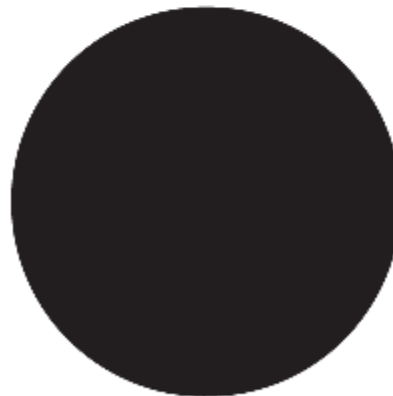
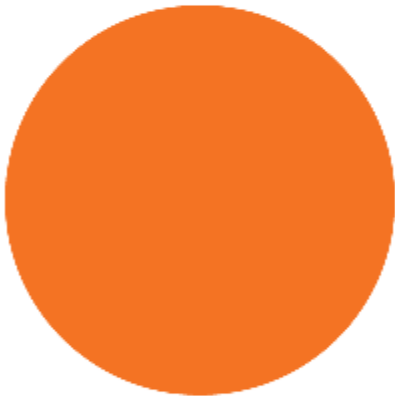




SMARTLINK

SmartLink 2.1

Technical Folder – Installation & Configuration manual - general – EN – v1.0



Regulatory Information

SmartLink 2.1 complies with:

- the 93/42/CEE Directive and with harmonised standard EN ISO 13485/2012 and further modifications.
- the 60601-1-8:2007 (+ A1:2013 + corrigenda 2010 and 2014) collateral standard, as part of a Distributed Alarm System (DIS - Distributed Information System, DAS – Distributed Alarm System, CDAS – Distributed Alarm System with operator Confirmation).
- the 80001-2-5:2014 technical report, as part of a Distributed Alarm System (DIS - Distributed Information System, DAS – Distributed Alarm System, CDAS – Distributed Alarm System with operator Confirmation).



About this manual

This manual is part of the available SmartLink 2.1 product documentation.

The product documentation is made of these documents:

- 1) SmartLink 2.1 Declaration of Conformity
- 2) SmartLink 2.1 User Manual – general
- 3) SmartLink 2.1 User Manual – Respiration Summary Reports
- 4) SmartLink 2.1 Installation and Configuration Manual – general
- 5) SmartLink 2.1 Administration manual – general
- 6) SmartLink 2.1 Installation and Configuration Manual - SmartPager
- 7) SmartLink 2.1 User Manual – SmartPager
- 8) SmartLink 2.1 SmartPager – Pager Assignment – User
- 9) SmartLink 2.1 SmartPager - Pager Assignment – Configuration

These documents are available in PDF format:

- On the desktop of the SmartLink 2.1 pre-installed virtual machines
- Included in the Installer compressed file
- In the reserved area of the Software Team website.

The documents can be saved on off-line supports and can be printed using Adobe Acrobat Reader version IX or more recent. In case of use of another PDF reader check all fonts and graphic parts be correctly displayed.

The documents cannot be disclosed in whole or in part, with any available mean, outside the organization where SmartLink 2.1 is used and to people different than the ones directly involved in the SmartLink 2.1 use, configuration, administration, maintenance.

Please take note that one or more of the listed manuals might belong to functions not included in your supply, even if the whole manuals set is included in the supplied items.

DOCUMENT INTENDED PURPOSE AND READERS

This document is an installation guide to SmartLink. It describes the SmartLink setup features, which allow to automatically install SmartLink files and Smartink configuration.

These document contents are for doctors, nurses and health workers, involved in SmartLink's capabilities evaluation, with the purpose to use SmartLink in their organisations.

Warning: not all the described functions are present in Smartlink EL edition or if they are present it is possible that are not active because they are not included in the supply contract.

CHANGES OF THIS DOCUMENT FROM TO PREVIOUS SOFTWARE VERSION (2.0)

In this document two section have been added : Configure eGateway (Mindray)and Configure Capsule technology Data captor that explain how to configure eGateway and Data Captor. The section SmartLink Update has been updated with the new method used to update SmartLink 2.1
 The images have been updated.

DOCUMENT FIRST ISSUE

| Document Name | Version | Date |
|---|---------|--------------|
| 1.06c - SL2.1 - Install&Config Manual-general | EN-v1.0 | Aug 24, 2015 |

DOCUMENT REVISIONS

| Document Name | Version | Date |
|---------------|---------|-------|
| ----- | ----- | ----- |

SMARTLINK 2.1 TECHNICAL FOLDER INSTALLATION AND CONFIGURATION - GENERAL

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1. TECHNICAL INFORMATION

SmartLink 2.1 operates with Mindray's monitoring systems, collecting all the data coming from Mindray's HyperVisor and PDS Gateway.

Data can be collected from Mindray's eGateway (without waveforms data flow) and from Capsule Technologies Data Captor (only for alarm messages coming from other bed side devices).

For each data gateway (CMS, or eGateway, or Data Captor) is necessary a computer with:

- Operating System: Windows 8 professional, Windows 7 professional, Windows Server 2008 or newer (For this topic please refer to the separate document: "1.09.1 - SL2.1 - Technical Requirements")
- Screen resolution: 1280 x 768
- Database: MySQL Server 5.2
- Memory: 4 to 8 Gbyte RAM
- Hard Disk: 60 Gbyte (space requirement depends on the number of replays to keep active for each monitor)
- Network Cards: one to connect the CMS, one to connect the PC to the web server

SmartLink 2.1 web application runs on IIS.

The web server must be configured to run xbp (.NET) applications.

The installation procedure will guide you through the installation and configuration of MySQL, IIS, .Net Framework and SmartLink 2.1 components.

1.1 – Note for Demo installation

If you are installing SmartLink 2.1 for demonstration purposes, and the computer is not connected to a patient monitor network, you will have to install additional components. In order to emulate the monitor network, the following components are required:

- Microsoft Loopback adapter (set to Gateway IP)
- Mindray PDS Gateway
- HyperVIDemo (in order to emulate patient monitor signals)

