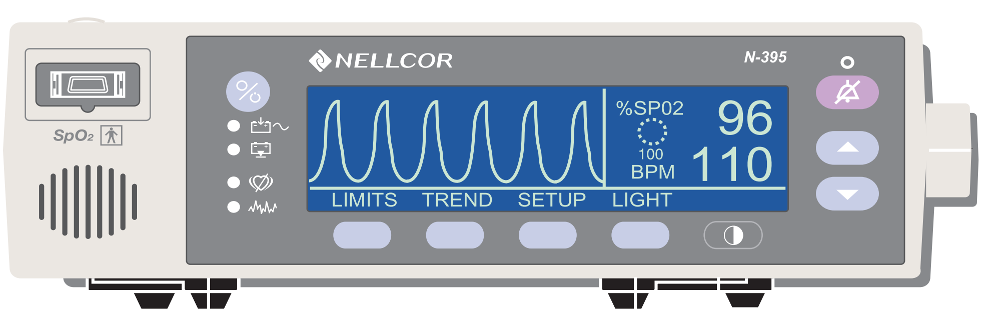
NELLCOR

N-395

Pulse Oximeter
Service Manual



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SECTION 1: INTRODUCTION

1.1 MANUAL OVERVIEW

The latest version of this manual is available on the Internet at:
http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

This manual contains information for servicing the Nellcor® model N-395 pulse oximeter. Only qualified service personnel should service this product. Before servicing the N-395, read the operator's manual carefully for a thorough understanding of operation.

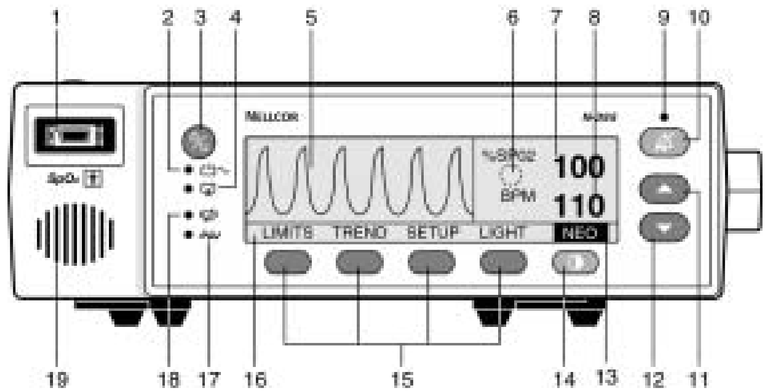
WARNING: Explosion hazard. Do not use the N-395 pulse oximeter in the presence of flammable anesthetics.

1.2 DESCRIPTION OF N-395 PULSE OXIMETER

The N-395 pulse oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-395 is intended for use with neonatal, pediatric, and adult patients during both no-motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only.

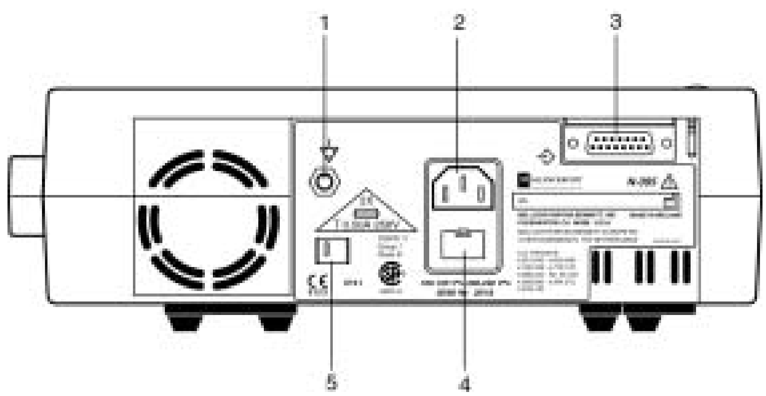
Note: "Hospital type" environments include surgicenters (including physician office based facilities, sleep labs, and skilled nursing facilities). Use with any particular patient requires the selection of an appropriate oxygen transducer as described in the operator's manual. Motion performance claims are applicable to Nellcor models D-25, N-25, I-20, D-20, and D-25L oximetry sensors.

Through the use of the four softkeys, the operator can access trend information, select an alarm limit to be changed, choose the language to be used, adjust the internal time clock, and change communications protocol. The N-395 can operate on AC power or on an internal battery. The controls and indicators for the N-395 are illustrated in Figure 1-1 and Figure 1-2.



1. SpO2 Sensor Port
2. AC/Battery Charging Indicator
3. Power On/Off Button
4. Low Battery Indicator
5. Waveform Display Area
6. SatSeconds™ Indicator
7. %SpO2 Indicator
8. Pulse Rate Display
9. Alarm Silence Indicator
10. Alarm Silence Button
11. Adjust Up Button
12. Adjust Down Button
13. Neonate Indicator
14. Contrast Button
15. Softkeys
16. Menu Bar
17. Motion Indicator
18. Pulse Search Indicator
19. Speaker

Figure 1-1: N-395 Front Panel



1. Equipotential (ground) Terminal
2. AC Inlet
3. DB-15 Interface Connector (Data Port)
4. Fuse Receptacle
5. Voltage Selection Switch

Figure 1-2: N-395 Rear Panel

Figures 1-3, 1-4, and 1-5 illustrate the various functions that are available through the use of the softkeys, and how to access them. A complete explanation of the keys is provided in the N-395 operator's manual.

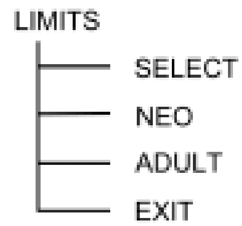


Figure 1-3: Limits Softkey Map

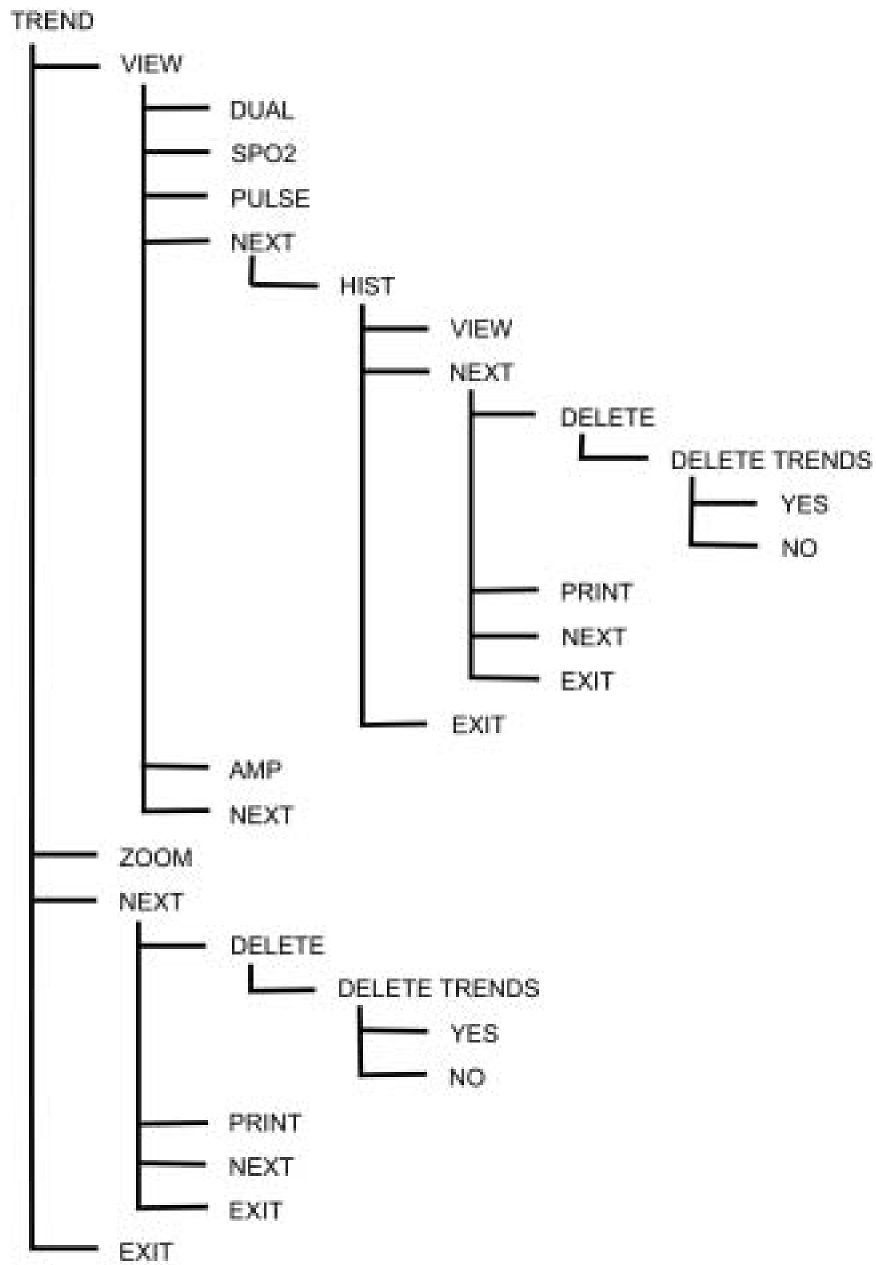


Figure 1-4: Trend Softkey Map

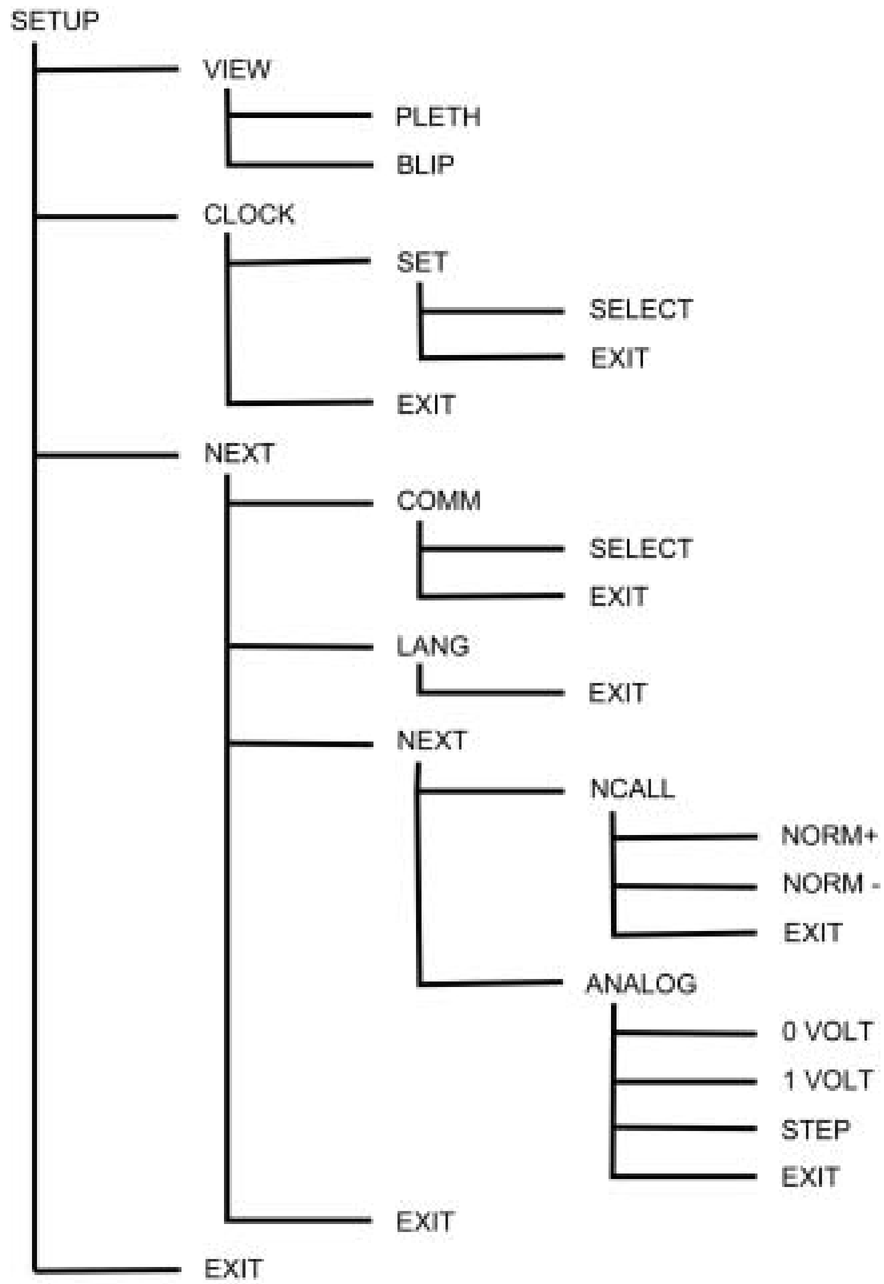


Figure 1-5: Setup Softkey Map

1.3 RELATED DOCUMENTS

To perform test and troubleshooting procedures, and to understand the principles of operation and circuit analysis sections of this manual, you must know how to operate the monitor. Refer to the N-395 operator's manual. To understand the various Nellcor sensors that work with the monitor, refer to the individual sensor's directions for use.

The latest version of this manual and Nellcor Sensor's directions for use are available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

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SECTION 2: ROUTINE MAINTENANCE

2.1 CLEANING

Caution: Do not immerse the N-395 or its accessories in liquid or clean with caustic or abrasive cleaners. Do not spray or pour any liquid on the monitor or its accessories.

To clean the N-395, dampen a cloth with a commercial, nonabrasive cleaner and wipe the exterior surfaces lightly. Do not allow any liquids to come in contact with the power connector, fuse holder, or switches. Do not allow any liquids to penetrate connectors or openings in the instrument cover. Wipe sensor cables with a damp cloth. For sensors, follow each sensor's directions for use.

2.2 PERIODIC SAFETY AND FUNCTIONAL CHECKS

The following checks should be performed at least every 2 years by qualified service technicians.

1. Inspect the exterior of the N-395 equipment for damage.
2. Inspect the safety labels for legibility. If the labels are not legible, contact Nellcor Technical Services Department or your local Nellcor representative.
3. Verify that the unit performs properly as described in paragraph 3.3.
4. Perform the electrical safety tests detailed in paragraph 3.4. If the unit fails these electrical safety tests, repair the unit or contact Nellcor Technical Services Department or your local Nellcor representative for assistance.
5. Inspect the fuses for proper value and rating (F1 & F2 = 0.5 amp slow blow).

2.3 BATTERY

Nellcor recommends replacing the instrument's battery every 2 years. When the N-395 is going to be stored for 3 months or more, remove the battery prior to storage. To replace or remove the battery, refer to Section 6, *Disassembly Guide*.

If the N-395 has been stored for more than 30 days, charge the battery as described in paragraph 3.3.1. A fully discharged battery requires 14 hours with the monitor in standby, or 18 hours if it is in use, to receive a full charge. The battery is being charged whenever the instrument is plugged into AC.

Note: If power stored in the battery is too low, the unit will not operate even when plugged into AC. If this occurs, leave the unit plugged in to allow the battery to charge as described in paragraph 3.3.1. After approximately 10 minutes, the battery should have enough charge to allow the unit to operate on AC.

SECTION 3: PERFORMANCE VERIFICATION

3.1 INTRODUCTION

This section discusses the tests used to verify performance following repairs or during routine maintenance. All tests can be performed without removing the N-395 cover. All tests except the battery charge and battery performance tests must be performed as the last operation before the monitor is returned to the user.

If the N-395 fails to perform as specified in any test, repairs must be made to correct the problem before the monitor is returned to the user.

3.2 EQUIPMENT NEEDED

Equipment	Description
Digital multimeter (DMM)	Fluke Model 87 or equivalent
Durasensor ® oxygen transducer	DS-100A
Oxisensor ® II oxygen transducer	D-25
Pulse oximeter tester	SRC-2
Safety analyzer	Must meet current AAMI ES1/1993 & IEC 601-1/1998 specifications
Sensor extension cable	SCP-10 or MC-10
Data interface cable	EIA-232 cable (optional)
Stopwatch	Manual or electronic

3.3 PERFORMANCE TESTS

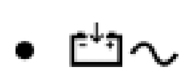
The battery charge procedure should be performed before monitor repairs whenever possible.

Note: This section is written using Nellcor factory-set defaults. If your institution has preconfigured custom defaults, those values will be displayed. Factory defaults can be restored. Refer to paragraph 4.4.3, *PARAM*, subparagraph *RESET*.

3.3.1 Battery Charge

Perform the following procedure to fully charge the battery.

1. Connect the monitor to an AC power source.
2. Verify that the monitor is off and that the AC Power/Battery Charging indicator is lit.



3. Charge the battery for at least 14 hours in standby.

3.3.2 Power-Up Performance

The power-up performance tests (3.3.2.1 through 3.3.2.2) verify the following monitor functions:

- 3.3.2.1 Power-On Self-Test
- 3.3.2.2 Power-On Defaults and Alarm Limit Ranges

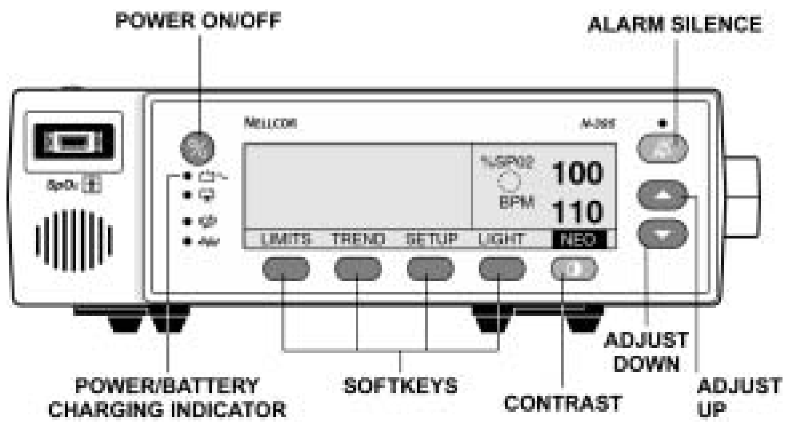


Figure 3-1: N-395 Controls

3.3.2.1 Power-On Self-Test

1. Connect the monitor to an AC power source and verify that the AC Power/Battery Charging indicator is lit.
2. Do not connect any input cables to the monitor.
3. Observe the monitor front panel. With the monitor off, press the POWER ON/OFF button (Figure 3-1). The monitor must perform the following sequence:
   a. Within 2 seconds, all LEDs are illuminated, all pixels on the LCD display are illuminated, and the backlight comes on.
   b. The indicators remain lighted.
   c. The LCD display shows NELLCOR and the software version of the N-395 (Figure 3-2).

Note: The software “Version” displayed in Figure 3-2 is X.X.X.X. The actual software version will be displayed on the monitor.

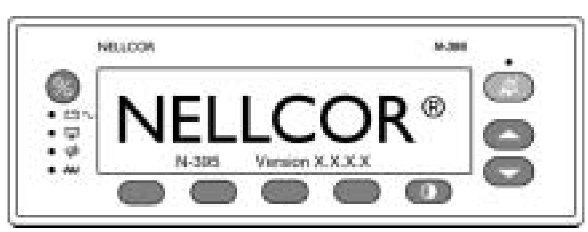


Figure 3-2: Self-Test Display

d. A 1-second beep sounds, indicating proper operation of the speaker, and all indicators turn off except the AC Power/Battery Charging indicator and the LCD screen.

e. The N-395 begins normal operation.

3.3.2.2 Power-On Defaults and Alarm Limit Ranges

Note: When observing or changing alarm limits, a 10-second timeout is in effect. If no action is taken within 10 seconds, the monitor automatically returns to the monitoring display.

Note: The descriptions that follow are based on the assumption that Pleth view is the view that has been selected. The steps for changing an alarm limit are the same if the view being used is Blip (Magnified) view (Figure 3-3).

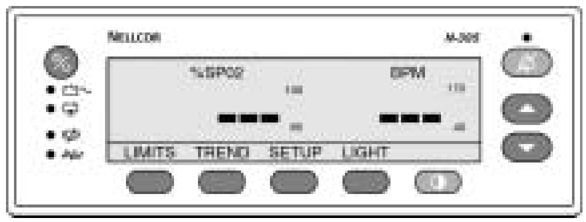


Figure 3-3: Blip (Magnified) View

Note: Power-on defaults will be the factory-set defaults or the defaults set by your institution.

1. Ensure that the monitor is on. Press and release the LIMITS softkey. Verify that the monitor emits a single beep and the pleth view is replaced with a display of the alarm limits. The upper alarm limit for %SpO_2 will indicate an alarm limit of "100" inside a box (Figure 3-4).

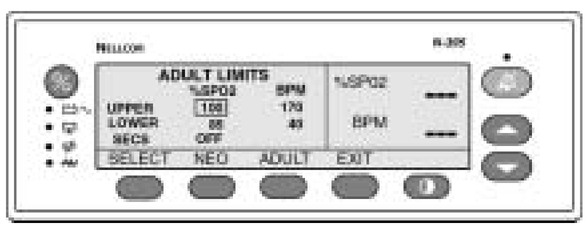


Figure 3-4: Adjusting %SpO_2 Upper Alarm Limit

Note: After 10 seconds with no activity, normal display is resumed.

2. Press the LIMITS softkey. Press and hold the DOWN ARROW button. Verify that the boxed number for %SpO_2 upper alarm limit reduces to a minimum of "85." See Figure 3-5.

Note: A decimal point in the display indicates that the alarm limits have been changed from factory default values.

3. Press the SELECT softkey. Verify that the monitor emits a single beep and the box moves to the %SpO_2 lower alarm limit of "85."

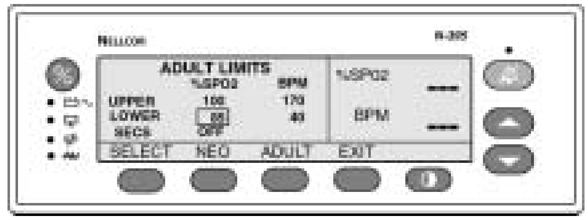


Figure 3-5: Adjusting % SpO_2 Lower Alarm Limit

4. Press and hold the DOWN ARROW button and verify that the %SpO_2 lower alarm limit display reduces to a minimum of "20." Press and hold the UP ARROW button and verify that the %SpO_2 lower alarm limit display cannot be raised past the upper alarm limit setting of "85." Press the EXIT softkey.

5. Press the LIMITS softkey and then press the SELECT softkey three times. Verify that the monitor emits a beep after each keystroke. The Pulse upper alarm limit should be "170" and should be boxed. See Figure 3-6.

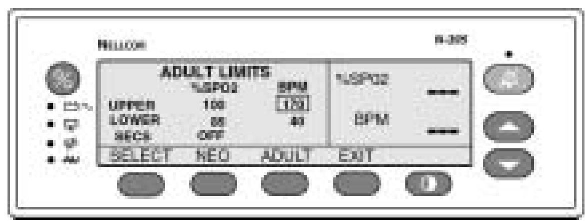


Figure 3-6: Adjusting High Pulse Rate Alarm

6. Press and hold the DOWN ARROW button. Verify that the minimum displayed value is "40" for the Pulse upper alarm limit. Press the EXIT softkey.

7. Press the LIMITS softkey and then press the SELECT softkey four times. Verify that the Pulse lower alarm limit display indicates an alarm limit of "40" and is boxed. See Figure 3-7.

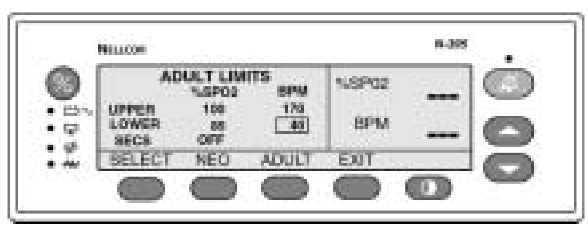


Figure 3-7: Adjusting Low Pulse Rate Alarm

8. Press and hold the DOWN ARROW button. Verify that the boxed Pulse lower alarm limit display reduces to a minimum of "30."

9. Press and hold the UP ARROW button and verify that the boxed Pulse lower alarm limit display cannot be adjusted above the Pulse high limit of "40."

10. Press the LIMITS softkey and then press the SELECT softkey two times. Verify that *SatSeconds* SECS alarm is selected. See Figure 3-8.

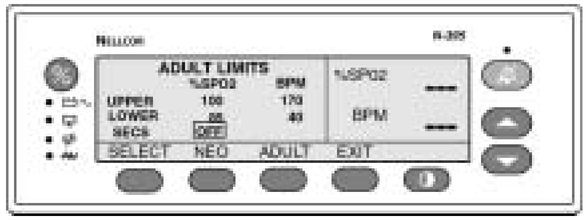


Figure 3-8: *SatSeconds* Alarm

11. Press the UP ARROW button repeatedly and verify that the *SatSeconds* alarm display cycles from OFF through 10, 25, 50, 100, OFF.
12. Press the POWER ON/OFF button to turn the monitor off.
13. Press the POWER ON/OFF button to turn the N-395 back on.
14. Press and release the LIMITS softkey. Verify that the $\%SpO_2$ upper alarm limit display is boxed and indicates an alarm limit of "100."
15. Press the SELECT softkey. Verify that the $\%SpO_2$ lower alarm limit display is boxed and indicates an alarm limit of "85."
16. Press the SELECT softkey. Verify that the *SatSeconds* SECS alarm is set to OFF.
17. Press the SELECT softkey. Verify that the Pulse upper alarm limit display is boxed and indicates an alarm limit of "170."
18. Press the SELECT softkey. Verify that the Pulse lower alarm limit display is boxed and indicates an alarm limit of "40."
19. Press the POWER ON/OFF button to turn the monitor off.

3.3.3 Operation with a Pulse Oximeter Tester

Operation with an SRC-2 pulse oximeter tester includes the following tests:

- 3.3.3.1 Alarms and Alarm Silence
- 3.3.3.2 Alarm Volume Control
- 3.3.3.3 Pulse Tone Volume Control
- 3.3.3.4 Dynamic Operating Range
- 3.3.3.5 Nurse Call
- 3.3.3.6 Analog Output
- 3.3.3.7 Operation on Battery Power

3.3.3.1 Alarms and Alarm Silence

1. Connect the SRC-2 pulse oximeter tester to the sensor-input cable and connect the cable to the monitor. Set the SRC-2 as follows:

SWITCH	POSITION
RATE	38
LIGHT	LOW
MODULATION	OFF
RCAL/MODE	RCAL 63/LOCAL

2. Press the POWER ON/OFF button to turn the monitor on. After the normal power-up sequence, press the following softkeys: SETUP, VIEW, and PLETH. Verify that the %SpO_2 and Pulse initially indicate zeroes.

3. Move the modulation switch on the SRC-2 to LOW.

4. Verify the following monitor reactions:

   a. The plethysmograph waveform begins to track the artificial pulse signal from the SRC-2.

   b. The pulse tone is heard.

   c. Zeroes are displayed in the %SpO_2 and Pulse displays.

   d. Within 20 seconds, the monitor displays saturation and pulse rate as specified by the tester. Verify that the values are within the following tolerances:

Oxygen Saturation Range	79% to 83%
Pulse Rate Range	37 to 39 bpm

   e. The audible alarm sounds and both the %SpO_2 and Pulse displays flash, indicating that both parameters have violated the default alarm limits.

5. Press and hold the ALARM SILENCE button on the front of the monitor for less than 3 seconds. Verify that the %SpO_2 display indicates "60" and the Pulse display indicates "SEC" while the ALARM SILENCE button is pressed. When the button is released, the alarm is silenced.

6. With the alarm silenced, verify the following:

   a. The alarm remains silenced for 60 seconds.

   b. The Alarm Silence indicator lights.

   c. The %SpO_2 and Pulse displays continue to flash.

   d. The pulse tone is still audible.

   e. The audible alarm returns in approximately 60 seconds.

7. Press and hold the ALARM SILENCE button. Within 3 seconds, press the DOWN ARROW button until the Pulse Rate display indicates "30." Press the UP ARROW button and verify that the displays indicate 60 SEC, 90 SEC, 120 SEC, and OFF. Release the button when the display indicates "OFF."

8. Press and release the ALARM SILENCE button. Verify that the Alarm Silence Indicator flashes.

9. Wait approximately 3 minutes. Verify that the alarm does not return. After 3 minutes, the alarm silence reminder beeps three times, and will continue to do so at approximately 3-minute intervals.

3.3.3.2 Alarm Volume Control

After completing the procedure in paragraph 3.3.3.1:

1. Press and hold the ALARM SILENCE button and verify the following:
   a. "OFF" is displayed for approximately 3 seconds.
   b. After 3 seconds, a steady tone is heard at the default alarm volume setting, the $\%SpO_2$ display indicates "VOL," and the Pulse Rate display indicates the default setting of 5.
2. While still pressing the ALARM SILENCE button, press the DOWN ARROW button until an alarm volume setting of 1 is displayed. Verify that the volume of the alarm has decreased but is still audible.
3. Continue pressing the ALARM SILENCE button and press the UP ARROW button to increase the alarm volume setting to a maximum value of 10. Verify that the volume increases. Press the DOWN ARROW button until a comfortable audio level is attained.
4. Release the ALARM SILENCE button. The tone will stop.

3.3.3.3 Pulse Tone Volume Control

1. Press the UP ARROW button and verify that sound level of the beeping pulse tone increases.
2. Press the DOWN ARROW button and verify that sound level of the beeping pulse tone decreases until it is no longer audible. Press the UP ARROW button to return the beep volume to a comfortable level.

3.3.3.4 Dynamic Operating Range

The following test sequence verifies proper monitor operation over a range of input signals.

1. Connect the SRC-2 to either the SCP-10 or MC-10 sensor cable, which is connected to the N-395 and turn the N-395 on.
2. Place the SRC-2 in the RCAL 63/LOCAL mode.
3. Set the SRC-2 as indicated in Table 3-1. Verify that the N-395 readings are within the indicated tolerances. Allow the monitor several seconds to stabilize the readings.

Note: An asterisk (*) indicates values that produce an alarm. Press the ALARM SILENCE button to silence the alarm.

Table 3-1: Dynamic Operating Range

SRC-2 Settings			N-395 Indications	
RATE	**LIGHT**	**MODULATION**	**SpO_2**	**Pulse Rate**
38	HIGH2	LOW	79 - 83*	35 - 41*
112	HIGH1	HIGH	79 - 83*	109 - 115
201	LOW	LOW	79 - 83*	198 - 204*
201	LOW	HIGH	79 - 83*	198 - 204*

3.3.3.5 Nurse Call

1. Connect the negative lead of a voltmeter to pin 5 and positive lead to pin 11 of the data port on the back of the instrument. Ensure that the audible alarm is not silenced or turned off.

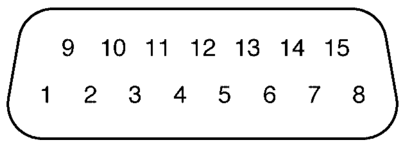


Figure 3-9: Data Port Pinouts

2. Set the SRC-2 Rate switch to 201 to create an alarm condition. Verify an output voltage at pins 5 and 11 between +5 to +12 VDC.
3. Press the ALARM SILENCE button. With no active audible alarm, the output voltage at pins 5 and 11 must be between -5 to -12 VDC. This verifies the RS-232 Nurse Call function.
4. With the instrument in an alarm condition, use a digital voltmeter (DVM) to verify that there is no continuity ($\geq$ 1 MΩ) between pins 8 and 15 and that there is continuity ($\leq$ 60 Ω) between pins 7 and 15.
5. Adjust the alarm limits so that there is no alarm condition. Use a DVM to verify that there is continuity between pins 8 and 15 and that there is not continuity between pins 7 and 15. This verifies the solid state Nurse Call function.

3.3.3.6 Analog Output

1. Connect the negative lead of a voltmeter to pin 10 and positive lead to pin 6 of the data port on the back of the instrument (Figure 10-3).
2. Press the following softkeys: SETUP, NEXT, NEXT, and ANALOG. Press the 1-VOLT softkey.
3. Verify that the output voltage is +1.0 ± 0.025 VDC. This verifies the analog SpO_2 function.
4. Leave the negative lead connected to pin 10 and verify 1.0 ± 0.025 VDC on pins 13 and 14. This verifies the BPM and Pleth function.

Note: If step 4 takes more than 2 minutes to complete, the analog output will time out. Repeat step 2 to initiate the analog output.

5. Move the positive lead back to pin 6.

6. Press the following softkeys; SETUP, NEXT, NEXT, and ANALOG. Press the 0-VOLT softkey.
7. Verify that the output voltage is +0.0 ± 0.025 VDC.
8. Leave the negative lead connected to pin 10 and verify 0.0 ± 0.025 VDC on pins 13 and 14.

Note: If step 8 takes more than 2 minutes to complete, the analog output will time out. Repeat step 2 to initiate the analog output.

9. Disconnect the voltmeter from the instrument.

3.3.3.7 Operation on Battery Power

1. With the instrument operating on AC, turn on the backlight.
2. Disconnect the instrument from AC and verify that the AC/Battery Charging indicator turns off.
3. Verify that the instrument continues monitoring normally and that the low battery indicator is not lit.

Note: If the low battery indicator is illuminated, perform the procedure outlined in step 3.3.1.

4. Connect the instrument to AC and verify that the AC/Battery Charging indicator turns on and that the instrument is monitoring normally.

3.3.4 General Operation

The following tests are an overall performance check of the system:

- 3.3.4.1 LED Excitation Test
- 3.3.4.2 Operation with a Live Subject

3.3.4.1 LED Excitation Test

This procedure uses normal system components to test circuit operation. A Nellcor *Oxisensor ® II* oxygen transducer, model D-25, is used to examine LED intensity control. The red LED is used to verify intensity modulation caused by the LED intensity control circuit.

1. Connect the monitor to an AC power source.
2. Connect an SCP-10 or MC-10 sensor input cable to the monitor.
3. Connect a D-25 sensor to the sensor-input cable.
4. Press the POWER ON/OFF button to turn the monitor on.
5. Leave the sensor open with the LEDs and photodetector visible.
6. After the monitor completes its normal power-up sequence, verify that the sensor LED is brightly lit.
7. Slowly move the sensor LED in proximity to the photodetector element of the sensor. Verify as the LED approaches the optical sensor, that the LED intensity decreases.
8. Open the sensor and notice that the LED intensity increases.

9. Repeat step 7 and the intensity will again decrease. This variation is an indication that the microprocessor is in proper control of LED intensity.

10. Turn the N-395 off.

3.3.4.2 Operation with a Live Subject

Patient monitoring involves connecting the monitor to a live subject for a qualitative test.

1. Ensure that the monitor is connected to an AC power source.
2. Connect an SCP-10 or MC-10 sensor input cable to the monitor.
3. Connect a Nellcor *Durasensor* ® oxygen transducer, model DS-100A, to the sensor input cable.
4. Clip the DS-100A to the subject as recommended in the sensor's directions for use.
5. Press the POWER ON/OFF button to turn the monitor on and verify that the monitor is operating.
6. The monitor should stabilize on the subject's physiological signal in about 15 to 30 seconds. Verify that the oxygen saturation and pulse rate values are reasonable for the subject.

3.4 SAFETY TESTS

N-395 safety tests meet the standards of, and are performed in accordance with, IEC 601-1 (EN 60601-1, Amendment 1, Amendment 2) and UL 2601-1, for instruments classified as Class 1 and TYPE BF and ANSI/AAMI Standard ESI.

Applicable tests for these standards are listed below. The technician must be familiar with the Standards applicable to their institution and country. Test equipment and its application must comply with the applicable standard.

- Ground Integrity
- Earth Leakage Current
- Enclosure Leakage Current
- Patient Applied Risk Current
- Patient Isolation Risk Current

Note: **Patient Applied Risk Current and Patient Isolation Risk Current**. The leakage test lead from the test equipment must be connected to the N-395 SpO_2 Sensor Port using a male 9-pin “D” type connector that has all pins shorted together.

SECTION 4: POWER-ON SETTINGS AND SERVICE FUNCTIONS

4.1 INTRODUCTION

This section discusses how to reconfigure power-on default values, and access the service functions.

4.2 POWER-ON SETTINGS

The following paragraphs describe how to change power-on default settings.

By using softkeys as shown in Figure 1-1, the user can change alarm limits, the type of display, baud rate, time and date, and trends to view.

Some values cannot be saved as power-on default values. An SpO_2 Lower Alarm limit less than 80 will not be saved as a power-on default. Audible Alarm Off will not be accepted as a power-on default. An attempt to save either of these values as default will result in an invalid tone. These limits can be adjusted lower for the current patient, but they will be lost when the instrument is turned off.

A decimal point is added to the right of a display when the alarm limit for that display has been changed to a value that is not a power-on default value. If the new value is saved as a power-on default value, the decimal point will be removed. By using the service functions, changes can be saved as power-on default values.

4.3 FACTORY DEFAULT SETTINGS

Factory power-on default settings for the N-395 are listed in Table 9-1 on page 9-2and Table 9-2 on page 9-3.

4.4 SERVICE FUNCTIONS

Service functions can be used to select institutional defaults and to access information about the patient or instrument. Only a Nellcor Customer Service Engineer should access some of the items available through the service functions. These items will be noted in the text that follows.

4.4.1 Accessing the Service Functions

Disconnect the sensor from the SCP-10 or MC-10 extension cable; or, disconnect the SCP-10 or MC-10 extension cable from the instrument. Simultaneously press the LIGHT softkey and the CONTRAST button for more than 3 seconds. The service function is only accessible from the main menu display. The menu bar will change to the headings listed in Figure 4-1.

Note: If the above steps are performed with a sensor cable connected, only the PARAM and EXIT softkeys appear on the screen.

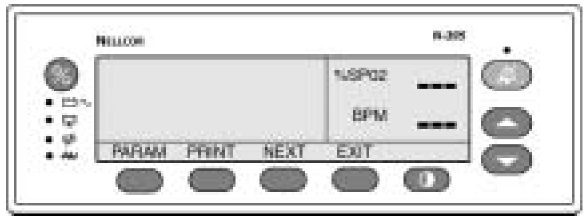


Figure 4-1: Service Function Softkeys

Figure 4-2 can be used as a quick reference showing how to reach different softkey functions. Each gray box represents a different set of softkeys that can be reached with the service function. Items reached through the PARAM softkey can be accessed during normal operation. Functions provided by the PRINT and NEXT softkeys cannot be accessed when a sensor cable is connected to the instrument. Each of the various functions is described in the text that follows.

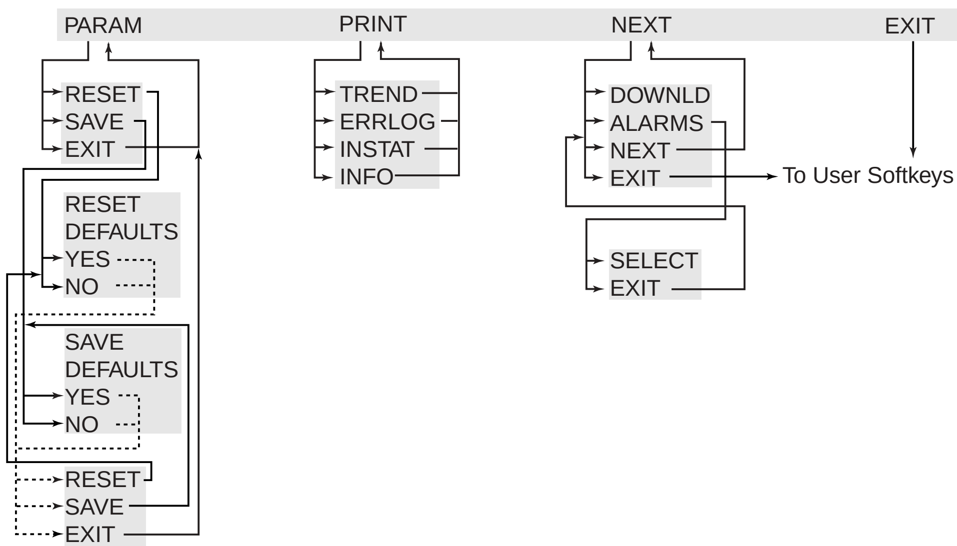


Figure 4-2: Service Function Softkey Map

4.4.2 EXIT & NEXT Softkeys

NEXT

There are not enough softkeys to display all of the options that are available at some levels of the menu. Pressing the NEXT softkey allows you to view additional options available at a given menu level.

EXIT

To back up one menu level, press the EXIT softkey. The service functions can be exited by repeatedly pressing the EXIT softkey.

4.4.3 PARAM

When the PARAM softkey is pressed, the function of the softkeys changes as shown in Figure 4-3. These options can be accessed without disconnecting the sensor cable from the instrument.

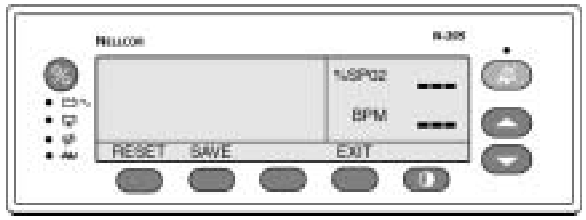


Figure 4-3: PARAM Softkeys

RESET

The RESET softkey can be used if any settings stored in memory have been changed from factory default values. If YES is pressed, the instrument sounds three tones and the settings return to factory default values. When NO is pressed, no changes are made to the settings stored in memory.

SAVE

When adjustable values are changed from factory default, the SAVE softkey can be used to preserve the settings as institutional power-on default values. Pressing YES stores the current settings in memory. The instrument sounds three tones indicating that the changes have been saved as power-on default values. The new saved values will continue to be used through power-on and off cycles until they are changed and saved again, or until they are reset. If NO is pressed, the changed values will not be saved.

Note: An invalid tone indicates a parameter value cannot be saved as a power-on default (see paragraph 4.2). Along with the invalid tone, a message will be displayed indicating which parameter could not be saved as a power-on default.

4.4.4 PRINT

PRINT

Accessing the PRINT softkey makes four printouts available. See Section 10 for information about how to make connections to the data port and how data is presented in a printout. The appropriate printout can be selected by pressing the corresponding softkey. Figure 4-4 represents the softkey configuration after the PRINT softkey has been selected.

Up to 48 hours of trend data can be viewed on the printouts described below. When the instrument is turned on, trend data is recorded every 4 seconds. As an example, an instrument that is used 6 hours a week would take approximately 8 weeks to fill its memory.

Note: The two-letter codes and the symbols that occur in the printout are described in Table 10-2 of Section 10 on page 10-11.

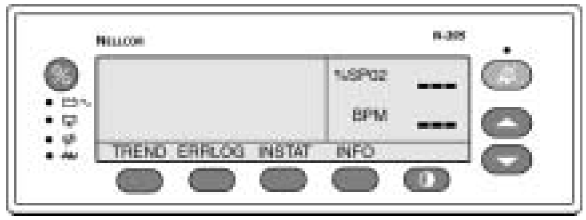


Figure 4-4: PRINT Softkeys

TREND

A Trend printout will include all data recorded for up to 48 hours of monitoring since the last Delete Trends was performed. A new trend point is recorded every 4 seconds. Figure 4-5 is an example of a Trend printout.

N-395 Version 1.0.0.000		TREND	SpO2 Limit: 30-100%		PR Limit: 100-180 bpm
TIME	%SpO2	PR (bpm)	PA		
01-Jul-99 14:00:00	100	120	220		
01-Jul-99 14:00:05	100	124	220		
01-Jul-99 14:00:10	100	190	220		
01-Jul-99 14:00:15	100	190	220		
01-Jul-99 18:00:43	- - -	- - -	- - -		
01-Jul-99 18:00:48	- - -	- - -	- - -		
N-395 Version 1.0.0.000		Trend	SpO2 Limit: 80-100%		PR Limit: 60-180 bpm
Time	%SpO2	PR (bpm)	PA		
01-Jul-99 18:00:53	- - -	- - -	- - -		
01-Jul-99 18:00:58	- - -	- - -	- - -		
01-Jul-99 18:01:03	98	100	140		
01-Jul-99 18:01:08	98	181*	190		
01-Jul-99 18:01:13	99	122	232		
Output Complete					

Figure 4-5: Trend Printout

The first row of the printout includes information about the type of instrument delivering the information, the software level, type of printout, and alarm parameters. The second line lists the headings for the columns. These lines are printed out every 25 lines, or when a change to an alarm limit is made.

Patient data is represented with a date and time stamp for the data. In the example above, the "- - -" means that a sensor was connected but the signal quality of the data being received was too low for the monitor to interpret the data. Patient data that is outside of an alarm limit is marked with an asterisk (*).

At the end of the printout "Output Complete" will be printed. This indicates that there was no corruption of data. If the Output Complete statement is not printed at the end of the printout, the data must be considered invalid.

ERRLOG (Nellcor Customer Service Engineer Only)

A list of all the errors recorded in memory can be obtained by pressing the ERRLOG softkey. The first line lists the type of instrument producing the printout, software level, type of printout, and the time of the printout are listed in the first line. The second line of the printout consists of column headings. If nothing prints out, there have been no errors. An example of an Errlog printout is shown in Figure 4-6.

N-395 Version 1.0.0.000		Error Log	Time:	14600:00:07	
Op Time	Error	Task	Addr	Count	
10713:21:03	52	12	48F9	100	
00634:26:01	37	4	31A2	3	
Output Complete					

Figure 4-6: Errlog Printout

INSTAT (Nellcor Customer Service Engineer Only)

The DELETE softkey, described in the operator's manual, allows the user to delete the most recent trend data. The current trend data, along with the deleted trends, can be retrieved from the instrument through an Instat printout.

The oldest deleted trend is Trend 01 on the Instat printout. If a Trend 01 already exists in memory from an earlier Delete, the next deleted trend will become Trend 02. Every time a DELETE is performed from the user softkeys, the number of existing trends will increase by 1. The current trend will have the largest trend number.

Figure 4-7 illustrates an Instat printout. Line one is for instrument type, software revision level, type of printout, and alarm parameter settings. The second line contains the column headings. A trend point is recorded for every 4 seconds of instrument operation. Up to 48 hours of instrument operation data can be recorded.

If the final line on the printout shows "Output Complete," then the data has been successfully transmitted with no corruption. If there is no "Output Complete" line printed, the data should be considered invalid.

N-395	Version 1.0.0.000	Instrument		SpO2 Limit: 30-100%	PR Limit: 100-180 bpm
TIME Trend 01	%SpO2	PR (bpm)	PA	SpO2 Status	UIF Status Aud
01-Jul-99 14:00:00	- - -	- - -	- - -	SD	BU LB AO L
01-Jul-99 14:00:05	- - -	- - -	- - -	PS	BU LB AO
01-Jul-99 14:00:10	100	120	220		BU LB
01-Jul-99 14:00:15	100	120	220		BU LB
N-395	Version 1.0.0.000	Instrument		SpO2 Limit: 80-100%	PR Limit: 60-180 bpm
TIME Trend 02	%SpO2	PR (bpm)	PA	SpO2 Status	UIF Status Aud
01-Jul-99 14:24:24	79*	58*	220	PS SL PL	BU LB M
01-Jul-99 14:24:29	79*	57*	220	PS SL PL	BU LB AS M
01-Jul-99 14:24:29	0*	0*	- - -	PS LP SL PL	BU LB AS H
N-395	Version 1.0.0.000	Instrument		SpO2 Limit: 80-100%	PR Limit: 60-180 bpm
TIME Trend 03	%SpO2	PR (bpm)	PA	SpO2 Status	UIF Status Aud
11-Jul-99 7:13:02	99	132*	220	PH	BU M
11-Jul-99 7:13:07	99	132*	220	PH	BU M
11-Jul-99 7:13:12	99	132*	220	PH	BU M
11-Jul-99 7:13:17	99	132*	220	PH	BU M
11-Jul-99 7:13:22	99	132*	220	PH	BU M
11-Jul-99 7:13:27	99	132*	220	PH	BU M
11-Jul-99 7:13:32	99	132*	220	PH	BU M
Output Complete					

Figure 4-7: Instat Printout

INFO (Nellcor Customer Service Engineer Only)

Pressing the INFO softkey produces a printout of instrument information as illustrated in Figure 4-8. A single line will be printed. The data presented in the printout, going from left to right is, the instrument type (N-395), software version level, type of printout (INFO), CRC (Cyclic Redundancy Check) number, and the ratio of current operating time to total operating time (the ratio itself has no units of measure.

N-395 Version XXXXXX INFO CRC:XXXX SEC: 123456789/987654321

Figure 4-8: INFO Printout

4.4.5 NEXT

Additional options can be accessed from the main Service Functions menu by pressing the NEXT softkey. When NEXT is pressed, the softkeys change to the functions shown in Figure 4-9.

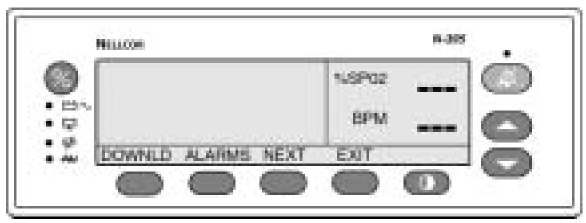


Figure 4-9: NEXT Softkeys

DOWNLD

When DOWNLD is selected, the instrument will display the revision of the Boot Code. To exit DOWNLD, cycle power to the instrument by pressing the POWER ON/OFF button. Consult the Directions for Use (DFU) provided with any downloads or upgrades to the FLASH firmware.

ALARMS

Pressing the ALARMS softkey can change characteristics of the audible alarm. When the ALARMS softkey is pressed, the softkey's functions change as shown in Figure 4-10.

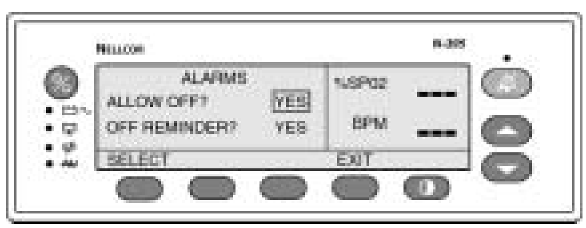


Figure 4-10: ALARMS Softkeys

SELECT

The SELECT softkey is used to select what function of the audible alarm is going to be changed. A box can be cycled between two choices: ALLOW OFF and OFF REMINDER.

How to select and set ALLOW OFF and OFF REMINDER:

1. Disconnect sensor from monitor.

Note: If the sensor is not disconnected, the only softkeys on the screen will be PARAM and EXIT.

2. Simultaneously press the fourth softkey from the left and the CONTRAST softkey for more than 3 seconds. The menu bar will change to the softkey headings shown in Figure 4-11.

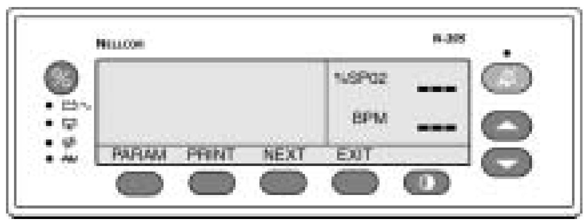


Figure 4-11: Service Function Softkeys

3. Press the NEXT softkey.

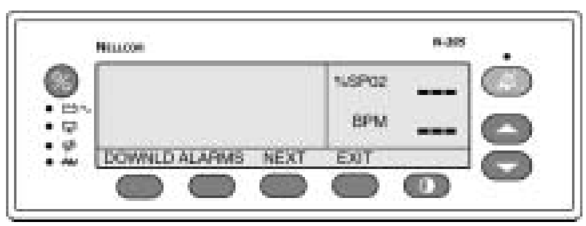


Figure 4-12: Service Function NEXT Softkey

4. Press the ALARMS softkey.

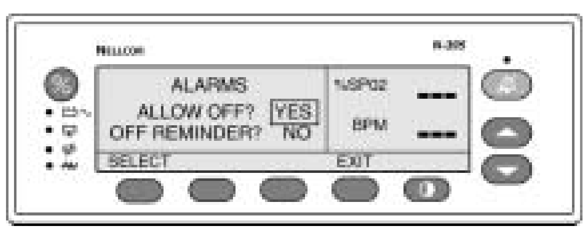


Figure 4-13: Service Function ALARMS Softkey

5. Use the UP ARROW or DOWN ARROW buttons to cycle between YES and NO. Use the SELECT softkey to toggle between ALLOW OFF and OFF REMINDER.

6. Press the EXIT softkey.

When ALLOW OFF is selected, a choice is given between allowing an audible alarm OFF or disabling the audible alarm OFF. Pressing the UP or DOWN ARROW key cycles between Yes and No. If Yes is selected, the operator has the option of selecting AUDIBLE ALARM OFF. If No is selected, the operator is not given the option of selecting AUDIBLE ALARM OFF as an alarm silence duration choice.

If the audible alarm is set to Off, a reminder tone can be sounded every 3 minutes to notify the user of this condition. The UP and DOWN ARROW keys can be used to change the choice from Yes to No. Selecting Yes enables the Reminder. Selecting No disables the Reminder when the audible alarm is set to Off.

4.5 SETTING INSTITUTIONAL DEFAULTS (SAMPLE)

The following default values may be set:

- Alarm Silence Duration (30, 60, 90, 120 seconds)
- Alarm Silence Restriction (none, sound reminder, do not allow OFF)
- Alarm Volume (1 to 10)
- Nurse Call Priority RS-232 (normally high, normally low)
- Pulse Beep Volume (0 to 10)
- Pulse Rate Upper Alarm Limit (low limit to 250 bpm)
- Pulse Rate Lower Alarm Limit (20 bpm to high limit)
- *SatSeconds* (OFF, 10, 25, 50, 100)
- Serial Port Baud Rate (2400, 9600, 19200)
- Serial Port Mode (ASCII, *OXINET*, CLINICAL, GRAPH, AGILEN, [Agilent HP monitor], SPACELB [SpaceLabs monitor], MARQ [GE Marquette monitor], DATEX [Datex-Ohmeda AS/3 monitor]). Available selections depend on the software installed in your N-395.
- SpO_2 Upper Alarm Limit (low limit to 100%)
- SpO_2 Lower Limit (80% to high limit)

1. Disconnect sensor from monitor.

Note: If the sensor is not disconnected, the only softkeys on the screen will be PARAM and EXIT.

2. Set desired values to the institutional values.

3. Simultaneously press the LIGHT softkey and the CONTRAST button for more than 3 seconds. The menu bar will change to the softkey headings shown in Figure 4-14.

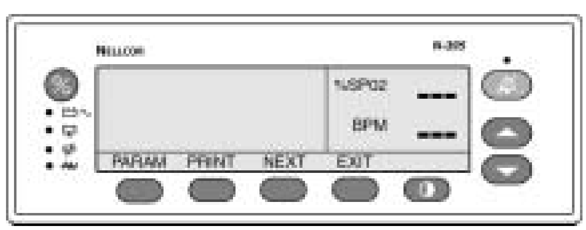


Figure 4-14: Service Function Softkeys

4. Press the PARAM softkey. See Figure 4-15.

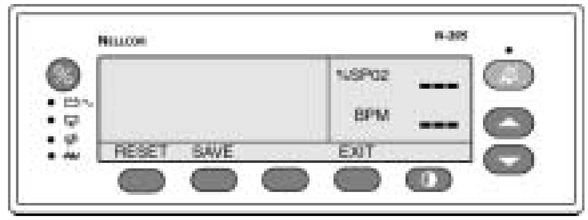


Figure 4-15: PARAM Softkeys

5. Press the SAVE softkey. See Figure 4-16.

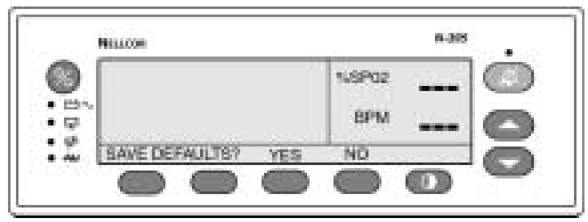


Figure 4-16: SAVE Softkeys

6. The monitor will sound 3 beeps indicating that defaults have been reset.

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SECTION 5: TROUBLESHOOTING

5.1 INTRODUCTION

This section explains how to troubleshoot the N-395 if problems arise. Tables are supplied that list possible monitor difficulties, along with probable causes, and recommended actions to correct the difficulty.

5.2 HOW TO USE THIS SECTION

Use this section in conjunction with Section 3, *Performance Verification*, and Section 7, *Spare Parts*. To remove and replace a part you suspect is defective, follow the instructions in Section 6, *Disassembly Guide*. The circuit analysis section in the Technical Supplement offers information on how the monitor functions.

5.3 WHO SHOULD PERFORM REPAIRS

Only qualified service personnel should open the monitor housing, remove and replace components, or make adjustments. If your medical facility does not have qualified service personnel, contact Nellcor Technical Services at 1.800.NELLCOR or your local Nellcor representative.

5.4 REPLACEMENT LEVEL SUPPORTED

The replacement level supported for this product is to the printed circuit board (PCB) and major subassembly level. Once you isolate a suspected PCB, follow the procedures in Section 6, *Disassembly Guide*, to replace the PCB with a known good PCB. Check to see if the trouble symptom disappears and that the monitor passes all performance tests. If the trouble symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB that was installed when you started troubleshooting) and continue troubleshooting as directed in this section.

5.5 RETURNING THE N-395

Contact Nellcor Technical Services Department or your local Nellcor representative for shipping instructions including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor's Technical Services Department, it is not necessary to return the sensor or other accessory items with the monitor. Pack the N-395 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the N-395 by any shipping method that provides proof of delivery.

5.6 OBTAINING REPLACEMENT PARTS

Nellcor's Technical Services provides technical assistance information and replacement parts. To obtain replacement parts, contact Nellcor or your local Nellcor representative. Refer to parts by the part names and part numbers listed in Section 7, *Spare Parts*.

The latest version of this manual is available on the Internet at:
http://www.nellcor.com/respiratory/resp/Serv_Supp/ProductManuals.html

5.7 TROUBLESHOOTING GUIDE

Problems with the N-395 are categorized in Table 5-1. Refer to the paragraph indicated for further troubleshooting instructions.

Note: Taking the recommended actions discussed in this section will correct the majority of problems you may encounter. However, problems not covered here can be resolved by calling Nellcor Technical Services at 1.800.NELLCOR or your local Nellcor representative.

Table 5-1: Problem Categories

Problem Area	Refer to Paragraph
1. Power • No power-up on AC and/or DC • Fails power-on self-test • Powers down without apparent cause	5.7.1
2. Buttons • Monitor does not respond properly to buttons	5.7.2
3. Display/Alarms • Displays do not respond properly • Alarms or other tones do not sound properly or are generated without apparent cause	5.7.3
4. Operational Performance • Displays appear to be operational, but monitor shows no readings • Suspect readings	5.7.4
5. Data Port • N-395 data port not functioning properly	5.7.5

All of the categories in Table 5-1 are discussed in the following paragraphs.

5.7.1 Power

Power problems are related to AC and/or DC. Table 5-2 lists recommended actions to power problems.

Table 5-2: Power Problems

Condition	Recommended Action
1. Battery Low indicator lights steadily while N-395 is connected to AC and battery is fully charged.	1. Ensure that the N-395 is plugged into an operational AC outlet and the AC indicator is on. 2. Check the fuses. The fuses are located in the Power Entry Module as indicated in paragraph 6.3 of the *Disassembly Guide* section 6. Replace if necessary. 3. Open the monitor as described in section 6. Verify the power supply's output to the battery while on AC by disconnecting the battery leads from the battery and connect a DVM to them. The voltage measured should be 6.80 VDC ± 0.15 VDC and the current should be 400 mA ± 80 mA. Replace the power supply if above values are not met. 4. Check the harness connection from the bottom enclosure to the User Interface PCB, as instructed in paragraph 6.11 of the *Disassembly Guide* section. If the connection is good, replace the User Interface PCB.
2. The N-395 does not operate when disconnected from AC power.	The battery may be discharged. To recharge the battery, refer to paragraph 3.3.1, Battery Charge. The monitor may be used with a less than fully charged battery but with a corresponding decrease in operating time from that charge.
3. Battery Low indicator on during DC operation and an alarm is sounding.	There are 15 minutes or less of usable charge left on the N-395 battery before the instrument shuts off. At this point, if possible, cease use of the N-395 on battery power, connect it to an AC source and allow it to recharge (approximately 14 hours). The N-395 may continue to be used while it is recharging. (A full recharge of the battery while the monitor is being used takes 18 hours.)
4. Battery does not charge.	1. Replace battery if it is more than 2 years old. 2. If the battery fails to hold a charge, replace the battery as indicated in Section 6, *Disassembly Guide*. 3. Open the monitor as described in Section 6. Verify the power supply's output to the battery while on AC by disconnecting the battery leads from the power supply and connect a DVM to them. The voltage measured should be 6.8 VDC ± 0.15 VDC and the current should be 400 mA ± 80 mA. Replace the power supply if above values are not met.

5.7.2 Buttons

Table 5-3 lists symptoms of problems relating to non-responsive buttons and recommended actions. If the action requires replacement of a PCB, refer to Section 6, *Disassembly Guide*.

Table 5-3: Button Problems

Symptoms	Recommended Action
1. The N-395 turns on but does not respond to some or all of the buttons.	1. Replace Top Case assembly. 2. If the buttons still do not work, replace interface PCB.

5.7.3 Display/Alarms

Table 5-4 lists symptoms of problems relating to nonfunctioning displays and audible tones or alarms, and recommended actions. If the action requires replacement of a PCB or module, refer to Section 6, *Disassembly Guide*.

Table 5-4: Display/Alarms Problems

Symptoms	Recommended Action
1. Display values are missing or erratic.	1. If the sensor is connected, replace the sensor extension cable. 2. If the condition persists, replace the sensor. 3. If the condition still persists, replace the interface printed circuit board.
2. Display pixels do not light.	1. Check the connection between the User Interface PCB and the Display PCB. 2. If the condition does not change, replace the Display PCB. 3. If the condition still persists, replace the User Interface PCB.
3. Alarm sounds for no apparent reason.	1. Moisture or spilled liquids can cause an alarm to sound. Allow the monitor to dry thoroughly before using. 2. If the condition persists, replace the User Interface PCB.
4. Alarm does not sound.	1. Check alarm silence status. 2. Replace the speaker as described in Section 6, *Disassembly Guide*. 3. If the condition persists, replace the User Interface PCB.

5.7.4 Operational Performance

Table 5-5 lists symptoms of problems relating to operational performance (no error codes displayed) and recommended actions. If the action requires replacement of a PCB or module, refer to Section 6, *Disassembly Guide*.

Table 5-5: Operational Performance Problems

Symptoms	Recommended Action
1. The Pulse Amplitude indicator seems to indicate a pulse, but the digital displays show zeroes.	1. The sensor may be damaged; replace it. 2. If the condition still persists, replace the User Interface PCB.
2. SpO_2 or Pulse values change rapidly; Pulse Amplitude indicator is erratic.	1. The sensor may be damp or may have been reused too many times. Replace it. 2. An electrosurgical unit (ESU) may be interfering with performance: – Move the N-395 and its cables and sensors as far from the ESU as possible. – Plug the N-395 power supply and the ESU into different AC circuits. – Move the ESU ground pad as close to the surgical site as possible and as far away from the sensor as possible. 3. Verify the performance with the procedures detailed in Section 3. 4. If the condition still persists, replace the User Interface PCB.

5.7.5 Data Port

Table 5-6 lists symptoms of problems relating to the data port and recommended actions. If the action requires replacement of the User Interface PCB, refer to Section 6, *Disassembly Guide*.

Table 5-6: Data Port Problems

Symptoms	Recommended Action
1. No printout is being received.	1. The monitor’s baud rate does not match the printer. Change the baud rate of the monitor following instructions in paragraph 10.2. 2. If the condition still persists, replace the User Interface PCB.
2. The RS-232 nurse call is not working.	1. Verify that connections are made between pins 5 (GND) and 11 (nurse call) of the data port. (See Figure 10-3) 2. Verify that the output voltage between ground pin 5 and pin 11 is -5 to -12 VDC (no alarm) and +5 to +12 VDC (during alarm). (See Figure 10-2) 3. If the condition still persists, replace the User Interface PCB.

5.8 ERROR CODES

An error code is displayed when the N-395 detects a non-correctable failure. When this occurs, the unit stops monitoring, sounds a low-priority alarm that cannot be silenced, clears patient data from the display, and displays an error code.
Table 5-7 provides a complete list of error codes and possible solutions.

Table 5-7: Error Codes

Code	Meaning	Possible Solutions
1	Failure of Power-On Self-Test (POST)	Replace User Interface PCB
4	Battery dead	1. Charge battery for 14 hours 2. Leads of battery reversed; see paragraph 6.6. 3. Replace battery
5	Too many microprocessor resets within a period of time	1. Cycle power 2. Replace User Interface PCB if code 5 repeatedly occurs 3. Replace Power Supply
6	Boot CRC error	1. Cycle power 2. Replace User Interface PCB
8 **11** **12**	Boot CRC Error Flash ROM corruption Excessive resets	1. Cycle power 2. Replace User Interface PCB if code repeatedly occurs

Table 5-7: Error Codes

Code	Meaning	Possible Solutions
52	Loss of settings	1. Cycle power 2. Check and reset settings if necessary 3. Check battery 4. Replace User Interface PCB if code repeatedly occurs
76	Error accessing EPROM	1. Cycle power 2. Replace User Interface PCB
80	Institutional default values lost and reset to factory default values	1. Cycle power 2. Replace User Interface PCB if code 80 repeatedly occurs
81	Settings lost (settings that were different from power-on default values have been lost)	1. Cycle power 2. Check and reset settings if necessary 3. Check battery 4. Replace User Interface PCB if code repeatedly occurs
82	Time clock lost	1. Reset time clock 2. Battery power was lost; check the battery 3. Replace the Power Supply
84	Internal communications error	1. Cycle power 2. Replace User Interface PCB if code repeatedly occurs

5.8.1 Other Messages

In addition to the error codes listed in Table 5-7, the following messages may be encountered:

DISALLOWED ON BATTERY - An attempt to print or download data port information while operating on battery power has been made. Connect to AC power and retry.

DISALLOWED ON LOW BATTERY - An attempt to turn on the backlight has been made while in a low battery condition. If the backlight is turned off during a low battery condition, it cannot be turned back on.

INVALID SILENCE DURATION - An attempt has been made to set the alarm silence duration power-on default to “OFF." The power-on default cannot be set to “OFF."

INVALID SpO_2 LIMIT - An attempt has been made to set either the upper or lower alarm limit power-on default below 80. The power-on default cannot be set below 80.

READING TRENDS - The monitor is gathering trend information for display.

SENSOR DISCONNECTED - The sensor has disconnected from the cable, the cable has disconnected from the monitor, or the sensor/cable wiring is defective. Press the ALARM SILENCE button to silence the alarm. Check the connections. If this does not correct the problem, replace the sensor and/or cable.

SENSOR OFF - The sensor has become disconnected from the patient. Press the ALARM SILENCE button to silence the alarm. Check the sensor-to-patient connection. If this does not correct the problem, replace the sensor.

SECTION 6: DISASSEMBLY GUIDE

6.1 INTRODUCTION

The N-395 can be disassembled down to all major component parts, including:

- PCBs
- battery
- cables
- chassis enclosures

The following tools are required:

- small Phillips-head screwdriver
- medium Phillips-head screwdriver
- small blade screwdriver
- needle-nose pliers or 1/4-inch socket
- torque wrench, 10 inch-pounds (1.13 Newton-meters)

WARNING: Before attempting to open or disassemble the N-395, disconnect the power cord from the N-395.

Caution: Observe ESD (electrostatic discharge) precautions when working within the unit.

Note: Some spare parts have a business reply card attached. When you receive these spare parts, please fill out and return the card.

6.2 PRIOR TO DISASSEMBLY

1. Turn the N-395 off by pressing the POWER ON/OFF button.
2. Disconnect the monitor from the AC power source.

6.3 FUSE REPLACEMENT

1. Complete the procedure in paragraph 6.2.
2. Disconnect the power cord from the back of the monitor.
3. Remove the fuse drawer from the power module by pressing down on the tab in the center and pulling out as shown in Figure 6-1.

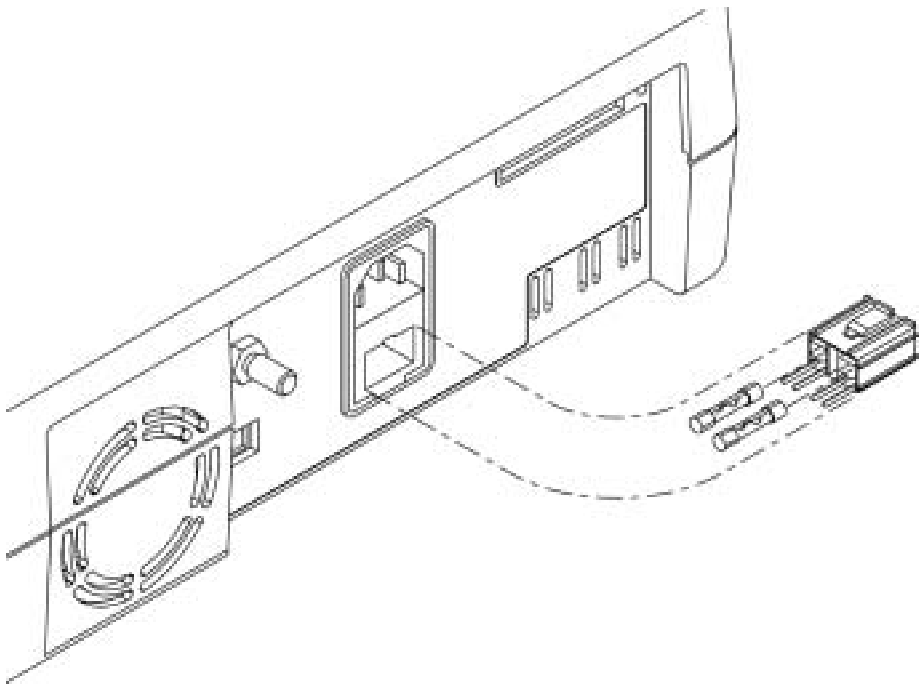


Figure 6-1: Fuse Removal

4. Put two new, 5- x 20-mm, slow blow, 0.5-amp, 250-volt fuses in the drawer and reinsert the drawer in the power entry module.

6.4 MONITOR DISASSEMBLY

1. Complete the procedure in paragraph 6.2.

2. Set the N-395 upside down, as shown in Figure 6-2.

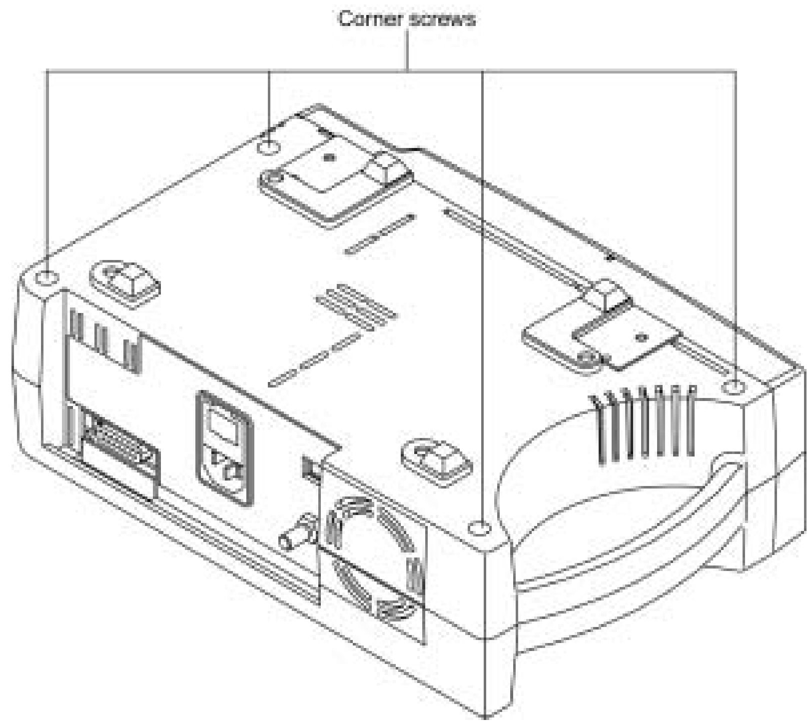


Figure 6-2: N-395 Corner Screws

2. Remove the four corner screws.

Caution: Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the N-395 and when handling any of the components of the N-395.

3. Separate the top case from the bottom case of the monitor, being careful not to stress the wire harnesses between the cases. Place the two halves of the monitor on the table as shown in Figure 6-3.

4. Disconnect the Power Supply harness from J6 on the User Interface PCB.

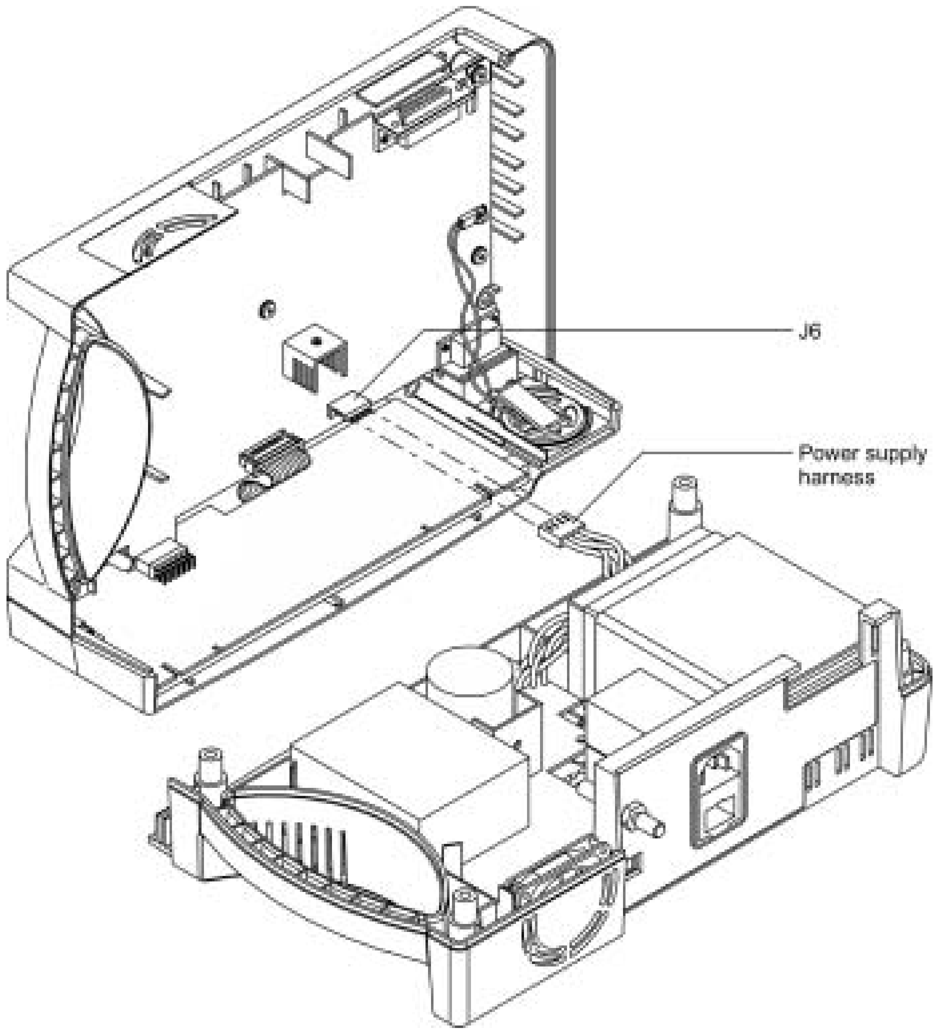


Figure 6-3: Separating Case Halves

6.5 MONITOR ASSEMBLY

1. Connect the Power Supply to J8 on the User Interface PCB.
2. Place the top case over the bottom case, being careful to align the Display PCB, Power Entry Module, and the fan with the slots in the case halves.

Caution: When reassembling the N-395, tighten the screws that hold the cases together to a maximum of 10 inch-pounds. Over-tightening could strip out the screw holes in the top case, rendering it unusable.

3. Install the four corner screws.

6.6 BATTERY REPLACEMENT

Removal

1. Follow the procedure in paragraphs 6.2 and 6.4.
2. Remove the two screws from the battery bracket and lift the battery out of the bottom case as shown in Figure 6-4.
3. Be sure to note the polarity of the leads. Use needle-nose pliers to disconnect the leads from the battery.

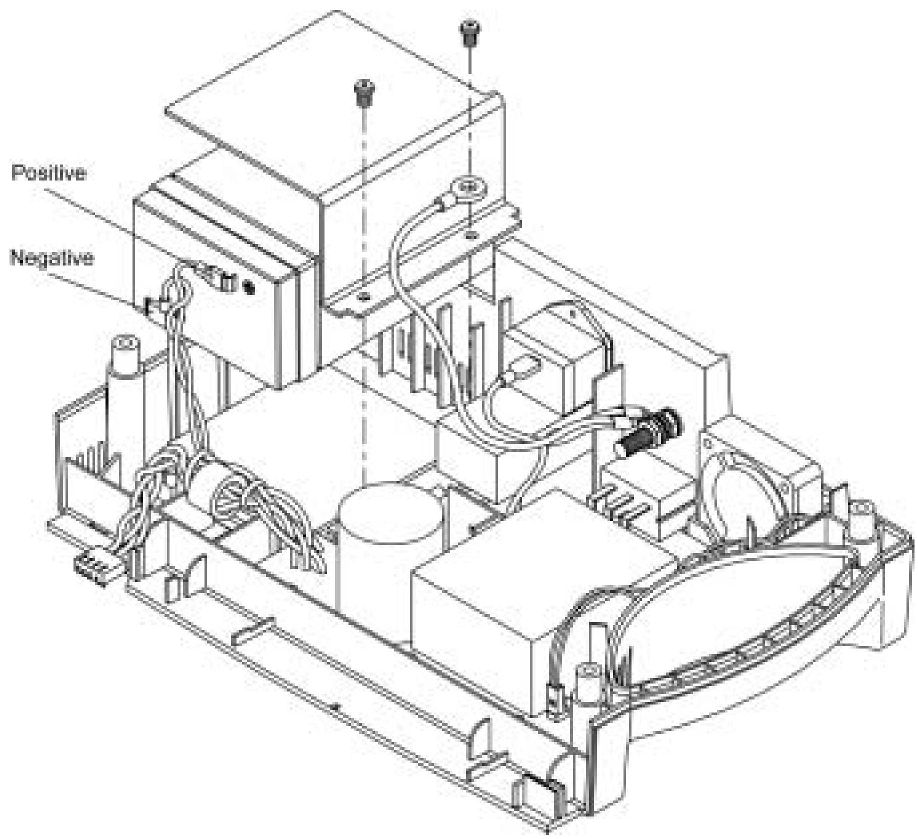


Figure 6-4: N-395 Battery

4. The lead-acid battery is recyclable. Do not dispose of the battery by placing it in the regular trash. Dispose of the battery in accordance with local guidelines or return it to Nellcor Technical Services for disposal.

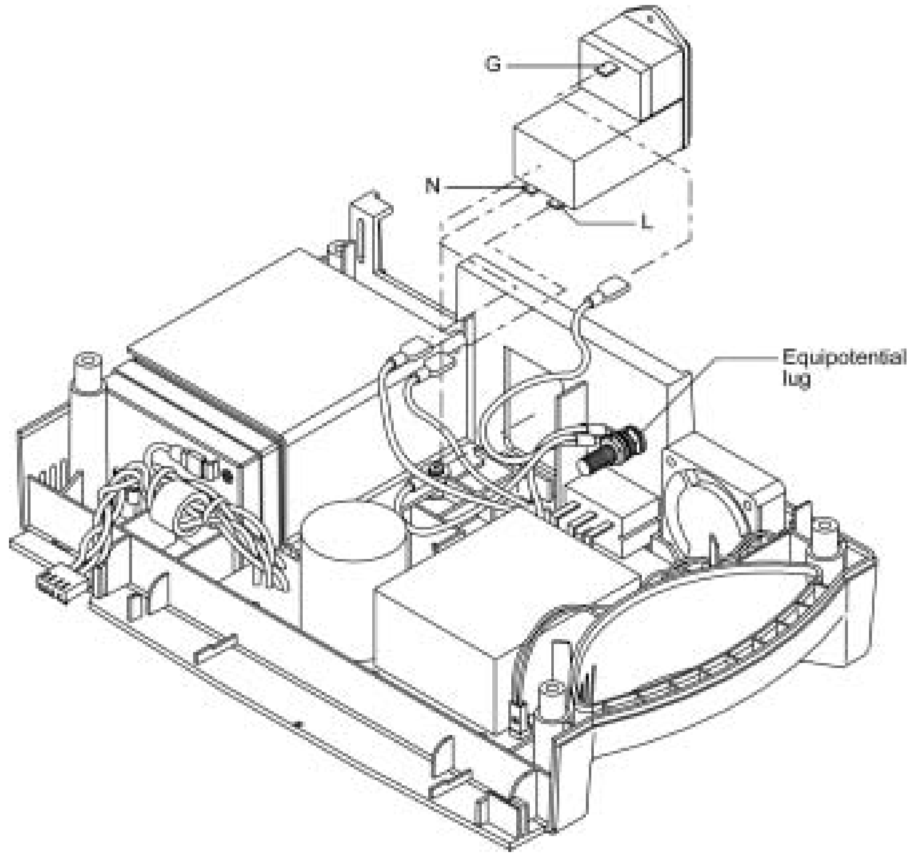
Replacement

5. Connect the leads to the battery. The red wire connects to the positive terminal, and the black wire connects to the negative terminal.
6. Insert the new battery into the bottom case with the negative terminal towards the outside of the monitor. Install the bracket and grounding lead with the two screws.
7. Complete the procedure in paragraph 6.5.
8. Turn the monitor on and verify proper operation.

6.7 POWER ENTRY MODULE (PEM) REMOVAL/REPLACEMENT

Removal

1. Follow the procedure in paragraphs 6.2 and 6.4.
2. Push the top of the Power Entry Module (PEM) in from the outside of the case, and lift up.
3. Use needle-nose pliers to disconnect the leads from the PEM (see Figure 6-5).



G, N, and L are labels on the PEM

Figure 6-5: **Power Entry Module**

Replacement

4. Reconnect the three power supply leads as indicated in Table 6-1.
5. Install the PEM in the bottom case with the fuse drawer facing down. A tab in the bottom case holds the PEM in place. Insert the bottom wing of the PEM between the tab and the internal edge of the sidewall of the bottom case. Push the PEM down and towards the outside of the monitor until it clicks into place.
6. Complete the procedure in paragraph 6.5.

6.8 POWER SUPPLY REMOVAL/REPLACEMENT

Removal

1. Follow the procedure in paragraphs 6.2 and 6.4.
2. Push the top of the Power Entry Module (PEM) in from the outside of the case, and lift up.
3. Use needle-nose pliers to disconnect the leads from the PEM (see Figure 6-5).
4. Disconnect the fan wire harness from J1 on the Power Supply PCB (see Figure 6-7).
5. Use a 10-mm wrench to disconnect the Power Supply ground lead from the equipotential lug (Figure 6-5).
6. Remove the seven screws shown in Figure 6-6.
7. Lift the Power Supply out of the bottom case.

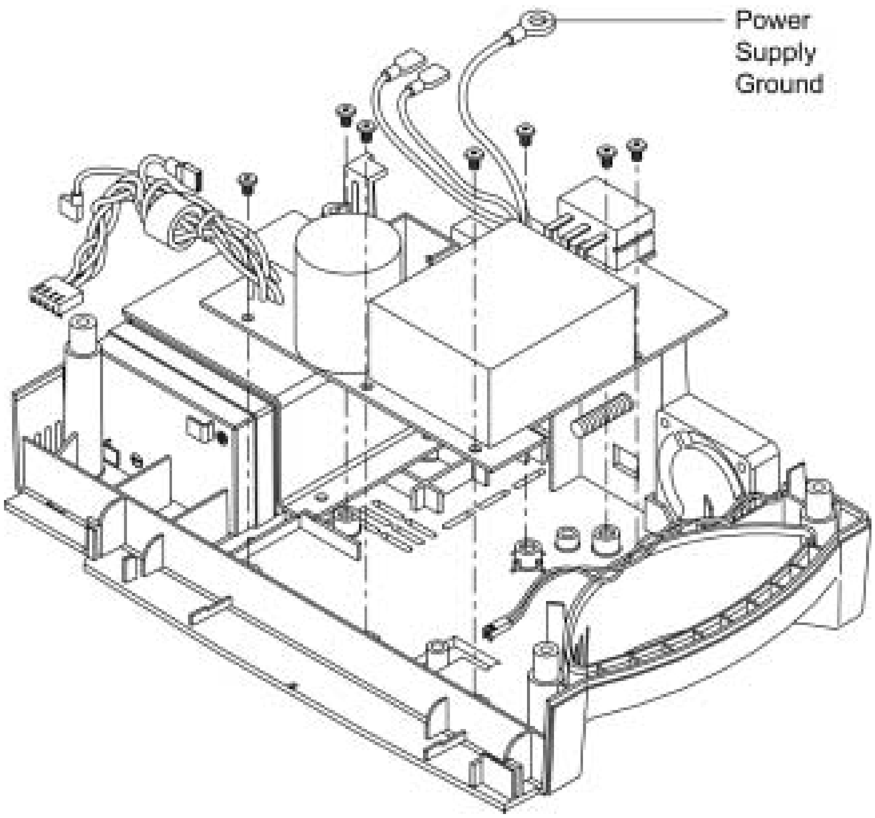


Figure 6-6: Power Supply

Replacement

8. Reconnect the leads to the PEM following the instructions in Table 6-1 below and Figure 6-5.

Table 6-1: Power Supply Lead Connections

Wire Color / Label	Connects To
Green & Yellow	Equipotential Lug
Brown/Labeled "L"	"L" on the Power Entry Module
Blue/Labeled "N"	"N" on the Power Entry Module
Red /Labeled +	Positive Battery Terminal
Black /Labeled –	Negative Battery Terminal

9. Place the Power Supply in the bottom case.

Caution: When installing the Power Supply, tighten the seven screws to a maximum of 4 inch-pounds. Over-tightening could strip out the screw holes in the bottom case, rendering it unusable.

10. Install the seven screws in the Power Supply and tighten.

11. Connect the fan harness to J1 on the Power Supply.

12. Install the PEM in the bottom case with the fuse drawer facing down. A tab in the bottom case holds the PEM in place. Insert the bottom wing of the PEM between the tab and the internal edge of the sidewall of the bottom case. Push the PEM down and towards the outside of the monitor until it clicks into place.

13. Complete the replacement procedure in paragraph 6.5.

6.9 COOLING FAN REMOVAL/REPLACEMENT

Removal

1. Complete the procedure in paragraphs 6.2 and 6.4.
2. Disconnect the fan wire harness from J1 on the Power Supply PCB (see Figure 6-7).
3. Lift the cooling fan from the slots in the bottom case.

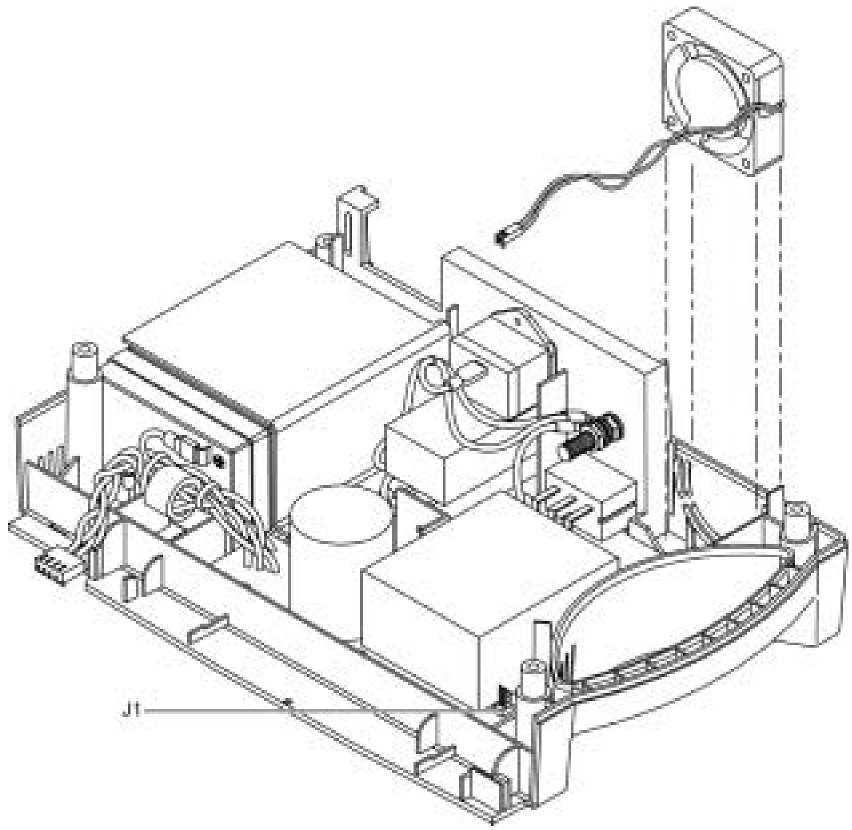


Figure 6-7: Cooling Fan

Replacement

4. Connect the cooling fan wire harness to J1 on the Power Supply PCB.
5. Insert the cooling fan into the slots in the bottom case with the padded sides on the top and bottom and the fan's harness to the handle side of the case.
6. Complete procedure 6.5.

6.10 DISPLAY PCB REMOVAL/REPLACEMENT

Removal

WARNING: The LCD panel contains toxic chemicals. Do not ingest chemicals from a broken LCD panel.

1. Complete the procedures in paragraphs 6.2 and 6.4.
2. Disconnect the CCFL harness (two white wires) from J7 of the User Interface PCB. See Figure 6-8.
3. Use a small blade screwdriver to pry the clip from either edge of J5, then disconnect the Display PCB ribbon cable from the connector.
4. Remove the screw holding the clamp to the ferrite on the ribbon cable of the Display PCB.
5. Separate the adhesive connection of the double-sided tape and lift the Display PCB up to remove it from the top case.
6. Remove the used double-sided tape.

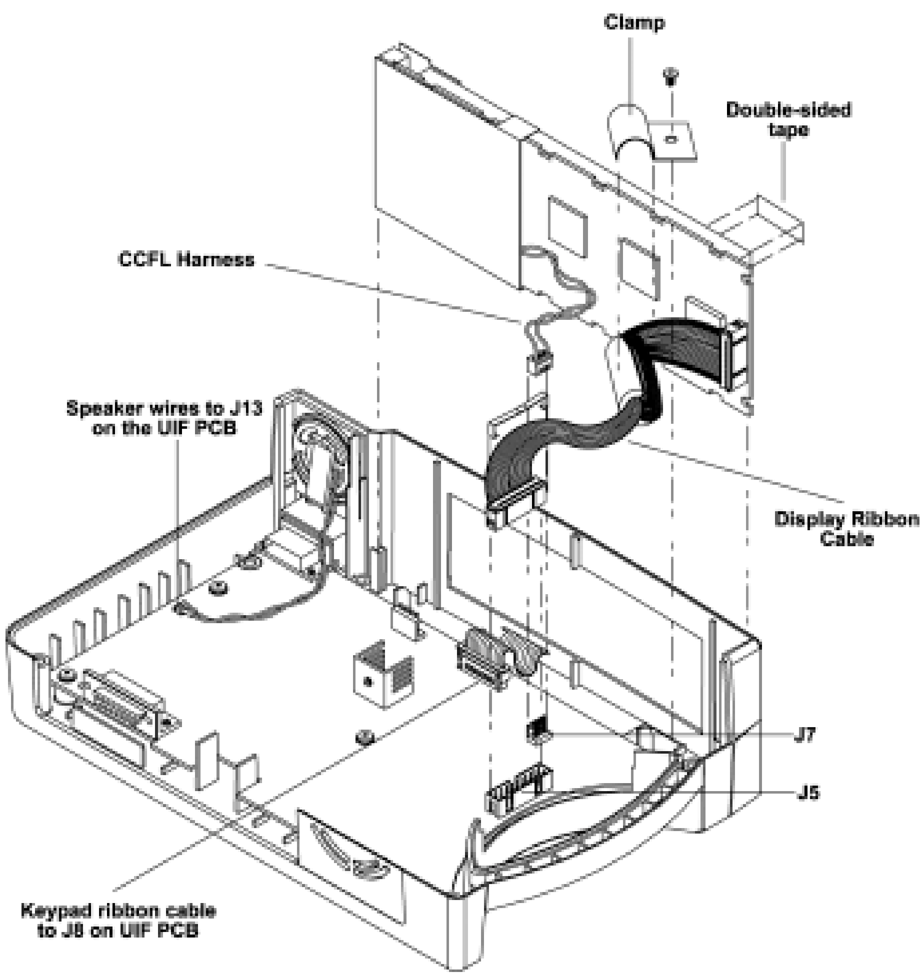


Figure 6-8: Display PCB

Replacement

7. Install new double-sided tape as shown in Figure 6-8.
8. Slide the Display PCB into the grooves in the top case. Check to make sure the Display PCB is firmly seated in the top case. Apply pressure between the top case and the display PCB to make good contact with the double-sided tape.
9. Connect the wire harness with two white wires to J7 of the User Interface PCB.
10. Connect the Display PCB ribbon cable to J5 of the User Interface PCB. Install the clip over the J5 connector.
11. Secure the ferrite on the ribbon cable from the Display PCB. Place the clamp over the ferrite, assure that no wires are pinched, and screw the clamp to the User Interface PCB.
12. Complete the procedure in paragraph 6.5.

6.11 USER INTERFACE PCB REMOVAL/REPLACEMENT

Removal

1. Complete the procedures in paragraphs 6.2 and 6.4.
2. Disconnect the CCFL harness (two white wires) from J7 of the User Interface PCB. See Figure 6-8.
3. Use a small blade screwdriver to pry the clip from either edge of J5, then disconnect the Display PCB ribbon cable from the connector.
4. Remove the screw holding the clamp to the ferrite on the ribbon cable of the Display PCB.
5. Disconnect the keypad ribbon cable from ZIF connector J8 on the User Interface PCB (Figure 6-8). Lift up on the ribbon cable’s outer shell until it clicks, then remove the cable from the connector.
6. Disconnect the speaker cable from J3 on the User Interface PCB (See Figure 6-8).
7. Remove the five screws in the User Interface PCB (Figure 6-9).
8. Remove the User Interface PCB from the top case.

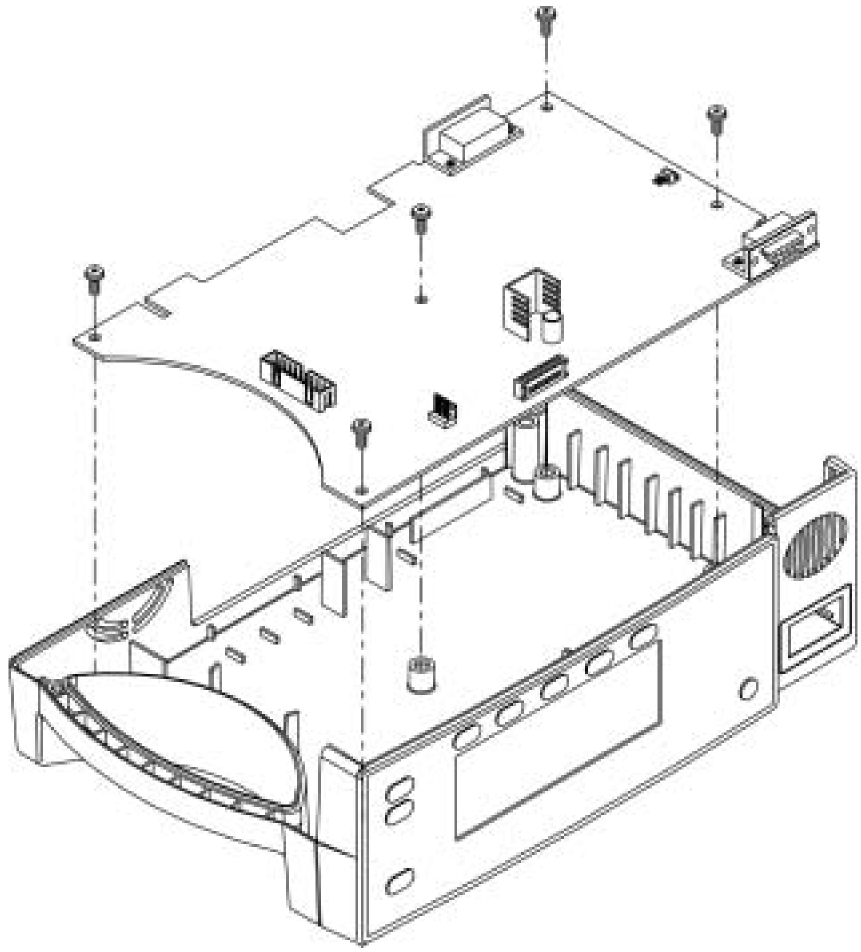


Figure 6-9: User Interface PCB

Replacement

Caution: When installing the User Interface PCB, hand tighten the five screws to a maximum of 4 inch-pounds. Over-tightening could strip out the screw holes in the top case, rendering it unusable.

9. Place the User Interface PCB in the top case.
10. Install the five screws in the User Interface PCB.
11. Lift up on the outer shell of J8 (Figure 6-8) on the User Interface PCB until it clicks. Insert the keypad ribbon cable into J8 of the User Interface PCB. Slide the outer shell of J8 down until it locks in place.
12. Connect the speaker cable to J3 of the User Interface PCB.
13. Connect the CCFL wire harness with two white wires to J7 of the User Interface PCB.
14. Connect the Display PCB ribbon cable to J5 of the User Interface PCB. Install the clip over the J5 connector.

15. Secure the ferrite on the ribbon cable from the Display PCB. Place the clamp over the ferrite, assure that no wires are pinched, and screw the clamp to the User Interface PCB.

16. Complete the procedure in paragraph 6.5.

6.12 ALARM SPEAKER REMOVAL/REPLACEMENT

Removal

1. Complete the procedures in paragraphs 6.2 and 6.4.

2. Disconnect the speaker wire harness from J3 on the User Interface PCB (Figure 6-10).

3. Pull the holding clip back from the speaker and lift the speaker out of the top case.

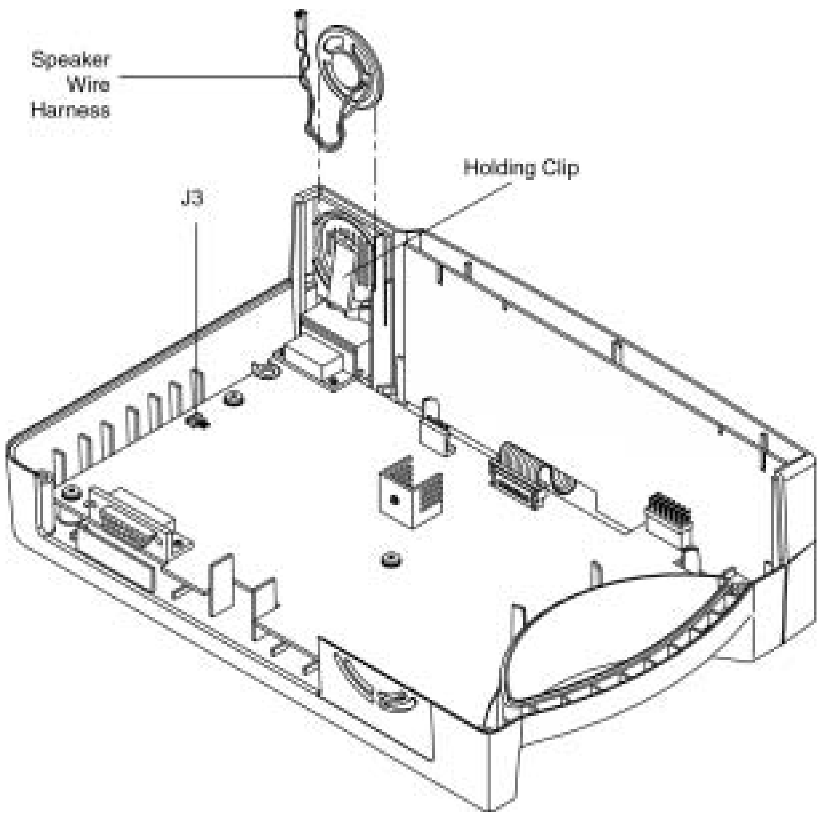


Figure 6-10: Alarm Speaker

Replacement

4. Pull the holding clip back, and insert the speaker into the top case.

5. Connect speaker wire harness to J3 on the User Interface PCB.

6. Complete the procedure in paragraph 6.5.

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SECTION 7: SPARE PARTS

7.1 INTRODUCTION

The latest version of this manual is available on the Internet at:
http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Spare parts, along with part numbers, are shown in Table 7-1. Item numbers correspond to the callout numbers in Figure 7-1.

Spare parts and accessories for the N-395 are listed on the Internet at:
http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/Apartweb/main/PartAcceMenu.html

Check the Internet for the latest part numbers.

Table 7-1: Parts List

Item	Description	Part Number
1	Top Case Assembly (Membrane Panel Included)	036562
	Bottom Enclosure Cover (not called out)	035318
2	Fuse Drawer	691500
3	Fuses	691032
4	Power Entry Module	691499
5	Cooling Fan	035469
6	Power Supply	SP036478
7	Display PCB	SP036333
8	Battery	640119
9	Battery Bracket	035307
10	User Interface PCB	SP036261
	Alarm Speaker (not shown)	033494
	Rubber Feet (not shown)	4-003818-00
	Power Cord (not shown) • USA • International • UK, Ireland	 049798 901862 901863
	Tilt Stand (not shown)	891340
	GCX Mounting Kit (not shown), roll stand or wall mount	035434
	Sensor Lock, SCP-10/MC-10 Cables, including pins (not shown)	040493

Figure 7-1 shows the N-395 expanded view with numbers relating to the spare parts list.

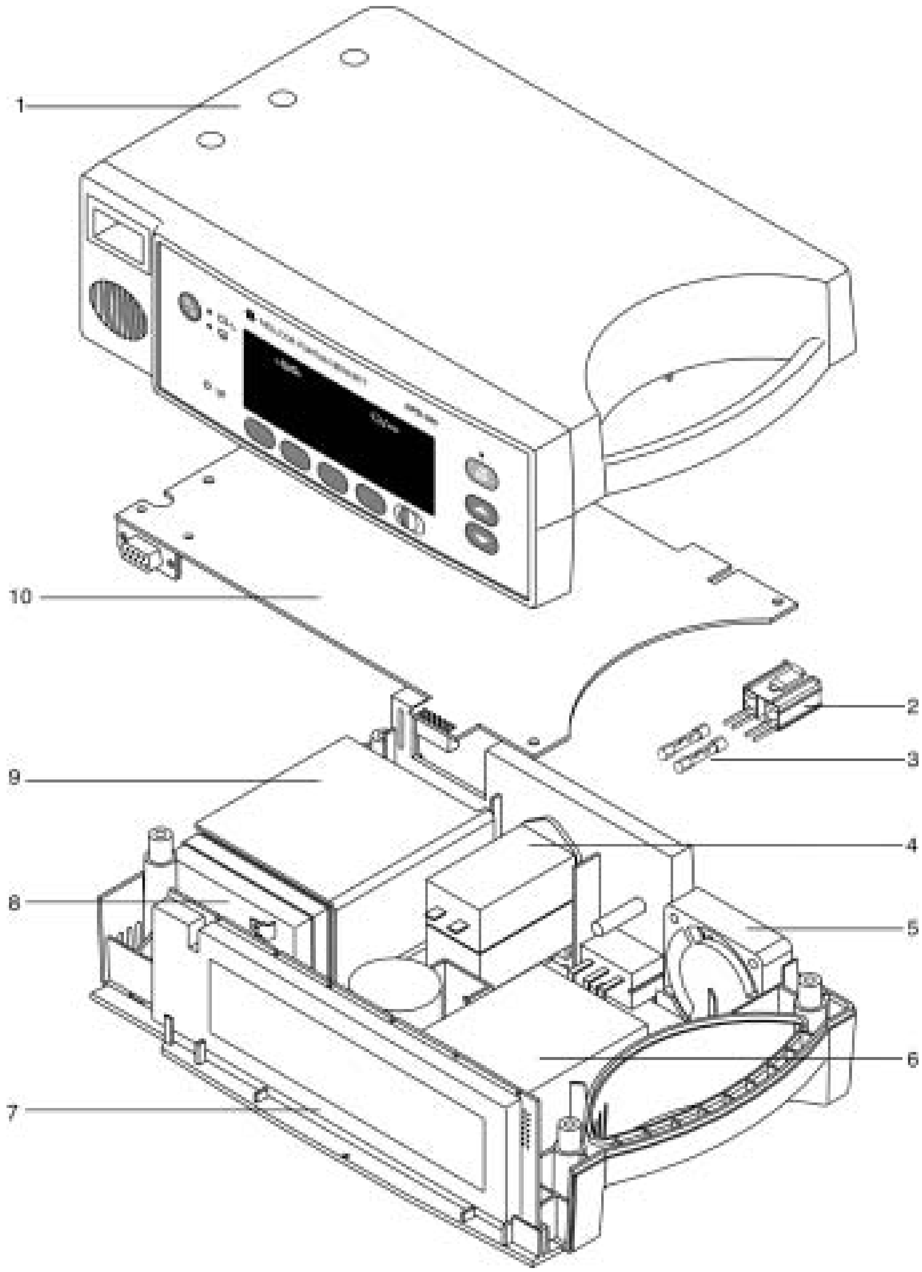

Figure 7-1: N-395 Expanded View

SECTION 8: PACKING FOR SHIPMENT

8.1 INTRODUCTION

To ship the monitor for any reason, follow the instructions in this section.

8.2 GENERAL INSTRUCTIONS

Pack the monitor carefully. Failure to follow the instructions in this section may result in loss or damage not covered by any applicable Nellcor warranty. If the original shipping carton is not available, use another suitable carton; North American customers may call Nellcor Technical Services Department to obtain a shipping carton.

Prior to shipping the monitor, contact your supplier or local Nellcor office (Technical Services Department) for a returned goods authorization number. Mark the shipping carton and any shipping documents with the returned goods authorization (RGA) number. Return the N-395 by any method that provides proof of delivery.

8.3 REPACKING IN ORIGINAL CARTON

If available, use the original carton and packing materials. See Figure 8-1. Pack the monitor as follows:

1. Place the monitor and, if necessary, accessory items in original packaging.

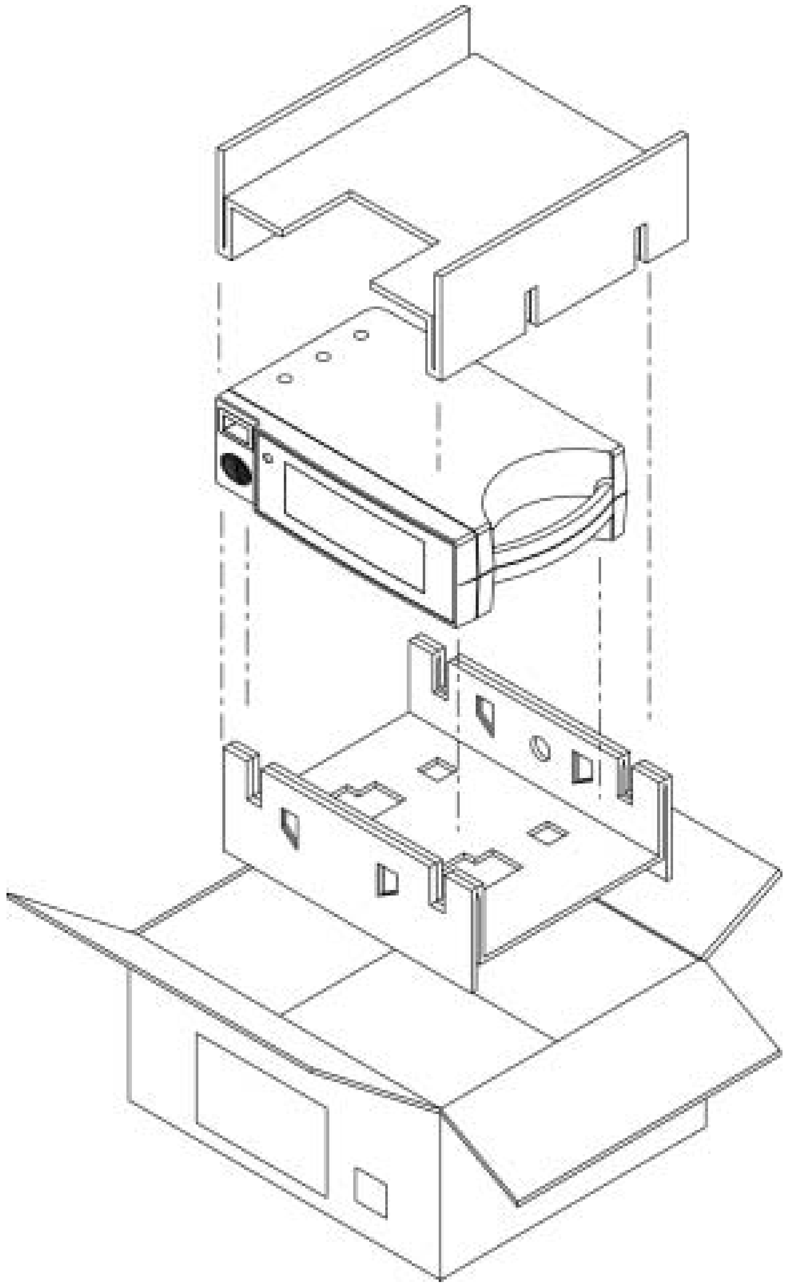

Figure 8-1: Repacking the N-395

2. Place in shipping carton and seal carton with packing tape.
3. Label carton with shipping address, return address, and RGA number, if applicable.

8.4 REPACKING IN A DIFFERENT CARTON

If the original carton is not available, use the following procedure to pack the N-395 (Figure 8-1):

1. Place the monitor in a plastic bag.
2. Locate a corrugated cardboard shipping carton with a busting strength of at least 200 pounds per square inch (psi).
3. Fill the bottom of the carton with at least 2 inches of packing material.
4. Place the bagged unit on the layer of packing material and fill the box completely with packing material.
5. Seal the carton with packing tape.
6. Label the carton with the shipping address, return address, and RGA number, if applicable.

SECTION 9: SPECIFICATIONS

9.1 GENERAL

Designed to meet safety requirements of:

UL 2601-1, CSA-C22.2 No. 601.1-M90, EN 60601-1, EN 865, EMC per EN 60601-1-2, and Canadian ICES-001.

9.2 ELECTRICAL

Protection Class

Class I

Degree of Protection

Type BF

Mode of Operation

Continuous

Battery

Type:	Rechargeable, sealed lead-acid, internal
Operating time:	2 hours minimum on new, fully charged battery under the following conditions: no alarms, no analog or serial output devices attached, no RS-232 level nurse call output and backlight on.
Recharge period:	14 hours for full charge (in standby) 18 hours for full charge (in use)
Fuses	2 each 5 x 20 mm Slow Blow 0.5 Amp 250 volts
AC Power	
Selectable by switch	100-120 VAC, 50/60 Hz or 200-240 VAC, 50/60 Hz 20 VA
Sensor	The wavelength of the light emitted is within the range of 500 nm to 1,000 nm with the energy not exceeding 10 mw.
Emission Compliance	EN 55011, CISPR 11, Group 1, Class B

9.3 PHYSICAL CHARACTERISTICS

Dimensions	3.3 in. H x 10.4 in. W x 6.8 in. D 8.4 cm H x 26.4 cm W x 17.3 cm D
Weight	5.7 lbs. 2.6 kg

9.4 ENVIRONMENTAL

Operating Temperature	5 °C to 40 °C (+41 °F to +104 °F)
Storage Temperature	-20 °C to +70 °C (-4 °F to +158 °F)
Operating Altitude	-390 m to +3,658 m (-1,280 ft. to +12,000 ft.)
Relative Humidity	15% RH to 95% RH, noncondensing

9.5 ALARMS

Alarm Limit Range

% Saturation:	20–100%
Pulse:	30–250 bpm

9.6 FACTORY DEFAULT SETTINGS

Table 9-1: Factory Default Settings (Adult)

Monitoring Mode	Adult
$\%SpO_2$ Lower Alarm Limit:	85%
$\%SpO_2$ Upper Alarm Limit:	100%
Alarm Silence Duration OFF Setting:	Enabled
Alarm Silence Duration:	60 seconds
Alarm Silence Reminder:	Enabled
Alarm Volume:	75 dB(A) peak at 1 meter (volume setting of 5)
Data Port Baud Rate:	9600
Data Port Protocol:	ASCII
Display Contrast:	Midrange
Display Format:	Pleth
Language:	English
Nurse Call Polarity:	Normally Low
Pulse Beep Volume:	72 dB(A) at 1 meter (volume setting of 4)
Pulse Rate Lower Alarm Limit:	40 beats per minute
Pulse Rate Upper Alarm Limit:	170 beats per minute
SatSeconds:	Off
Trend Display:	$\%SpO_2$

Table 9-2: Factory Default Settings (Neonate)

Monitoring Mode	Neonate
%SpO_2 Lower Alarm Limit:	80%
%SpO_2 Upper Alarm Limit:	95%
Pulse Rate Lower Alarm Limit:	90 beats per minute
Pulse Rate Upper Alarm Limit:	190 beats per minute
SatSeconds:	Off

9.7 PERFORMANCE

Measurement Range

SpO_2:	1–100%
Pulse/Heart Rate:	20–250 bpm

Accuracy[1]

Saturation (%SpO_2 ±1 SD):	
Without Motion:	
Adults	70 to 100% ±2 digits
Neonates	70 to 100% ±3 digits
	1 to 69% unspecified
With Motion[2]:	
Adults and Neonates	70 to 100% ±3 digits
	1 to 69% unspecified

Pulse Rate[3]

Without Motion	20 to 250 ±3 digits
With Motion	Normal physiologic range (e.g., 55 – 125 bpm) ±5 digits

[1] Accuracies are expressed as plus or minus "X" digits (saturation percentage points) between saturations of 70-100%. This variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population. All accuracy specifications are based on testing the subject monitor on healthy adult volunteers in induced hypoxia studies across the specified range. Adult accuracy determined with Oxisensor II D-25 sensors. Neonatal accuracy determined with Oxisensor II N-25 sensors.
[2] For a definition of motion, as applicable to the N-395, contact Nellcor's Technical Services Department.
[3] Pulse rate accuracy is expressed as plus or minus "X" digits (bpm) across the display range. This variation equals ± one standard deviation (1 SD), which encompasses 68% of the population.

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SECTION 10: DATA PORT INTERFACE PROTOCOL

10.1 INTRODUCTION

When connected to the data port on the back of the N-395, printouts can be obtained, or patient data can be communicated to a Nellcor *Oxinet* II Monitoring System or personal computer (PC). Analog signals representing %SpO_2, Pulse Rate, and Pulse Amplitude are also provided by the data port. A nurse call function is also available from the data port. Each of these is discussed in more detail in the paragraphs that follow.

The N-395, software version 1.7 and above, provides a bedside monitor interface for interfacing the N-395 with Agilent (HP), SpaceLabs, Marquette, and Datex monitors.

10.2 CONFIGURING THE DATA PORT

Items pertaining to the data port can be adjusted by following the softkey map in Figure 10-1. For a complete description of the softkeys, see the operator's manual.

LIMITS	TREND	SETUP ↓	LIGHT
VIEW	CLOCK	NEXT ↓	EXIT
COMM	LANG	NEXT ↓	EXIT
BAUD (2400 9600 or 19200) **PROTOCOL** (ASCII, OXINET, GRAPH, CLINICAL, AGILENT, SPACELBS, MARQ, or DATEX)	ENGLISH, FRANCAIS, DEUTSCH, ITALIANO, ESPANOL, NEDERLANDS, or PORTUG		
NCALL	ANALOG	NEXT	EXIT
NORM +	0 VOLT		
NORM -	1 VOLT		
	STEP		

Press the Softkey under the desired parameter then press EXIT to return to the user menu.

Figure 10-1: Data Port Softkeys

The COMM key is used to select from eight communication protocols supported by the data port. The selections are:

- ASCII used for printouts or interface with *Intouch*
- GRAPH for graphic printouts
- CLINICAL intended for Nellcor use only
- OXINET to enable communication with *Oxinet* II
- AGILEN interfaces the N-395 with an Agilent (HP) monitor
- SPACELBS interfaces the N-395 with a SpaceLabs monitor
- MARQ interfaces the N-395 with a GE Marquette monitor
- DATEX interfaces the N-395 with a Datex-Ohmeda AS/3 monitor

Note: Communication protocols for AGILEN, SPACELBS, MARQ, and DATEX are only available in N-395 software version 1.7 and higher.

To change the communication protocol, press SETUP, NEXT, COMM, and SELECT. Use the ADJUST UP/DOWN buttons to select the desired communications protocol.

The baud rate may need to be changed to match the abilities of the attached equipment. To change the baud rate, press SETUP, NEXT, and COMM. Use the ADJUST UP/DOWN buttons to select a baud rate of 2400, 9600, or 19200.

Seven languages can be viewed on the screen and sent to the printer. The language being used can be changed by pressing SETUP, NEXT, and LANG. Use the ADJUST UP/DOWN buttons to select the desired language.

The voltage polarity for the Nurse Call, available at pins 11 and 5, can be selected through the softkeys. By pressing SETUP, NEXT, NEXT, and NCALL, a choice of NORM + or NORM – is offered. NORM + sets the voltage to +5 VDC to +12 VDC and NORM - sets the voltage to –5 VDC to –12 VDC when there is no audible alarm. When an audible alarm occurs, these voltages switch polarity. This signal is available only if the instrument is operating on AC power. For more information on Nurse Call, see paragraph 10.9 in this section.

Analog calibration signals are provided to adjust a recorder to the output of the instrument. Selectable calibration signals are +1.0 VDC, 0.0 VDC, and Step. The signals are accessed by pressing SETUP, NEXT, NEXT, and ANALOG. For more information on the analog signals, see paragraph 10.10 in this section.

10.2.1 Agilent (HP) Communications

The N-395 sends SpO2, pulse rate, and alarm status data to the Agilent monitor.

The Agilent monitor requires an Agilent VueLink™ Aux Plus B interface module to interface with the N-395 pulse oximeter.

The RS-232 hardwire interface cable has a DB-15 connector for the N-395 and the applicable connector for the Agilent monitor. Nellcor cable part number 902256 is recommended for this interface.

A blank screen on the Agilent monitor will indicate corrupt data. The Agilent monitor will detect corrupt data in less than 100 milliseconds.

When the N-395 is in the Agilent mode of operation, the interface baud rate must be set to 19,200 bits per second. Press the SETUP softkey, then the NEXT softkey, and then the COMM softkey to select BAUD. Use the ADJUST UP or ADJUST DOWN buttons to select the correct baud rate.

WARNING: Do not silence the N-395 audible alarm or decrease its volume if patient safety could be compromised.

The Agilent monitor only displays visual alarm indications for equipment interfaced through the Agilent VueLink™ Aux Plus B interface module. The N-395 monitor must be able to sound an audible alarm in order to maintain patient safety.

Note: The parameters setup for the Agilent bedside monitor interface may be saved as institutional default settings, see paragraph 4.5, *Setting Institutional Defaults (Sample)*, page 4-8. Use care when performing this procedure because all settings will be saved as institutional default settings.

10.2.2 SpaceLabs Communications

The N-395 sends SpO2, pulse rate, and alarm status data to the SpaceLabs monitor.

Figure 10-2 illustrates the connections between the N-395 and the SpaceLabs Monitor.

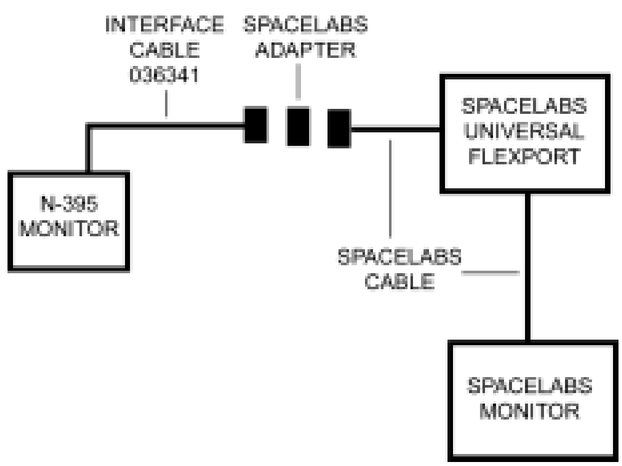

Figure 10-2: SpaceLabs Connection

Caution: The SpaceLabs monitor must be turned on before the N-395 monitor is turned on.

The SpaceLabs monitor requires a Universal FlexPort ™ interface module to interface with the N-395 pulse oximeter.

The RS-232 hardwire interface cable has a DB-15 connector for the N-395 and the applicable connector for the SpaceLabs monitor. Nellcor cable part number 036341 is recommended for this interface.

Corrupt data will be indicated by a Communications Error displayed on the SpaceLabs monitor. The SpaceLabs monitor will detect corrupt data in less than 11 seconds.

When the N-395 is in the SpaceLabs mode of operation, the interface baud rate must be set to 9,600 bits per second. Press the SETUP softkey, then the NEXT softkey, and then the COMM softkey to select BAUD. Use the ADJUST UP or ADJUST DOWN buttons to select the correct baud rate.

WARNING: Do not silence the N-395 audible alarm or decrease its volume if patient safety could be compromised.

The SpaceLabs monitor provides both audible and visual alarm indications for equipment interfaced through the Universal FlexPort ™ interface module. Silencing the N-395 alarms will also silence the SpaceLabs monitor alarms. The monitors must be able to sound an audible alarm in order to maintain patient safety.

Note: The parameters setup for the SpaceLabs bedside monitor interface may be saved as institutional default settings, see paragraph 4.5, *Setting Institutional Defaults (Sample)*, page 4-8. Use care when performing this procedure because, all settings will be saved as institutional default settings.

10.2.3 Marquette Communications

The N-395 sends SpO2, pulse rate, and alarm status data to the Marquette monitor.

The Marquette monitor requires an Octanet ™ interface module to interface with the N-395 pulse oximeter. The interface module comes with an interface cable, GE Marquette part number 417961-033, that connects to the Nellcor interface cable.

The RS-232 hardwire interface cable has a DB-15 connector for the N-395 and the applicable connector for the Marquette Octanet ™ interface module cable. Nellcor cable part number 902254 is recommended for this interface.

Corrupt data will be indicated by a Communications Error displayed on the Marquette monitor. The Marquette monitor will detect corrupt data in less than 7 seconds.

When the N-395 is in the Marquette mode of operation, the interface baud rate must be set to 9,600 bits per second. Press the SETUP softkey, then the NEXT softkey, and then the COMM softkey to select BAUD. Use the ADJUST UP or ADJUST DOWN buttons to select the correct baud rate.

The GE Marquette monitor only sounds audible alarms for equipment interfaced through the Octanet ™ interface module. Silencing the N-395 audible alarm has no effect on the GE Marquette monitor sounding an alarm.

Note: The parameters setup for the Marquette bedside monitor interface may be saved as institutional default settings, see paragraph 4.5, *Setting Institutional Defaults (Sample)*, page 4-8. Use care when performing this procedure because, all settings will be saved as institutional default settings.

10.2.4 Datex-Ohmeda Communications

The Datex-Ohmeda monitor AS/3 must be configured for communications with the Nellcor N-200 monitor in order to communicate with the N-395 monitor. Refer to the AS/3 operator's manual for instructions on configuring the AS/3 monitor.

The N-395 sends SpO2, pulse rate, and alarm status data to the Datex AS3 monitor.

The RS-232 hardwire interface cable has a DB-15 connector for the N-395 and the applicable connector for the Datex monitor. Nellcor cable part number 902255 is recommended for this interface.

Corrupt data will be indicated by a Communications Error displayed on the Datex monitor. The Datex monitor will detect corrupt data in less than 11 seconds.

When the N-395 is in the Datex mode of operation, the interface baud rate must be set to 2,400 bits per second. Press the SETUP softkey, then the NEXT softkey, and then the COMM softkey to select BAUD. Use the ADJUST UP or ADJUST DOWN buttons to select the correct baud rate.

WARNING: Do not silence the N-395 audible alarm or decrease its volume if patient safety could be compromised.

The Datex-Ohmeda monitor does not indicate audible or visual alarms for equipment interfaced. The N-395 monitor must be able to sound an audible alarm in order to maintain patient safety.

Note: The parameters setup for the Datex-Ohmeda bedside monitor interface may be saved as institutional default settings, see paragraph 4.5, *Setting Institutional Defaults (Sample)*, page 4-8. Use care when performing this procedure because all settings will be saved as institutional default settings.

10.3 CONNECTING TO THE DATA PORT

Data is transmitted in the RS-232 format (pins 2, 3, and 5) or RS-422 (pins 1, 4, 9, and 12). RS 232 data can be transmitted a maximum of 25 feet, RS-422 up to 4000 feet. The pin outs for the data port are listed in Table 10-1.

Table 10-1: Data Port Pin Outs

Pin	Signal
1	RXD+ (RS-422 positive input)
2	RXD 232 (RS-232 input)
3	TXD 232 (RS-232 output)
4	TXD+ (RS-422 positive output)
5	Signal Ground (isolated from earth ground)
6	AN_SpO2 (analog saturation output)
7	Normally Open (N.O.), Dry Contacts, for Nurse Call (N.O. with no audible alarm)
8	Normally Closed (N.C.), Dry Contacts, for Nurse Call (N.C. with no audible alarm)
9	RXD- (RS-422 negative input)
10	Signal Ground (isolated from earth ground)
11	Nurse Call (RS-232 level output {-5 to -12 VDC with no audible alarm} {+5 to +12 VDC with audible alarm})
12	TXD- (RS-422 negative output)
13	AN_Pulse (analog pulse rate output)
14	AN_Pleth (analog pleth wave output)
15	Nurse Call Common for Dry Contacts

Note: When the instrument is turned off, the contact at pin 7 becomes closed and the contact at pin 8 becomes open.

The pin layout is illustrated in Figure 10-3. An AMP connector is used to connect to the data port. Use AMP connector (AMP P/N 747538-1), ferrule (AMP P/N 1-747579-2), and compatible pins (AMP P/N 66570-2).

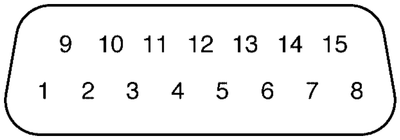

Figure 10-3: Data Port Pin Layout

When building an RS-422 cable, a resistor (120 Ω , 1/2 watt, 5%) must be added between pins 1 and 9 of the cable. The end of the cable with the resistor added must be plugged into the N-395. This resistor is not necessary for RS-232 cables.

The data cable must be shielded (example: Beldon P/N 9616). Connectors at both ends of the data cable must have the shield terminated to the full 360 degrees of the connector's metal shell. If rough handling or sharp bends in the cable is anticipated, use a braided shield.

10.4 COMMUNICATIONS WITH A PC

Data can be sent from the N-395 to a PC by using a data cable with a Null modem connector installed between the instrument and the PC. Select the ASCII Comm protocol. Data sent to the PC is serial, 8 data bits, no parity, 1 stop bit XON/XOFF flow control and is space delineated. When the connection is made, real-time data will be sent to the PC. A new line of data will be sent every 2 seconds. The information presented will be the same as described in Real-Time Printouts later in this section.

Holding the Control key on the PC keyboard and pressing "C" twice can access an interactive mode. When the interactive mode has been accessed, real-time serial output is stopped and serial input is accepted. Printouts can be requested or the date and time can be adjusted via the PC. The PC monitor will display 5 options:

1) Dump Instrument Info
2) Set Date and Time
3) Dump Trend
4) Dump Error Log
5) Exit Interactive Mode

Dump Instrument Info

This allows Instrument Info to be printed or displayed on the PC screen. This option is intended for Nellcor field service personnel. Instrument Info is a single line of data, which includes software version, CRC number, and total operating time.

Date and Time

When the instrument is shipped from the factory the date and time are set to the Time Zone at the manufacturer. If the battery has been removed or disconnected, the time clock will not reflect the actual date and time. After battery power has been restored, it will be necessary to reset the date and time.

When Item 2 has been selected, the date and time can be changed via the PC. The format for date and time is DD-MMM-YY HH:MM:SS. Move the cursor under the value to be changed and enter the new value.

Dump Trend

Selecting option 3 outputs current trend information. Up to 48 hours of trend information can be viewed. Information presented includes:

- instrument type
- software revision level
- printout type
- alarm limits
- date and time
- %SpO_2
- pulse rate
- pulse amplitude.

Dump Error Log

A list of all of the error codes in memory can be obtained by selecting item 4. The information that can be viewed includes: instrument type, software revision level, printout type, time of printout, operating time of the recorded error, error number, task number, address, and count. This option is intended for Nellcor field service personnel.

Exit Interactive Mode

Selecting item 5 exits the interactive mode and returns the data port to normal operation.

10.5 USING DATA ON THE PC

Data displayed on the PC screen can be captured for use in a word-processing spreadsheet.

Open a terminal program such as HyperTerminal. Verify that the communications format is compatible with the data port of the N-395. If the communications format is compatible, real-time data will begin to be displayed on the PC. Capture the text to a file. Use Control C to stop data flow.

Import the data file into the spreadsheet. The data can now be manipulated by the commands of the spreadsheet. Some formatting of the data may be necessary.

10.6 REAL-TIME PRINTOUT

When a real-time display or printout is being transmitted to a printer or PC, a new line of data is printed every 2 seconds. Every 25th line is a Column Heading line. A column heading line is also printed any time a value in the column heading line is changed. A real-time printout is shown in Figure 10-4.

Note: If the data output stops transmitting, turn the power off and back on again, or, if the monitor is connected to a PC, send an XON (Ctrl-q) to resume transmission.

N-395 VERSION 1.0.0.1	CRC: XXXX	SpO_2 Limit: 30-100%			PR Limit: 100-180 bpm
TIME	%SpO_2	BPM	PA	Status	
01-Jul-99 14:00:00	100	120	220		
01-Jul-99 14:00:02	100	124	220		
01-Jul-99 14:00:04	100	190	220		
01-Jul-99 14:00:06	100	190*	220	PH	
01-Jul-99 14:00:08	100	190*	220	PH	
01-Jul-99 14:00:10	100	190*	220	PH	
01-Jul-99 14:00:12	100	190*	220	PH	
01-Jul-99 14:00:14	100	190*	220	PH	
01-Jul-99 14:00:16	100	190*	220	PH LB	
01-Jul-99 14:00:18	100	190*	220	PH LB	
01-Jul-99 14:00:20	100	190*	220	PH LB	
01-Jul-99 14:00:22	- - -	- - -	- - -	SD LB	
01-Jul-99 14:00:24	- - -	- - -	- - -	SD LB	
01-Jul-99 14:00:26	- - -	- - -	- - -	SD	
01-Jul-99 14:00:28	- - -	- - -	- - -	SD	
01-Jul-99 14:00:30	- - -	- - -	- - -	SD	
01-Jul-99 14:00:32	- - -	- - -	- - -	SD	
01-Jul-99 14:00:34	- - -	- - -	- - -	PS	
01-Jul-99 14:00:36	- - -	- - -	- - -	PS	
01-Jul-99 14:00:38	- - -	- - -	- - -	PS	
01-Jul-99 14:00:40	- - -	- - -	- - -	PS	
01-Jul-99 14:00:42	- - -	- - -	- - -	PS	
01-Jul-99 14:00:44	- - -	- - -	- - -	PS	
N-395 VERSION 1.0.0.1	CRC: XXXX	SpO_2 Limit: 30-100%			PR Limit: 100-180 bpm
TIME	%SpO_2	BPM	PA	Status	
01-Jul-99 14:00:46	- - -	- - -	- - -	PS	
NELLCOR-25 VERSION 1.0.0.1	CRC: XXXX	SpO_2 Limit: 80-100%			PR Limit: 100-180 bpm
TIME	%SpO_2	BPM	PA	Status	
01-Jul-99 14:00:48	79*	59*	220	SL PL LB	
01-Jul-99 14:00:50	79*	59*	- - -	PS SL PL LB	

Figure 10-4: Real-Time Printout

10.6.1 Column Heading

To explain the printout it will be necessary to break it down to its key components. The first two lines of the chart are the Column Heading shown below. Every 25th line a Column Heading is printed. A column heading is also printed whenever a value of the Column Heading is changed. There are three Column Headings shown in Figure 10-4. The third Column Heading was printed because the SpO_2 limits changed from 30-100% to 80-100%.

N-395	VERSION 1.0.0.1	CRC: XXXX	SpO_2 Limit: 30-100%		PR Limit: 100-180 bpm
TIME	%SpO_2	BPM	PA	Status	

Data Source

N-395	VERSION 1.0.0.1	CRC XXXX	SpO2 Limit: 30-100%		PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status	

Data in the highlighted box above represents the source of the printout or display, in this case the N-395.

Software Revision Level

N-395	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status

The next data field tells the user the software level, (Version 1.0.0.1) and a software verification number (CRC XXXX). Neither of these numbers should change during normal operation. The numbers will change if the monitor is serviced and receives a software upgrade.

Alarm Limits

N-395	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status

The last data field in the top line indicates the high and the low alarm limits for %SpO_2 and for the pulse rate (PR). In the example above, the low alarm limit for SpO_2 is 30% and the high alarm limit is 100%. Pulse Rate alarm limits are, 100 bpm (low), and 180 bpm (high).

Column Headings

N-395	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status

Actual column headings are in the second row of the Column Heading. Patient data presented in the chart, from left to right, is the time that the line was obtained, the current %SpO_2 value being measured, the current Pulse Rate in beats per minute (bpm), the current Pulse Amplitude (PA), and the operating status of the N-395.

10.6.2 Patient Data and Operating Status

Time

TIME	%SpO2	BPM	PA	Status
01-Jul-97 14:00:00	100	120	220	

The Time column represents the N-395 real-time clock.

Patient Data

N-395	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status
01-Jul-97 14:00:06	100	190*	220	PH

Patient data and the operating status of the unit are highlighted in the display above. Parameter values, at the time of the printout, are displayed directly beneath the heading for each parameter. In this example the %SpO_2 is 100, and the pulse rate (PR) is 190 beats per minute. The asterisk (*) next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available, three dashes (- - -) will be displayed in the printout.

Pulse Amplitude (PA) can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information and is an indication of a change in pulse volume, pulse strength, or circulation.

Operating Status

N-395	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 100-180 bpm
TIME	%SpO2	BPM	PA	Status
01-Jul-97 14:00:06	100	190*	220	PH

The Status column indicates alarm conditions and operating status of the N-395. In this example the PH means Pulse High. The status codes are listed in Table 10-2. As many as 4 codes can be displayed at one time in the Status column.

Table 10-2: Printout Codes

Code	Meaning
BU	**B**attery in **U**se
LB	**L**ow **B**attery
AS	**A**larm **S**ilence
AO	**A**larm **O**ff
SD	**S**ensor **D**isconnect
PS	**P**ulse **S**earch
LP	**L**oss of **P**ulse
SH	**S**at **H**igh Limit Alarm
SL	**S**at **L**ow Limit Alarm
PH	**P**ulse Rate **H**igh Limit Alarm
PL	**P**ulse Rate **L**ow Limit Alarm
MO	**Mo**tion
LM	**L**oss of Pulse with **M**otion
- - -	No Data Available
*	Alarm Parameter Being Violated

Note: A Sensor Disconnect will also cause three dashes (- - -) to be displayed in the patient data section of the printout.

10.7 TREND DATA PRINTOUT (ASCII MODE)

The format of data displayed when a trend printout is requested is similar to that of the real-time data. The only differences are that "TREND" is displayed in the top row instead of the "CRC:XXXX" software verification number, and there is no "Status" column (Figure 10-5).

Readings are displayed in 4-second intervals. The values on each row are an average for the 4-second period.

At the end of the printout, an "Output Complete" line indicates that the transmission was successful. If the "Output Complete" line is not present, the data should be considered invalid.

```
              VERSION 1.0.0.1      TREND            SpO2 Limit:  30-100%          PR Limit: 100-180 bpm
TIME                 %SpO2              PR (bpm)      PA
22-Nov-99 14:00:05         100               120             150
22-Nov-99 14:00:09         100               121             154
22-Nov-99 14:00:13         100               120             150
Output Complete
```

Figure 10-5: Trend Data Printout (ASCII Mode)

10.8 TREND PRINTOUT (GRAPH MODE)

The graph mode (Figure 10-6) disables all printout functions except trend data. Trend printouts will be graphical if connected to a serial printer that supports Epson ESC protocol.

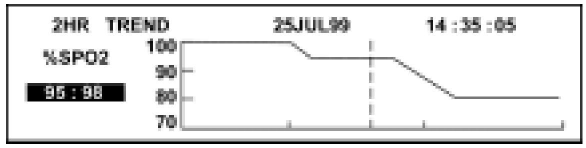

Figure 10-6: Trend Data Printout (GRAPH MODE)

10.9 NURSE CALL

An RS-232 Nurse Call signal (pins 5 and 11) can be obtained by connecting to the data port. It is in the form of a positive or negative voltage chosen by the user.

The remote location will be signaled anytime there is an audible alarm. If the audible alarm has been set to Off, or silenced, the Nurse Call function is also turned off.

Pin 11 on the data port is the RS-232 Nurse Call signal and in 5 is ground (see Table 10-1). When there is no audible alarm, the voltage between pins 10 and 11 will be -5 VDC to -12 VDC, or +5V DC to +12 VDC, depending on the option chosen via the softkeys (either NCALL+ or NCALL-). Whenever there is in an audible alarm, the output between pins 5 and 11 will reverse polarity.

An internal Nurse Call relay (pins 7, 8, and 15) provides dry contacts that can be used to signal a remote alarm. Pin 15 is common, pin 7 is normally open (N.O.), and pin 8 is normally closed (N.C.). Table 10-3 shows the state of the contacts for alarm and no alarm conditions, and for instrument off. Table 10-4 defines the ratings of the Nurse Call relay.

Table 10-3: Nurse Call Relay Pin States

Pin	No Alarm or Alarm Silenced	Audible Alarm	Instrument Off
7 N.O.	Open	Closed	Closed
8 N.C.	Closed	Open	Open

Table 10-4: Rating of Nurse Call Relay

Maximum Input Voltage	30 V AC or DC (polarity is not important)
Load Current	120 mA continuous (peak 300 mA @ 100 ms)
Minimum Resistance	26.5 Ω to 50.5 Ω (40.5 Ω typical) during alarms
Ground Reference	Isolated Ground
Electrical Isolation	1500 Volts

10.10 ANALOG OUTPUT

Analog outputs are provided for Saturation, Pulse Rate, and a plethysmographic waveform.

The output voltage is 0.0 to +1.0 VDC for all three parameters. A 1.0 VDC output for saturation equals 100%; for pulse rate it equals 250 bpm; and for plethysmographic waveform, it equals 254 pulse amplitude units. The voltage will decrease as the values for these parameters decrease. If no data for a parameter is available, the output voltage for that parameter will be 1.0 VDC.

At power-on after the completion of power-on self-test (POST), the instrument will initiate an automatic three-step calibration signal. The calibration signal will begin at 0.0 VDC and hold that point for 60 seconds. It will then jump up to 1.0 VDC and hold that value for 60 seconds. The third part of the calibration signal is a stair step signal. The stair step signal will start at 0.0 VDC and increase up to 1.0 VDC in 0.1-VDC increments. Each increment will be held for 1 second. Through use of the softkeys, the 0.0 VDC, 1.0 VDC, or stair step signal can be selected individually (paragraph 3.3.3.6).

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SECTION 11:   TECHNICAL SUPPLEMENT

11.1   INTRODUCTION

This Technical Supplement provides the reader with a discussion of oximetry principles and a more in-depth discussion of N-395 circuits. Block and schematic diagrams support a functional overview and detailed circuit analysis. The schematic diagrams are located at the end of this section.

11.2   OXIMETRY OVERVIEW

The N-395 is based on the principles of spectrophotometry and optical plethysmography. Optical plethysmography uses light absorption technology to reproduce waveforms produced by pulsatile blood. The changes that occur in the absorption of light due to vascular bed changes are reproduced by the pulse oximeter as plethysmographic waveforms.

Spectrophotometry uses various wavelengths of light to measure light absorption through given substances. Many times each second, the N-395 passes red and infrared light into the sensor site and determines absorption. Light transmission is affected by blood in the arteries, capillaries, and veins, and by solid tissue. The variation of absorption during the cardiac cycle is caused primarily by pulsatile changes in the amount of arterial blood in the tissue. By tracking red and infrared absorption during the whole cardiac cycle, the N-395 determines the portion of light absorption which is caused by the pulsating arterial blood. Because oxyhemoglobin and deoxyhemoglobin differ in red and infrared absorption, this corrected measurement can be used to determine the percent of oxyhemoglobin in arterial blood: SpO_2 is the ratio of corrected absorption at each wavelength.

11.2.1   Functional Versus Fractional Saturation

Like any two-wavelength pulse oximeter, the N-395 cannot recognize the presence of significant levels of dyshemoglobins. In the presence of significant amounts of methemoglobin, such oximeters become inaccurate; clinicians are trained to evaluate the possible presence of methemoglobin by other means. In the presence of carboxyhemoglobin, two-wavelength pulse oximeters do approximately indicate functional saturation. Unlike pulse oximeters, some instruments such as CO-Oximeters measure fractional saturation, that is, oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including dyshemoglobins.

Consequently, before comparing N-395 measurements with those obtained by an instrument that measures fractional saturation, measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\%\,\text{carboxyhemoglobin} + \%\,\text{methemoglobin})} \times 100$$

11.2.2 Measured Versus Calculated Saturation

When saturation is calculated from a blood gas measurement of the partial pressure of arterial oxygen (PO_2), the calculated value may differ from the N-395 SpO_2 measurement. This is because the calculated saturation may not have been corrected for the effects of variables that can shift the relationship between PO_2 and saturation.

Figure 11-1 illustrates the effect that variations in pH, temperature, partial pressure of carbon dioxide (PCO_2), and concentrations of 2,3-DPG and fetal hemoglobin may have on the oxyhemoglobin dissociation curve.

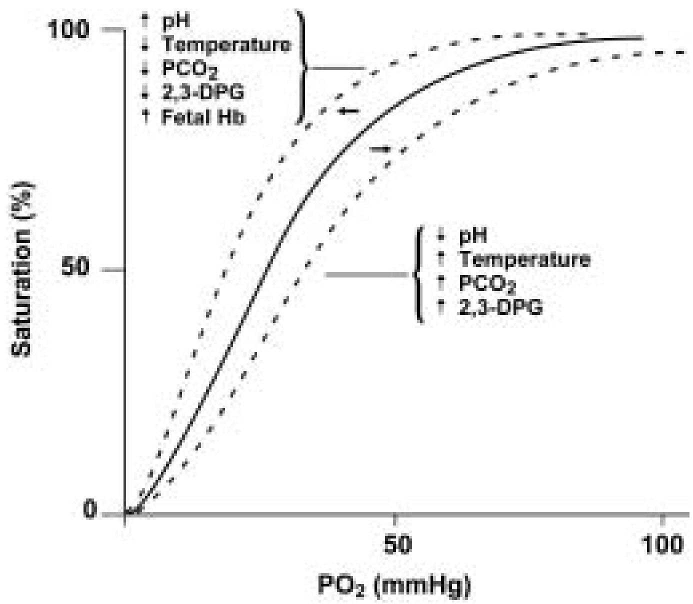


Figure 11-1: Oxyhemoglobin Dissociation Curve

11.3 *SATSECONDS* ALARM MANAGEMENT

The N-395 utilizes Nellcor *SatSeconds* alarm management technique. *SatSeconds* is a function of the software within the N-395. With the *SatSeconds* technique, upper and lower alarm limits are set in the same way as traditional alarm management. The clinician also sets a *SatSeconds* limit that allows monitoring of $\%SpO_2$ below the selected low alarm limit for a period of time before an audible alarm sounds. Refer to the N-395 Operator's manual for managing *SatSeconds*.

11.4 READS THROUGH MOTION

The N-395 takes advantage of increased microprocessing power with advanced mathematical algorithms. *Oxismart*™ XL advanced signal processing allows the N-395 to read through challenging motion conditions to deliver accurate saturation and pulse rate values. For a definition of motion, as applicable to the N-395, contact Nellcor's Technical Services Department.

11.5 CIRCUIT ANALYSIS

The following paragraphs discuss the operation of each of the printed circuit boards within the N-395 pulse oximeter. (Refer to the appropriate schematic diagram at the end of this supplement, as necessary.)

11.6 FUNCTIONAL OVERVIEW

The monitor functional block diagram is shown in Figure 11-2. Most of the functions of the N-395 are performed on the User Interface PCB. Functions on the User Interface PCB include the MC 68331 microprocessor, DSP, and Memory. Other key components of the N-395 are the Power Entry Module (PEM), Power Supply, and the LCD Display.

The Display module includes the Membrane Panel and the LCD Display. The Membrane panel contains annunciators and push buttons, allowing the user to access information and to select various available parameters. The LCD Display PCB contains the LCD that presents the patient data.

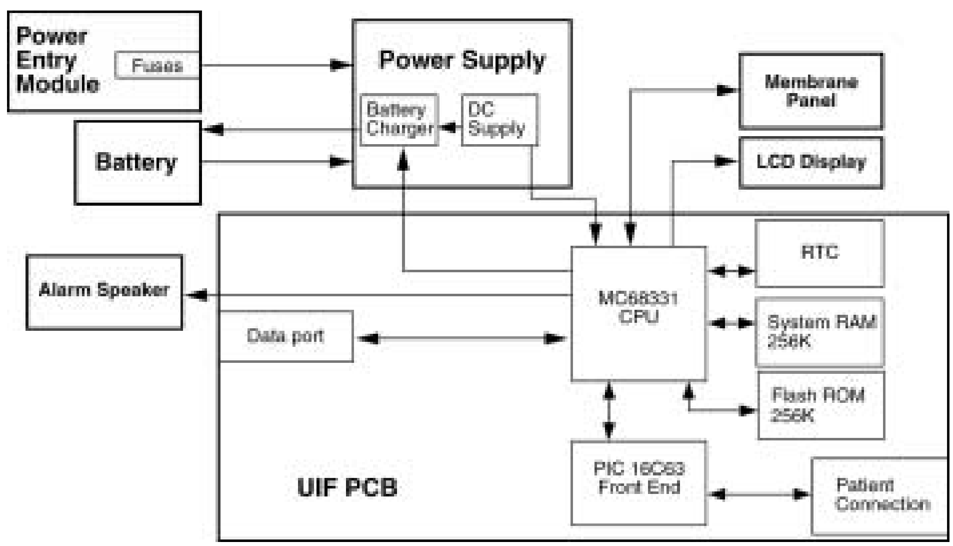


Figure 11-2: N-395 Functional Block Diagram

11.7 AC INPUT

A selector switch on the back of the N-395 allows the user to connect the monitor to AC power ranging from 100 VAC to 240 VAC. The switch has two positions, one for 100 VAC through 120 VAC and one for 210 VAC through 240 VAC. Verify that the switch selection matches the AC power at your location before plugging the monitor into an AC outlet.

AC power enters the N-395 through the PEM. A 0.5-amp fuse is placed in both the "Hot" and "Neutral" lines. These user-accessible fuses are located in a fuse drawer, which is part of the PEM on the back of the instrument.

11.8 POWER SUPPLY PCB

The N-395 uses an unregulated linear power supply. This power supply provides the DC power needed to charge the battery, run the cooling fan and to power User Interface. Protection from Electro Static Discharge (ESD) and patient isolation from mains are also provided by the power supply.

AC power from the PEM is passed through a step-down transformer, T2, which has two primary and two secondary windings. If switch SW1 on the back of the monitor is in the 120 VAC position, the primary windings are in parallel. The primary windings are in series if SW1 is in the 240 VAC position.

Each secondary winding is fused with a 0.5-amp, 250-volt fuse (F1 and F2). If a short circuit should occur in the DC circuitry, these fuses prevent the transformer from overheating. The output of the transformer varies, depending on load and input. Voltage measured between the outlet of a secondary winding and ground can be from 6 to 20 VAC. High frequency noise from the AC line and from the User Interface PCB is filtered by C6 and C8 before passing through the bridge rectifier.

Two outputs from the bridge rectifier are used in the N-395. The fan control circuit uses the negative output. The positive output is the Main DC ranging from 7 to 18 VDC. This positive voltage is used for the battery circuit and to power the User Interface PCB.

11.8.1 Fan Control

A fan control circuit on the Power Supply PCB is used to control the temperature inside the case of the N-395. The temperature sensor used in this circuit is U3. U3 turns on the cooling fan if the temperature inside the case exceeds approximately 31 °C. The cooling fan runs on approximately 15 VDC.

Note: The fan is disabled if the unit is running on battery power.

11.8.2 Battery Circuits

Two circuits are included in this section of the Power Supply PCB. One circuit is used to charge the battery and the other circuit provides battery protection.

Charging Circuit

The Power Supply will charge the battery while the N-395 is connected to AC power, even if the monitor is not turned on. The voltage applied to the battery is 6.8 ± 0.15 VDC and is current limited to 400 ± 80 mA.

Battery voltage is checked periodically by the processor. A signal from the processor turns the charging circuit off to allow this measurement to be taken. If the processor determines the battery voltage is below 5.85 ± 0.1 VDC, a low battery alarm is declared.

Battery Protection

Two types of battery protection are provided by the Power Supply: protection for the battery and protection from the battery.

SW2 is a resettable component that protects the battery. SW2 opens and turns the charging circuit off if the temperature of the battery rises above 50° C. If the output of the battery exceeds 5.0 amps, F3 opens. F3 protects the battery from a short to ground of the battery output.

Protection from the battery is provided in the event the battery is connected backwards. Components on the User Interface PCB and the Power Supply block and limit the voltage to provide protection to circuits in the instrument.

11.9 BATTERY

A lead-acid battery is used in the N-395. It is rated at 6 VDC, 4 amp-hours. When new and fully charged, the battery will operate the monitor for 2 hours under the following conditions: no alarms, no analog or serial output devices attached, no RS-232 level nurse call output, and backlight on. The battery can withstand 400 charge/discharge cycles. Recharging the battery to full capacity, from a completely discharged battery, will take 14 hours in standby or 18 hours if the instrument is being used.

Changeover from AC to battery power will not interrupt the normal monitoring operation of the N-395. However, when the unit is running on battery power, the cooling fan will be turned off.

The CPU on the User Interface PCB monitors the charge level of the battery. If the voltage of the battery falls below 5.85 ± 0.1 VDC, a low battery alarm is declared. The instrument will continue monitoring and alarming for 15 minutes and then power down. This 15-minute alarm and power-down sequence can be repeated by turning the unit back on, provided the battery voltage remains above the critical level.

Battery voltage is considered critical when it decreases to 5.67 ± 0.1 VDC. If the instrument is turned on and battery voltage is at the critical level, an error code is displayed and the instrument will not monitor the patient. The instrument will run for 15 minutes with the error code displayed and then power down.

Both conditions can be corrected by plugging the unit into an AC source for 14 hours to allow the battery to fully recharge.

11.10 USER INTERFACE PCB

The User Interface PCB is the heart of the N-395. All functions except the unregulated DC power supply, LCD display, and membrane keypad reside on the User Interface PCB.

11.10.1 Regulated DC Power Supply

The User Interface PCB receives the MAIN_DC unregulated voltage of 7 to 18 VDC from the Power Supply or 5.8 to 6.5 VDC from the internal battery. From either of these signals, the regulated power supply on the User Interface PCB generates +5.0 VDC.

11.10.2 Controlling Hardware

Two microprocessors reside on the User Interface PCB. The CPU is a Motorola MC68331CF (331). The second microprocessor, TMS320C32, is referred to as the DSP and is controlled by the CPU.

CPU (Central Processing Unit)

The 331 is the main controller of the N-395. The 331 controls the front panel display, data storage, instrument status, sound generation, and monitors and controls the instrument's power. The 331 also controls data port communication and the Nurse Call feature.

Battery voltage is checked periodically by the processor. A signal from the processor turns the charging circuit off to allow this measurement to be taken. If the processor determines that the battery voltage is below 5.85 ± 0.1 VDC, the CPU declares a low battery alarm. If battery voltage on the User Interface PCB is measured below 5.67 ± 0.1 DCV, the monitor will display an error code and sound an audible alarm. (Voltages measured at the battery will be slightly higher than the values listed above.) The user will be unable to begin monitoring a patient if the battery voltage remains below this point. If either event occurs, plug the unit into an AC source for 14 hours to allow the battery to fully recharge.

When the N-395 is powered by AC or on battery power, the RS-232 Nurse Call function is available. If no audible alarm conditions exist, the output will be -5 to -12 VDC or +5 VDC to +12 VDC. These voltages are dependent upon the option selected by the use of the softkeys. Should an audible alarm occur, the output will change polarity.

The 331 also controls a set of dry contacts provided by a pair of solid state relays on the User Interface PCB. These solid state relays provide the Nurse Call signals available at the data port pins 7 and 15 and pins 8 and 15. The relay will function normally on AC power or on the internal battery power.

When the CPU sends a tone request, three items are used to determine the tone that is sent to the speaker. First, pulse tones change with the %SpO_2 value being measured. The pulse beep tone will rise and fall with the measured %SpO_2 value. Second, three levels of alarms, each with its own tone, can occur: High, Medium, and Low priority. Third, the volume of the pulse tone and alarm is user adjustable. Alarm volume can be adjusted from level 1 to level 10, with level 10 being the highest volume. Pulse tones can be turned off, by setting the volume to zero.

A real-time clock is provided by the N-395. This is provided by a dedicated real-time clock chip.

User's interface includes the front panel display and the keypad. By pressing any of nine keys on the keypad the operator can access different functions of the N-395. The 331 will recognize the keystroke and make the appropriate change to the monitor display to be viewed by the operator. The monitor uses any changes made by the operator until it is turned off. Default values will be restored when the unit is powered-on again.

Patient data is stored by the N-395 and can be downloaded to a printer through the data port provided on the back of the monitor. An in-depth discussion of the data port is covered in Section 10 of this manual.

DSP (Digital Signal Processor)

The DSP controls the SpO_2 function and communicates the data to the 331.

The DSP controls the intensity of the LEDs in the sensor and the gain of the amplifiers receiving the return signals from the photodetector in the sensor.

Analog signals are received from the SpO_2 circuit on the User Interface PCB. An A/D converts these signals to digital values for %SpO_2 and heart rate. The values are interpreted by the DSP and sent to the 331 to be displayed and stored.

11.10.3 Sensor Output/LED Control

The SpO_2 analog circuitry provides control of the red and IR LEDs such that the received signals are within the dynamic range of the input amplifier. The variability in opacity of sensor application sites exceeds the range that can be accommodated by changing only the LED drive levels. Therefore the DSP controls both the currents to the LEDs and the amplification in the signal channel.

At initialization of transmission, the LEDs' intensity level is based on previous running conditions, and the transmission intensity is adjusted until the received signals match the range of the A/D converter. If the LEDs reach maximum output without the necessary signal strength, the DSP will increase the channel gain.

The LED drive circuit switches between red and IR transmission and disables both for a time between transmissions in order to provide a no-transmission reference. To prevent excessive heat build-up and prolong battery life, each LED is on for only a small portion of the duty cycle. Also, the frequency of switching is well above that of motion artifact, and is selected to avoid low harmonics of 50 Hz and 60 Hz power line frequencies. The IR transmission alone, and the red transmission alone, will each be on for about one-fourth of the duty cycle.

11.10.4 Input Conditioning

Input to the SpO_2 analog circuit is the current output of the sensor photodiode. In order to condition the signal current, it is necessary to convert the current to voltage.

Because the IR and red signals are absorbed differently by body tissue, their received signal intensities are at different levels. Therefore, the IR and red signals must be demodulated and then amplified separately in order to compare them to each other. De-multiplexing is accomplished by means of two circuits that alternately select the IR and red signals. Two switches that are coordinated with the IR and red transmissions control selection of the circuits. A filter with a large time-constant follows to smooth the signal and remove noise before amplification.

11.10.5 Signal Gain

The separated IR and red signals are amplified so that their DC values are within the range of the A/D converter. Because the received IR and red signals are typically at different current levels, the signal gain circuits provide independent amplification for each signal as needed. The gain in these circuits is adjusted by U68, U53, and U54.

After the IR and red signals are amplified, they are filtered to improve the signal-to-noise ratio and clamped to a reference voltage to prevent the combined AC and DC signal from exceeding an acceptable input voltage from the A/D converter.

11.10.6 Real-Time Clock (RTC)

Real time is tracked by the N-395. As long as battery power or AC power is available, the instrument will keep time. If the battery is removed, the time clock will have to be reset. The LCD will display the time and date for the data period highlighted by the cursor on a trend display. A time stamp is printed for each line of data on a printout. Real-time data is displayed and printed as Day, Month, Year, Hours, Minutes, and Seconds.

11.10.7 Patient Data Storage

Patient data is captured and stored once every 4 seconds. A maximum of 48 hours of trend data can be stored. Up to 50 alarm limit changes can be retained.

If battery power is disconnected or depleted, trend data and user settings will be lost. All data is stored with error detection coding. If data stored in memory is found to be corrupted, it is discarded.

11.11 FRONT PANEL DISPLAY PCB AND CONTROLS

11.11.1 Display PCB

The Front Panel Display PCB provides visual patient data and monitor status.

At power up, all indicators and pixels are illuminated to allow verification of their proper operation. Next, the NELLCOR logo and the software revision level are displayed. After this cycle has been completed, the instrument is ready to begin monitoring.

The LCD allows the user to select among several different types of displays. Graphs, which are used for trend screens, can be displayed. Real-time patient data can include a plethysmographic waveform and digital values for SpO_2 and BPM. If a plethysmograph is not desired, the operator can select to view only digital data for SpO_2 and BPM along with a blip bar to show pulse intensity.

