

CRITICARE SYSTEMS INC /DE/
Form 10-Q
November 12, 2004

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

X QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2004

OR

____ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 0-16061

CRITICARE SYSTEMS, INC

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or
organization)

39-1501563
(IRS Employer Identification No.)

20925 Crossroads Circle, Suite 100
Waukesha, Wisconsin
(Address of principal executive offices)

53186
(Zip Code)

Registrant's telephone number including area code (262) 798-8282

N/A

Former name, former address and former fiscal year, if changed since last report.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No _____

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).
Yes _____ No X

Number of shares outstanding of each class of the registrant's classes of common stock as of September 30, 2004:
Class A Common Stock 11,452,321 shares.

CRITICARE SYSTEMS, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2004 AND JUNE 30, 2004

(UNAUDITED)

| ASSETS | September 30, 2004 | June 30, 2004 |
|---|-----------------------|----------------------|
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 2,490,712 | \$ 3,738,825 |
| Accounts receivable, less allowance for doubtful accounts of \$300,075 and \$260,000, respectively | 5,924,548 | 6,489,884 |
| Other receivables | 76,646 | 359,806 |
| Inventories | 6,630,693 | 6,418,135 |
| Prepaid expenses | 224,225 | 364,375 |
| Total current assets | 15,346,824 | 17,371,025 |
| Property, plant and equipment - net | 2,062,816 | 2,094,330 |
| License rights and patents - net | 75,234 | 76,985 |
| TOTAL ASSETS | \$ 17,484,874 | \$ 19,542,340 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | \$ 2,192,948 | \$ 3,237,405 |
| Accrued liabilities: | | |
| Compensation and commissions | 825,114 | 863,113 |
| Product warranties | 460,000 | 444,000 |
| Liability under guarantees | 490,000 | 490,000 |
| Out of court settlement | 50,000 | 200,000 |
| Obligations under capital lease | 58,929 | 57,712 |
| Other | 45,903 | 174,395 |
| Total current liabilities | 4,122,894 | 5,466,625 |
| LONG-TERM LIABILITIES: | | |
| Obligations under capital lease | 249,574 | 264,770 |
| Other long-term obligations | 18,028 | 21,646 |
| Total long-term liabilities | 267,602 | 286,416 |

| | | |
|--|----------------------|----------------------|
| TOTAL LIABILITIES | 4,390,496 | 5,753,041 |
| STOCKHOLDERS' EQUITY: | | |
| Preferred stock - \$.04 par value, 500,000 shares authorized no shares issued or outstanding | - | - |
| Common stock - \$.04 par value, 15,000,000 shares authorized, 11,574,749 shares issued, and 11,452,321 and 11,450,021 outstanding, respectively | 462,990 | 462,990 |
| Additional paid-in capital | 23,967,004 | 23,965,900 |
| Common stock held in treasury (122,428 and 124,728 shares, respectively) | (405,155) | (409,439) |
| Retained earnings (accumulated deficit) | (10,926,979) | (10,226,670) |
| Cumulative translation adjustment | (3,482) | (3,482) |
| Total stockholders' equity | 13,094,378 | 13,789,299 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 17,484,874 | \$ 19,542,340 |

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
THREE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(UNAUDITED)

| | 2004 | 2003 |
|---------------------------------------|------------------|------------------|
| NET SALES | \$ 5,331,357 | \$ 6,372,417 |
| COST OF GOODS SOLD | 3,459,923 | 3,798,010 |
| GROSS PROFIT | 1,871,434 | 2,574,407 |
| OPERATING EXPENSES: | | |
| Sales and marketing | 1,314,487 | 1,507,446 |
| Research, development and engineering | 541,118 | 600,593 |
| Administrative | 749,904 | 901,258 |
| Total | 2,605,509 | 3,009,297 |
| LOSS FROM OPERATIONS | (734,075) | (434,890) |
| OTHER INCOME (EXPENSE): | | |
| Interest expense | (6,661) | - |
| Interest income | 8,608 | 9,739 |
| Other income | 31,819 | 33,421 |

| | | |
|---|---------------------|---------------------|
| Total | 33,766 | 43,160 |
| LOSS BEFORE INCOME TAXES | (700,309) | (391,730) |
| INCOME TAX PROVISION | - | - |
| NET LOSS | <u>\$ (700,309)</u> | <u>\$ (391,730)</u> |
| NET LOSS PER COMMON SHARE | | |
| Basic | \$ (0.06) | \$ (0.04) |
| Diluted | \$ (0.06) | \$ (0.04) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: | | |
| Basic | 11,451,465 | 11,074,738 |
| Diluted | 11,451,465 | 11,074,738 |