2. ENVIRONMENT DESCRIPTION

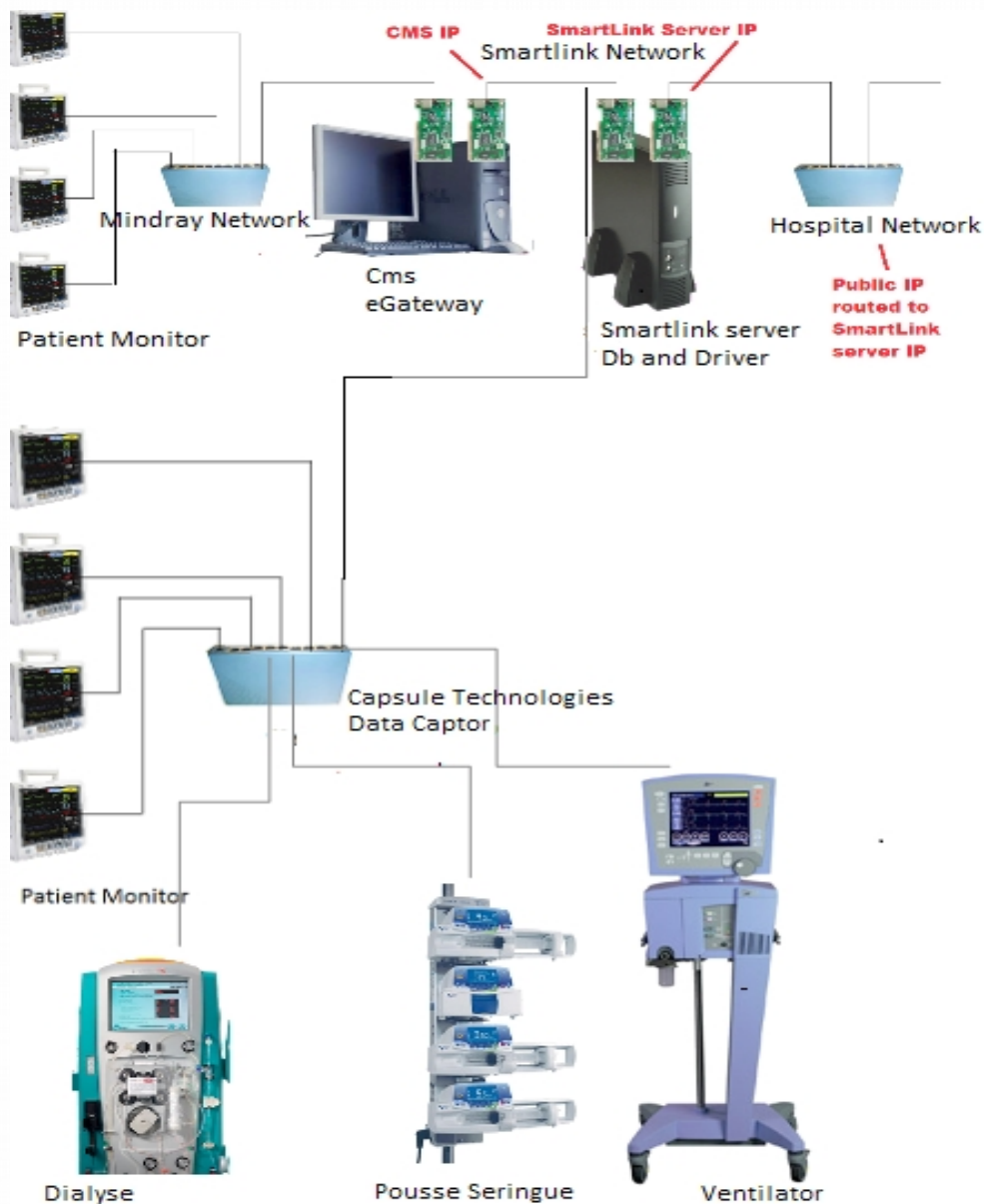
SmartLink 2.1 environment is made of three different networks: Data sources network, SmartLink 2.1 network and Hospital network.

Data sources network: this network carries the network traffic between patient monitors and HyperVisor (Mindray), between patient monitors and eGateway (Mindray), between other bed side devices and Data Captor (Capsule Technologies). The data sources network(s) is an existing network.

SmartLink 2.1 network: it is a simple connection between the data gateways (CMS, eGateway, Data Captor) and the SmartLink 2.1 Server. This network could carry a heavy broadcast traffic (more or less the same of Mindray network). This is a separate network: Mindray HyperVisor/eGateway and SmartLink 2.1 server have separate network cards to manage this traffic. SmartLink network has to be set up.

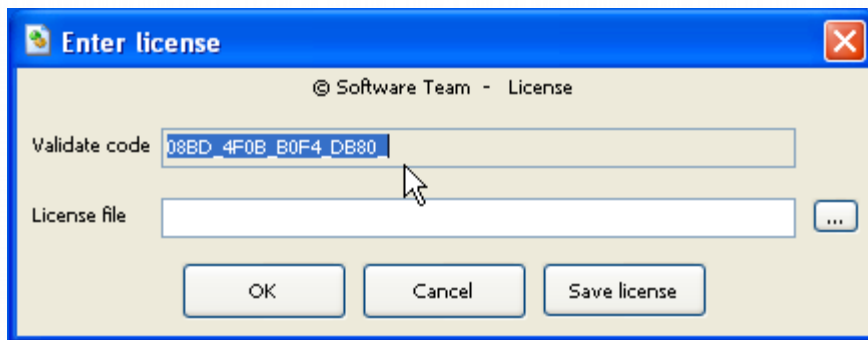
The SmartLink 2.1 server can be installed on a dedicated PC placed close to the data source gateway (CMS, eGateway, Data Captor), or in a server room on physical or virtual server machines.

Hospital network: it is the actual network used by hospital applications. SmartLink 2.1 server accesses this network to communicate with the Web Server, that can be located anywhere in the Hospital network. The Web Server will run SmartLink 2.1 Web Application, allowing remote users to access patient monitors waveforms and parameters. The traffic between SmartLink 2.1 server and the Web servers is very light. SmartLink 2.1 server is connected to the Hospital network using a separate network card.



3. LICENSE INSTRUCTIONS

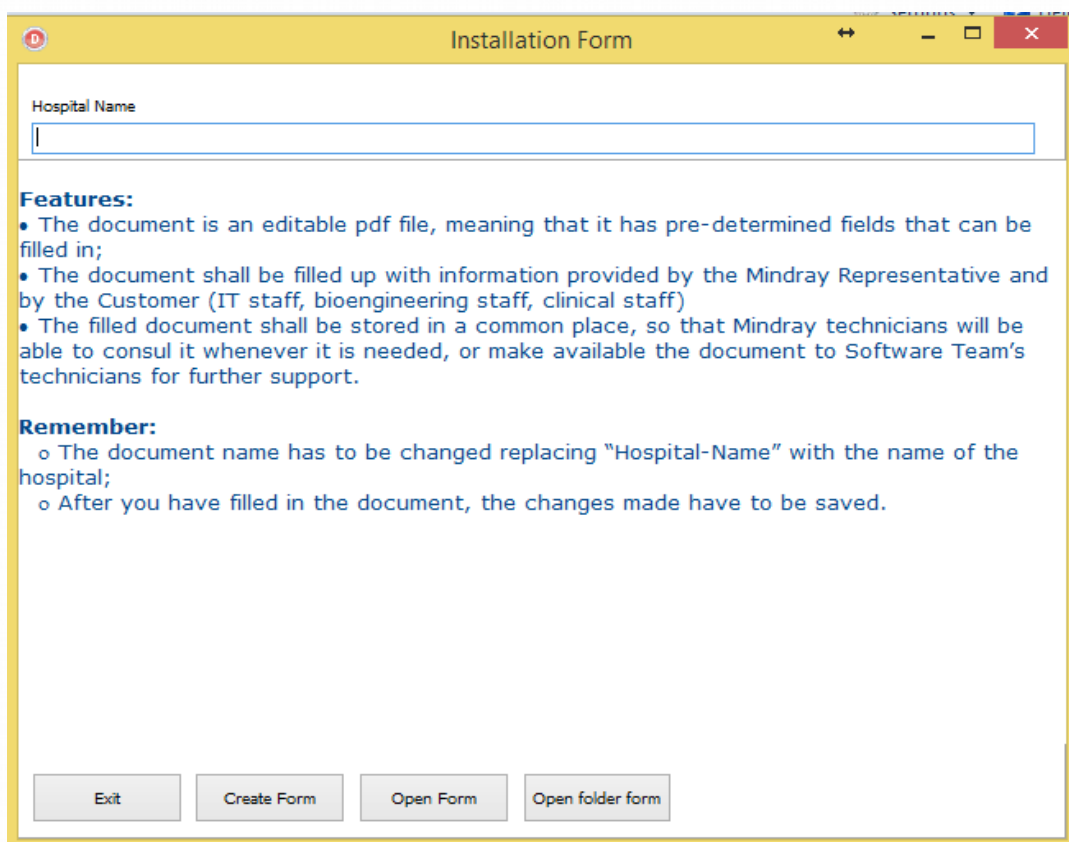
After your request for a personalized setup, you will receive an email with preliminary instructions and the file required for the license. Save and unzip the attachment on the computer where you are going to install SmartLink 2.1, then run the file license.exe. Copy the text in the “Validate code” field and fill in the corresponding field in the Information Form on the next page.



Please note that the license is effective for a single computer, so make sure to run the file license.exe on the same computer where you are going to install SmartLink 2.1.

