



epoc[®] Blood Analysis System

Product Update – epoc[®] Enterprise Data Manager Lite, Version 1.0

Overview

This product update announces the release of epoc[®] Enterprise Data Manager Lite (“EDM Lite”), version 1.0, intended for small installations (one or two Hosts). This is the initial release of this software product.

EDM Lite is a personal computer application for Windows operating system, providing means for managing test results obtained from epoc[®] Host Mobile Computer(s), and performing simple maintenance functions, such as epoc[®] System software updates. Connection to epoc[®] Host mobile computer may be achieved through either Bluetooth or Wi-Fi.

Action(s) Required

Please review this update in its entirety before installing EDM Lite version 1.0 and contact Alere[™] Technical Services at 1.877.308.8293, if you have any questions regarding installation or operation of EDM Lite.

System Requirements

1. Hardware prerequisites.

The application will be supported on standard personal computer hardware, with the following specifications:

- 1 GHz or faster, 32-bit (x86) or 64-bit (x64) processor
- 1 GB (minimum) RAM
- 1 GB (minimum) of available hard disk space
- Display adapter with minimum resolution of 1024 x 768
- Network adapter
- Bluetooth network adapter and Microsoft Bluetooth stack (required if Bluetooth-based communication with epoc[®] Hosts is desired)
- Wi-Fi adapter or Wi-Fi capable network router (required if Wi-Fi based communication with epoc[®] Hosts is desired)

2. Operating Systems.

The application will be supported on the following English-based operating systems (32-bit and 64-bit editions) updated to their respective latest service packs that include .NET Framework 3.5:

- Windows XP Pro SP3
- Windows 7
- Windows 8



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3. Optional 3rd party software applications.

Some 3rd party applications may be necessary to view reports and documents created by the application:

- Adobe Reader, to view PDF files created by the application.
- Microsoft Office Excel (2003 or later), for convenient view of text CSV reports created by the application.
- Text files viewer (or editor) to view text files created by the application and setup program.

4. epoc[®] System requirements.

- epoc[®] System software version 3.13.x or older (Wi-Fi data synchronization only)
- epoc[®] System software version 3.14.x or newer (Wi-Fi and Bluetooth data synchronization)

Installation

Installation of EDM Lite is performed in three easy steps:

1. Double-click the EDMLite_1.0.7.exe.
2. Accept the default installation folder by clicking “Install.”
3. Click “OK.”

The installation process will place a shortcut to EDMLite.exe on the user’s desktop. To run the application, double-click the shortcut icon.

Diagnostic Information

In a case of a technical problem, Technical Services may request that the customer provides raw data (diagnostic information) on the system. Raw data are automatically saved by the EDM Lite to the following address: C:\Program Files\Epocal\EDMLite\deviceFiles\epoc. The customer needs to zip the epoc folder and send it to Technical Services.