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
THREE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

(UNAUDITED)

| | <u>2004</u> | <u>2003</u> |
|---|--------------------|----------------|
| OPERATING ACTIVITIES: | | |
| Net loss | \$ (700,309) | \$ (391,730) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | | |
| Depreciation | 152,656 | 143,178 |
| Amortization | 1,751 | 1,750 |
| Provision for doubtful accounts | 40,075 | 2,352 |
| Provision for obsolete inventory | 75,000 | 95,000 |
| Changes in assets and liabilities: | | |
| Accounts receivable | 525,261 | 122,497 |
| Other receivables | 283,160 | 98,262 |
| Inventories | (352,326) | (43,842) |
| Prepaid expenses | 140,150 | (23,883) |
| Accounts payable | (1,044,457) | 153,026 |
| Accrued liabilities | (304,109) | 86,267 |
| Net cash (used in) provided by operating activities | <u>(1,183,148)</u> | <u>242,877</u> |

| | | |
|--|--------------|--------------|
| INVESTING ACTIVITIES: | | |
| Purchases of property, plant and equipment, net | (56,374) | (96,664) |
| Net cash used in investing activities | (56,374) | (96,664) |
| FINANCING ACTIVITIES: | | |
| Retirement of obligations under capital lease | (13,979) | - |
| Proceeds from issuance of common stock | 5,388 | 3,663 |
| Net cash (used in) provided by financing activities | (8,591) | 3,663 |
| NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS | (1,248,113) | 149,876 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 3,738,825 | 3,716,446 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 2,490,712 | \$ 3,866,322 |
| SUPPLEMENTAL CASH FLOW INFORMATION: | | |
| Cash paid for: | | |
| Income taxes paid-net | - | - |
| Interest | \$ 6,661 | - |

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC.
Condensed Notes to Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation

The accompanying unaudited financial statements have been prepared by Criticare Systems, Inc. (the "Company") pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and, in the opinion of the Company, include all adjustments necessary for a fair statement of results for each period shown. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such SEC rules and regulations. The Company believes that the disclosures made are adequate to prevent the financial information given from being misleading. It is suggested that these financial statements be read in conjunction with the financial statements and notes thereto included in the Company's latest annual report and previously filed Form 10-K. Certain amounts from the fiscal 2004 financial statements have been reclassified to conform to the 2005 presentation.

2. Inventory Valuation

Inventory is stated at the lower of cost or market, with cost determined on the first-in, first-out method. Components of inventory consisted of the following at September 30, 2004 and June 30, 2004, respectively:

| | September 30, 2004 | June 30, 2004 |
|--|--------------------|---------------|
| | | |

| | | | | |
|--------------------------------|----|------------------|----|------------------|
| Component parts | \$ | 2,351,674 | \$ | 1,988,414 |
| Work in process | | 984,216 | | 781,156 |
| Finished units | | 3,979,803 | | 4,258,565 |
| | | <u>7,315,693</u> | | <u>7,028,135</u> |
| Total inventories | | 7,315,693 | | 7,028,135 |
| Less: reserve for obsolescence | | 685,000 | | 610,000 |
| | | <u>6,630,693</u> | | <u>6,418,135</u> |
| Net inventory | \$ | 6,630,693 | \$ | 6,418,135 |

3. Property, Plant and Equipment

Property, plant and equipment consist of the following:

| | September 30, 2004 | | June 30, 2004 | |
|--------------------------------------|--------------------|------------------|---------------|------------------|
| | \$ | | \$ | |
| Machinery and equipment | \$ | 2,686,899 | \$ | 2,675,093 |
| Furniture and fixtures | | 938,893 | | 937,906 |
| Leasehold improvements | | 218,423 | | 218,423 |
| Production tooling | | 2,074,201 | | 2,030,618 |
| Demonstration and loaner monitors | | 914,194 | | 945,339 |
| | | <u>6,832,610</u> | | <u>6,807,379</u> |
| Property, plant and equipment - cost | | 6,832,610 | | 6,807,379 |
| Less: accumulated depreciation | | (4,769,794) | | (4,713,049) |
| | | <u>2,062,816</u> | | <u>2,094,330</u> |
| Property, plant and equipment - net | \$ | 2,062,816 | \$ | 2,094,330 |

4. Contingencies

The import and export rules applicable to all United States companies engaged in international business transactions contain compliance guidelines. Violations may result in civil or criminal penalties, or both, as well as the potential loss of export privileges.

On August 6, 2002, in part due to the new regulations imposed under the Sarbanes-Oxley Act, the Company initiated an internal review of its import and export procedures. On August 28, 2002, senior management of the Company became aware of previous events that may have violated United States import/export laws and regulations. Senior management of the Company immediately authorized an internal audit of these possible violations, focusing on the sale of medical equipment directly or indirectly into an embargoed country and possible marking issues.

The factual investigation pursuant to the internal audit is complete, no additional compliance issues arose, and no material marking issues were identified as a result of the investigation.

Subsequently, the Company has taken action to adopt and implement a written compliance program with respect to applicable import/export rules. The Company has also undertaken a voluntary disclosure with the relevant government agencies and has filed its completed internal audit report and all requested documents. Although there is no assurance,

based upon the results of the completed internal audit and precedents, the Company believes a negotiated settlement of any violations will not have a material adverse effect on the Company. In addition, the Company does not believe that the audit result supports the denial of export privileges; however, any such penalty would have a material adverse effect on the Company's business. The Company further believes that the voluntary disclosure, along with other internal actions taken, will serve to mitigate any potential adverse consequences that otherwise might accrue.

5. Guarantees

Criticare Integration, Inc., a wholly owned U.S. subsidiary of the Company, was incorporated on April 8, 2003 to supply medical equipment and supplies to medical facilities in countries in the Black Sea Economic Zone. The Company had set up a standby letter of credit for \$300,000 on behalf of an International distributor it is working with in connection with this project. The standby letter of credit served as a guarantee for a \$2,000,000 line of credit that had been extended by a large Austrian bank to the International distributor to fund this project. The standby letter of credit was to expire on November 15, 2003. The line of credit was no longer deemed necessary to fund the project and was therefore cancelled prior to expiration. The related standby letter of credit from the Company guaranteeing the line of credit was also cancelled on October 20, 2003.

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The Company also maintained a second standby letter of credit (SBLC) for \$300,000 on behalf of the International distributor that served as a guarantee to fund borrowings by the International distributor used to set up and market this project. This SBLC was to expire on November 1, 2003, but was renewed through November 1, 2004 on October 16, 2003. Due mainly to more favorable credit terms obtained from another bank, on December 24, 2003 this \$300,000 SBLC was cancelled and replaced by a \$400,000 SBLC guaranteeing a \$450,000 line of credit that expires on December 31, 2004. This standby letter of credit would only be called if the cash flows from the project were not adequate to fund the costs to support the project and the International distributor would not be able to retire the debt. Due to adverse events relating to the International distributor subsequent to the end of fiscal 2004, Criticare believes that the project will not generate sufficient cash flow to fund the debt, which will lead to the standby letter of credit being called. Thus, in fiscal 2004, Criticare recognized a charge to other expenses in the amount of \$400,000 to reserve for the impending call of this guarantee.

In addition, Criticare also has an outstanding receivable due from the International distributor relating to equipment sold by Criticare to the International distributor. Criticare believes it is unlikely it will be able to collect the receivable due from the International distributor or recover the equipment shipped. Accordingly, in fiscal 2004, Criticare wrote off the receivable of \$421,340. A reserve in the amount of \$90,000 was also established to satisfy a claim for duties and Value Added Tax associated with importation of products into a foreign country on behalf of the International distributor.

In the fiscal second quarter ended December 31, 2003, the Company also set up two new standby letters of credit to two suppliers of medical equipment for the project totaling \$100,000. These two SBLC s were set up to secure payment for the suppliers and would only be called if the cash flows from the project were not adequate to fund equipment purchases from these suppliers. Currently no purchases have been made from either supplier. As of September 2, 2004, one standby letter of credit in the amount of \$35,000 was voluntarily canceled by the supplier.