3.1 – Installation Form

To compile the installation form, access the SmartLink 2.1 Configuration, log in with User: **gg** and Password: **gg** and click on Installation Template and then on Installation Form. In this area you can create and then open the form.



The screenshot shows a web application window titled "Installation Form". At the top, there is a text input field labeled "Hospital Name". Below this, the text "Features:" is followed by a bulleted list:

- The document is an editable pdf file, meaning that it has pre-determined fields that can be filled in;
- The document shall be filled up with information provided by the Mindray Representative and by the Customer (IT staff, bioengineering staff, clinical staff)
- The filled document shall be stored in a common place, so that Mindray technicians will be able to consult it whenever it is needed, or make available the document to Software Team's technicians for further support.

Below the features, the text "Remember:" is followed by a bulleted list:

- The document name has to be changed replacing "Hospital-Name" with the name of the hospital;
- After you have filled in the document, the changes made have to be saved.

At the bottom of the window, there are four buttons: "Exit", "Create Form", "Open Form", and "Open folder form".

One copy of the installation form shall be filled for each installation (CMS, eGateway, Data Captor) and sent to Software Team at the adress smartlink@swt.it

4. SMARTLINK 2.1 INSTALLATION

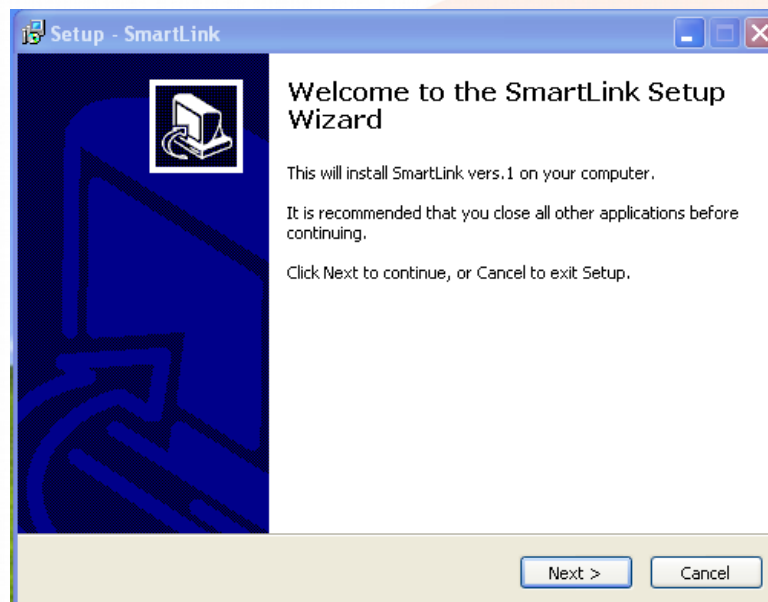
Save and run the file SmartLinkSetup.exe. If available, copy the folder “My Program Dependencies” in the same location of SmartLinkSetup.exe.

The installer will check if the following components are already installed:

- Internet Information Service (IIS);
- .Net Framework 4.0;
- MySQL environment (MySQL 5.5 requires .NET Framework 4.0 and Visual C++ 2010 Redistributable).

If any of the prerequisites is missing, SmartLink setup will install it by searching its setup in the folder “My Program Dependencies” or downloading it from the official distributors.

Please note that the computer must have Adobe Reader installed and must have an active internet connection. Windows installation CD could be required for the installation of IIS. You must be logged as an administrator in order to run the setup.



4.1 - Internet Information Service (IIS)

SmartLink Setup checks if IIS is already installed on your computer. If IIS is not installed, SmartLink Setup will launch the default procedure to add Windows components (on Windows XP Professional you could be asked for Windows installation CD).

Alternatively, you can manually install IIS and then launch the SmartLink 2.1 installation software.

The procedure to install IIS is the following:

1. Open Control Panel and the Program and Features
2. Click “Activate or deactivate Program”
3. Select “Activate or deactivate Windows functionalities”
4. Select IIS entry and follow installation

4.2 - .NET Framework 4.0

SmartLink Setup checks if .NET Framework 4.0 or later is already installed on your computer. Usually .NET Framework is installed by default.

If .NET Framework is not installed, SmartLink Setup will download the installer from the official Microsoft website.

The .NET Framework program will perform extraction and loading of the components to be installed. Accept license contract and wait for .NET Framework download. After a few minutes the program will proceed with the installation of the downloaded components.

Alternatively, you can install .NET Framework manually before executing SmartlinkSetup.exe.

Download .NET Framework installer from <http://www.microsoft.com/en-us/download/details.aspx?id=17851>, accept the license and wait for .NET Framework to be downloaded and installed.

4.3 - MySQL environment

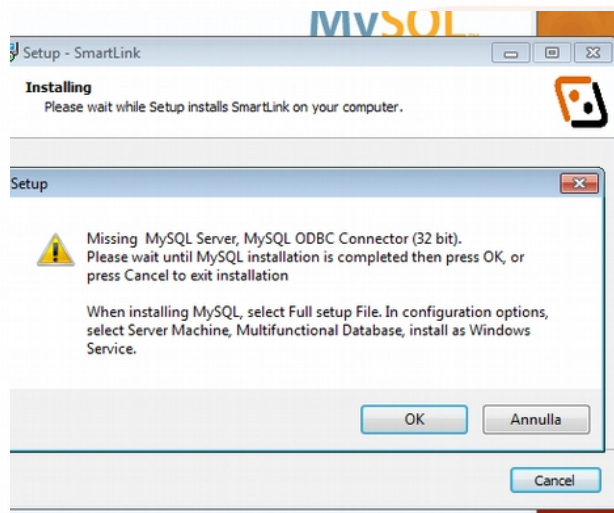
SmartLink Setup checks if MySQL Server and MySQL ODBC Connector are already installed on your computer.

If MySQL environment is not installed, SmartLink Setup will check MySQL prerequisites (.NET Framework 4.0 and Visual C++ 2010 Redistributable), install the missing ones and launch MySQL installer.

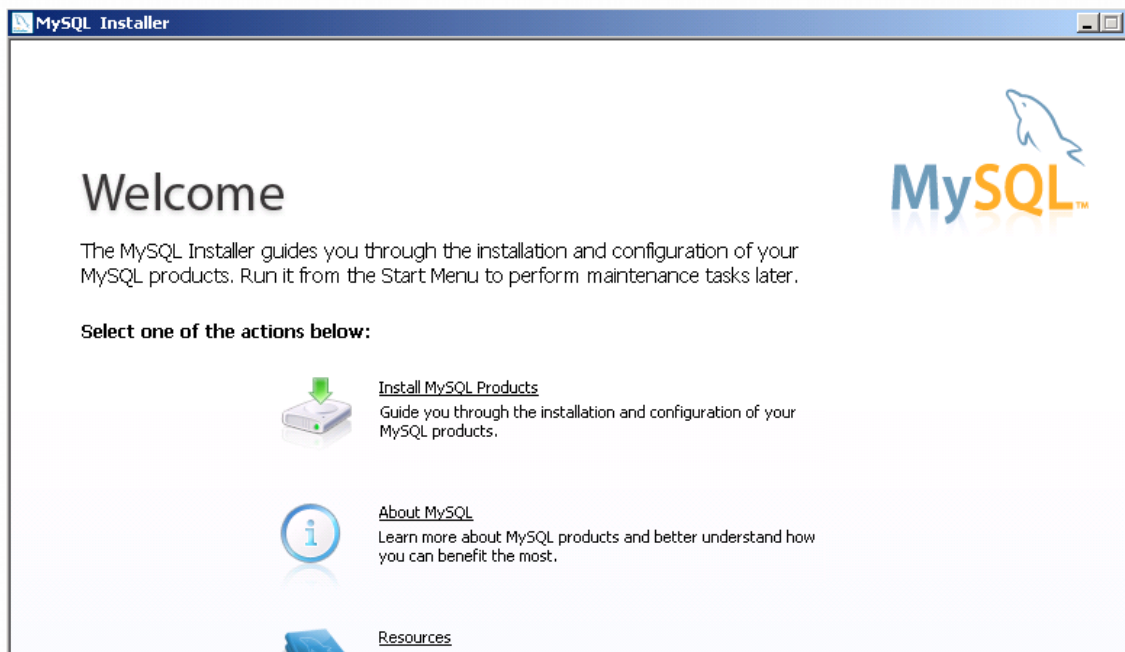
Alternatively, you can install MySQL environment manually before executing SmartlinkSetup.exe.

