Web Upload Functionality of the ACCU-CHEK® Smart Pix Device Reader

Implementation Guide for IT Professionals



This document provides the reader with the following information:

- ACCU-CHEK Smart Pix device reader V2.0 product overview
- Specifications of the Web upload functionality including the server interface
- Structure of the XML file generated by the ACCU-CHEK Smart Pix device reader to supply data downloaded from devices for further customer use
- Summary of the steps in the upload process

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1. Introduction

The ACCU-CHEK Smart Pix device reader is a standard USB device, designed to improve the overview and analysis of diabetes relevant data. It is enabled to read information stored in the memory of ACCU-CHEK blood glucose meters and insulin pumps, as well as ACCU-CHEK software for diary devices. The data is presented on a personal computer in form of graphs, tables and statistics and can be printed, stored or sent via e-mail attachment to healthcare professionals (HCPs).

Along with the firmware version V2.0 of the ACCU-CHEK Smart Pix device reader (launched end of 2007), it is possible to upload the collected device data stored as XML file(s) to a Web server. This functionality can be enabled and customized by a special setup procedure. The following methods are used for the upload: HTTP-Post-Method or HTTPS-Post-Method.

On the Web server site, a server extension needs to be available which receives and temporarily saves the post-data, extracts and interprets them and covers customer's needs for further data presentation and utilization on the Web platform.

2. Document Information

2.1. Purpose of This Document

This document is designed for IT specialists assigned to the development of the server extension. It contains information about the ACCU-CHEK Smart Pix device reader V2.0, the Web upload mechanism and specifies the XML file structure used by the ACCU-CHEK Smart Pix device to supply downloaded device data for further customer use. Within this document examples are used for illustration purposes only. Data that are included in the examples are fictitious and may be different in real situations.

2.2. Version History

Version Number	Date	Changes to prior versions
1.0	06.2008	

2.3. Abbreviations

Abbreviations used in this document:

Term	Explanation
bG	Blood glucose
ACSPIX	ACCU-CHEK Smart Pix = product name and project name of ACCU-CHEK Smart Pix V2.0
IP	Insulin Pump

TBR	Temporal Basal Rate
IU	Insulin Units

3. ACCU-CHEK Smart Pix Device Reader V2.0

3.1. Product Overview

The ACCU-CHEK Smart Pix device reader is a computer accessory, enabled to read information stored in the memory of ACCU-CHEK blood glucose meters, ACCU-CHEK insulin pumps and ACCU-CHEK diary devices. The information is transferred from the aforementioned devices via an incorporated infrared (IR) port and an IR-communication protocol and is temporarily stored on the ACCU-CHEK Smart Pix device as XML file(s).

The ACCU-CHEK Smart Pix device is a certified USB device connected to the USB port of a computer. The corresponding IDs are: **USB Vendor ID: 0x173A**, **USB Product ID: 0x83A**. Power to operate the device is provided through the computer USB port; no software needs to be installed on the hosting system.

The ACCU-CHEK Smart Pix device reader is validated for use with Microsoft **Microsoft XP Home** and **Professional** (NOT Microsoft Windows 98 or NT). To access the user interface a standard Web browser is necessary: **Microsoft Internet Explorer 6.x & 7.x, Firefox 2.x or later**. The user interface is optimized for a screen resolution of 1024x768 pixels or higher.

The device reader consists of the two following components:

- Human Interface Device (HID) - communication layer USB to IR (currently not supported and reserved for future ACCU-CHEK software applications)
- Mass Storage Device (MSD) – ACCU-CHEK Smart Pix file system, including the following file formats:

    - XML documents ext.: *.XML
    - XSL style sheets ext.: *XSL
    - HTML files ext.: *.HTML
    - Setup information ext.: *.INF
    - Image files ext.: *BMP, *.GIF, *.PNG
    - JScript script files ext.: *.JS
    - Cascading Style Sheet documents ext.: *.CSS
    - Text files for logging ext.: *.LOG
    - Icon ext.: *.ICO

The files are located in several folders on the ACCU-CHEK Smart Pix system. Not all files will be available in all operational states.

The *.XML files are generated by the ACCU-CHEK Smart Pix device reader's firmware after data have been transferred via the IR port to the device reader. The name of the XML file is generated according to the following scheme: files containing data from ACCU-CHEK bG meter start with the letter "G" followed by the seven last digits of the unique bG meter ID number (G*.XML), files containing data from an insulin pump start with an "I," followed by the seven last digits of the unique pump ID number (I*.XML). The XML files are stored in the folder REPORT. The XML files are volatile and will automatically be discarded from the ACCU-CHEK Smart Pix device reader's file system in case the device is disconnected form the computers USB port.

The *.XML files are accompanied by an *.XSL file which provides formatting information needed to display the XML file in a user friendly form.

The *.HTML files are necessary to access the user interface. The ACCU-CHEK Smart Pix device reader is operated by a standard Web browser which navigates to the HTML pages provided on the ACCU-CHEK Smart Pix file system. Therefore, no internet access is required for viewing the data. The HTML files also support the Web upload function.