6. Stock Options

The Company has adopted the disclosure-only provisions of SFAS No. 123, "Accounting for Stock-Based Compensation" and SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." If the Company had elected to recognize compensation cost for the options granted for the three months ended September 30, 2004 and 2003, consistent with the method prescribed by SFAS No. 123, net loss and net loss per share would have been changed to the pro forma amounts indicated below:

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| | Three Months ended September 30 | |
|--|---------------------------------|--------------|
| | 2004 | 2003 |
| Net loss - as reported | \$ (700,309) | \$ (391,730) |
| Net loss - pro forma | \$ (729,671) | \$ (406,441) |
| Basic and diluted net loss per share - as reported | \$ (0.06) | \$ (0.04) |
| Basic and diluted net loss per share - pro forma | \$ (0.06) | \$ (0.04) |

For the three months ended September 30, 2004 the Company granted options totaling 50,000 shares at an exercise price of \$2.61, which are valued at \$46,345. The fair value of stock options used to compute pro forma net loss and net loss per share is the estimated present value at the grant date using the Black-Scholes option-pricing model.

7. Income Taxes

No income tax provision has been made in the consolidated income statements due to federal and state net operating loss carry forwards that will be utilized to offset taxable income earned. At September 30, 2004, the Company had federal net operating loss carry forwards of approximately \$16,980,000 (which expire from 2008 through 2024) and state net operating loss carry forwards of approximately \$11,476,000 (which expire from 2004 through 2019) available to offset future taxable income. The Company has recorded a valuation allowance to offset the related deferred income tax assets arising from these net loss carry forwards due to the uncertainty of realizing the benefits of these assets in future years.

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CRITICARE SYSTEMS, INC.
Management's Discussion and Analysis of
Results of Operations and Financial Condition
Three Months Ended September 30, 2004 and 2003

Results of Operations

Net sales of \$5,331,357 for the three months ended September 30, 2004 were down 16% from \$6,372,417 for the same period in fiscal 2004. A 22.2% decrease in the number of units shipped and a 1.0% reduction in the average

sales price per unit were partially offset by a 15.5% increase in accessory sales in the current year. The reduced sales were driven by a \$691,261 decrease in domestic sales and a \$448,294 decrease in sales to our largest OEM partner in the current period. The OEM sales decrease was partially offset by \$240,362 in sales to our OEM partner for medical imaging applications. The decrease in domestic sales was due in part to lost sales following the cancellation of two oral surgery shows in Florida and one oral surgery show in Louisiana as a result of the hurricanes. In addition, the AAOMS show sales for fiscal 2005 were split between September and October. Normally the AAOMS show and all its sales are in September.

The gross profit percentage of 35.1% for the three months ended September 30, 2004 decreased from 40.4% for the same period in fiscal 2004. The reduced margins in the current period were mainly due to the decreased manufacturing overhead absorption, due to the decrease in the number of units shipped and fixed overhead costs.

Operating expenses for the three months ended September 30, 2004 decreased \$403,788 from the same period in fiscal 2004. The decrease of \$192,959 in sales and marketing expenses was due mainly to an \$144,733 decrease in the commissions earned by dealers and employees. In addition, there was a decrease of \$32,922 in advertising, trade shows and sales promotion spending. The decrease of \$59,475 in research, development and engineering expenses was mainly due to a \$33,000 reduction in depreciation expense. Administration expenses decreased by \$151,354 mainly due to a \$72,222 reduction in consulting expenses and a \$101,293 reduction in accounting fees that were partially offset by a \$13,437 increase in legal fees.

Total other income for the three months ended September 30, 2004 decreased \$9,395 from the same period in fiscal 2004. This reduction was mainly caused by the interest expense of \$6,661 for a new capital lease, which began in April 2004.

The \$702,973 reduction in gross profit, partially offset by the reduction in operating expenses of \$403,788, resulted in a \$(700,309) loss for the three months ended September 30, 2004 as compared to the \$(391,730) loss recognized for the same period in fiscal 2004.

Liquidity and Capital Resources

As of September 30, 2004, the Company had a cash balance of \$2,490,712 that was \$1,248,113 lower than its balance at June 30, 2004 of \$3,738,825. The Company continues to maintain a long-term bank debt free balance sheet since August 30, 2002 when it sold its building and used the proceeds from the sale to retire the long-term bank debt on the facility.