Download MySQL installer from <http://dev.mysql.com/downloads/mysql>. If you choose the custom setup, you need to install MySQL Server, MySQL Workbench and MySQL ODBC Connector 32-bit (both on 32-bit and 64-bit machines).

SmartLink Setup will not continue until MySQL installation is complete, showing an error message. In this case check if MySQL installer is in background and complete MySQL installation first. Only a MySQL error stop the installation of SmartLink 2.1.

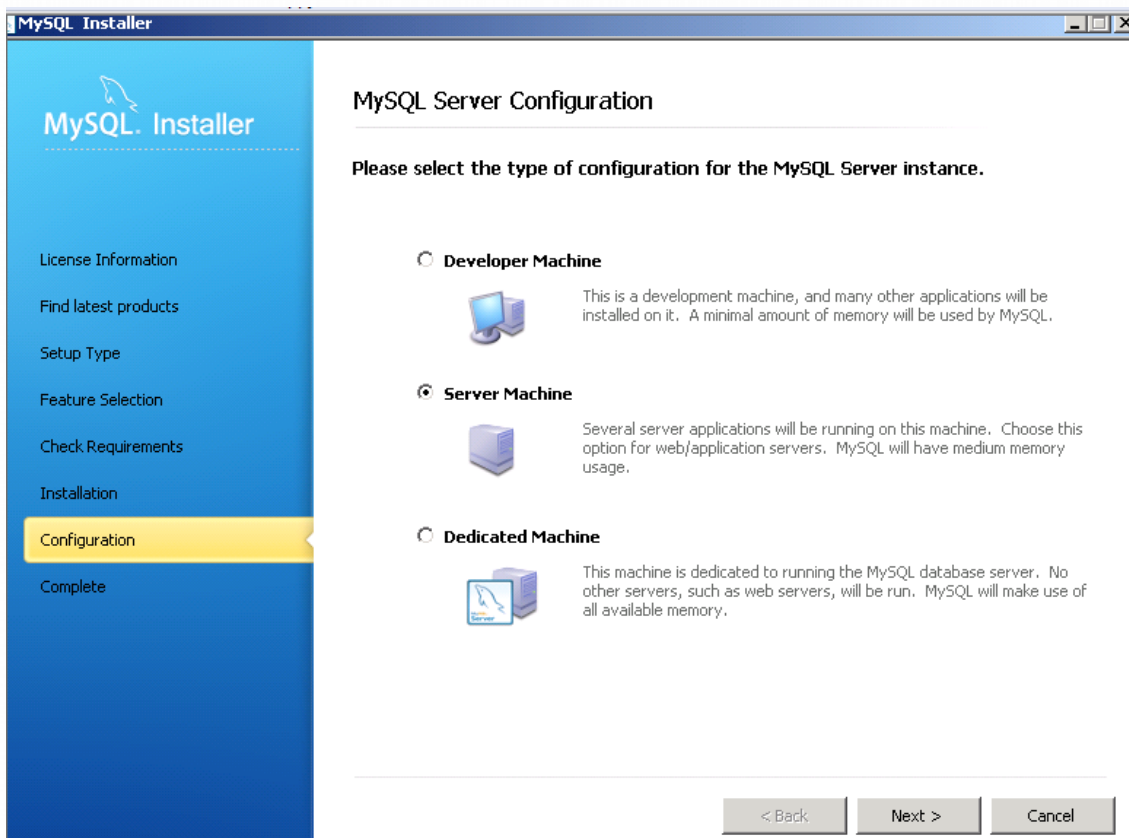


Run MySQL installer, select “Install MySQL Products” and click next to continue, accept the license and select “Full” setup File.



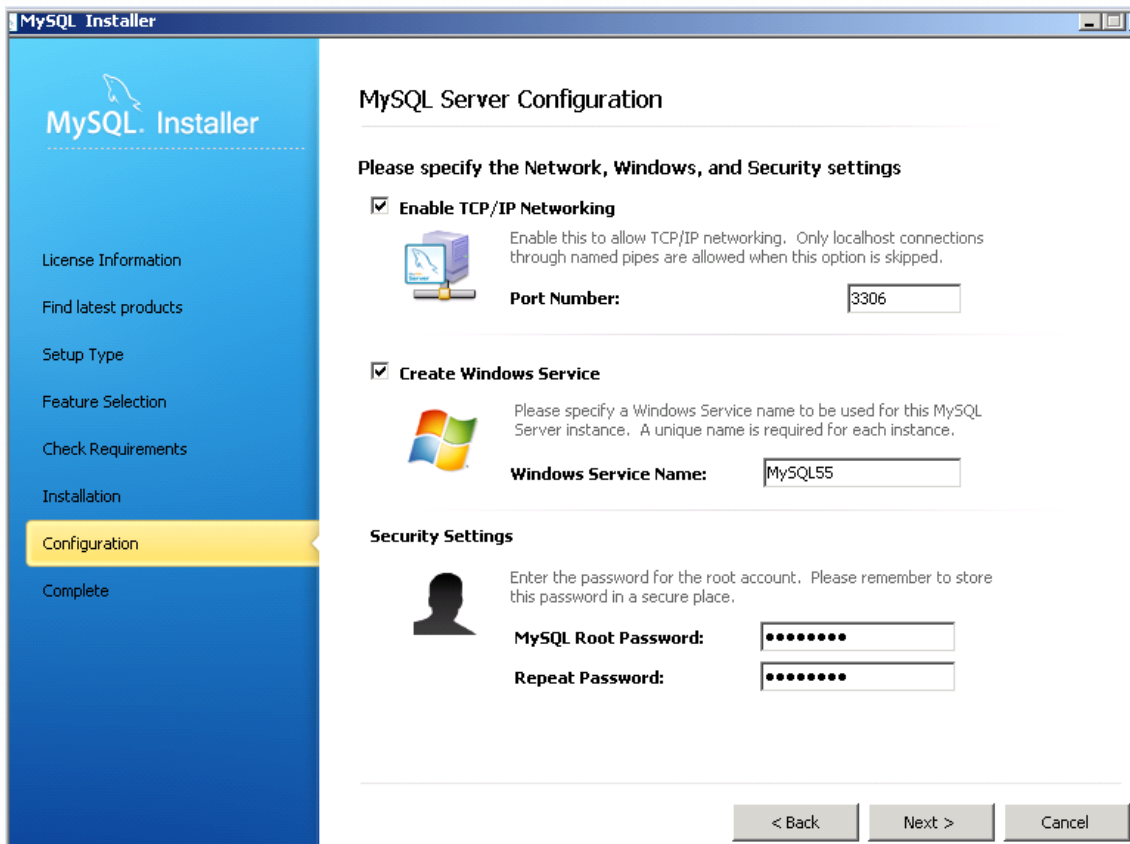
Click on “Install” to execute the installation of MySQL Server.

Select “Server Machine” and click “Next” (note: if you use this machine for other purposes you can select “Developer Machine”).



On the next page select “Multifunctional Database” and click “Next”. On the following pages keep the default parameters and click “Next”.

Select “Install as Windows Service” and create a password for your administration user root (it will be used for configuration).