Features and Functions

1. EDM Lite has a convenient user interface (Fig. 1).

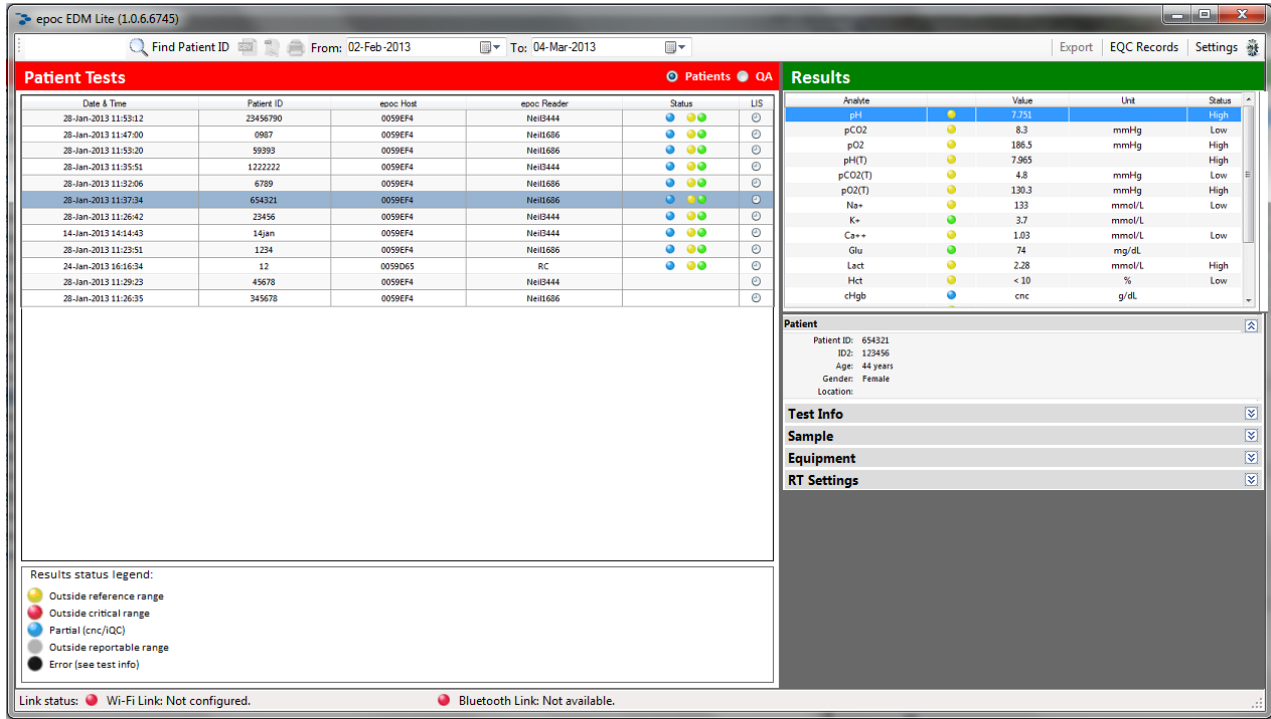


Fig. 1.

2. Elements of the Screen.

- The operator has the option to toggle between Patient Tests and QA Tests (Fig. 2; or Fig. 1, top, radio buttons).



Fig. 2.

- The operator may look up a Patient ID or Lot ID, depending on the type of results displayed (Fig. 3, or Fig. 1, top left corner).

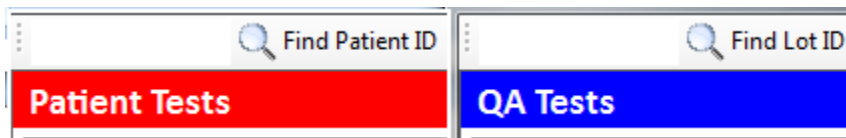


Fig. 3.

- Tests records are arranged in the Tests table with 5 columns: Date & Time, Patient ID (QA Lot), epoc[®] Host, epoc[®] Reader, Status, (Fig. 4; or Fig. 1, top left quadrant) with Status data being color coded (Fig. 5; or Fig. 1, bottom left quadrant).

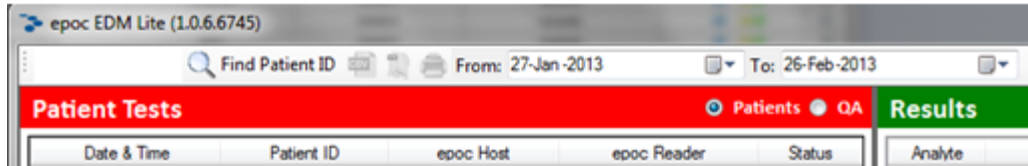


Fig. 4.

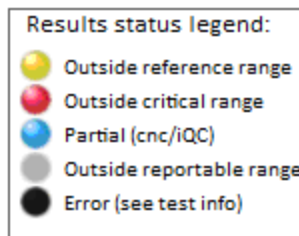


Fig. 5.

- The operator may select the From/To dates to view the tests within a certain time period (Fig. 6; or Fig. 1, top toolbar). The tests will appear in the Test Table (Fig. 7).



Fig. 6






















Date & Time	Patient ID	epoc Host	epoc Reader	Status
28-Jan-2013 11:53:12	23456790	0059EF4	NeilB444	  
28-Jan-2013 11:47:00	0987	0059EF4	Neil1686	  
28-Jan-2013 11:46:52	9876	0059EF4	NeilB444	  
28-Jan-2013 11:40:24	arthur	0059EF4	NeilB444	  
28-Jan-2013 11:53:20	59393	0059EF4	Neil1686	  
28-Jan-2013 11:35:51	1222222	0059EF4	NeilB444	  
28-Jan-2013 11:32:06	6789	0059EF4	Neil1686	  
28-Jan-2013 11:37:34	654321	0059EF4	Neil1686	  
28-Jan-2013 11:23:51	1234	0059EF4	Neil1686	  
24-Jan-2013 16:16:34	12	0059D65	RC	  
18-Jan-2013 14:44:57	vvv	0058B00	Karens Rdr339	  

Fig. 7

- The operator may save the entire displayed range of results as a CSV file  , export an individual test to a PDF file  , or send an individual test to a printer .
- The operator can view EQC records for each epoc[®] Reader (Fig. 9) by clicking on the corresponding box in the top right corner of the screen (Fig. 8).

