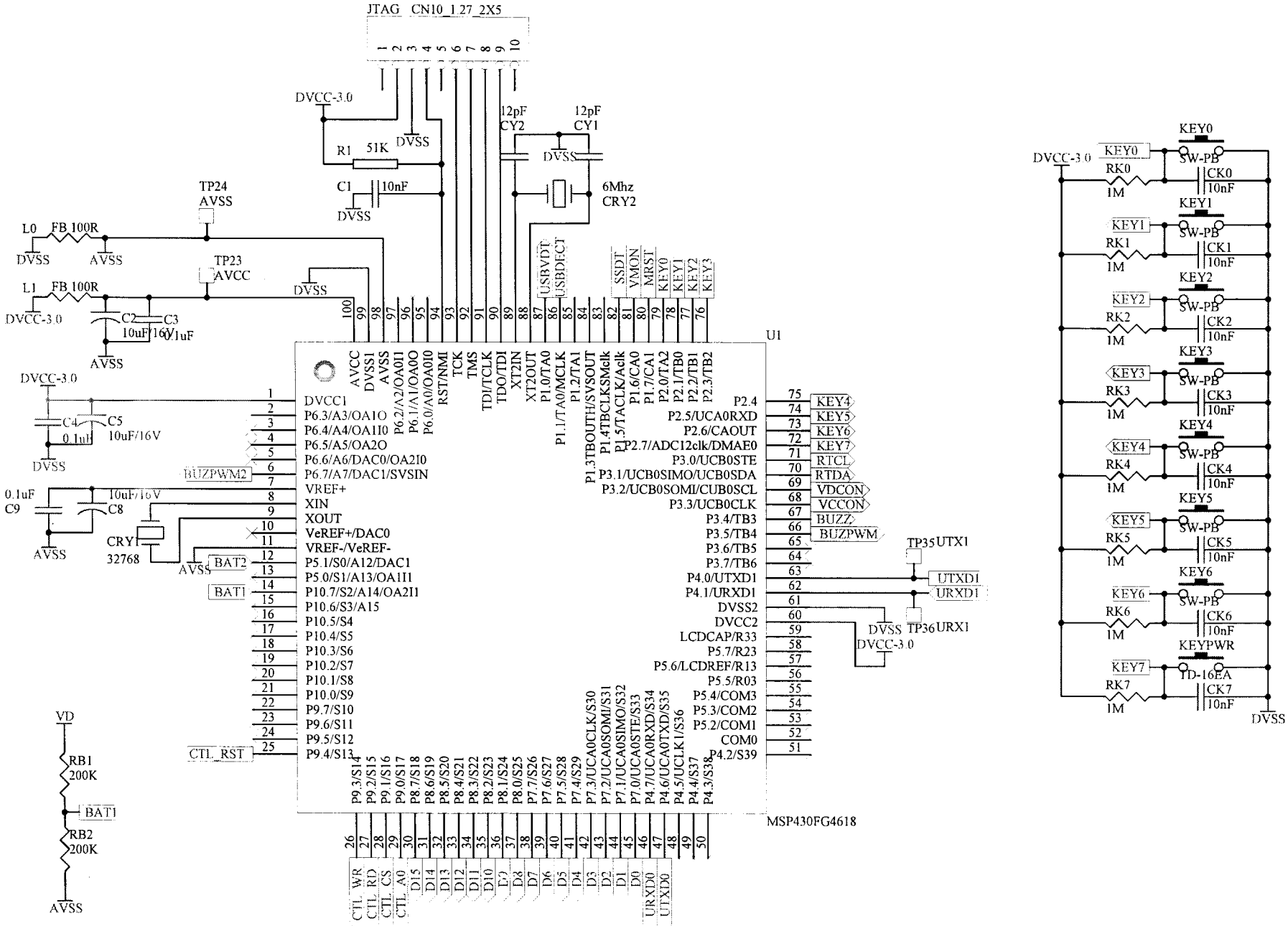
2160 V2.1 RTC and USB



2160 V2.1 OLED and BUZZEF



2160 V2.1 Chipox Probe Input



2160 V2.1 MCU & Kepac

Battery Information Viamed 2160 Spot check Pulse Oximeter

The 2160 Spot check Pulse Oximeter has two main sources of current drain.

1. The OLED Colour display
2. The Pulse oximeter chip which drives the SpO_2 probe LED's

Using standard (recommended by Viamed) Duracell ProcellMN15000 (AA) 1.5v Alkaline battery the following current drains can be expected.

- Unit Total 75.1mA
- Finger IN 57.6
- Finger OUT 36.9
- NO sensor 34.1mA
- NO SpO_2 Module Unit 61.5mA

Estimated Battery Life 2700/75 = 36hrs