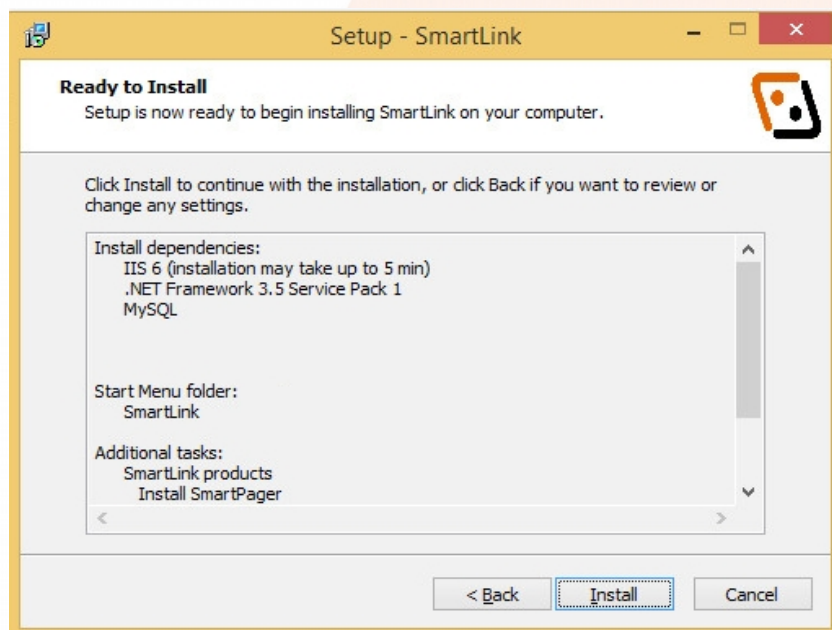
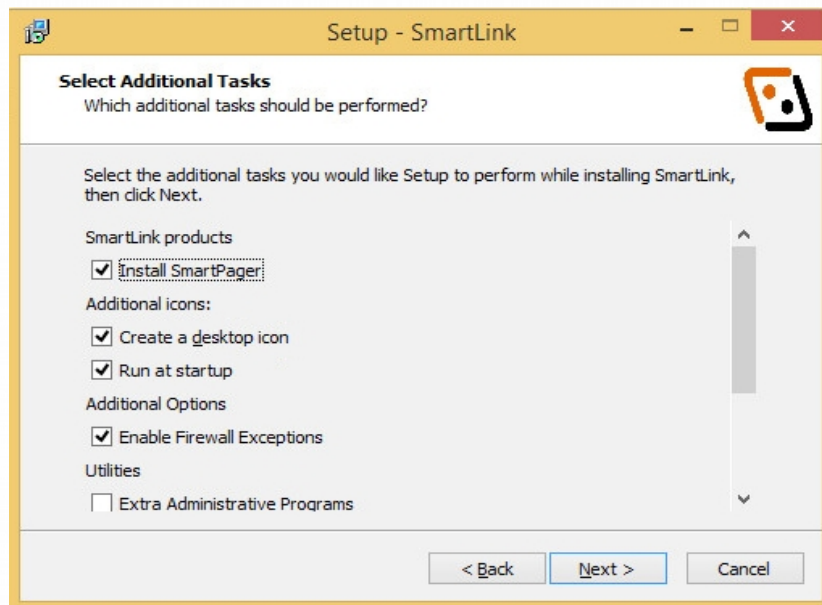
SmartLink Setup will later change some DB parameters:

- key_buffer_size (175M)
- sort_buffer_size (256K)
- innodb_additional_mem_pool_size (7M)
- innodb_buffer_pool_size (339M)
- max_allowed_packet (15M)
- wait_timeout (2147400)

You can check these variables with MySQL WorkBench, in the section “Administrator” under “Startup Variables”.

4.4 - SmartLink Setup

Choose the additional tasks (i.e. Run at Startup) and proceed with the installation.

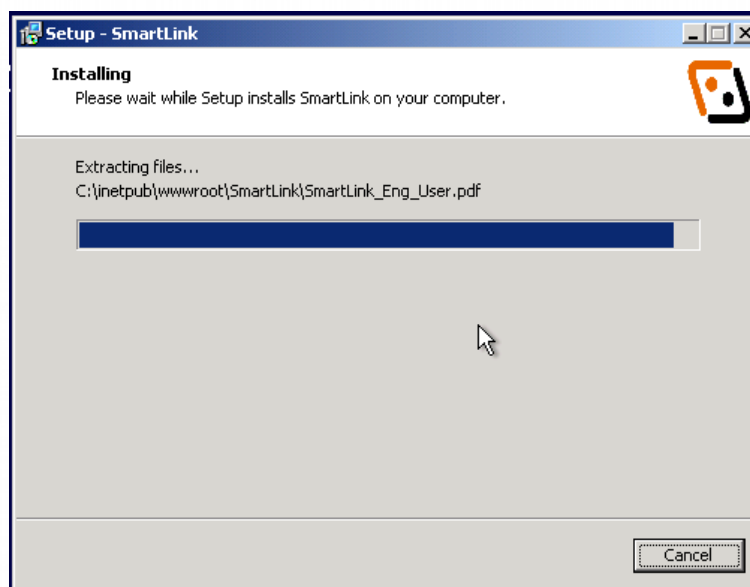


SmartLink Setup will install SmartLink 2.1 program files in the folder [C:\iMonitor](#) and will copy the web application folder in the correct location (C:\inetpub\wwwroot\SmartLink).

The setup process creates two ODBC connections (smartcom_mindray and smartcom_monitor) with MySQL ODBC 5.1 Driver. You can check ODBC connections by opening the 32-bit ODBC connection manager (on Windows 32-bit: %WINDIR%\system32\odbcad32.exe, on Windows 64-bit: %WINDIR%\SysWOW64\odbcad32.exe).

If the installation was successful, a wizard will show up to guide you through your server configuration (see next paragraph for more information).

In the last page of SmartLink Setup you will be asked for MySQL root credentials (password) in order to create users and schema in MySQL database.



4.5 - IIS configuration

Next step is the configuration of a new website where SmartLink will be launched. You can deploy a Windows Presentation Foundation (WPF) application, such as SmartLink, from a web server configured with the appropriate Multipurpose Internet Mail Extensions (MIME) types. You must register the following MIME types and file extensions so that the browser on the client system can load the correct handler:

| Extension | MIME type |
|--------------|--------------------------------|
| .xaml | application/xaml+xml |
| .application | application/x-ms-application |
| .xbap | application/x-ms-xbap |
| .deploy | application/octet-stream |
| .xps | application/vnd.ms-xpsdocument |

MIME types and file extensions on client systems are automatically registered when you install Microsoft .NET Framework.

To open Internet Information Service Manager click the Start Menu, open the Control Panel, open the Administrative Tools and click “Internet Information Services (IIS) Manager”. You can also launch this application from the command line using “%SystemRoot%\system32\inetsrv\iis.msc”;

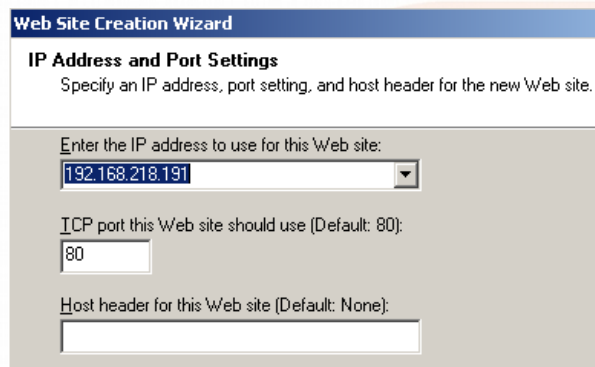
In IIS 5:

On the left exposer of IIS Manager, right click on “Default Web Site” and select New → Web Site...