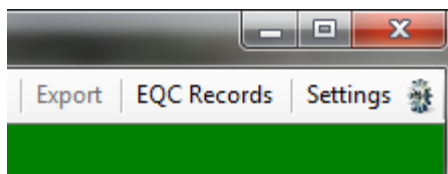


Fig. 8.



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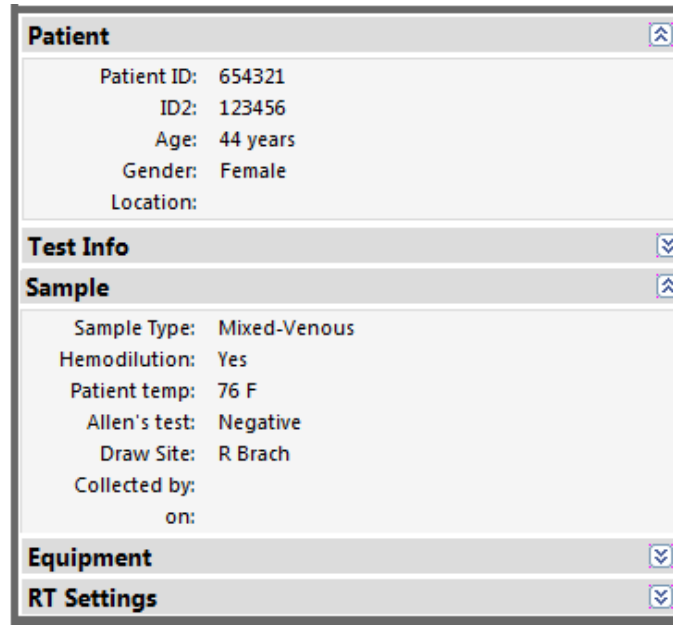
Reader	User ID	Date/Time	Sensor config	Host version	Reader version	Hardware version	Amb. temp.	Amb. press.	Battery	Result	Error
01217	both	2013-02-13 13:56:04	18.6	3.13.4 ca	2.2.8.1	15.0 13.7	78.30 F	752.62 mmHg	26.36	Pass	0
00339	both	2013-02-13 13:55:51	18.6	3.13.4 ca	2.2.8.1	12.0 9.0	78.17 F	755.92 mmHg	74.72	Pass	0
01686	canna	2013-02-13 13:52:03	19.0	3.13.11	2.2.8.1	16.0 14.9	79.11 F	753.43 mmHg	52.71	Pass	0
03444	canna	2013-02-13 13:51:49	19.0	3.13.11	2.2.8.1	17.0 16.10	79.24 F	753.03 mmHg	85.29	Pass	0
01686	canna	2013-02-13 13:42:43	19.0	3.13.11	2.2.8.1	16.0 14.9	78.63 F	752.28 mmHg	58.72	Pass	0
03444	canna	2013-02-13 13:42:34	19.0	3.13.11	2.2.8.1	17.0 16.10	78.79 F	752.35 mmHg	85.27	Pass	0

Fig. 9.

- Test results are presented to the right of the Tests table, in the Results Table (Fig. 10), with relevant additional information available via expandable boxes (Fig. 11). This information includes (1) patient’s ID, age, gender, and location; (2) test date, operator, department, status, and whether the test was rejected; (3) sample type, hemodilution settings, patient temperature, Allen’s test, draw site, and by whom the sample was collected; (4) equipment details regarding Host and Reader; and (5) respiratory therapy settings.

Analyte		Value	Unit	Status
pH	●	7.751		High
pCO2	●	8.3	mmHg	Low
pO2	●	186.5	mmHg	High
pH(T)	●	7.965		High
pCO2(T)	●	4.8	mmHg	Low
pO2(T)	●	130.3	mmHg	High
Na+	●	133	mmol/L	Low
K+	●	3.7	mmol/L	
Ca++	●	1.03	mmol/L	Low
Glu	●	74	mg/dL	
Lact	●	2.28	mmol/L	High
Hct	●	< 10	%	Low
cHgb	●	cnc	g/dL	

Fig. 10.