The *.INF files contain setup information for the ACCU-CHEK Smart Pix device reader, e.g., user name, address, language settings. This information can be modified by the user.

The last five types of files available on the ACCU-CHEK Smart Pix file system are used for presenting the collected data in form of graphs, tables and statistics and to navigate the system.

Based on the technical design of the ACCU-CHEK Smart Pix device reader, all files, whether permanently or temporarily available on the ACCU-CHEK Smart Pix file system, are generated by the firmware of the ACCU-CHEK Smart Pix device itself. None of these files contains viruses, trojan horses or other kinds of code, malicious to the hosting system.

Storing files from the hosting system to the ACCU-CHEK Smart Pix file system is not supported. Only files generated by the ACCU-CHEK Smart Pix firmware itself can be accessed. There are two exceptions to this rule:

- Some settings for the ACCU-CHEK Smart Pix device reader (e.g., user name, address, time bins for data evaluation or settings activating the Web upload functionality) can be made by storing a file (SETTINGS.TXT) into the root directory of the ACCU-CHEK Smart Pix file system. To change a parameter, a unique parameter KEY is used in the settings file. This file is then checked and processed by the firmware of the ACCU-CHEK Smart Pix device reader. If the file and the settings herein are accepted by the firmware, settings are changed and the file is erased from the ACCU-CHEK Smart Pix device reader's drive. If the file does not meet the requirements, it is immediately discarded.
- Update of the ACCU-CHEK Smart Pix device reader with new, enhanced functionality by transmitting and installing a firmware update in the root of the ACCU-CHEK Smart Pix device reader's drive. Update files will be developed and distributed exclusively by Roche after being successfully validated and in particular checked for being not harmful for the hosting system. Update files are secured by special mechanisms for consistency, integrity and security. The ACCU-CHEK Smart Pix firmware will check a stored file against these mechanisms and perform a firmware update only upon successful completion of these checks. Otherwise, the file will be not be installed and discarded immediately.

3.2. Configuration/Customization

As mentioned above, the Web upload functionality of ACCU-CHEK Smart Pix device reader V2.0 can be activated/deactivated by storing a special file e.g. SETTINGS.TXT on the ACCU-CHEK Smart Pix file system. The following parameters can be adjusted in the customization process using the below mentioned keys:

Parameter Name	Content	Length	Key
szUploadWebURL	Full URL of upload server (= action target)	60 Bytes	UU
szUploadText	Name of upload server or service; the text appears in the user interface, e.g. “Test Server”	60 Bytes	UT
"upload enabled"	Flag indicating if the upload function is enabled. This is the case if szUploadWebURL ≠ null string		n/a

If the upload function is enabled, a button to open the upload dialogue will be added to the top navigation bar within the user interface on the ACCU-CHEK Smart Pix device reader. This [UPLOAD] button does not use text, a graphic element is used instead (filename “img/upload.GIF”). As long as no data have been uploaded to the ACCU-CHEK Smart Pix device reader, the button is non functional (grey).

Graphic 1: Top Navigation Bar with Disabled [UPLOAD] Button

As soon as data were uploaded to the ACCU-CHEK Smart Pix device, the [UPLOAD] button becomes active.

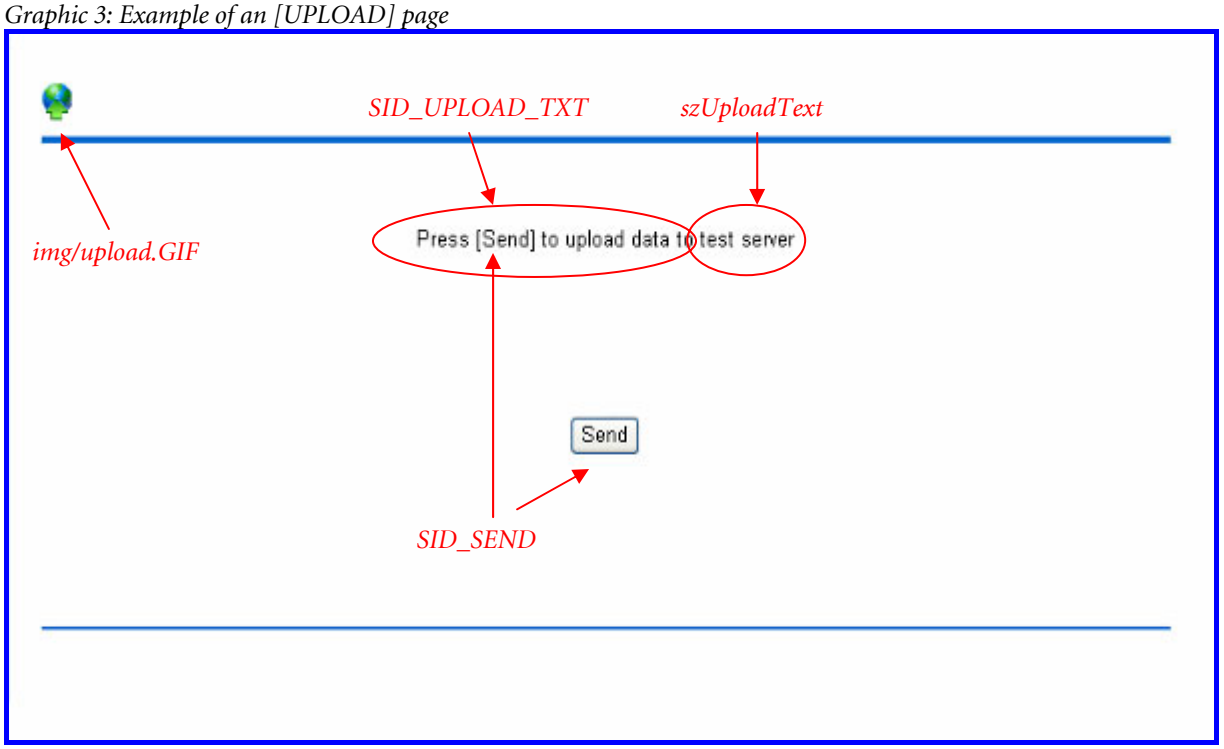
Graphic 2: Top Navigation Bar with Enabled [UPLOAD] Button