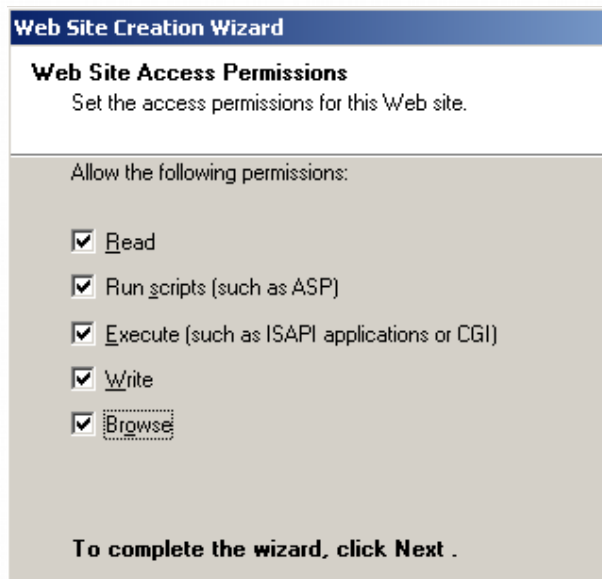
The selection starts the Web Site Creation Wizard; follow these instructions:

- Website creation description: write “SmartLink” in the “Description” field and click Next;
- IP Address and Port Settings: select PC IP (the one netted on internet) from the list of configured IPs;



- Web Site Home Directory: select the path where the application has been placed (C:\inetpub\wwwroot\SmartLink);

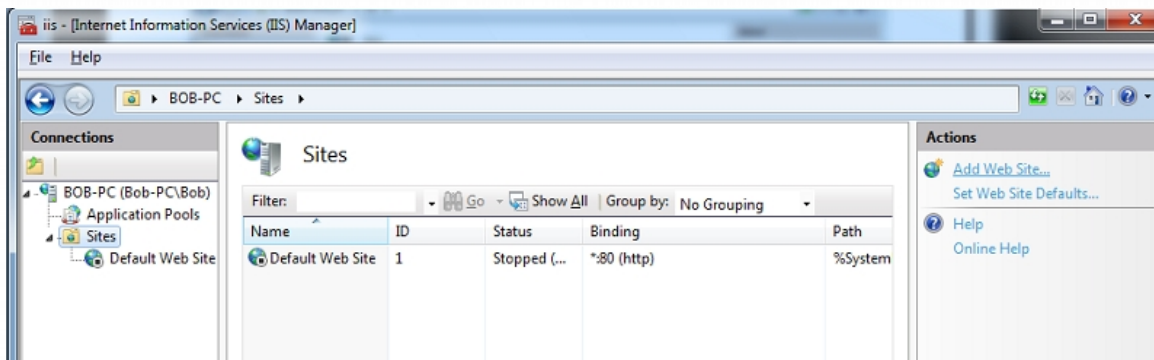
- Web Site Creation Wizard: select the parameters as shown below and click “Next” to complete the wizard.



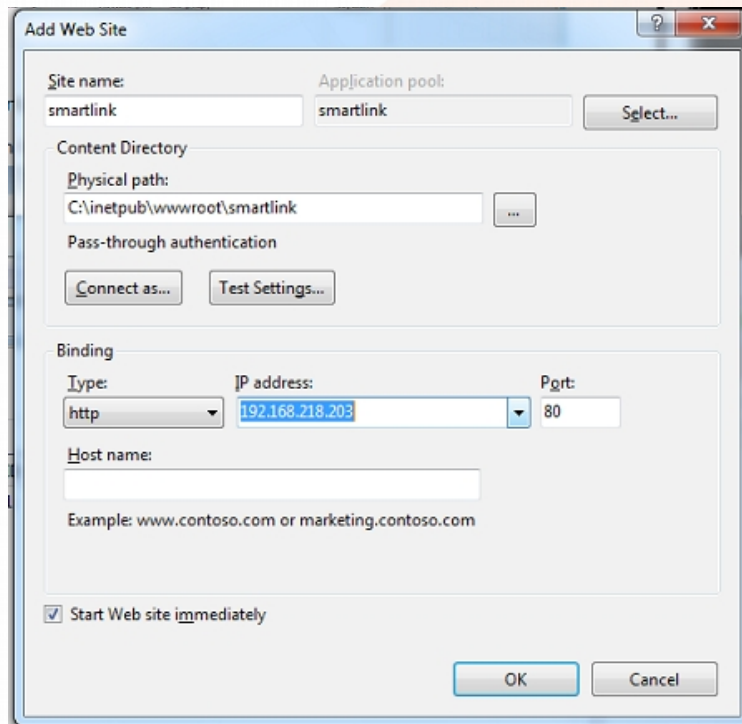
- Create a new Virtual Directory and name it “SmartLink”. The path of the directory will be C:\inetpub\wwwroot\SmartLink;
- Expand the IIS tree until you find the SmartLink Web Site node;
- Right-click SmartLink Web Site and select “Properties” from the context menu;
- Select the HTTP Headers tab and click “Enable Content Expiration”;
- Set the content to expire after 1 minute;
- Click the button “File Types”;
- Click the button “New Type...” to add the file types listed in the table above, if they are not registered yet.

In IIS 6:

- In the right exposer, right-click and select New → Web Site...
 This menu is located in “Default Web Site Exposer”, on the right of the figure below.



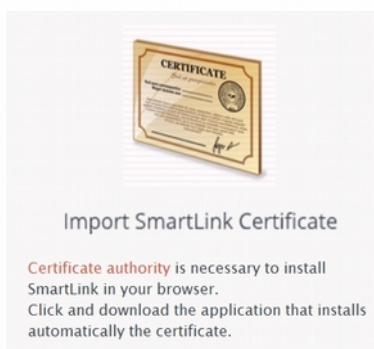
- In the Site name write “SmartLink” and click “Next” to continue, then select the Physical path where the application has been placed during the installation (C:\inetpub\wwwroot\SmartLink);



- Create a new Virtual Directory and name it “SmartLink”. The path of the directory will be C:\inetpub\wwwroot\SmartLink;
- Select the HTTP Headers icon;
- On the HTTP Response Headers page enter the Action panel and click “Set Common Headers”;
- Go to “HTTP Response Headers”;
- Click on “Set Common Header” and then set “Enable Content Expiration”;
- Set the content to expire after 1 minute;
- Select the MIME Types Icon;
- In the Action panel click on “Add...” to add the file types listed in the table above, if they are not registered yet.

4.6 - Configure .NET Framework – Import Certificate

After the installation of .NET Framework you can configure your browser to accept the download of .NET objects. To get the application which installs the certificate go to <http://www.swt.it/smartlink-technical-docs> and click on “Import SmartLink Certificate”. Accept to download and execute the file, then click on “Import SmartLink Certificate”.



After the installation, the message “Import completed successfully” will appear.

4.7 - Configure Mindray PDS Gateway

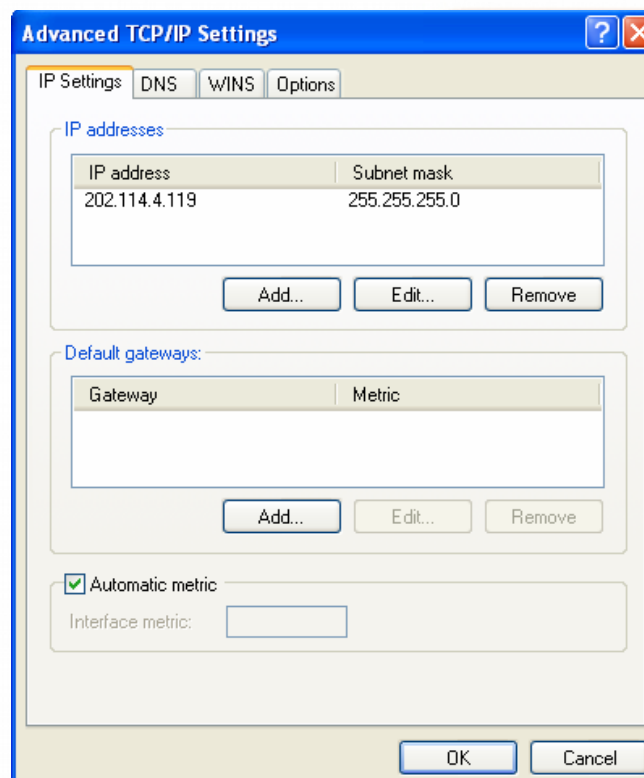
Mindray PDS Gateway and HyperVisor VI Central Monitoring System (CMS) allow communication between SmartLink 2.1 and monitors.