The screenshot shows a software window with several sections:

- Patient**: Patient ID: 654321, ID2: 123456, Age: 44 years, Gender: Female, Location: (blank).
- Test Info**: (Section header, currently collapsed).
- Sample**: Sample Type: Mixed-Venous, Hemodilution: Yes, Patient temp: 76 F, Allen's test: Negative, Draw Site: R Brach, Collected by: (blank).
- Equipment**: (Section header, currently collapsed).
- RT Settings**: (Section header, currently collapsed).

Fig. 11.

3. Settings.

- The Settings option in the top right corner of the screen (Fig. 12) allows the operator to enter customer information, manage epoc[®] Host updates, configure epoc[®] Link server settings, and test export options.

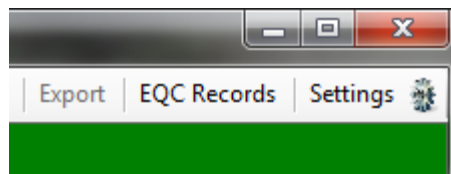


Fig. 12.

- General/Customer Info: Enter customer name and address in respective fields, tap **Save**. The entered name and address will appear on PDF and printed reports.

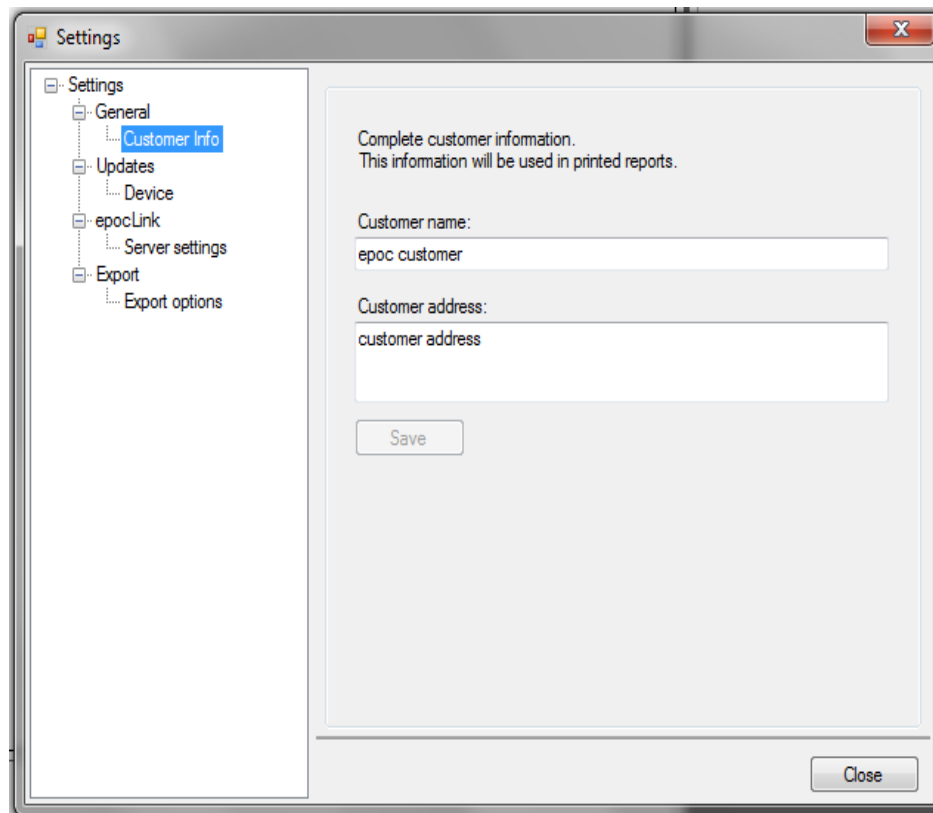


Fig. 13.

- Device Updates Info: See the subsection below entitled “How to Upgrade the epoc[®] Host Software Using the EDM Lite” for more information.
- epoc[®] Link/Server Settings: See the subsection below entitled “How to Connect with EDM Lite” for more information.

- **Export Options:** The results may be exported to HL7-formatted text file and saved in the designated export folder to be then sent to LIS (Fig. 14). The version of HL7 is identified below the browser bar. Tap “Save” before closing to keep your selections.

