



Important – Please Read

Cholestech LDX[®] System Update

New Cholestech LDX[®] ROM Pack upgrade now available

November, 2010

Dear Customer,

According to our records your facility is currently in possession of one or more Cholestech LDX[®] Systems. As a result of our on-going product improvement processes, we have developed a new version of the ROM Pack that enhances overall product quality. We have now incorporated a humidity sensor into the ROM pack that will enable the Cholestech LDX[®] analyzer to make adjustments for changes in humidity. To receive your free ROM pack(s), see below.

Please complete the enclosed postage-paid business reply card and drop it in the mail to us. Please include the serial number(s) of all the Cholestech LDX[®] analyzers in your possession. Once we receive this information, we will ship you a ROM pack for each analyzer you have listed. Alternatively, you may email LDXROM@alere.com to request an electronic form to complete and return via email. You may expect your ROM packs approximately 10 to 14 business days after we receive your request.

If you have transferred ownership to another party, please email us at LDXROM@alere.com with the updated contact information.

If you are not currently using your Cholestech LDX[®] System, it is recommended that the ROM Pack upgrade be installed prior to restarting use of any Cholestech LDX[®] analyzer.

Should you have any questions regarding this communication, or if we may assist you in any way, please call us at 877-441-7440, option 1, or email LDXROM@alere.com.

Sincerely,

Alere North America, Inc.

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Technical Bulletin

Cholestech LDX[®] System

ROM Pack v3.40 User Manual Updates

A new version of the ROM Pack that enhances overall product quality has been developed. We have now incorporated a humidity sensor into the ROM Pack that will enable the Cholestech LDX[®] Analyzer to make adjustments for changes in humidity. An additional feature has also been incorporated into this new ROM Pack. Changes due to the humidity sensor and instructions for use of the new feature will be reflected in the next revision of the Cholestech LDX[®] System User Manual. This Technical Bulletin identifies these changes pending the availability of the new User Manual.

There is a new error message associated with the humidity sensor. A description of the error message and the action to take when it is observed has been added to the **Corrective Action** section of the User Manual:

Error Message	Problem	Action to Take
RH Sensor Fail	The humidity sensor has become disconnected or has failed.	Call Technical Service.

The **Environmental Conditions** have been updated in the **General Specifications** section of the User Manual. The new environmental conditions related to temperature and humidity are:

- Temperature 68 – 87°F (20 – 31°C)
- Relative humidity from 20% to 80%

A new calculated test parameter has been added: the LDL/HDL ratio. You have the option of configuring the Cholestech LDX[®] Analyzer to report either this new ratio or the traditional TC/HDL ratio. The LDL/HDL ratio will only be calculated for test cassettes that include TC, HDL, and TRG (i.e. Lipid Profile and Lipid Profile•GLU). The TC/HDL ratio is calculated for all test cassettes that include TC and HDL. The default setting for this option is “Off.” The information below has been added to the **Setting the Configuration Menu** section of the User Manual:

LDL/HDL ratio	Off = LDL/HDL function turned off, TC/HDL function turned on On = LDL/HDL function turned on, TC/HDL function turned off
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An updated **Configuration Menu Flowchart** showing how the LDL/HDL ratio option is selected appears on the second sheet of this Technical Bulletin.

Should you have any questions, or if Alere may assist you in any way, please call us at 1-877-308-8289, or email ServiceCholestech@alere.com.