To install the Gateway enter the Gateway directory in the Installation Kit and open Setup.exe. Click “Next” on the Welcome page and select the folder where you want to install the product, then click “Next”.

Before the execution of the installation you have to enter the license code, then click “OK” and the Gateway will be installed.

To allow communication, the Gateway PC must intercept monitor IPs. You can find them in monitor’s maintenance options (e.g. family 202.114.4.xxx and 19.76.0.xxx).

You have to add these IPs in LAN configuration. Open Start → Control Panel → Network Connections and select the active connection. After selection, right-click on LAN connection to display the Local Area Network Properties. Select the item “Internet Protocol (TCP/IP)”, click “Properties”, then click the “Advanced” button.



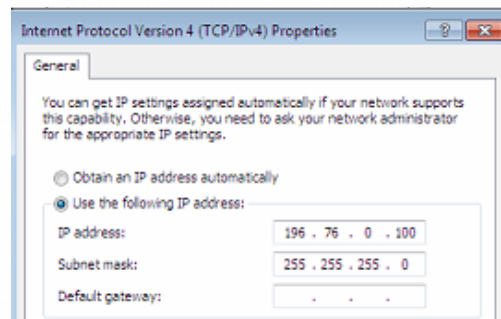
Click the “Add” button in the IP Addresses section. In the TCP/IP Address window write your IP in the “IP Address” field and “255.255.255.0” in the “Subnet Mask” field.

You can test if the connection was successful using PDSClientTest.exe: type your new PC IP and click on “Connect”; if a bed list is shown the connection was successful.

It is possible that you need to adjust your Firewall settings in order to allow communications on ports 20001, 20002, 20003, 20004 (UDP) and 20005 (TCP).

4.8 - Configure eGateway

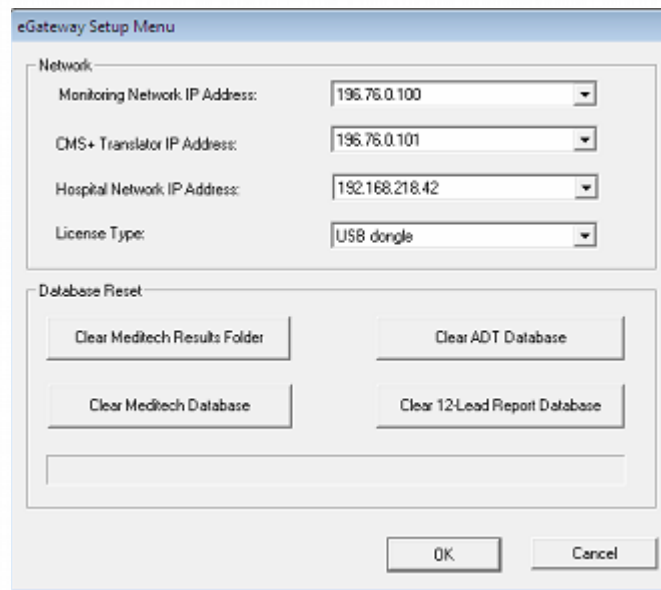
eGateway allows communication between SmartLink 2.1 and monitors. Start with stopped eGateway. It is necessary to configure two network card: the first is the Hospital Network ,that has to be in the same class of SmartLink Computer,the second has to be configured inserting two IP address, both in the same class of Mindray network.



To install the eGateway enter:

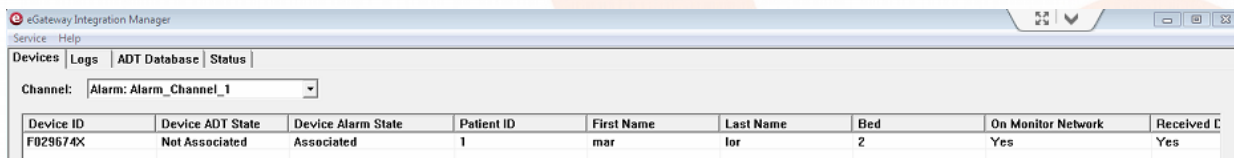
```
C:\Program Files\Mindray\eGateway\config\gatewayconfig.exe
```


Start the Tool and configure the eGateway software.
 Start the configurator and insert in 'Monitoring Networking' and 'CMS Translator' the IP of the Mindray network, while in 'Hospital Network' the Ip of the Hospital Network.



Now you can start the e Gateway.

If everything is correctly configured it will appear the Monitor in the list of the connected devices



If the monitor will not appear discharge and admit again the patient.
 It is possible that you need to adjust your Firewall settings in order to allow communications on ports 7500,7501,7502 (UDP).

4.9 - Configure Capsule Technology Data Captor

Data Captor 5 allows communication between SmartLink 2.1 and other medical devices as Monitos, ventilator, dialyse and pousse seringue.

To install Data Captor lanch the Data Captor 5.0.27_setup.msi using the Add/remove programm in the control Panel

It is possible that you need to adjust your Firewall settings in order to allow communications on ports 7500(UDP).

4.8 - Launch SmartLink

SmartLink 2.1 is launched at the end of the installation process and at every startup. A batch process will launch SmartLink 2.1 components (iMonitor, SmartAlarm, SmartTrend) and ensure SmartLink 2.1 is restarted if iMonitor is accidentally closed or crashes.

Please make sure that the PDS Gateway, if installed (or CMS real time interface) is correctly working.

Do the same for other data gateways (eGateway, Data Captor).

To use SmartLink 2.1, in Internet Explorer go to <http://<smartlinkserverIP>/smartlink/> or to <http://<externallIP>/smartlink/>.

In case of client computers, remember to import the certificate as described in the “Configure .NET Framework - Import Certificate” paragraph.

Once the application is loaded, you will be asked for your access credentials.

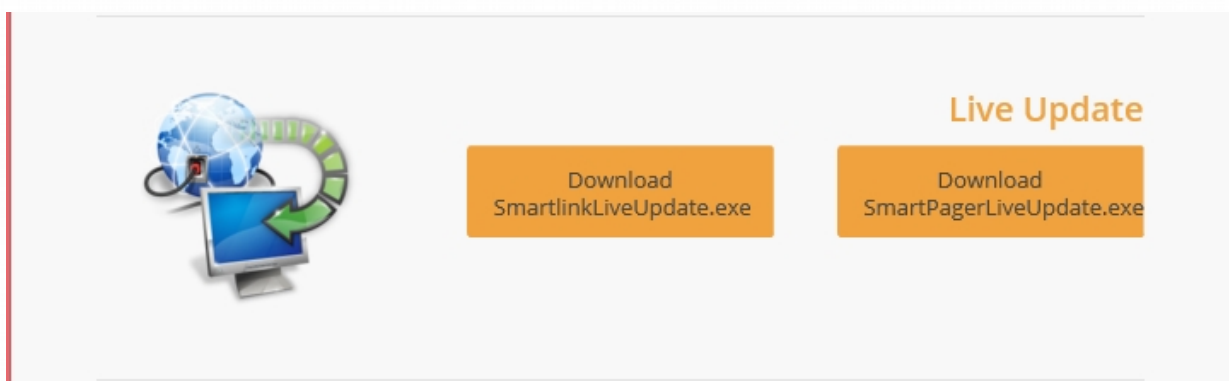
If you can't connect to SmartLink 2.1 go to the “Config” section (in the right-lower corner of the Login window) and then go to the “TestPort” tab.