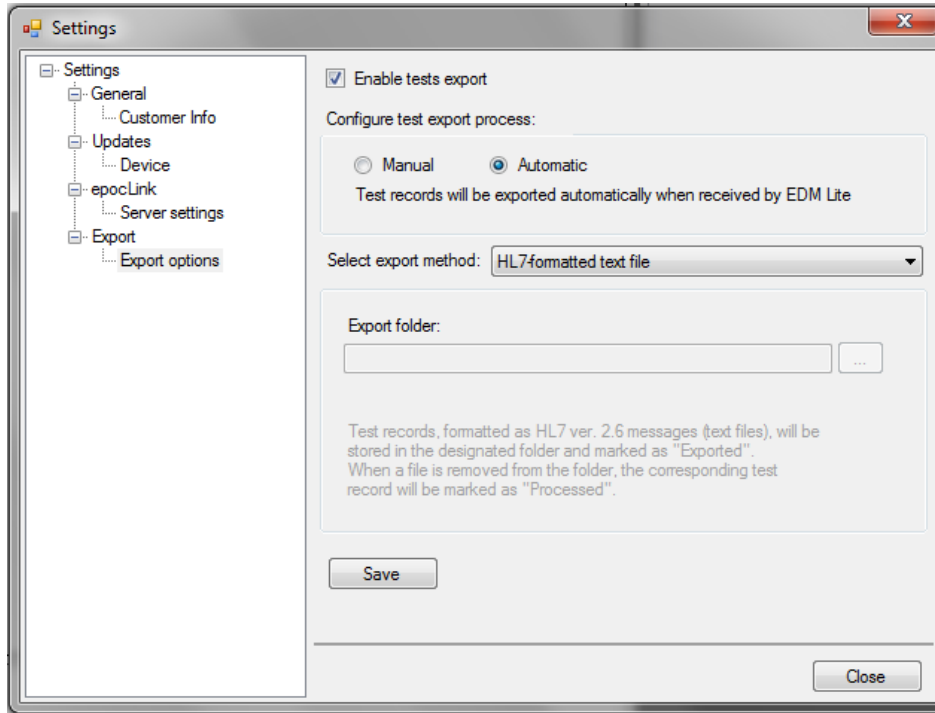


Fig. 14.

When text exporting is enabled, an additional column “LIS” will appear in the Test Table (Fig. 15).

Patient Tests						Patients	QA
Date & Time	Patient ID	epoc Host	epoc Reader	Status	LIS		
28-Jan-2013 11:53:12	23456790	0059EF4	NeilB444	● ● ●	⊖		
28-Jan-2013 11:47:00	0987	0059EF4	Neil1686	● ● ●	⊖		
28-Jan-2013 11:53:20	59393	0059EF4	Neil1686	● ● ●	⊖		
28-Jan-2013 11:35:51	1222222	0059EF4	NeilB444	● ● ●	⊖		
28-Jan-2013 11:32:06	6789	0059EF4	Neil1686	● ● ●	⊖		
28-Jan-2013 11:37:34	654321	0059EF4	Neil1686	● ● ●	⊖		
28-Jan-2013 11:26:42	23456	0059EF4	NeilB444	● ● ●	⊖		
14-Jan-2013 14:14:43	14jan	0059EF4	NeilB444	● ● ●	⊖		
28-Jan-2013 11:23:51	1234	0059EF4	Neil1686	● ● ●	⊖		
24-Jan-2013 16:16:34	12	0059D65	RC	● ● ●	⊖		

Fig. 15.

How to Connect with EDM Lite

On EDM Lite:

1. If using Wi-Fi, enter the IP Address and port number. The port number can be any whole number (e.g. 12345 as shown in Fig 16). If using Wi-Fi infrastructure at your institution, consult your IT department for a suggested port number.
2. If using Bluetooth, add a valid Bluetooth address (as shown in Fig 16, no port number needed).
3. Press “Start” to establish communications. When “Start server automatically” is enabled, the corresponding link server will start automatically whenever the application starts.