3.3. *Principle of the Upload Mechanism of the ACCU-CHEK Smart Pix Device Reader V2.0*

3.3.1. *[UPLOAD] Page with XML Data as "Hidden Fields"*

Pressing the [UPLOAD] button in the top navigation bar opens the [UPLOAD] page (filename: "upload.HTM") which contains all XML data of the uploaded devices as "Hidden-Fields." For security reasons, the XML files(s) do not contain any personal patient information, such as name, birthday, etc. Instead, each XML file contains the unique ACCU-CHEK Smart Pix device reader's number and the unique bG meter/insulin pump device ID number.

Graphic 3: Example of an [UPLOAD] page



The following text strings are available on the ACCU-CHEK Smart Pix device reader in more than 30 languages. Dependent on the language setting of the ACCU-CHEK Smart Pix device reader, they will be used for the dialogue:

Name	**Content**
SID_SEND	Label for the [SEND] button on the upload page
SID_UPLOAD_TEXT	Text for the upload page. Contains a reference to the upload target (szUploadText), e.g. "Press [SEND] to upload data to test server "

3.3.2. *Method of Data Transmission*

The [SEND] button submits the [UPLOAD] page (upload.HTM) to the URL defined in the parameter szUploadWebURL in the setup process.

The following method is used for the upload: **HTTP-Post-Method.**

The upload complies with the following standards which are supported by the main internet browsers (MS-IE, Firefox):

Method = " **POST**"
Enctype = "**application/x-www-form-urlencoded**"
Accept-charset = "**ISO-8859-1**"

To increase the security of the electronic data transfer, also **HTTPS-Post-Method** can be used (a security certificate needs to be allocated to the Web server). As a result, any information exchanged with this site cannot be viewed by anyone else on the Web. The user will be asked to confirm the security certificate and to identify him-/herself with a user name and password before the upload process.

3.3.3. *Server Interface*

The [UPLOAD] page submits the following form parameters to the Web server:

Name	**Description**
BGFILE	Name of the XML file containing blood glucose data
BGDATA	Content of the blood glucose XML file
IPFILE	Name of the XML file containing insulin pump data
IPDATA	Content of the insulin pump XML file

The following HTML form is used for the upload (example – XML data shortened). The upload URL is taken from the parameter szUploadWebURL defined in the customization process of the ACCU-CHEK Smart Pix device reader:

```
<html>
<head>
<title>ACCU-CHEK Smart Pix MID_UPLOAD</title>
</head>
<body>
<p style="margin-top: 50px; text-align: center">Press [SEND] to upload data to
test server.</p>
<form style="margin-top: 100px; margin-bottom: 104px; text-align: center"
action="http://62.157.175.170/wsmartpix.dll/data"
method="POST"
enctype="application/x-www-form-urlencoded"
accept-charset="ISO-8859-1">
```

```
<input type="hidden" name="BGFILE" value="G0003101.XML"
<input type="hidden" name="BGDATA" value="<?xml version="1.0" .... </xml>">
<input type="hidden" name="IPFILE" value=""
<input type="hidden" name="IPDATA" value="">
<input type="submit" name="SendButton" value="Send">
</form>
<body>
</html>
```

Content of the XML file as described in Point 4

In all cases, 4 parameters (BGFile, BGData, IPFile, IPData) are transmitted. If no blood glucose or insulin pump data are available, the according values are empty. The used file names are identical to the file names on the ACCU-CHEK Smart Pix file system (G*.XML/I*.XML). The server may use these file names or rename the files before storing or processing.

The ACCU-CHEK Smart Pix device reader has no influence on the answering page after pressing on the [SEND] button. This is the sole responsibility of the Web server.

4. ACCU-CHEK Smart Pix Device Reader - XML File Specifications

4.1. Formats

4.1.1. XML file

The XML file in general shall be a well formed and valid XML file. An internal document type definition (DTD) is supplied for validation. The file complies with the following standards by the World Wide Web Consortium (W3C):

- Extensible Markup Language (XML) 1.0 (Third Edition) - W3C Recommendation 04 February 2004 (http://www.w3.org/TR/2004/REC-xml-20040204).