If the connection is successful, you will immediately see the bed list and other features from the Menu.

4.9 - SmartLink Update

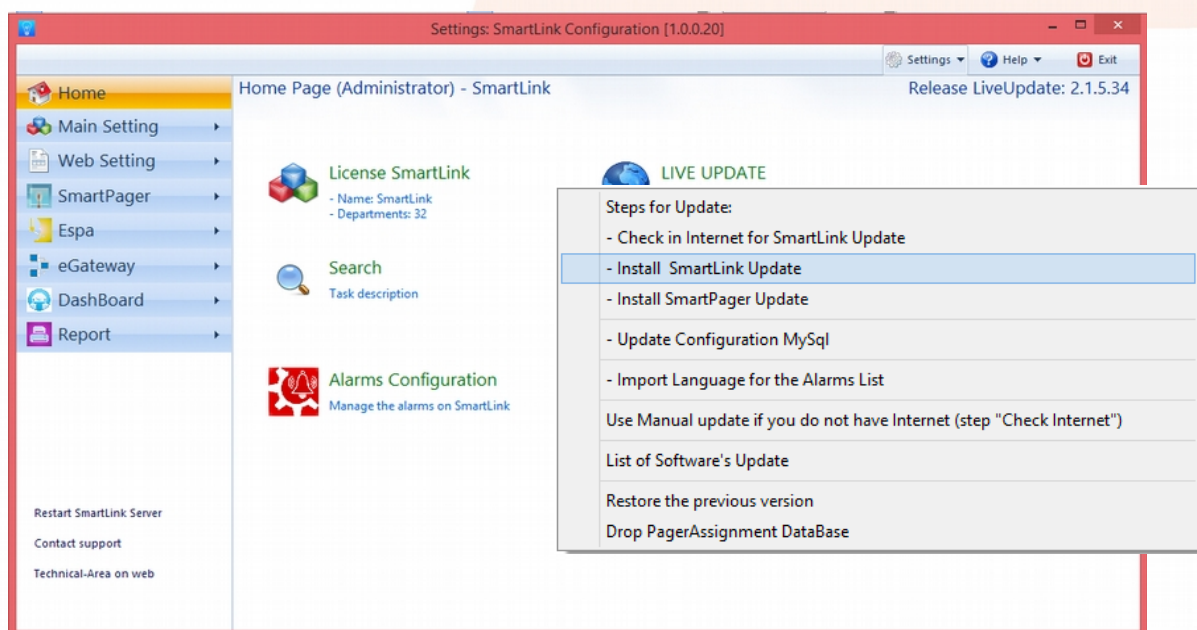
- The first way for updating the software is : Login on the Software Team site with user and password the update .

Download SmartlinkLiveUpdate.exe and SmartpagerLiveUpdate.exe.

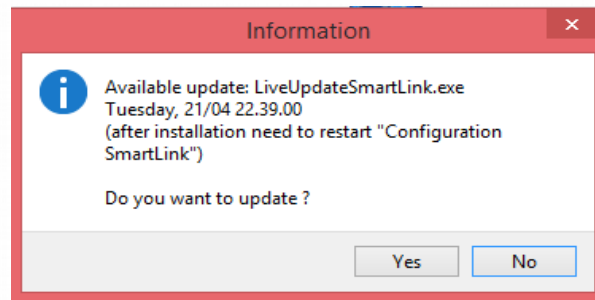


- It is possible to release the update of SmartLink and SmartPager, firstly making a login on SmartConfig. After entering the password, select the **live update** section.

If it is possible to have an internet connection click on :



1. *INSTALL SMARTLINK UPDATE*

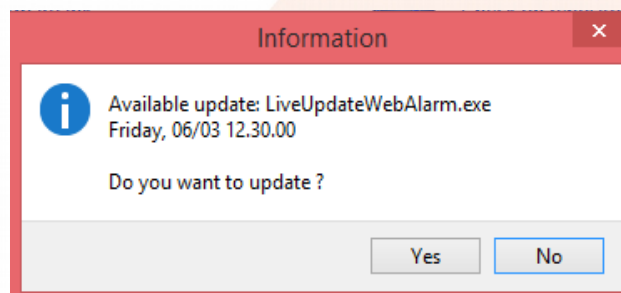


This window will appear so click on **YES**.

This window will appear so click on **YES**.

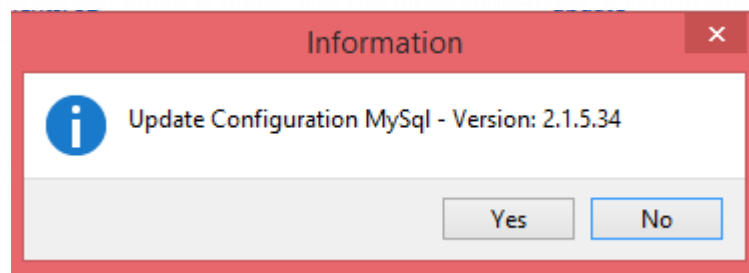
2. *INSTALL SMARTPAGER UPDATE*

This window will appear so click on **YES**.

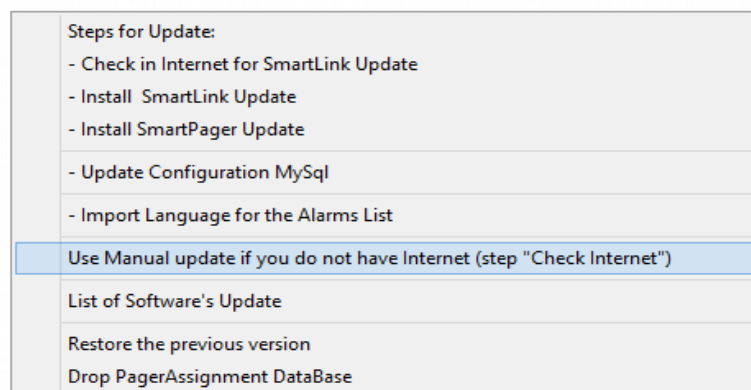


3. Finally also the configuration of mysql has to be updated so click on **UPDATE CONFIGURATON MYSQL**

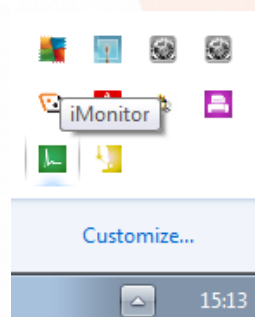
This window will appear so click on **YES**.



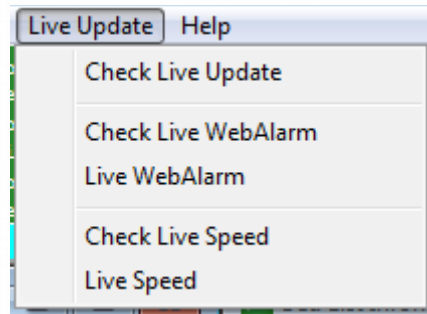
If there isn't an internet connection click on **USE MANUAL UPDATE IF YOU DO NOT HAVE INTERNET** and update SmartLink.



Finally the last way is Start SmartLink and Right-click the green iMonitor icon from the tray bar and select "Restore Form".



Click on “Live Update” in the top menu.



Click “Check Live Update” to check if there are any updates to download. If updates are available, click on the button shown below to install the updates.



For the WebAlarm application: click on “Check Live WebAlarm” if there are any updates to download. If updates are available, click on “Live WebAlarm” to install the updates.



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