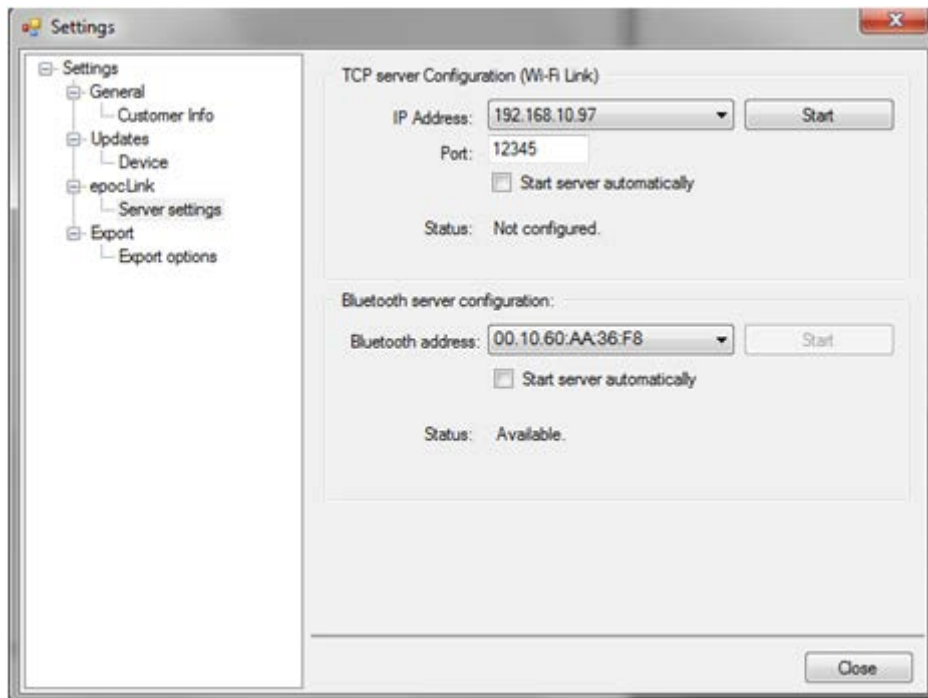


Fig. 16.

The status of connection via either Wi-Fi or Bluetooth is shown in the bottom status bar (Fig. 17). The green circle in the status bar indicates that the corresponding link server is listening, while the red circle indicates that the server is not started, not configured, or an error has occurred.



Fig. 17.

On epoc[®] Host:

1. Log in to the Host as **Administrator**.



2. Select **Tools**→**Options**→**EDM Options** (Fig. 18).
3. Set **EDM present?** To “Yes”.
4. Enter the same EDM address and Port number as on EDM Lite.

Note: If using Bluetooth, the port number is ignored.

5. Tap **Save**

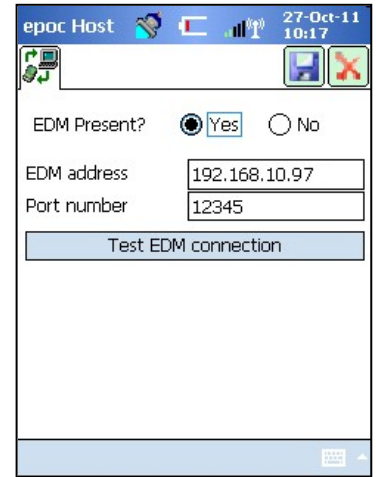


Fig. 18

How to Upgrade the epoc[®] Host Software Using the EDM Lite

*Note: the following **version** and **file names** are examples only.*

On EDM Lite:

1. Start the EDM Lite application. In EDM Lite, navigate to **Settings** → **Updates** → **Device** → **Select file** → **C:\alere\hostupgrades\epoc.3.14.7b.upg** → **Open** → **Verify file** (Fig. 19).

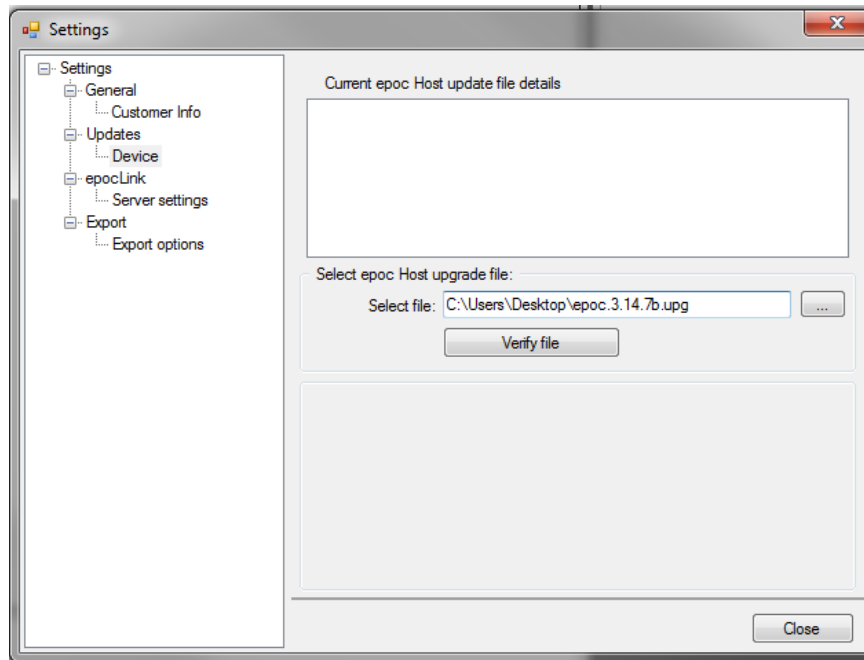


Fig.19.

The “Upgrade File verification” message box opens (Fig. 20), containing the following information:

- epoc[®] Host software version
- epoc[®] Reader software version
- Sensor configuration

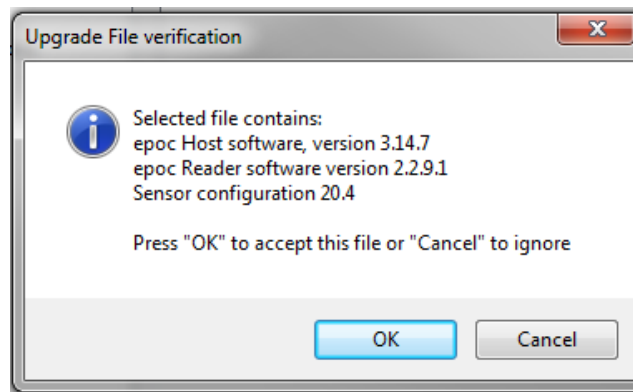


Fig. 20.

If the upgrade file contains an older version of the epoc[®] Host than the one currently loaded in EDM Lite, a warning will also be displayed.

2. Press “OK” to accept the selected file or “Cancel” to ignore the selection.
3. If “OK” is pressed, the upgrade file will be loaded into EDM Lite and delivered to epoc[®] Hosts when requested.

On epoc[®] Host:

1. Log in to the Host as **Administrator**.




2. Select **Tools**→**Perform upgrade**→**From EDM** (Fig. 21).



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3. When the message appears, tap on “Yes” to perform upgrade (Fig. 22) and wait until the confirmation message appears (Fig. 23).
4. Tap the red X  in the top left corner and wait while epoc[®] Host upgrades.
5. Verify the Host software version at the bottom right of the Login screen (Fig. 24) or log in and select **Help→About**.
6. The epoc[®] Host is now ready for use.

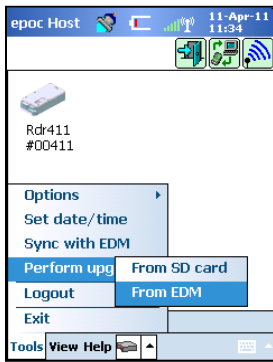


Fig. 21.

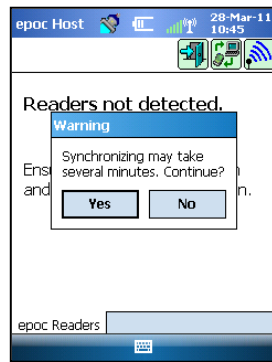


Fig. 22.

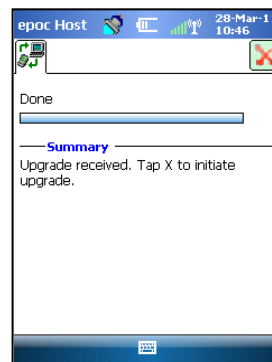


Fig. 23.

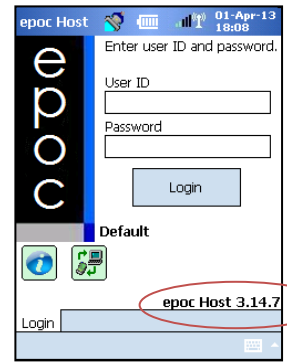


Fig. 24.

Questions

Please contact Alere[™] Technical Services at 1.877.308.8293, if you have questions regarding this Product Update or the epoc[®] System.

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