The decrease in the Company's cash position by \$1,248,113 for the three months ended September 30, 2004, was mainly due to the pay down of \$1,044,457 against the accounts payable balance.

The Company believes all capital and liquidity requirements for the remainder of fiscal 2005 will be satisfied by cash generated from operations and its current cash balances. The Company's \$1,000,000 line of credit expires in November 2004. The Company and the bank have agreed to extend the line of credit subject to the completion of final loan documentation. At September 30, 2004 there were no borrowings outstanding under this line of credit. The Company violated loan covenants under this line of credit related to achieving minimum levels of tangible net worth and income. The bank waived compliance with these covenants subsequent to September 30, 2004.

Forward Looking Statements

A number of the matters and subject areas discussed herein that are not historical or current facts deal with potential future circumstances and developments. These include anticipated product introductions, expected future financial results, liquidity needs, financing ability, management's or the Company's expectations and beliefs and similar matters discussed in Management's Discussion and Analysis or elsewhere herein. The discussions of such matters and subject areas are qualified by the inherent risk and uncertainties surrounding future expectations generally, and also may materially differ from the Company's actual future experience.

The Company's business, operations and financial performance are subject to certain risks and uncertainties which could result in material differences in actual results from management's or the Company's current expectations. These risks and uncertainties include, but are not limited to, general economic conditions, demand for the Company's products, costs of operations, the development of new products, the reliance on single sources of supply for certain components in the Company's products, government regulation, health care cost containment programs, the effectiveness of the Company's programs to manage working capital and reduce costs, competition in the Company's markets, compliance with product safety regulations and product liability and product recall risks, risks relating to international sales and compliance with U.S. export regulations, unanticipated difficulties in outsourcing the manufacturing of the majority of its products to foreign manufacturers and risks related to foreign manufacturing, including economic and political instability, trade and foreign tax laws, production delays and cost overruns and quality control.

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Quantitative and Qualitative Disclosures about Market Risk

The Company has a demand line of credit facility with a commercial bank with interest payable monthly at 25 basis points above the bank's reference rate. The Company had no borrowings outstanding under this bank facility at September 30, 2004 and June 30, 2004. Due historically to the lack of need to borrow from this credit facility and due to the Company's current cash position, the Company is not subject to financial risk on this obligation if interest rates in the market change significantly.

The Company's net sales are primarily denominated in United States dollars, except for a small amount of net sales from the Company's operation in India denominated in Indian rupees. As a result, part of the Company's accounts receivable are denominated in rupees and translated into U.S. dollars for financial reporting purposes. A 10% change in the exchange rate of the U.S. dollar with respect to the Indian rupee would not have a material adverse effect on the Company's financial condition or results of operations for the quarter ended September 30, 2004. The Company does not use any hedges or other derivative financial instruments to manage or reduce exchange rate risk.

Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Vice President - Finance, of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company's Chief Executive Officer and Vice President - Finance concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company required to be included in the Company's periodic filings with the Securities and Exchange Commission. It should be noted that in

designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving the desired control objectives and based upon the evaluation described above, the Company's Chief Executive Officer and Vice President -Finance concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance.

There was no change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

Item 6. Exhibits.

3.1 Restated Certificate of Incorporation of the Company (incorporated by reference to the Registration Statement filed on Form S-1, Registration No. 33-13050).

3.2 By-Laws of the Company (incorporated by reference to the Registration Statement filed on Form S-1, Registration No. 33-13050).

4.1 Specimen Common Stock certificate (incorporated by reference to the Registration Statement filed on Form S-1, Registration No. 33-13050).

4.2 Rights Agreement (incorporated by reference to the Company's Current Report on Form 8-K filed on April 18, 1997).

31.1 Certification of Emil H. Soika, President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Joel D. Knudson, Vice President - Finance and Secretary (Principal Financial Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32* Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.

* This Certification is not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CRITICARE SYSTEMS, INC.
(Registrant)

Date: November 12, 2004 BY /s/ Joel D. Knudson

Joel D. Knudson
Vice President - Finance
(Chief Accounting Officer and
Duly Authorized Officer)