4.1.2. Date and Time

Dates (calendar dates) format: "YYYY-MM-DD." E.g.: "2005-12-31"

Time is formatted in 24-hour format: "HH:MM:SS." E.g.: "19:31:00"

4.1.3. BG Values

bG values are given either in mmol/l (format "#0.0") or mg/dl (format "##0"). If a bG value is not available, "—" is given. bG values above and below measurement limits are given as "HI" or "LO."

4.1.4. Insulin and Carbohydrates Values

Insulin values shall use the format "#0.0." Exception: Basal rate IU data format "#0.00."

4.1.5. Flags

Flag information is given as 1 character: "A," "B," "D," "E," "M," "T." AST-Flag is given as "*."

A = above target range (only by control tests to verify testing accuracy of the bG device), B = below target range (control tests only), D = test was done with an used test strip drum, E = expired test strip, M = manually entered, T = temperature warning.

4.1.6. Events

Event information is numeric, format "#0."

4.1.7. Special Events

Special event information (meal, Hsym) is given as: M1, M3 = Meal with the meaning 1=before and 3=after main meal. Hy = hypo symptoms (feel hypo). Can be entered in some ACCU-CHEK bG devices and saved in the memory.

4.2. XML File Structure

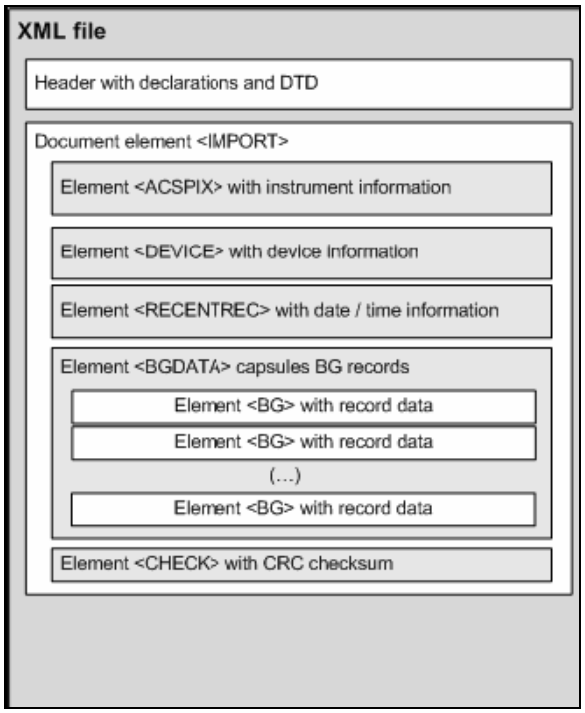
4.2.1. General Structure of XML file

The XML file consists of a header and a data part. The header consists of XML and Stylesheet declarations and an internal document type definition (DTD). In the data part of the file the outer document element <IMPORT> contains the following elements:

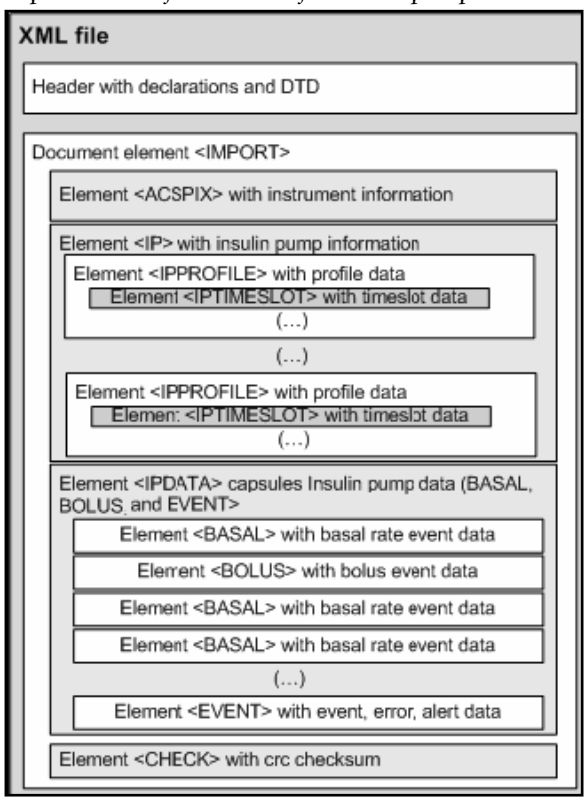
<ACSPIX> with ACSPIX instrument information	
For meters and diary devices: <**DEVICE**> with meter or diary device information for each loaded meter <**RECENTREC**> date/time of recent loaded record (measurement order, not according date/time stamp)	*For insulin pumps:* <**IP**> with insulin pump information containing profile information in <**IPPROFILE**> elements which contain <**IPTIMESLOT**> elements
<**BGDATA**> containing downloaded bG records in <**BG**> elements	<**IPDATA**> containing downloaded pump records in <**BASAL**>, <**BOLUS**>, <**TBR**> and <**EVENT**> elements
<**CHECK**> with a crc checksum	

Attributes are not optional if not noted otherwise. Optional attributes must be left out if no fitting data exists.

Graphic 4: XML file structure for meter and diary device data



Graphic 5: XML file structure for insulin pump data



4.2.2. *File Header*

The file header consists of XML declaration, reference to Stylesheet and internal document type definition (DTD).

- XML declaration:

```
<?xml version="1.0" encoding="ISO-8859-1" ?>
```

- Reference to Stylesheet:

```
<?xml-stylesheet type="text/xsl" href="ACSPIXMT.xsl" ?>
```

- Internal Document Type Definition (DTD):

```
<!DOCTYPE IMPORT [
<!ELEMENT IMPORT (ACSPIX, DEVICE+, RECENTREC, BGDATA, CHECK)>
<!ELEMENT ACSPIX  EMPTY>
<!ATTLIST ACSPIX
 Type  CDATA #REQUIRED
 SN  CDATA #REQUIRED
 Ver  CDATA #REQUIRED
>
<!ELEMENT DEVICE EMPTY>
<!ATTLIST DEVICE
 Name  CDATA #REQUIRED
 SN  CDATA #REQUIRED
 Dt  CDATA #REQUIRED
 Tm  CDATA #REQUIRED
 BGUnit CDATA #REQUIRED
 TrgLo CDATA #IMPLIED
 TrgHi CDATA #IMPLIED
 Hypo  CDATA #IMPLIED
 TmBins CDATA #IMPLIED
>
<!ELEMENT RECENTREC EMPTY>
<!ATTLIST RECENTREC
 Dt  CDATA #REQUIRED

 Tm  CDATA #REQUIRED
>
<!ELEMENT BG  (#PCDATA)>
<!ATTLIST BG
 Val  CDATA #REQUIRED
 Dt  CDATA #IMPLIED
 Tm  CDATA #IMPLIED
 Flg  CDATA #IMPLIED
 Ctrl  CDATA #IMPLIED
 Carb  CDATA #IMPLIED
 Ins1  CDATA #IMPLIED
 Ins2  CDATA #IMPLIED
 Ins3  CDATA #IMPLIED
 Evt  CDATA #IMPLIED
 D  CDATA #IMPLIED
>
<!ELEMENT BGDATA (BG*)>
<!ELEMENT CHECK EMPTY>
<!ATTLIST CHECK
 CRC  CDATA #REQUIRED
>
]>
```

4.2.3. Document Element IMPORT

This is the element that capsules all other elements as mentioned in the following sub-points.

Example:

```
<IMPORT>
[…]
</IMPORT>
```

4.2.3.1. Element ACSPIX

This is an empty element with this information in attributes:

- Type: Model type number of ACSPIX
- SN: Serial number of ACSPIX
- Ver: Software version

Example:

```
<ACSPIX Type="2106" SN="UI00001317" Ver="2.00.00"/>
```

4.2.3.2. Element DEVICE

This is an empty element that is used for meter and diary devices only. It exists for each loaded meter. Order of <DEVICE> elements is order of loading meters. The <IP> element must be used for pumps.

The element <DEVICE> describes meter and diary devices with these information in attributes:

- Name Name of device
- SN: Serial number of device
- Dt Current date of device (date of download); if date is not valid attribute is filled with "—"
- Tm: Current time of device (time of download); if time is not valid attribute is filled with "—"
- BGUnit: Unit used by the device for bG values (mmol/L or mg/dL)
- TrgLo: Low border of target range (is supported by the device, e.g. diary device ACCU-CHEK Pocket Compass - PoCo)
- TrgHi: Upper border of target range (if PoCo)
- Hypo: Hypo threshold on device (if PoCo)
- TmBins Comma separated list of start times of time bins for data evaluation (if PoCo)

Examples 1:

```
<DEVICE Name="Aviva" SN="12345678901" Dt="2005-08-31" Tm="15:38" Unit="mmol/L"/>
```

Example 2:

```
<DEVICE Name="PoCo" SN="86488865" Dt="2005-09-07" Tm="11:34" BGUnit="mg/dL"
TrgLo="70" TrgHi="175" Hypo="55" TmBins="05:30, 08:00, 11:00, 12:30, 17:00, 18:30,
21:30, 00:00"/>
```

4.2.3.3. Element RECENTREC

This element contains date/time of the recent record. Recent record is not necessarily the youngest one. It is the record of the last done measurement which has date/time.

Attributes:

- Dt: Date of the most recent record. If date is invalid, Dt="—" is used
- Tm: Time of the most recent record. If time is invalid, Tm="—" is used

Example:

```
<RECENTREC Dt="2007-04-03" Tm="11:07"/>
```

4.2.3.4. Element IP (Insulin Pump only)

This element is used for insulin pumps and describes the pump (equivalent to the element <DEVICE> in XML files containing data from bG meters and diary devices)

The IP element can contain <IPPROFILE> elements.

The IP element has this information in it's attributes:

- IP Name Model name of the insulin pump
- Type Pump type
- SN Serial number of pump
- Dt Current date of pump (date of download); if date is not valid attribute is filled with "—"
- Tm Current time of pump (date of download); if time is not valid attribute is filled with "—"
- RestUseDays Remaining usage time of pump in days
- ActiveProf Active profile

Example (<IPPROFILE> elements abbreviated):

```
<IP Name="AC Spirit" Type="4711" SN="12345678901" Dt="2004-11-19" Tm="18:21:00"
RestUseDays="245" ActiveProf="1"> <IPPROFILE Name="1" […]/> <IPPROFILE Name="2"
[…]/> <IPPROFILE Name="3" […]/> </IP>
```

4.2.3.5. Element IPPROFILE (Insulin Pump only)

This element is contained in elements <IP> and describes profile settings. It also contains <IPTIMESLOT> elements

- Name Profile name (for D-TRON: "A," "B"; for Spirit "1," "2," "3," "4," "5"; "0" not running)
- Active "1" if profile is active, "0" if not
- IUday Insulin units in 24 hours

Example (<IPTIMESLOT> elements abbreviated):

```
<IPPROFILE Name="A" Active="1" IUday="17.7" > <IPTIMESLOT Number="1" […]/>
<IPTIMESLOT Number="2" […]/> <IPTIMESLOT Number="3" […]/> <IPTIMESLOT Number="4"
[…]/> […] </IPPROFILE>
```

4.2.3.6. Element IPTIMESLOT (Insulin Pump only)

This empty element is contained in <IPPROFILE> elements and describes timeslot settings of the profile in attributes.

- Number Timeslot number
- IU Insulin units per hour

Example (<IPTIMESLOT> elements abbreviated):

```
<IPTIMESLOT Number="1" IU="0.7"/>
```

4.2.3.7. Element BGDATA

This element is used only for meter and diary device data. It capsules the <BG> elements that contain the downloaded bG information. For insulin pump data the <IPDATA> element will be used.

Example (<BG> elements abbreviated):

```
<BGDATA <BG […]/> <BG […]/> <BG […]/> <BG […]/> <BG […]/> […]/>
```

4.2.3.8. Element BG

This is a sub-element of the BGDATA element and contains the downloaded data records. It is an empty element and contains information in these attributes:

- Val bG value depending on meter settings either in mmol/L or mg/dL
- Dt Date of measurement (if device has information)
- Tm Time of measurement (if device has information)
- Flg Flag information (if device has information)
- Ctrl Control: this is set to "1" when measurement was a control measurement
- Carb Carbohydrates (if device has information)
- Ins1 Insulin 1 (if device has information)
- Ins2 Insulin 2 (if device has information)
- Ins3 Insulin 3 (if device has information)
- Evt Event (if device has information); if more than one event separate with commata
- D Specifies from which device this record is loaded (n=1..3). With the ACCU-CHEK Smart Pix device reader V2.0 it is possible to upload and merge bG values from multiple bG meters.

Examples:

```
<BG Val="123" Dt="2005-04-27" Tm="11:14" Flg="M1, Hy, M" Carb="45" Ins1="5.0"
Ins3="1.0" Evt="29, 31" D="1"/>

<BG Val="10.1" Dt="2004-11-19" Tm="18:21" Ctrl="1" D="1"/>
```

Remark: In some regional settings (e.g. German) the bG Value "10.1" is interpreted as 10th of January when imported into the MS Excel spreadsheet program. This can be avoided by changing the MS Excel setting decimal separator from ,"" to ."" before importing.

4.2.3.9. Element IPDATA (Insulin Pump only)

This is the element that capsules the <BASAL>, <BOLUS> or <EVENT> elements that contain the downloaded insulin pump information. For meter and diary device data the <BGDATA> element will be used.

Example (<BASAL>, <BOLUS> and <EVENT> elements abbreviated):

```
<IPDATA >
    <BASAL […]/>
    <BASAL […]/>
    <BOLUS […]/>
    <EVENT […]/>
    <EVENT […]/>
    <BASAL […]/>
    […]
</IPDATA>
```

4.2.3.10. Element BASAL (Insulin Pump only)

This is a sub-element of the <IPDATA> element and contains the downloaded basal rate information including temporary basal rate changes.

It is an empty element and contains information in these attributes:

- Dt depending on settings (date format), year depends also on settings in case of Advantage
- Tm start time on every change or at full hour
- cbrf current basal rate flow; this value must reflect the influence of a TBR increase or decrease; e.g.: if the programmed basal flow is 0.50 IU/h and the TBR is 80% then the value 0.40 IU/h must be given.
- profile name of profile
- TBRinc percentage of TBR increase (only if TBR increase), with 20% relative increase the value 120% should be given (so values must be above 100% in any case)
- TBRdec percentage of TBR decrease (only if TBR decrease) , with 20% relative decrease the value 80% should be given (so values must be below 100% in any case)
- remark gives duration of TBR, optional for non TBR

Example 1:

```
<BASAL Dt="2005-05-29" Tm="18:00:00" cbrf="0.50" profile="A"/>
```

Example 2:

```
<BASAL Dt="2005-06-25" Tm="00:04" cbrf="0.00" profile="0" remark="Stop"/>
```

Example 3:

```
<BASAL Dt="2005-05-29" Tm="18:00:00" cbrf="0.45" profile="A" TBRdec="90%"
remark="dur 01:00 h"/>
```

4.2.3.11. Element BOLUS (Insulin Pump only)

This is a sub-element of the IPDATA element and contains the downloaded bolus information.
It is an empty element and contains information in these attributes:

- Dt — Depending on settings (date format), year depends also on settings in case of Advantage
- Tm — Start time on every change
- amount — Actual delivered bolus amount (only bolus)
- type — Standard, scroll, extended, multiwave (only bolus); values to be used are "Std," "Scr," "Ext," "Mul," not needed when Tm has values "total" or "day total" (special functions for daily sums; see above)
- remark — Remark for bolus: duration of extended or multiwave, bolus amount of multiwave. special function 1: when remark has the value "Bolus Total" the actual delivered 24-hours-total bolus amount of IU will be given (sum of bolus deliveries of the day). The Tm attribute is empty in that case. Special function 2: when remark has the value "Bolus+Basal Total" the actual delivered 24-hours-total amount of IU will be given (sum of basal hourly rates of the day plus sum of bolus amount). This value shall be calculated by ACSPIX. The Tm attribute is empty in that case.

Example:

```
<BOLUS Dt="2005-05-29" Tm="18:21:00" amount="7.5" type="ex" remark="0:45 h"/>
```

Example for special function 1 (Tm and bolus type omitted):

```
<BOLUS Dt="2005-06-24" Tm="" type="" amount="20.30" remark="Bolus Total"/>
```

Example for special function 2 (Tm and bolus type omitted):

```
<BOLUS Dt="2005-06-24" Tm="" type="" amount="43.06" remark="Bolus+Basal Total"/>
```

4.2.3.12. Element EVENT (Insulin Pump only)

This is a sub-element of the IPDATA element and contains the downloaded event data. It is an empty element and contains information in these attributes:

- Dt — Year depends also on settings in case of Advantage
- Tm — Start time on every occurrence
- shortinfo — Number of error or alert, prime volume, time shift forwards
- description — Detailed description of event (optional)

Example:

```
<EVENT Dt="2005-05-29" Tm="18:21:00" shortinfo="E4" description="occlusion"/>
```

4.2.3.13. Element CHECK CRC

This is an empty element that holds a CRC number of the file in the attribute CRC. The CRC-16 CCITT method with reflection shall be used. All lines of the file are included in calculation with exception of CRC-Line. CRC algoritm (same as pumps uses):

Width: 16 bit Polynom: 0x1021 Init: 0xFFFF Reflect In: yes Reflect Out: yes XOR out: 0x0000

Example:

```
<CHECK CRC="4711"/>
```

5. Server Extension

5.1. Server Requirements

- Web Server (Windows or Linux)
- Ability to receive data traffic of min 100kByte
- Definition of target URL for data upload (Domain or IP)
  - Domain:
    Example ISAPI: http\\server.de\smartpix\getdata.dll?GetData
    Example CGI: http:\\server.de\smartpix\getdata.exe?GetData
    Example PHP: http\\server.de\smartpix\getdata.php?GetData
  - IP:
    Example PHP: http\\123.456.789.001\smartpix\getdata.dll?GetData
- The Web server should be able to receive XML data sent per POST-METHOD on the client site

5.2. Functionality of the Server Receiving Module

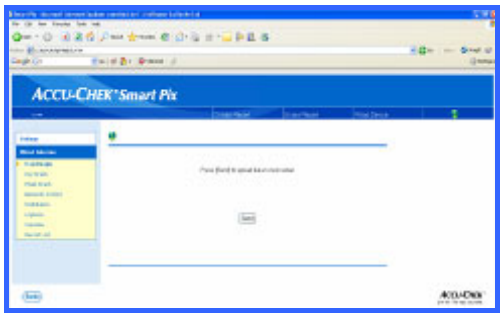
- Receive and temporarily save the Post-data
- Extract data fields (BGFile, BGData, IPFile, IPData)
- Interpret XML-data
- Send HTML response to client (Smart Pix)

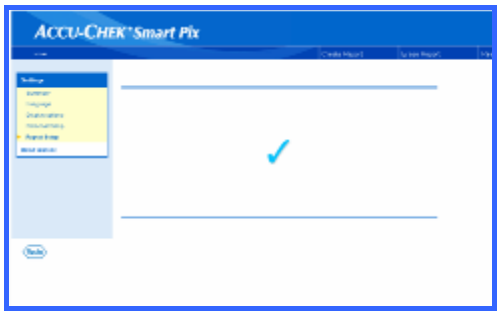
An example of codes for a basic server receiving module is available on request.

5.3. Functionality of the Data Utilization Module

The functionality of the data utilization module of the server extension is to present and utilize the data on the Web platform according to customer's needs (data presentation as graphs, tables, reports, possibility to add comments, edit data...). On request, Roche might support the customer to adapt the visualization of the data on the Web platform to the graphs used in the ACCU-CHEK Smart Pix device.

6. Summary of the Steps in the Upload Process (Example)

Step	Client (ACCU-CHEK Smart Pix V2.0)	Web Server
1. Configuration/ Customization	Writing SETTINGS.TXT file and saving it into the FAT system of the ACCU-CHEK Smart Pix device Examples of URL definition: http://198.157.175.170/wsmartpix.dll/data https://198.157.175.170/wsmartpix.dll/data	Programming of the Web server extension (DLL, EXE, PHP,..)
2. Begin Session Initiate Upload	 By pressing on the [SEND] button, the collected device data (XML file) will be submitted to the Web server via HTTP or HTTPS- Post-Method. The ACCU-CHEK Smart Pix device reader has no influence on the answering page after pressing on the [SEND] button. This is sole responsibility of the Web server.	Waiting for data…
3. Data-transmission		Receive and temporarily save the post-data. Extract data fields (BGFile, BGData, IPFile, IPData) Verify correctness Send HTML response to Client (transmission status)

4. Response from Server	 Client receives a response confirming the transmission status	

Appendix

XML File (Example bG Meter ACCU-CHEK Compact Plus)

File name : G0509597.XML

```
<?xml version="1.0" encoding="ISO-8859-1" ?>
<?xml-stylesheet type="text/xsl" href="ACSPIXMT.xsl" ?>

<!DOCTYPE IMPORT [
<!ELEMENT IMPORT (ACSPIX, DEVICE+, RECENTREC, BGDATA, CHECK)>
<!ELEMENT ACSPIX  EMPTY>
<!ATTLIST ACSPIX
 Type  CDATA #REQUIRED
 SN  CDATA #REQUIRED
 Ver  CDATA #REQUIRED
>
<!ELEMENT DEVICE EMPTY>
<!ATTLIST DEVICE
 Name  CDATA #REQUIRED
 SN  CDATA #REQUIRED
 Dt  CDATA #REQUIRED
 Tm  CDATA #REQUIRED
 BGUnit CDATA #REQUIRED
 TrgLo CDATA #IMPLIED
 TrgHi CDATA #IMPLIED
 Hypo  CDATA #IMPLIED
 TmBins CDATA #IMPLIED
>
<!ELEMENT RECENTREC EMPTY>
<!ATTLIST RECENTREC
 Dt  CDATA #REQUIRED
 Tm  CDATA #REQUIRED
>
<!ELEMENT BG  (#PCDATA)>
<!ATTLIST BG
 Val  CDATA #REQUIRED
 Dt  CDATA #IMPLIED
 Tm  CDATA #IMPLIED
 Flg  CDATA #IMPLIED
 Ctrl  CDATA #IMPLIED
 Carb  CDATA #IMPLIED
 Ins1  CDATA #IMPLIED
 Ins2  CDATA #IMPLIED
 Ins3  CDATA #IMPLIED
 Evt  CDATA #IMPLIED
 D  CDATA #IMPLIED
>
<!ELEMENT BGDATA (BG*)>
<!ELEMENT CHECK EMPTY>
<!ATTLIST CHECK
 CRC  CDATA #REQUIRED
>
]>

<IMPORT>
<ACSPIX Type="2106" SN="UI00100344" Ver="0.44.00"/>
<DEVICE Name="Compact+" SN="00509597" Dt="2007-08-01" Tm="15:21" BGUnit="mmol/L"/>
<RECENTREC Dt="2007-06-29" Tm="07:30"/>
<BGDATA>
<BG Val="11.7" Dt="2007-06-29" Tm="07:30" D="1"/>
<BG Val="9.9" Dt="2007-06-29" Tm="01:01" D="1"/>
<BG Val="9.4" Dt="2007-06-28" Tm="20:00" D="1"/>
<BG Val="3.9" Dt="2007-06-28" Tm="17:45" D="1"/>
```

```
<BG Val="3.6" Dt="2007-06-28" Tm="15:00" D="1"/>

<BG Val="2.2" Dt="2007-06-28" Tm="12:27" D="1"/>
<BG Val="16.6" Dt="2007-06-28" Tm="10:18" D="1"/>
<BG Val="17.2" Dt="2007-06-28" Tm="07:37" D="1"/>
<BG Val="10.4" Dt="2007-06-28" Tm="01:10" D="1"/>
<BG Val="3.9" Dt="2007-06-27" Tm="22:00" D="1"/>
<BG Val="3.9" Dt="2007-06-27" Tm="20:10" D="1"/>
<BG Val="4.7" Dt="2007-06-27" Tm="17:27" D="1"/>
<BG Val="3.7" Dt="2007-06-27" Tm="15:17" D="1"/>
<BG Val="1.8" Dt="2007-06-27" Tm="12:25" D="1"/>
<BG Val="16.6" Dt="2007-06-27" Tm="10:05" D="1"/>
<BG Val="17.6" Dt="2007-06-27" Tm="07:41" D="1"/>
<BG Val="12.2" Dt="2007-06-27" Tm="00:05" D="1"/>
<BG Val="11.1" Dt="2007-06-26" Tm="19:55" D="1"/>
<BG Val="13.3" Dt="2007-06-26" Tm="17:45" D="1"/>
<BG Val="6.1" Dt="2007-06-26" Tm="16:10" D="1"/>
<BG Val="2.7" Dt="2007-06-26" