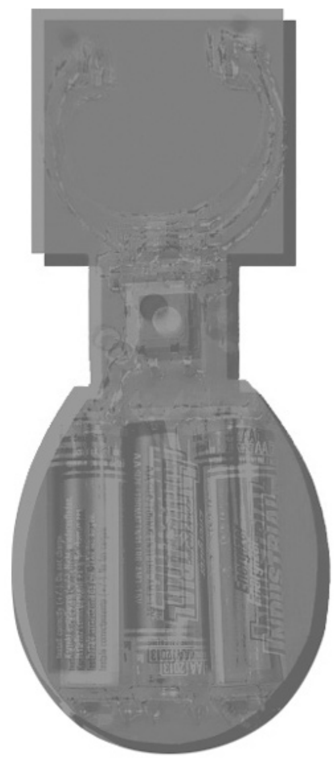
Introduction:

360° Test Labs has been retained to independently analyze the design for an updated version of a medical instrument product called the client's predecessor device.

Supplied to 360° Test Labs:

- One working client's predecessor device
- One working client's new-design new-design (pictured at right)



Statement of Work: 360° Test Labs agreed to perform the following analysis of the client's new-design:

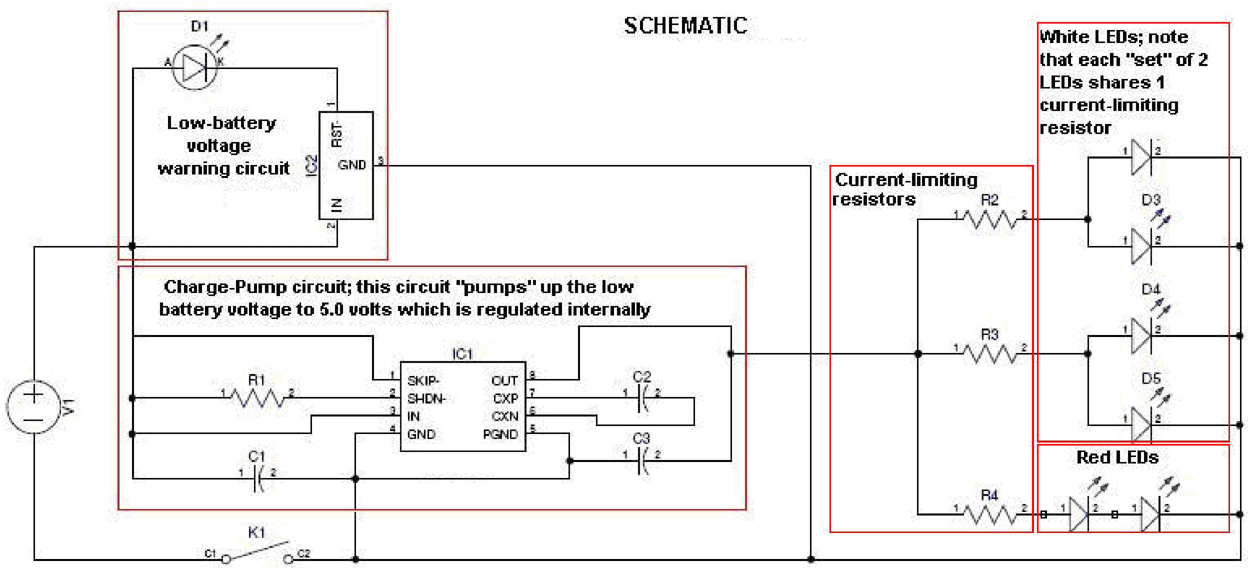
- Review the product's schematic to ascertain that the circuit will work as intended.
- Perform detailed calculations using the circuit's published component values to ascertain that those values are both reasonable, and are well within tolerances so as to minimize production fall-out (Monte Carlo tolerance analysis)
- Review the published printed circuit board design.
- After confirming the product's electrical design we will closely examine the published parts list to determine that the selected parts and their suppliers are both viable and the most economical solutions available.

Conclusions from our analysis follow:

360° Test Labs identified a number of design deficiencies, at least one of which will result in reduced lifespan of the main integrated circuit that drives the LEDs, and several of which can result in inoperative units due to production component tolerance variations. We also found a potential parts-supply problem with this design.

Schematic: The designer of the circuit used in the new client's device chose a branded IC part Charge Pump Integrated Circuit as the heart of the client's device. This allows the use of only three 1.5-volt AA batteries to power the four white and two red LEDs that illuminate the patient's body, and will continue to operate until the battery voltage drops below 1-volt each. A Charge Pump is an electronic circuit that generates an output voltage larger than its input voltage.

The branded IC part (IC1 in the below schematic) is a low-input-voltage (3.3V) integrated circuit originally designed for use in laptop computers, but with many other applications. In addition to the Charge Pump circuit, the IC also contains an internal 5-volt regulator. The 5-volt regulator will maintain a constant output voltage until the total battery voltage drops to about 2.7 volts, at which point the Charge Pump circuit will shut off; this is equivalent to 0.9 volts per battery, slightly higher than most alkaline battery manufacturers' specification for End-Of-Life.



Because the LEDs are driven from the output of the voltage regulator, even as the batteries are approaching End-Of-Life, the voltage will remain constant and so the amount of light available from the six LEDs will also remain constant. When the total battery voltage drops below 3.0 volts, another IC, a branded IC part (IC2 on the schematic), will cause a low battery LED (D1) to illuminate to warn the clinician of the need to change batteries. In this application, IC2 does not require any external components.

The part device requires only four external components: one resistor and three capacitors (R1, C1, C2 and C3 in the schematic above).

- Resistor R1 sets the frequency of the internal oscillator;
- Capacitor C2 is the charge transfer capacitor for the charge pump;
- Capacitor C1 provides high frequency AC bypassing on the input; and
- Capacitor C3 filters the high frequency ripple on the output of the device.

None of these component values are critical and in fact, branded IC claims the value of C3 can be anything over a range of 10 to 1. Due to the relatively-high, 1 MHz oscillation frequency (set by the resistor), all three capacitors can have very low capacitance values in comparison to what would be required for the same function with many other similar power supply ICs.

Design Deficiency #1

The output of the part charge pump drives four bright-white LEDs and two red LEDs. The client's device mounts these with two white LEDs on one arm and the other two on the other arm. One red LED is also placed at the tip of each arm. The circuit designer chose to wire the two white LEDs on each arm in parallel, then through a single current-limiting resistor. The two red LEDs; however, are wired in series with a single current-limiting resistor. Had these LEDs been driven individually, another resistor for the second red LED would have been necessary.

The reason that the white LEDs are not connected in series is because of their higher turn-on voltage specification of 3.2 volts minimum and 3.6 volts for the maximum. The turn-on voltage specification for the red LEDs is much lower at 2.0 to 2.4 volts (no minimum turn-on voltage spec is listed by the manufacturer; 2.0 volts is shown as the typical turn-on voltage). The regulated output voltage from the part is about 5.0 volts; thus, two white LEDs in series would require a minimum of 6.4 volts to insure turn-on. On the other hand, two red LEDs in series requires only 4.0 to 4.8 volts, and so the series-connected string can be driven by the part. The series connection also insures that the two red LEDs are drawing the same amount of current and thus will have nearly the same luminance intensity.

However, paralleling LEDs as the white versions are connected, where both share the same current limiting resistor, does not allow for the possibility that the two white LEDs may come from different production lots, and thus might have different turn-on voltages. If this were to happen, each white LED would draw a different current at the same voltage, and thus emit a different intensity from the other LED. For example, if one LED just meets the minimum turn-on voltage specification of 3.2 volts but the other just meets the maximum specified turn-on voltage of 3.6 volts, then the lower-voltage unit will be more brilliant and draw more current. This may also noticeably decrease the lifetime of the LED. When connecting current-driven devices in parallel, good engineering practice is to use a separate current-limiting resistor for each device. 360° Test Labs believes that to insure that all four of the white LEDs emit the same luminance intensity, and also to achieve the maximum possible lifetime, each LED should have its own current limiting resistor. This would require adding two more resistors to the parts list for the present client's device "new design". The additional cost, in production volumes in the tens of thousands, will be between 5 and 10 cents per client's device.

Design Deficiency #2

The current design requires that the part IC provide 120 milliamperes to drive all six LEDs. The maximum power dissipation of the part in the SO-8 package style is specified at 471 milliwatts, or just under ½ watt. The part is driving three sets of LEDs, each of which is set up by current-limiting resistors to draw 40 milliamperes; thus, the total output current drawn from the part is three times 40 milliamperes or 120 milliamperes. branded IC gives the formula for calculating the part's internal power dissipation as:

$P_{DISS} = I_{OUT} * ((2 * V_{IN}) - V_{OUT})$, where

I_{OUT} is the output current; 120 milliamperes (mA) in this design;

V_{IN} is the input voltage to the part, which is the total battery voltage

or about 1.5V * 3 batteries = 4.5 volts; and

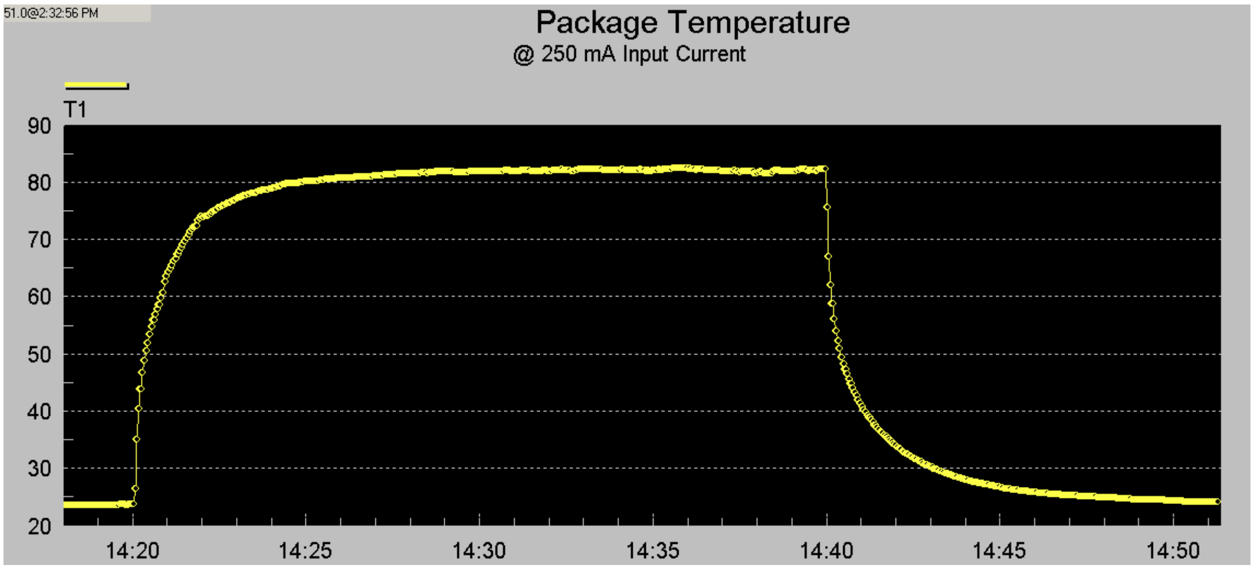
V_{OUT} is the output voltage of the part, which is 5.0 volts.

Inserting the values above into the formula, we have:

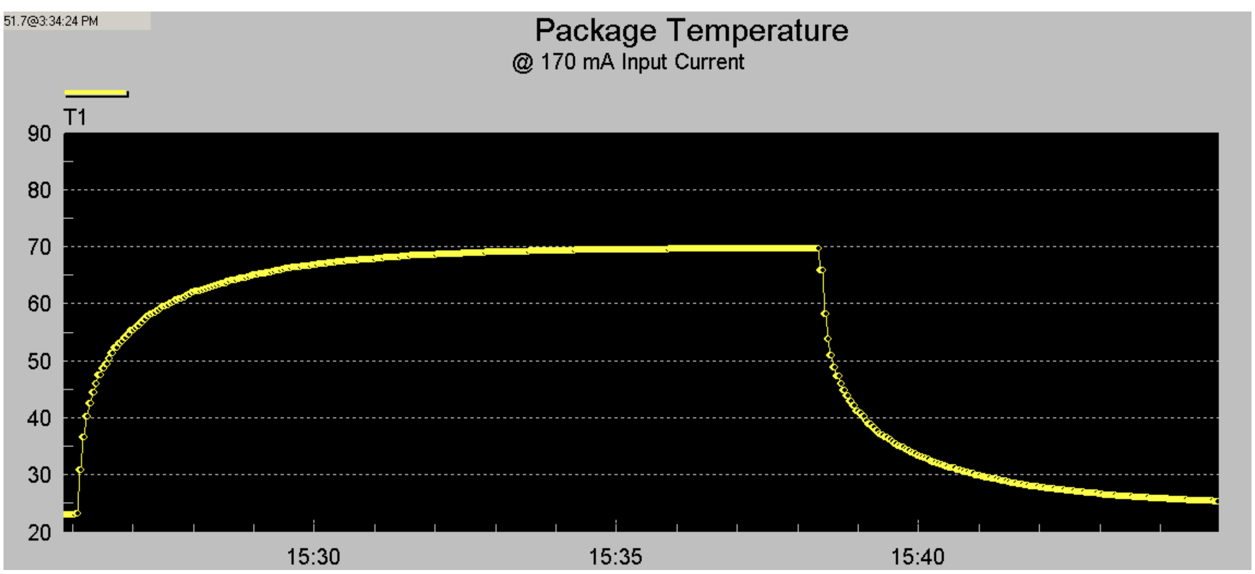
P_{DISS} = 120 * ((2 * 4.5) – 5.0)

P_{DISS} = 480 milliwatts

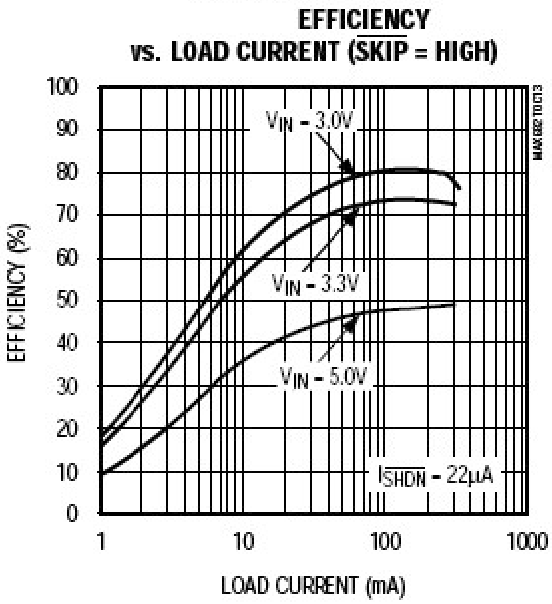
Thus, we calculate that the part is dissipating about 480 milliwatts, slightly more than branded IC's Absolute maximum Rating of 471 milliwatts. The following graph shows the temperature rise of the case of the part on the prototype new-design, as measured by a thermocouple held onto the top surface of the chip while the chip was supplying 120 milliamperes to the three sets of LEDs. The input current drawn by the part was measured at 250 milliamperes with the input voltage set to 4.5 volts, illustrating the fact that the device is operating at only 43% efficiency. The graph shows that the case temperature can get as hot as 82.4° C.



The following graph shows the temperature rise of the part when the input current dropped to 170 milliamperes due to disconnecting one pair of parallel-connected white LEDs (i.e., the output current was reduced to 80 milliamperes, reducing the internal power dissipation to 320 milliwatts and raising the power conversion efficiency to 53%). Note that the peak temperature only reached 69.7° C compared to a peak of 82.4° C when supplying 120 milliamperes.



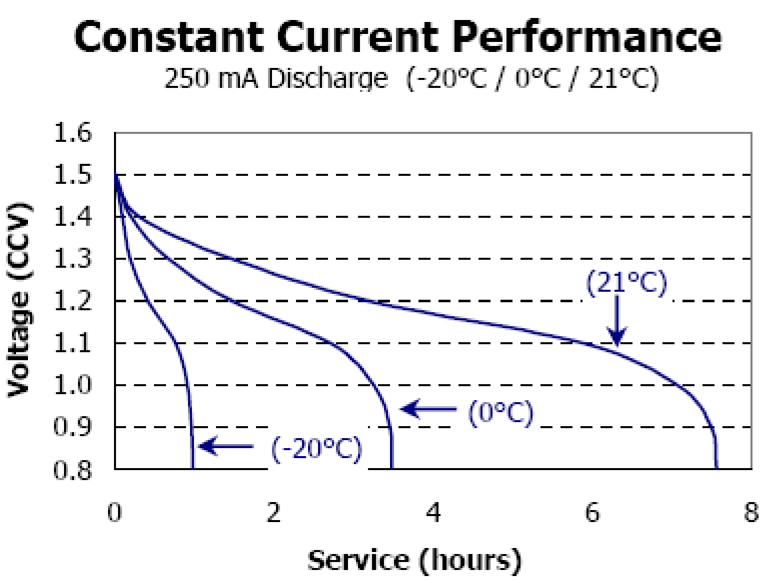
The case temperature can be predicted mathematically by noting that the thermal resistance of the part's SO-8 package is 160°C per watt.



The high temperatures measured and plotted above turns out to be worst-case, because the part actually becomes MORE efficient as the battery voltage drops, as seen in this plot (right) taken from the part specification sheet:

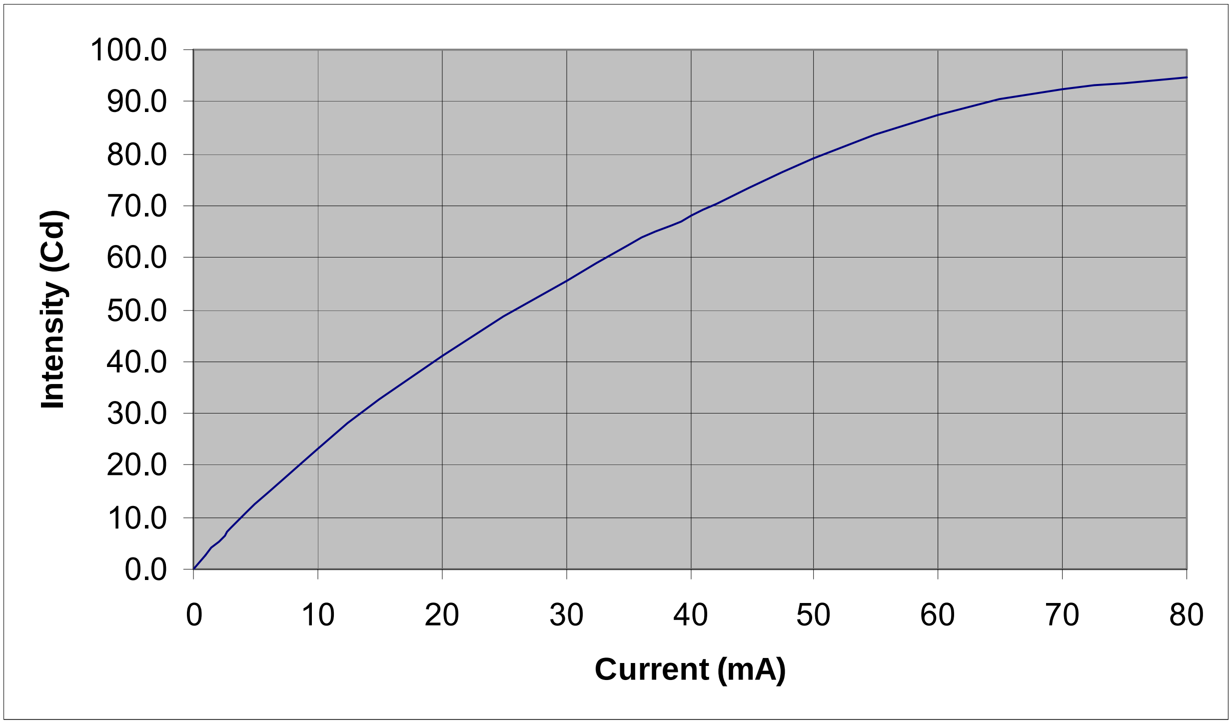
The graph doesn't have a data curve representing an input voltage of 4.5 volts so we must interpolate a curve representing fresh batteries with a total battery voltage of 4.5 volts; that curve would be plotted slightly above the 5.0 volt curve. Note that the efficiency for 4.5 volts, at 120 milliamperes load current, appears to be 50%. Also note that when the battery voltage has dropped to 3.3 volts, the efficiency should rise by more than 20% to almost 75%.

Thus, it is clear that as the batteries lose charge, the part will operate even more efficiently and also cooler at the lower voltage.



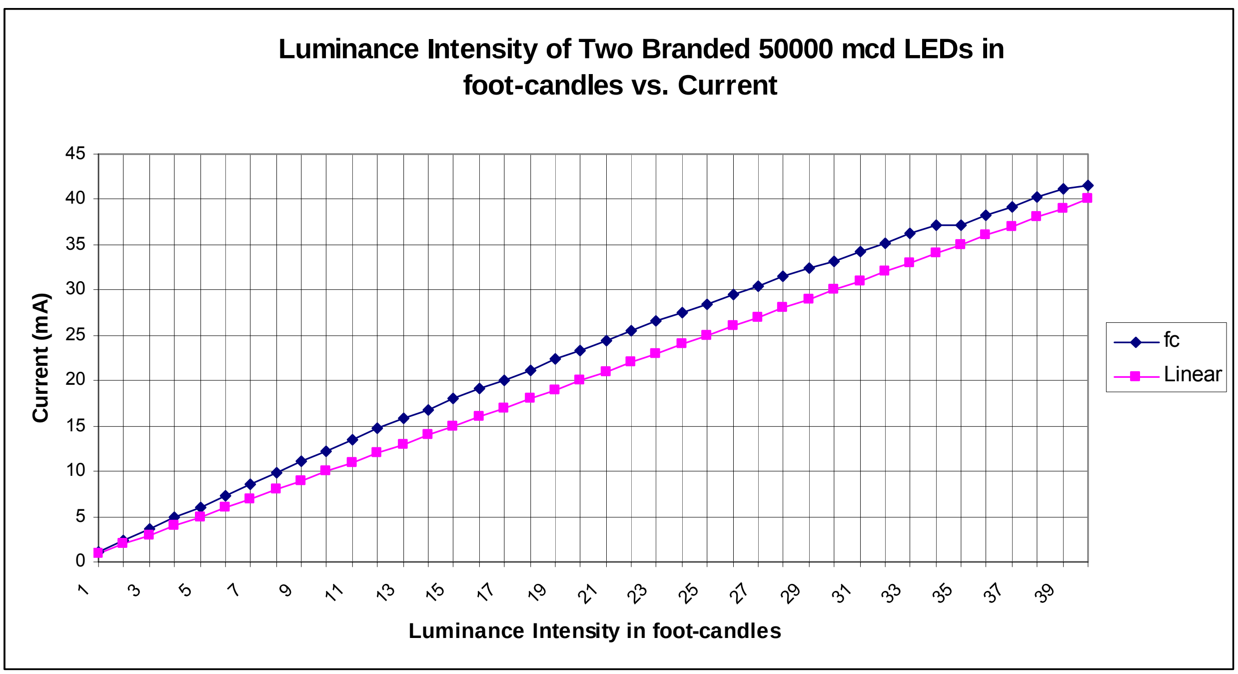
The graph to the left shows the voltage of an Energizer AA battery with a constant discharge current of 250 milliamperes versus time. Note that the battery voltage will drop to less than 1.4 volts within less than ½ hour of continuous discharge at 250 milliamperes (equivalent to 4.2 volts with three cells in series in the client's device). Although this set of curves is typical for a continuous discharge over several hours, intermittent high-current discharge such as with a client's device will produce very similar curves. These curves imply that in this new-design client's new-design, after installing fresh batteries, the part most likely will only exceed its maximum power dissipation specification during the first few 5 to 15 minutes of clinic-usage. After these initial uses, the batteries will have discharged sufficiently that the power dissipation should drop into the safe region for the part.

A chart provided to 360° Test Labs shows the measured light intensity of the Jeled 50000 mcd white LEDs (apparently provided by Jeled), and is reproduced below for the following discussion:



In the client's new-design, the white LEDs are each operating at 20 milliamperes (mA), and so, according to the chart, should be emitting about 40 candelas.

The following chart shows the measured luminance intensity in foot-candles of two of the Jeled 50000 mcd LEDs versus driving current; however, due to the lack of a precision intensity standard against which to check calibration, the luminance values shown should be considered relative.



The line marked fc is the measured intensity; note that the intensity increases slightly more than a one-to-one ratio with increasing current until about 30 milliamperes (15 mils per LED), where the intensity values show slight compression, and the ratio of current to measured intensity begins dropping below the one-to-one ratio. This data shows that reducing the current to the LEDs by a few milliamperes will cause only a slight drop in intensity. It also illustrates that increasing the current beyond the present 20 milliamperes per LED will not increase the intensity significantly. Thus, if the current to the LEDs is reduced to the point where the part power dissipation is no longer being exceeded, then the LED intensity should be decreased only slightly.

An option would be to incorporate a two-position intensity switch, with the “normal” position allowing slightly less current than is presently used and the “high” position increasing the current by some amount. If, to select “high”, this switch were spring-loaded so that it has to be continuously depressed to select “high”, then it is unlikely that the power dissipation of the part will be exceeded for a long period of time, thus protecting the IC.

Design Deficiency #3

There is no current limiting resistor between the RESET output of IC2 and low-battery LED D1. This low-battery detection circuit should only trigger when the battery voltage has dropped below 2.85 to 3.0 volts; however, the chip, which was intended for use to assert a RESET signal to microprocessors when power is first applied, also triggers on for 350 milliseconds when power is first applied. It is when power is first applied, that the LED will draw the most current through the IC, since the battery voltage will be at its highest. As a point of interest, we noted that the prototype triggers at 2.91 volts, which is equivalent to each battery being at 0.97 volts

Due to the lack of a current-limiting resistor, the LED will draw as much current as IC2 will allow. Unfortunately, the manufacturer’s specification sheet does not show a maximum output current specification for IC2 but if it did, it is unlikely to be more than a few milliamperes because of the intended use of the chip, which was to provide a RESET signal to microprocessors. In that application, the microprocessor would only draw several milliamperes. The possibility exists that due to the lack of the current-limit resistor to the LED, IC2 could fail, most likely after installation of a fresh set of batteries when the client’s device is first turned on and the battery voltage is highest. However, if IC2 does fail, it should not otherwise affect the operation of the client’s device; only the low-battery detection feature would be permanently disabled.

Component Tolerance

The table below is the original client's new-design parts list provided to 360° Test Labs with tolerances (taken from the components' data sheets) inserted into three new columns on the right-hand side.

Part	Desc.	Manu.	Manu. PN	Package Style	Tolerances		
					Min.	Typ.	Max
IC1	Charge Pump	omitted	omitted	8-SOIC	4.8	5.05	5.2
IC2	Voltage Supervisor			SOT23-3	2.85	2.925	3
R1	510KΩ, 1/8W Resistor			0805 SMD	+/-5%, +/- 200ppm/deg.C		
R2, R3	40.2Ω, 1/8W Resistor			0805 SMD	+/-1%, +/- 100ppm/deg C		
R4	6.8Ω, 1/10W Resistor			0603 SMD	+/-1%, +/- 200ppm/deg C		
C1	1µF Capacitor			1210 SMD	+/-10%	+/-15%	
C2	0.47µF Capacitor			0805 SMD	+/-10%	+/-15%	
C3	2.2µF Capacitor			1210 SMD	+/-10%	+/-15%	
D1	Low Battery LED (Red)			T1 (3mm)	------	1.8	2.4
D2-D5	Super Bright White LED			T1-3/4 (5mm)	3.2	3.4	3.6
D6,D7	Super Bright Red LED			T1-3/4 (5mm)	------	2	2.4
K1	Power Switch			NA			
V1, V3, V5	Positive Battery Contact			NA			
V2, V4, V6	Negative Battery Contact			NA			

A component value-tolerance analysis reveals several possible production problems should the value of certain critical components fall at the extreme low or high ends of their specifications. However, it should be noted that the likelihood of such extreme component values is very small, particularly if the manufacturers are utilizing good control practices over their manufacturing processes. The risk of such value-extremes, however, is extremely low when the parts are obtained from manufacturers adhering to industry-standard 6-Sigma process control techniques. For example 6-Sigma allows up to 3.4 defects out of 1,000,000 parts. 3-Sigma process control allows up to 66,738 defects per million parts, or 6.7% of the parts. When calculating the risk of a defective production client's device, the individual risks of defective critical parts must be added together.

The following is a discussion of certain critical parts and how an extreme value-shift would affect a production client's new-design.

The brilliance of the white and red LEDs depends upon the output voltage of the part (IC1), which can range from a low of 4.8 to a high of 5.2 volts. The resistance value of R2 and R3 set the current through the LEDs which establishes their brilliance. If IC1's output voltage is low, and R2 and R3's values are high, and the white LEDs meet their high turn-on voltage specification, then the current through each white LED will be 16.92 milliamperes. Reading from the luminance intensity chart which was created from measurements at 360° Test Labs, this will cause the luminous intensity to decrease from a nominal 17 ft-cd at 20 milliamperes, to 14 ft-cd, a reduction of about 18%.

On the other hand, if IC1's output voltage is high, and R2 and R3's values are low, and the white LEDs meet the low turn-on voltage specification, then the current through each white LED will be 25.15 milliamperes, which will result in the luminous intensity increasing from a nominal 17 ft-cd at 20 milliamperes, to 21.5 ft-cd, an increase of 26%. There should be very little effect upon the lifetime of either LED (assuming both are drawing equal amounts of current) since the maximum current specification for the white LEDs is 40 milliamperes.

So the major effect of component variation upon the white LEDs will be an 18% drop to a 26% increase in luminous intensity.

The story for the red LEDs is grim, however. In this case, the manufacturer did not give a low voltage turn-on specification; only typical and maximum turn-on voltages are listed in the data sheet. One reason for this may be that the red LEDs can be ordered from the manufacturer from a "minimum intensity bin", as well as a "maximum intensity bin". For the following discussion of low voltage turn-on of the red LEDs, we will reasonably assume that the red LEDs turn on at 1.8 volts, compared to the rating of "typical" turn-on of 2.0 volts.

If IC1's output voltage is low, and R4's resistance is high, and both red LEDs are on the high end of their specified turn-on voltage, then neither will turn on. This is because the low voltage specification for IC1 is 4.8 volts, and the high turn-on voltage specification for the red LEDs is 2.4 volts each. Since the two LEDs are connected in series, they will require 4.8 volts to turn on. Thus, no current will flow; the red LEDs will not turn on, or at best just begin to glow.

On the other hand, if IC1's output voltage is high, and R4's resistance is low, and both red LEDs are on the low end of their specified turn-on voltage (assumed here to be 1.8 volts), then since both red LEDs are connected in series, they will both be passing the same current which will be 238 milliamperes; they will burn out immediately since the manufacturer's Absolute maximum Rating for current is 50 milliamperes.

In this case, the tolerance of R4 has negligible effect upon the current drawn by the two LEDs. If IC1's voltage is on the high side and the LEDs' turn-on voltage is on the low side, then if R4's value is low, the current through the LEDs will be 238 milliamperes. If R4's value is on the high side, then the current will drop slightly to 233 milliamperes. In either case, one or both of the LEDs will immediately burn out.

A solution to this problem is to drive each of the red LEDs with its own current-limiting resistor, instead of connecting them in series in an attempt to reduce production costs by omitting one resistor. This will allow limiting the current range through the red LEDs, regardless whether IC1's output voltage is on the high or low side, to 15.4 to 22.3 milliamperes (calculated using the typical output voltage of IC1, typical turn-on voltage of the red LEDs, over the tolerance range of the new value of R4). The manufacturer of the red LEDs, Agilent, does not have a published chart of luminosity versus current, but it should be similar to that of the white LEDs; using the measured luminance intensity data measured by 360° Test Labs for the white LEDs, this would be a range of about 13 to 18.5 foot-candles, compared to nominal intensity of about 17 foot-candles at 20 milliamperes, or a decrease in intensity by about 24% to an increase to about 9%. The additional production cost will be that of one more resistor, roughly five to ten cents per client's device. This small additional parts cost should be compared to the reduction of the risk of production defects due to extreme tolerance variations of IC1 or the red LEDs.

The effect of component value variations due to tolerances in the low battery circuit was previously discussed in the discussion of **Design Deficiency #3**.

The remaining circuit is that of IC1 itself. Variations within the published tolerance values of the three capacitors and one resistor around IC1 will not materially affect the output voltage of IC1; the main effect will be to cause its internal oscillation frequency to shift.

LED Observations

During our testing, we measured the temperature of the face of the lens of the LEDs to determine whether they were likely to burn or cause discomfort to a patient. The highest temperature we found, after the LEDs had been illuminated for five minutes, was 84.7° F; thus, we believe there is no danger of harm or discomfort.

During our research into discovering possible substitutes for the white LEDs, we came across several comments on several internet web sites mentioning that there is some concern springing up about the very high light emission from these types of Super Flux LEDs and the possibility of causing eye damage. However, we did not find any indication that there is any movement toward regulating such LEDs such as high power lasers have been regulated.

Printed Circuit Board Design

The client’s new-design prototype was built on a home-etched PC board. The existing circuit layout looks good and should be producible in high volume. We would, however, strongly suggest that great attention be paid to the mounting method of the six LEDs since considerable pressure will be exerted upon the LEDs, both directly toward the PC board and when the client’s device is dragged or pushed along the patient’s skin. This can easily break the solder joints. In addition, the PC board at the tips of the “arms” should be well-supported so that it does not flex within the arms, which can crack the copper wiring traces.

Parts List Analysis

360° Test Labs examined the parts list to detect any components which might prove to be close to End-Of-Production, or difficult to obtain, or for which there may be cheaper alternatives. The table on the following page summarizes our opinion, based upon performing exhaustive research using the on-line internet-accessible catalogs and any available hard copy catalogs of a number of Western electronics parts suppliers.

Conclusions

The new device design is basically good although 360° Testing Labs did find several design shortcomings as well as potential parts availability problems. The part IC is unique and appears to have no pin-for-pin compatible substitute. In addition, it appears to be nearly 10 years old and thus potentially at risk of obsolescence. There are many other ICs that perform the same basic function although they are generally in larger packages and may required additional components such as inductors. The small-quantity cost of such substitutes is about the same as the 100-piece quantity cost from Digikey for the part IC1.

Part	Description	Manu.	Manu. PN	Comments
IC1	Charge Pump	omitted	omitted	**B**randed IC1 does not seem to be stocked or even carried by many Western suppliers, Digikey being one exception although this part is not shown as available in any lesser quantity than 100 pieces. The part appears to have been introduced around 1997-1998, and so could be approaching End-Of-Production status. The part is unique, with no known pin-for-pin replacement although its function is duplicated by parts from many other manufacturers. Because of the apparent scarcity of suppliers, the part's uniqueness, and the lack of a pin-for-pin equivalent, and the part's age, we strongly recommend that a substitute be found, especially for a new product such as the client's new-design.
IC2	Voltage Supervisor			Many Western suppliers were found for this part, and we consider the risk of supply problems disrupting client's device production to be very low.
R1, R2, R3	1/8W Resistor			The following applies to all three resistor types. These are very common values, tolerances and package styles which will be available throughout the foreseeable future; thus, we deem their risk as negligible.
R4	1/10W Resistor			
C1	1μF Capacitor			The following applies to all three resistor types. These are very common values, tolerances and package styles which will be available throughout the foreseeable future; thus, we deem their risk as negligible.
C2	0.47μF Capacitor			
C3	2.2μF Capacitor			
D1	Low Battery LED (Red)			This part is non-critical to the operation of the client's device, and there are many substitute or replacement parts widely available from many suppliers. Thus, its supply shortage risk is very low.
D2-D5	Super Bright White LED			This part appears to be unique and available from only one supplier who sells on eBay. However, we also believe that similar or equivalent parts will become widely available within the near future. We were unable to locate a replacement with intensity specification more than half of this manufacturer's claim, except from another Chinese company advertising on eBay whose product is claimed to be 50% brighter at 75,000 mcd. We deem the risk of this part as very high due to the present lack of more than one substitute, and the location of its manufacturer.
D6,D7	Super Bright Red LED			Although this part is unique, its manufacturer is one of North America's more reliable and stable. We were able to locate several possible replacements although their specifications differed in one aspect or another, and would probably have to be tested for their suitability. We deem the risk of this part as moderate.
K1	Power Switch			This part may be considered unique and at high risk. There are substitutes which perform one or more of the same functions, or have the same printed circuit board footprint, or have the same size button; but none were found that were essentially identical. Thus, our risk rating for this part is high.
V1, V3, V5	Positive Battery Contact			Variations of these parts are widely available, particularly from overseas suppliers. Thus, we deem the risk of these parts as low.
V2, V4, V6	Negative Battery Contact			