11.11.2 Membrane Keypad

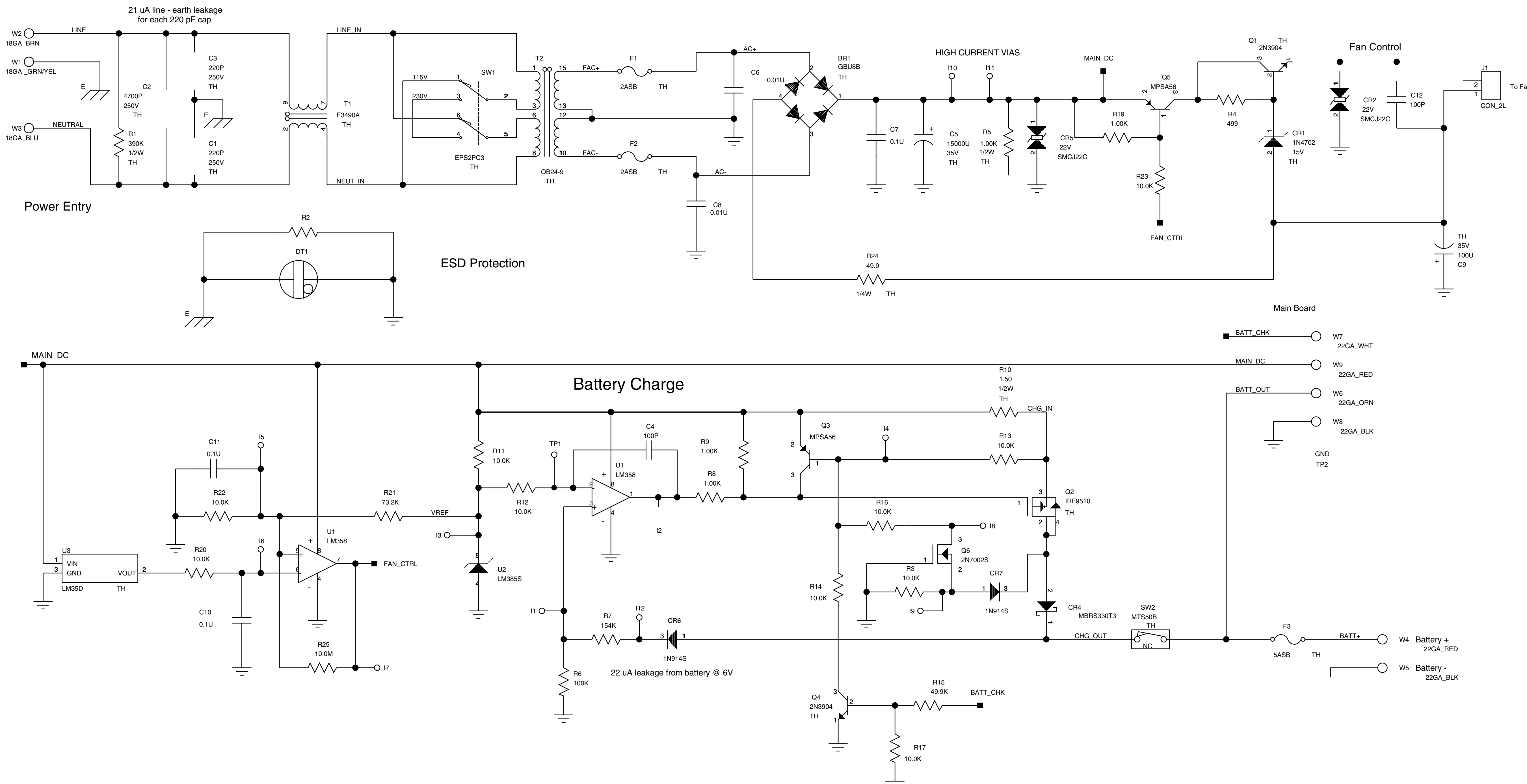
A membrane keypad is mounted as part of the top case. A ribbon cable from the keypad passes through the top case and connects to the User Interface PCB. Nine keys allow the operator to access different functions of the N-395.

These keys allow the user to select and adjust the alarm limits, cycle power to the unit, and to silence the alarm. Alarm volume and alarm silence duration can also be adjusted via the keypad. Pressing the softkeys can access a number of other functions. These functions are discussed in greater detail in Section 4.

Five LEDs are also part of the membrane keypad. These LEDs indicate AC power available, low battery, pulse search, alarm silence, and noise/motion.

11.12 SCHEMATIC DIAGRAMS

The following schematics are included in this section:



Note: All resistors 1/8W 1206 unless otherwise noted.

Figure 11-3
Linear Power Supply Schematic

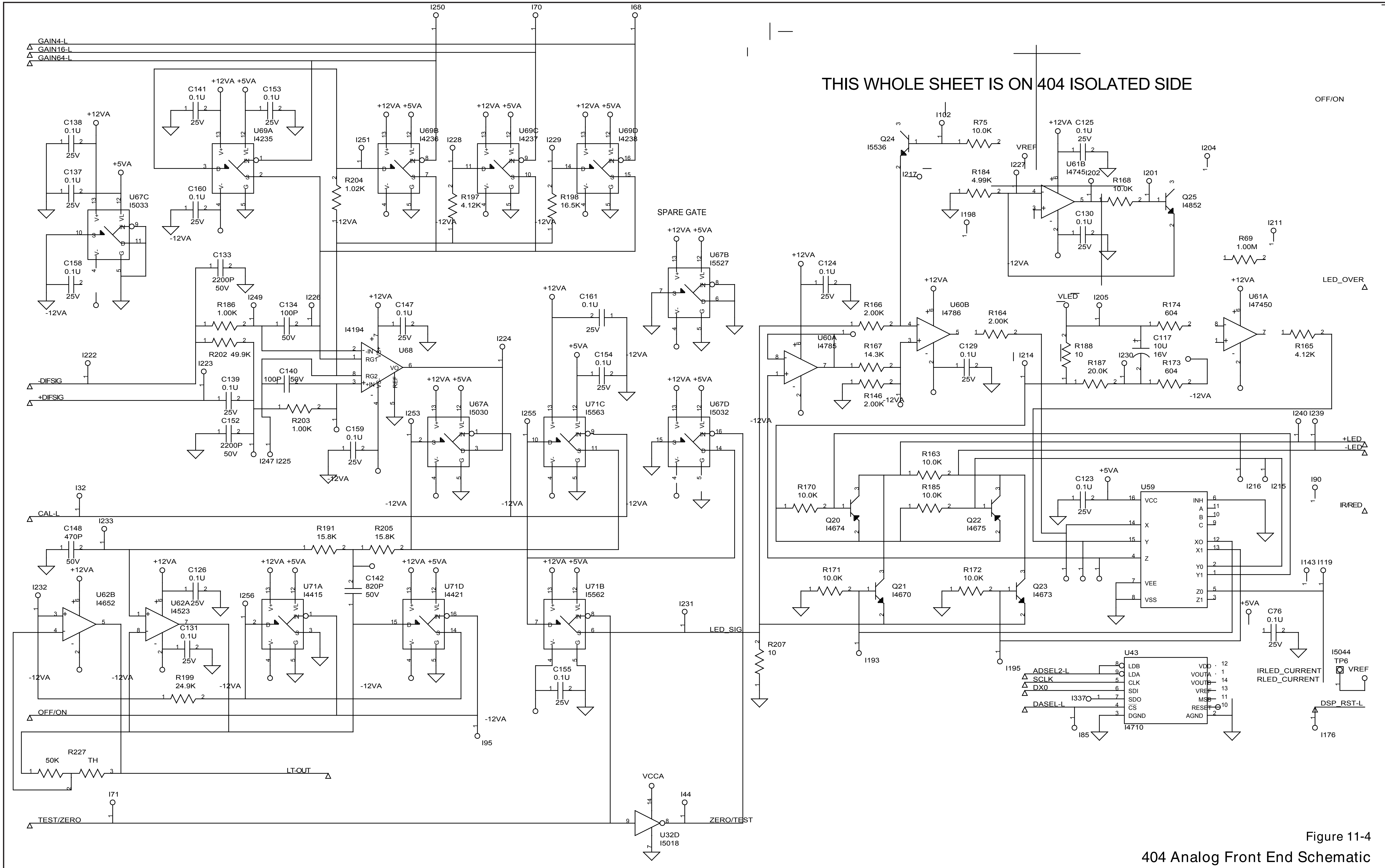


Figure 11-4

404 Analog Front End Schematic

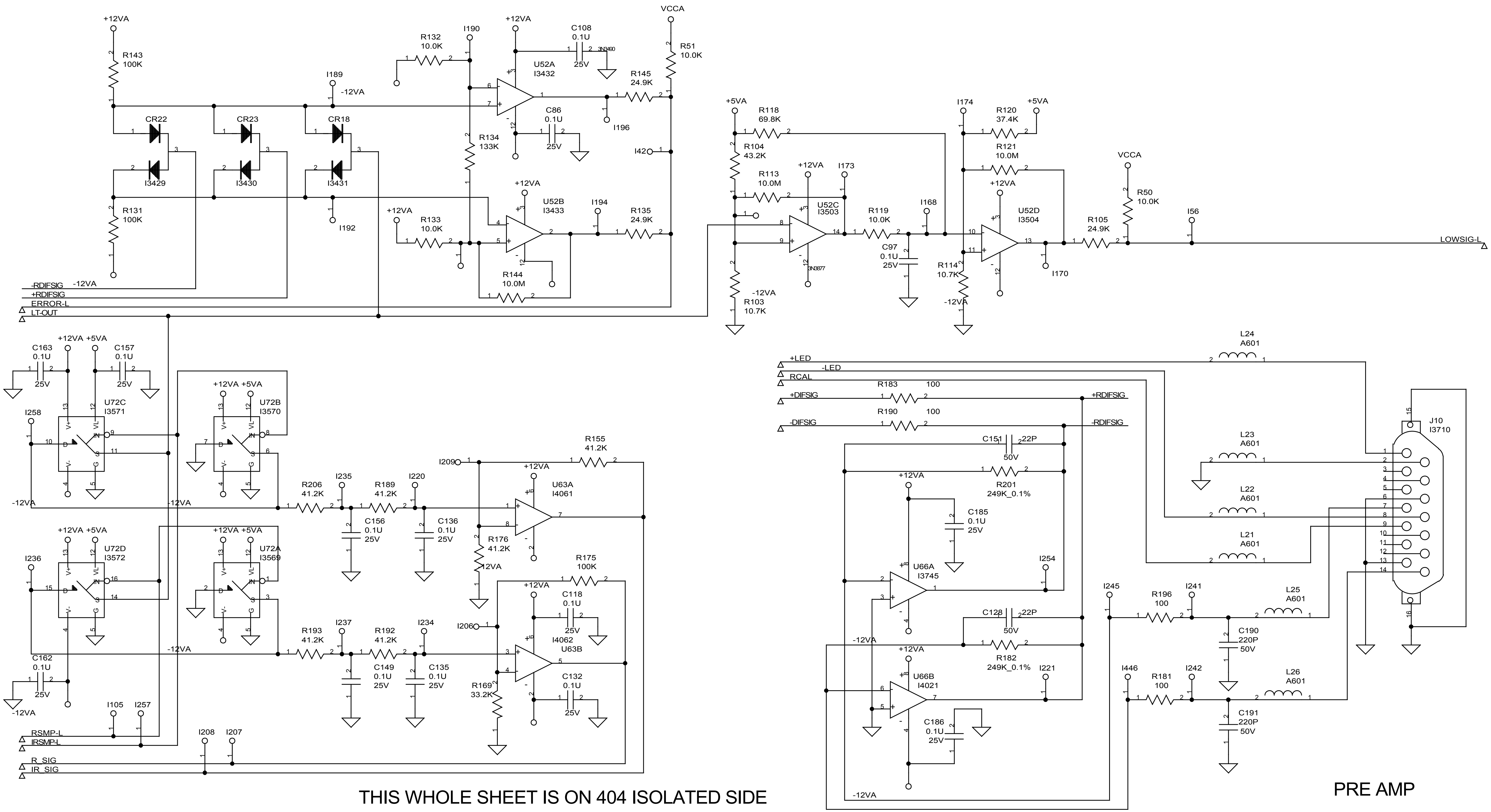


Figure 11-5

404 Analog Front End and Pre-Amp Schematic

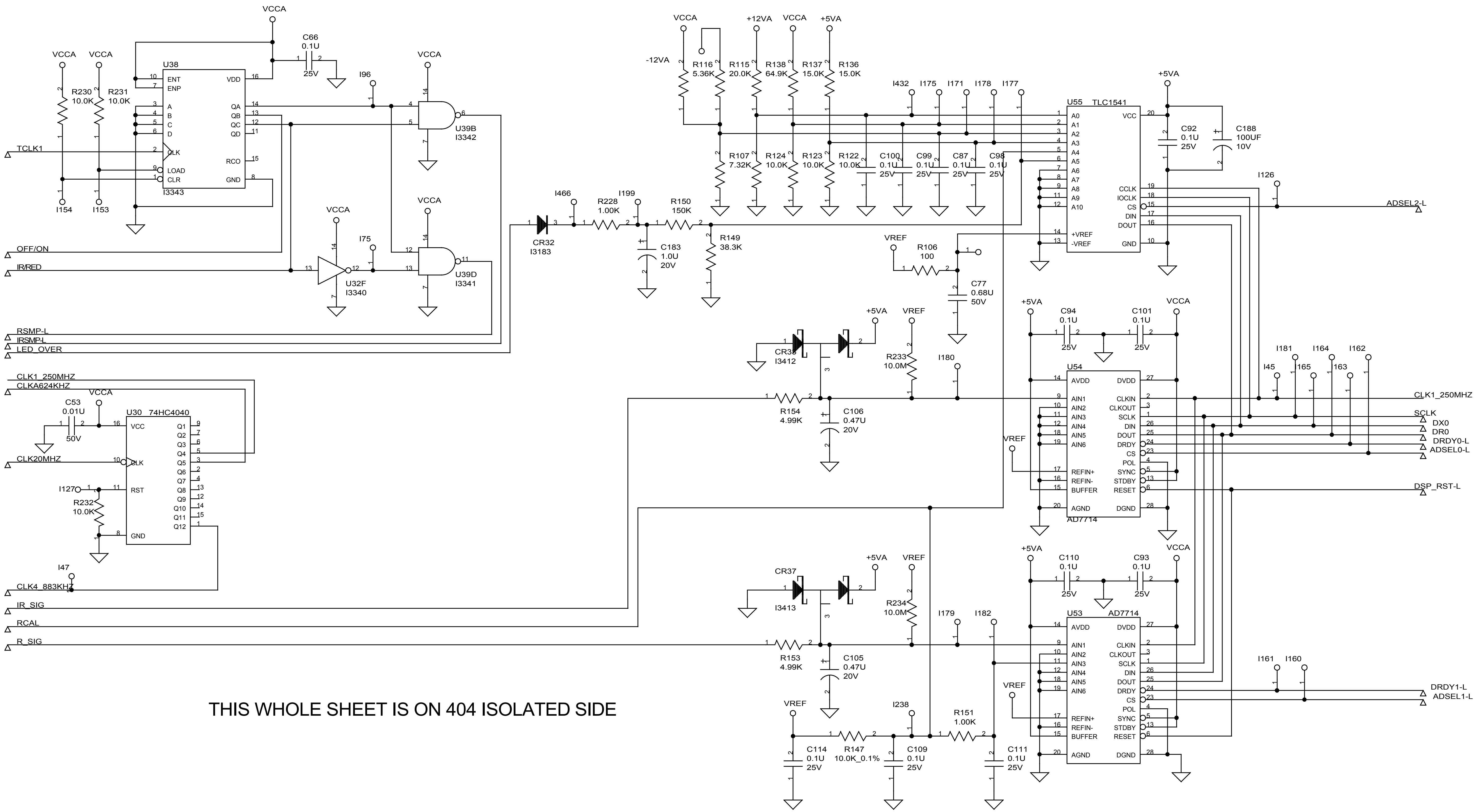


Figure 11-6

404 Analog and Digital Schematic

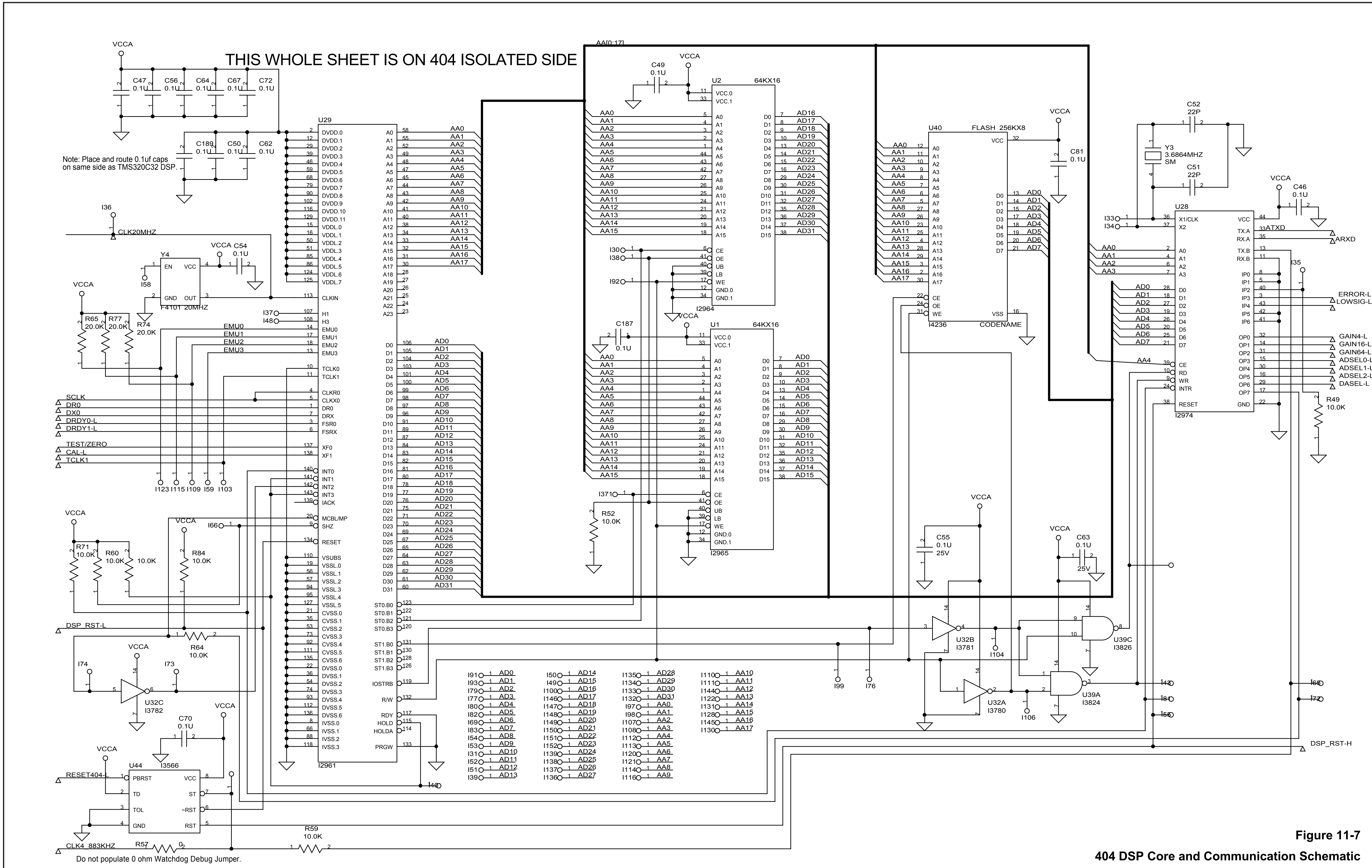


Figure 11-7

404 DSP Core and Communication Schematic

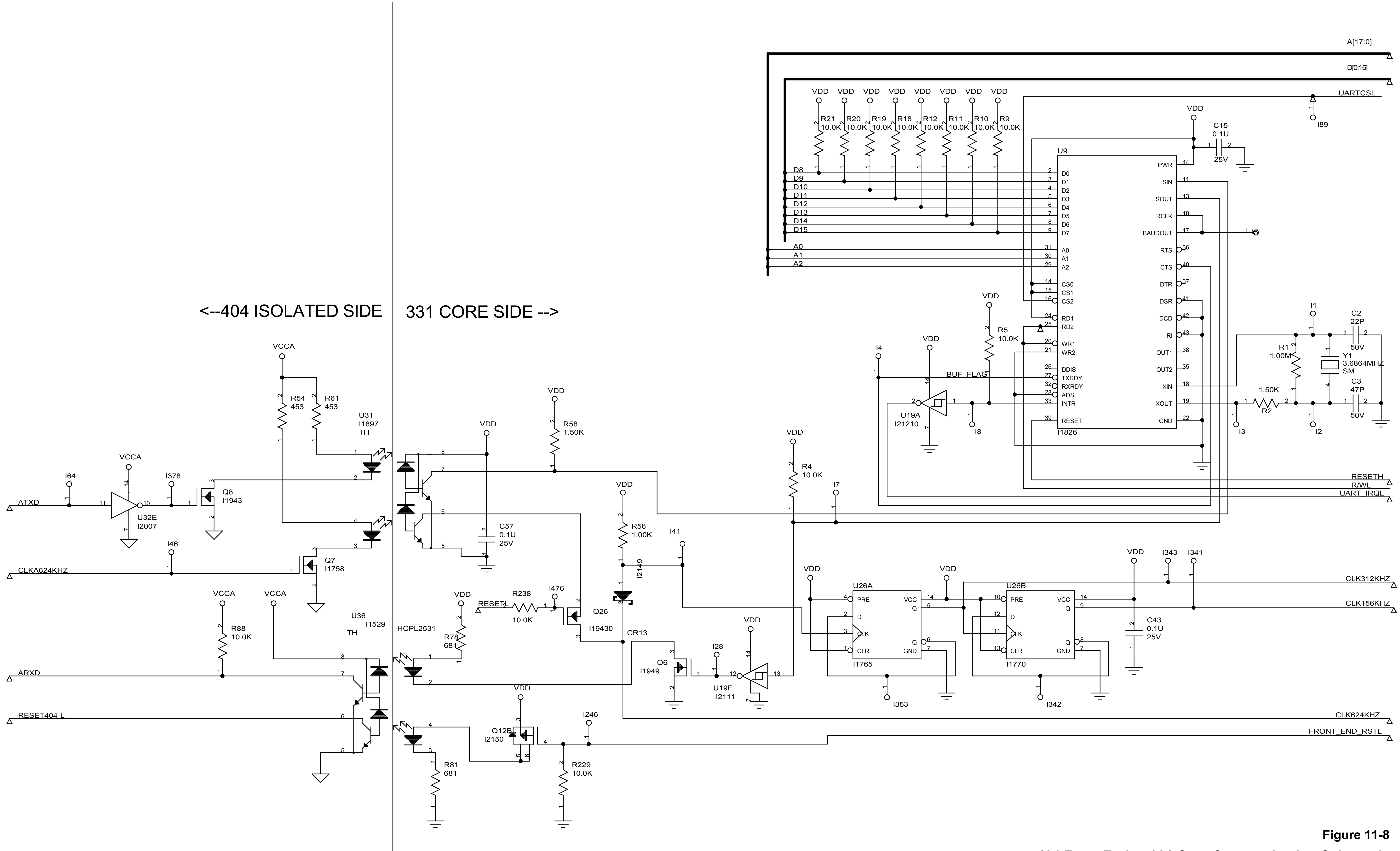


Figure 11-8

404 Front End to 331 Core Communication Schematic

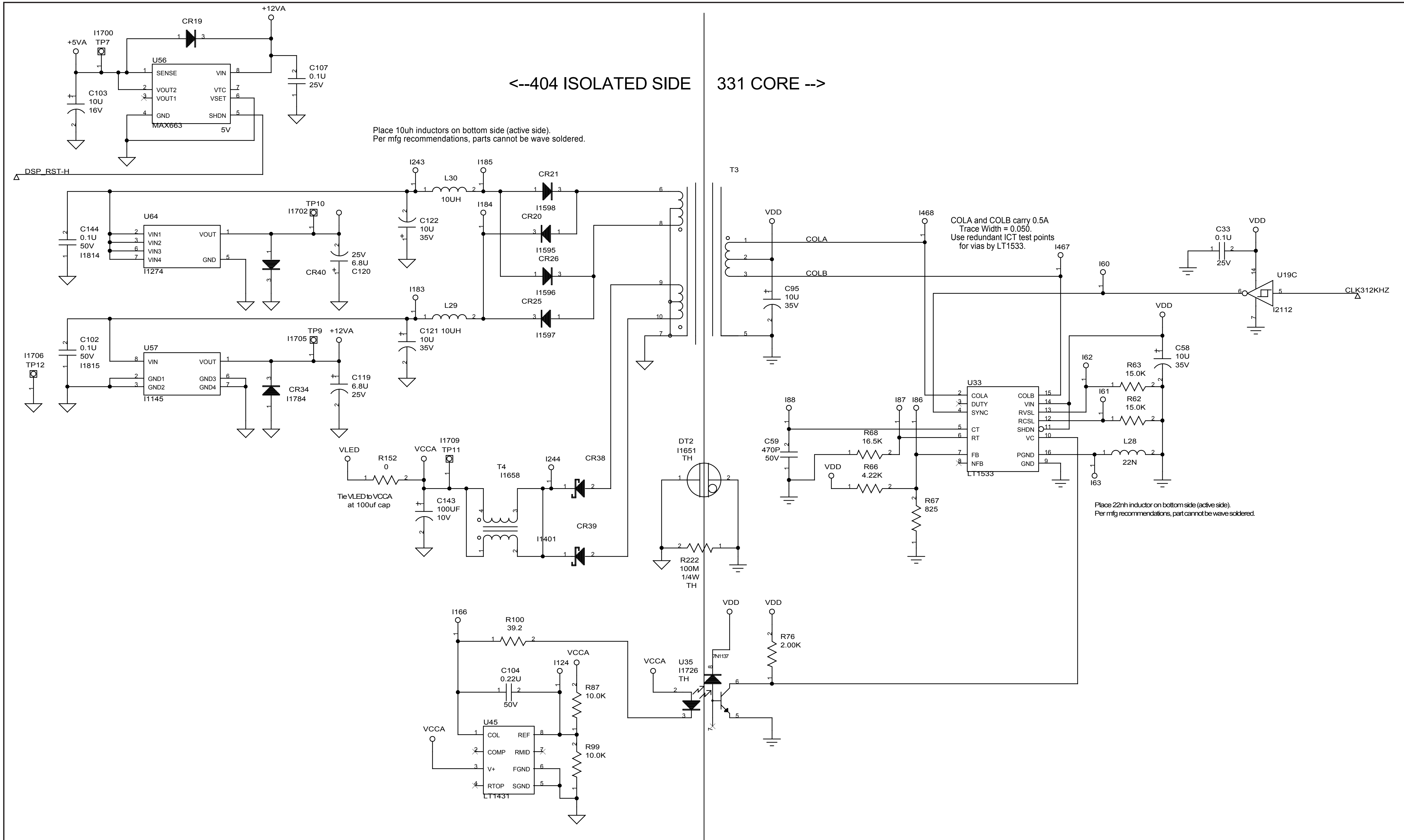


Figure 11-9

404 Front End Power Supply Schematic

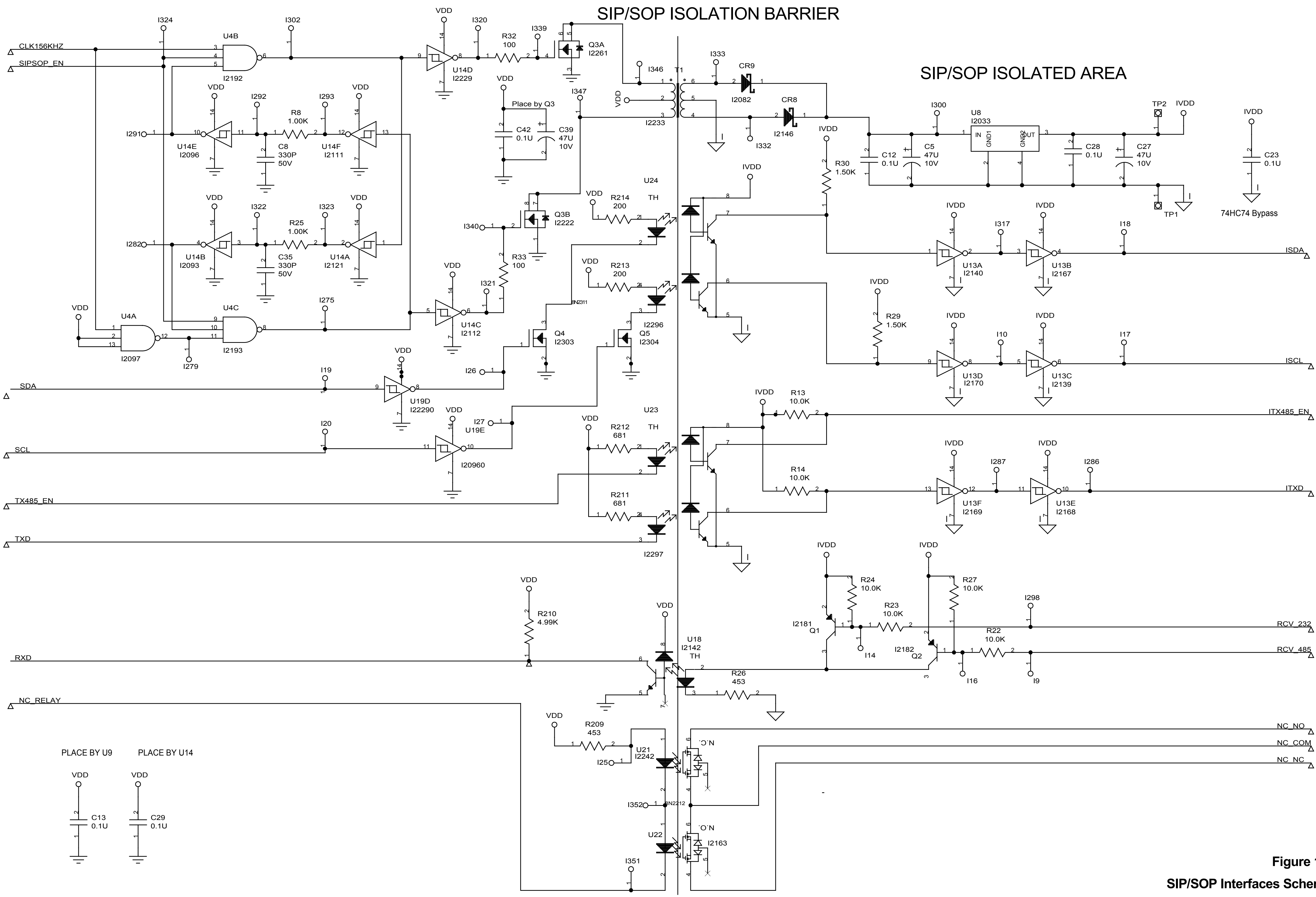


Figure 11-10

SIP/SOP Interfaces Schematic

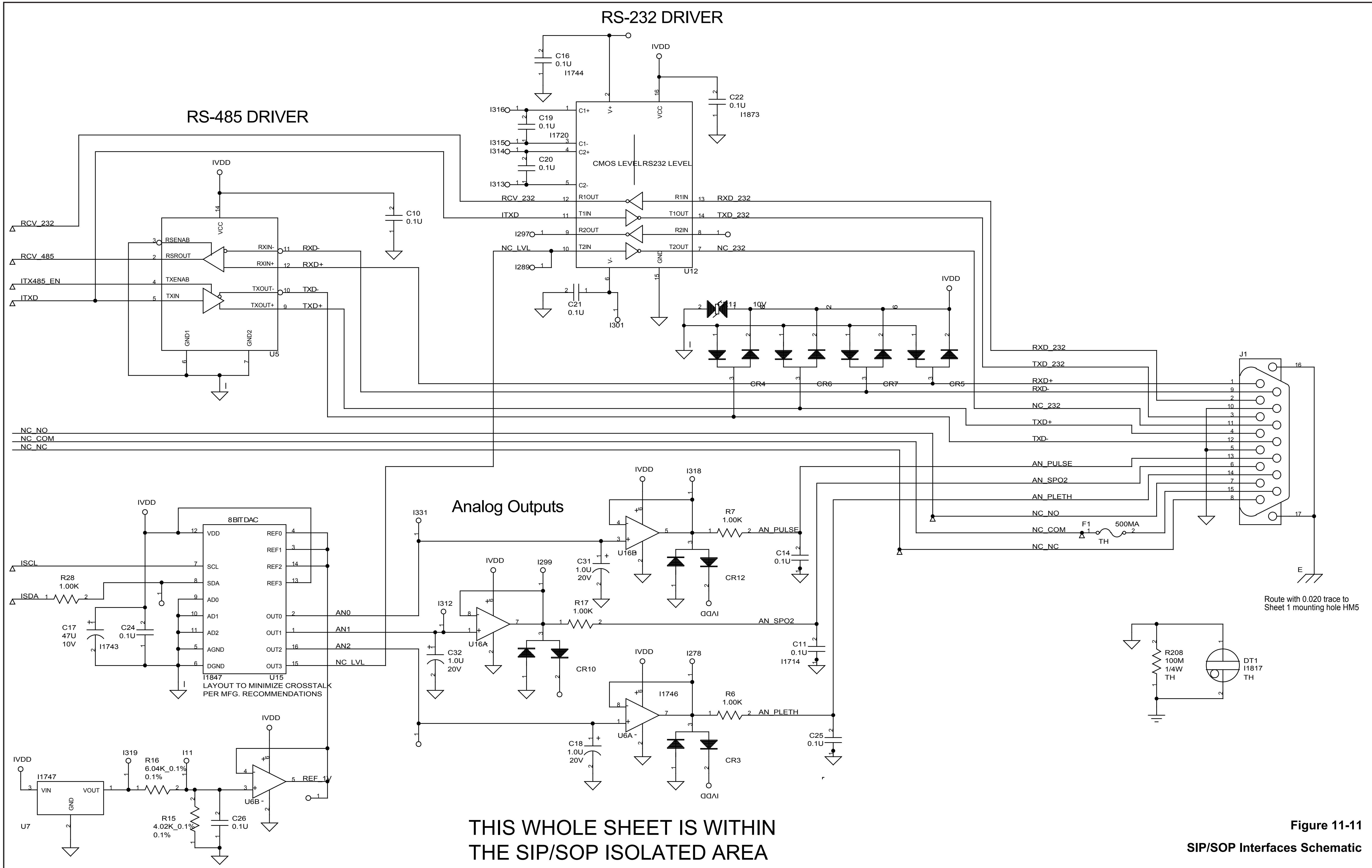


Figure 11-11

SIP/SOP Interfaces Schematic

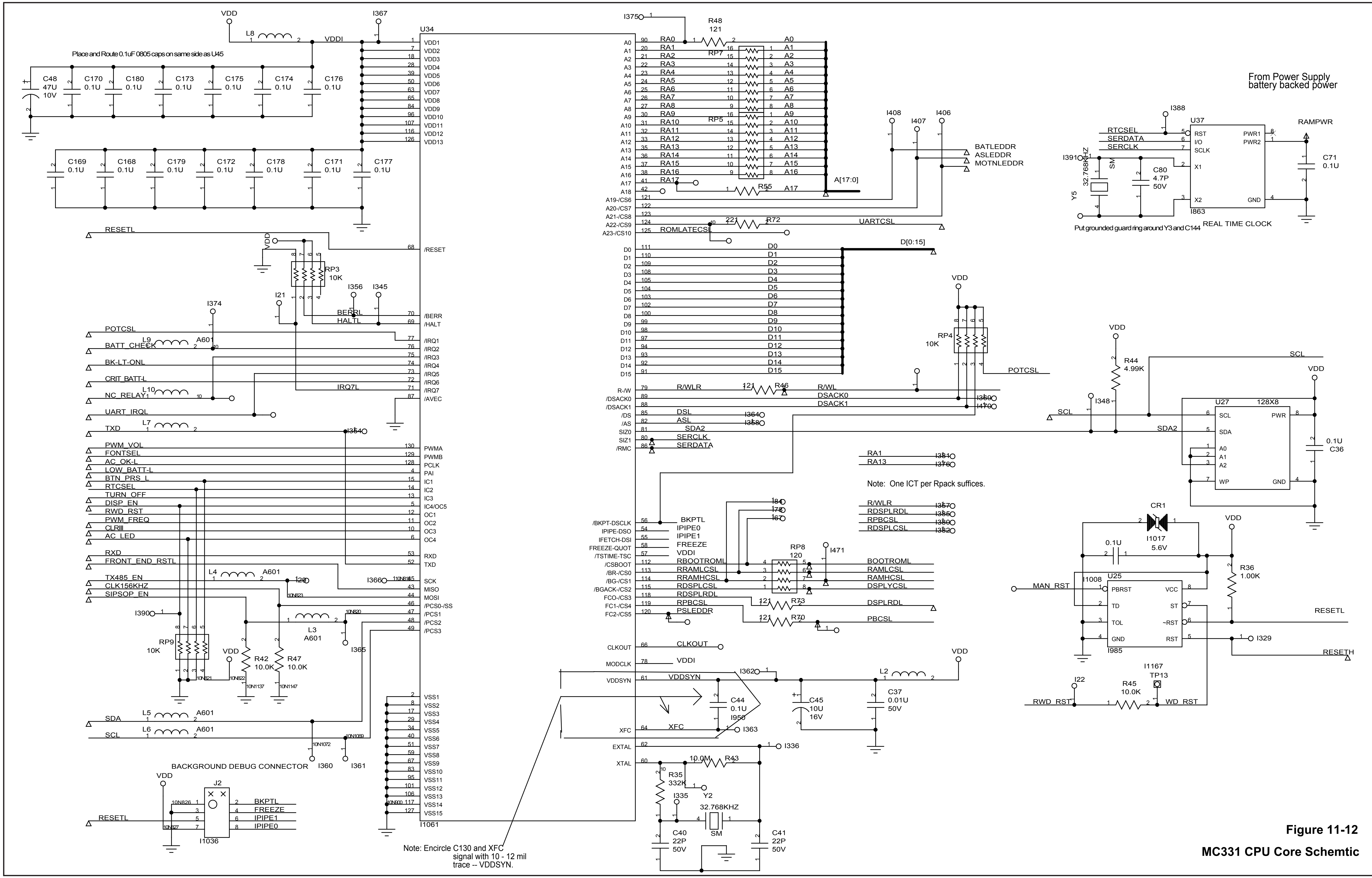


Figure 11-12

MC331 CPU Core Schemtic

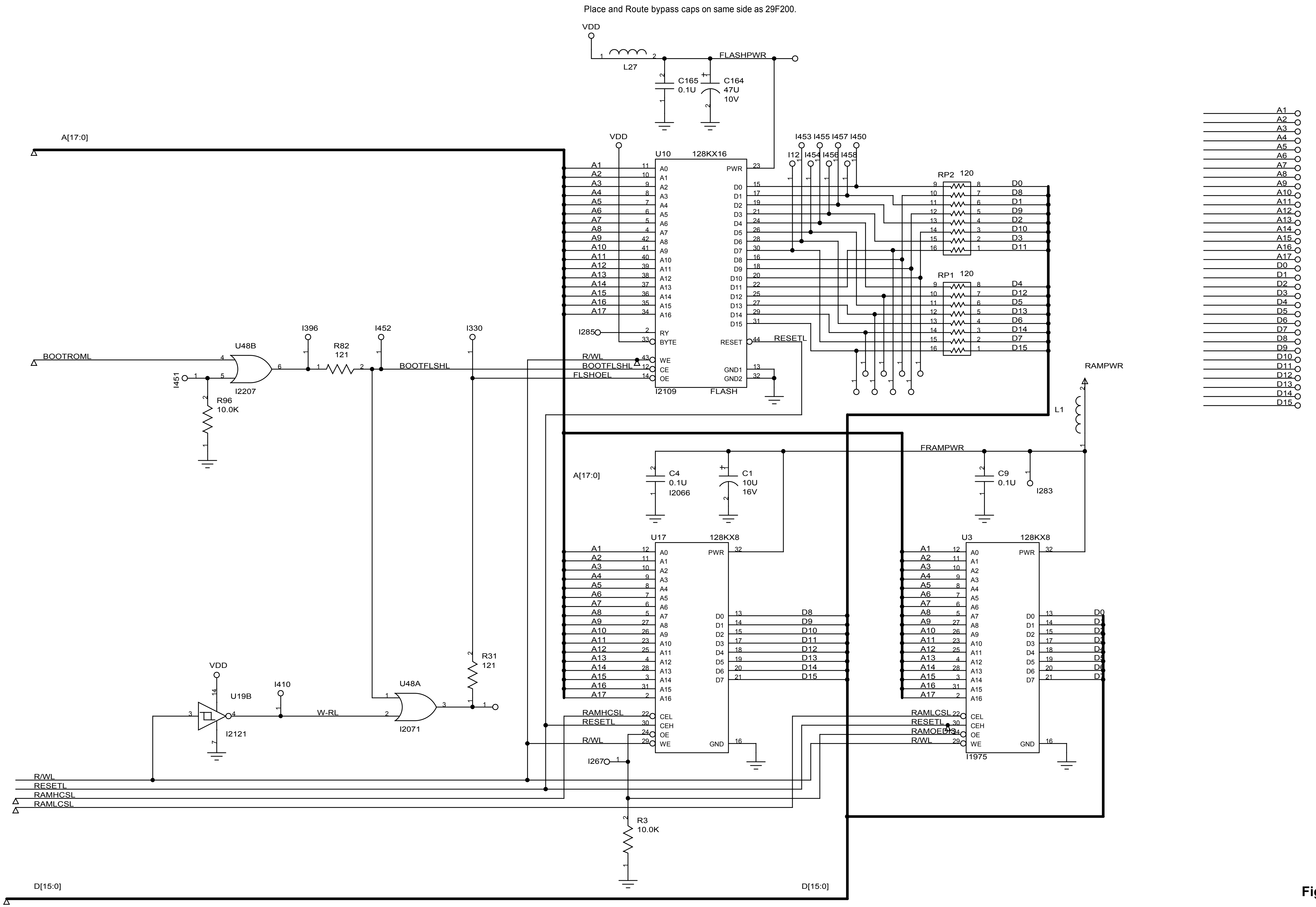


Figure 11-13

MC331 Memory Schematic

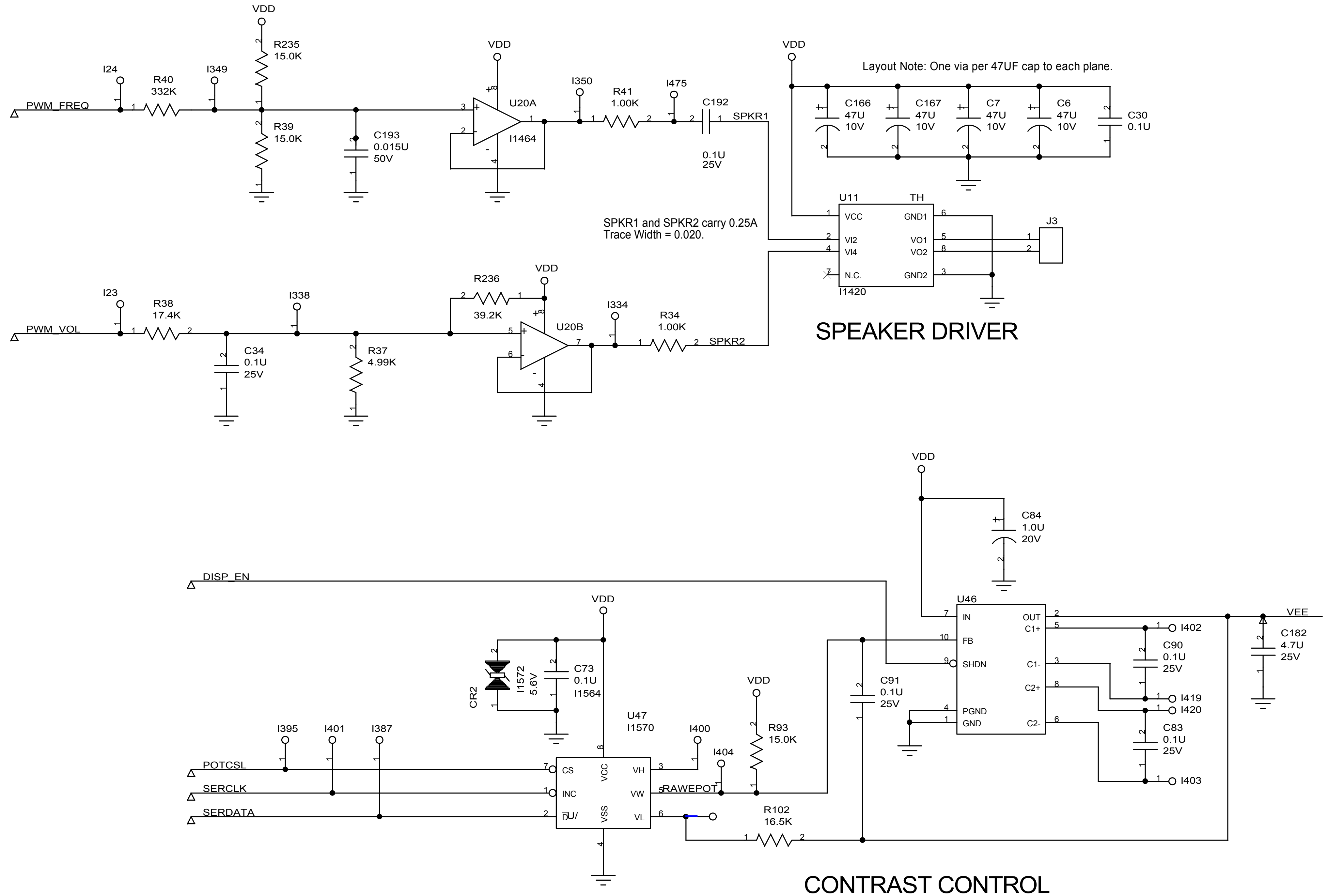


Figure 11-14

Contrast and Sound Schematic

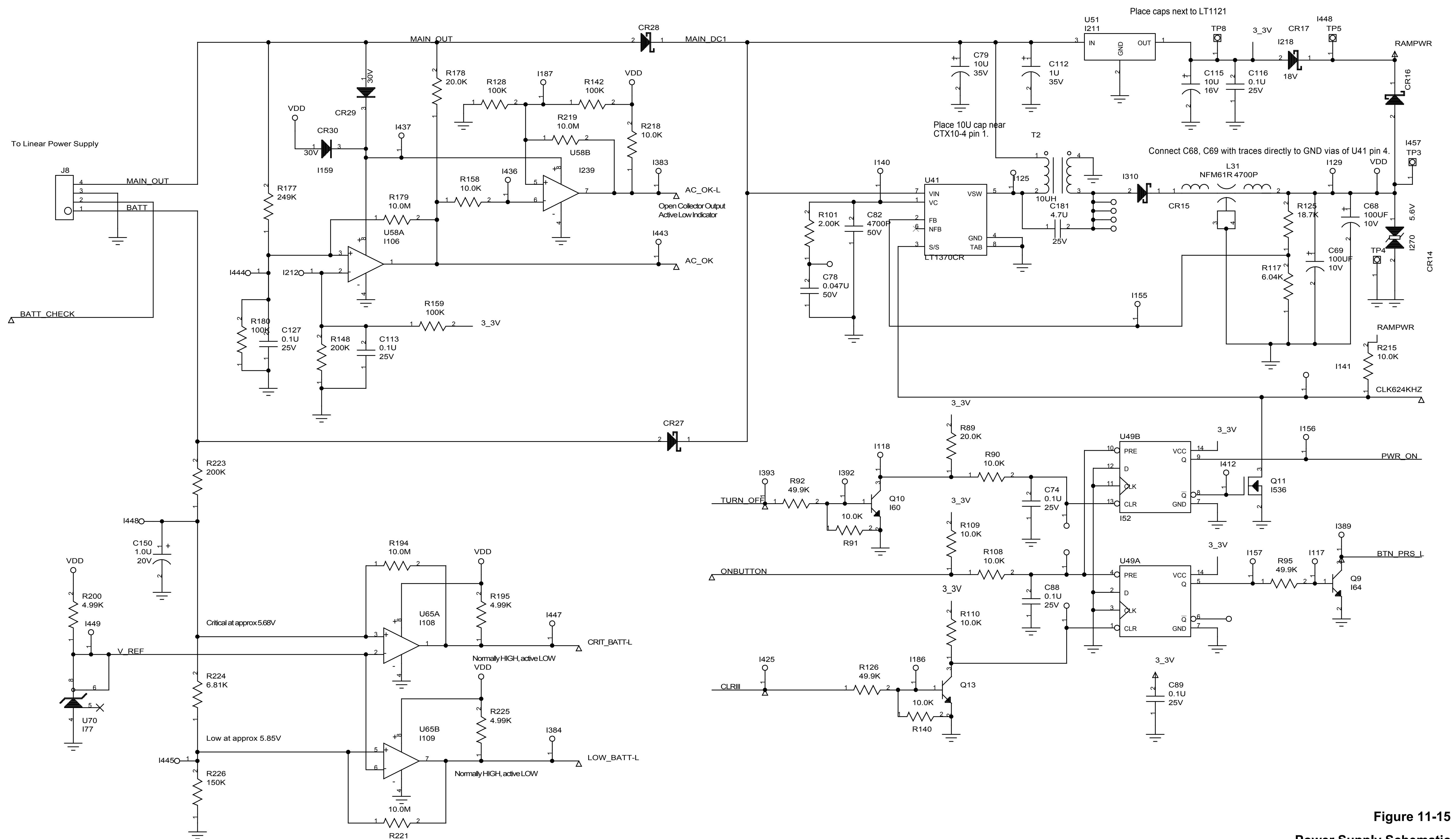


Figure 11-15

Power Supply Schematic

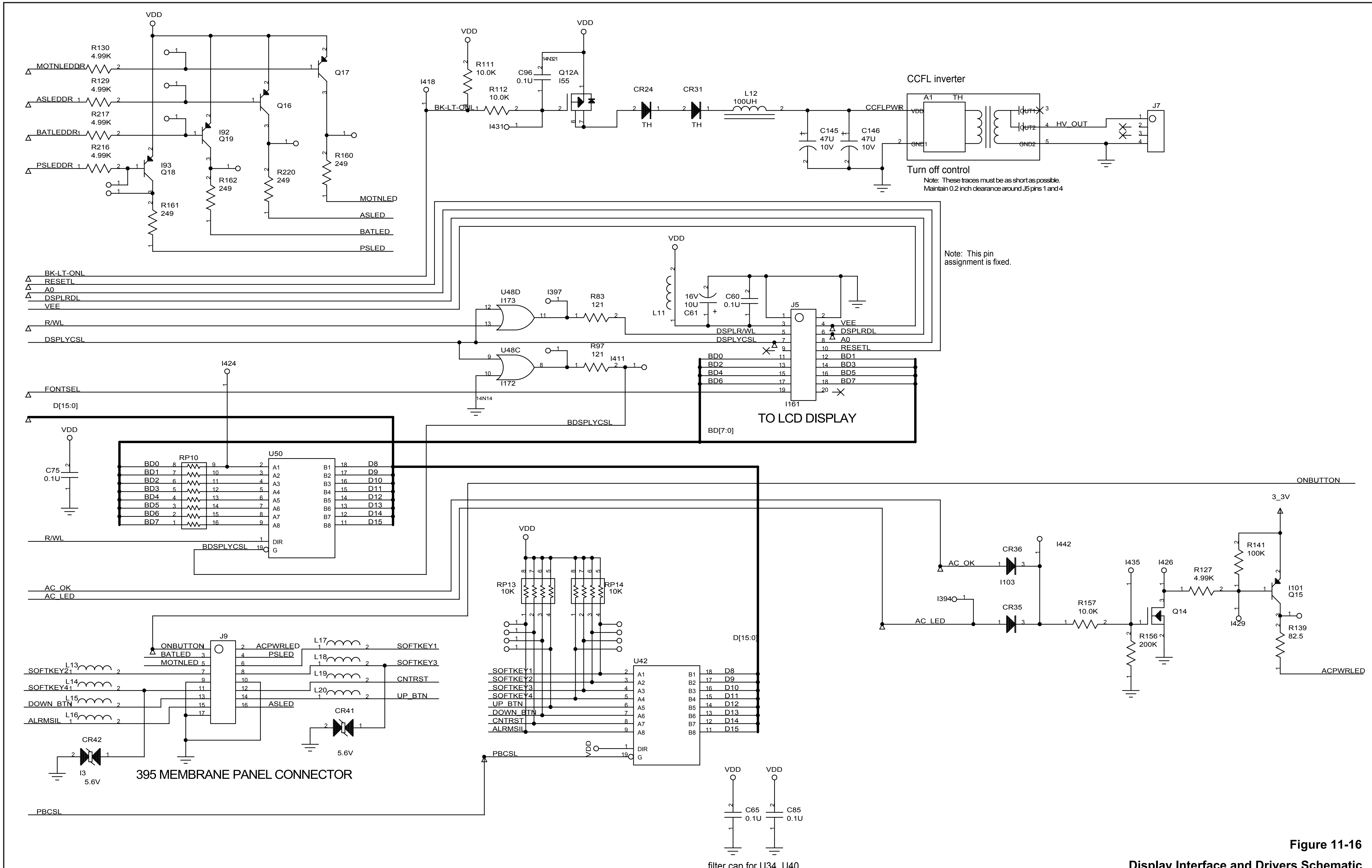


Figure 11-16

Display Interface and Drivers Schematic

SECTION 12: INDEX

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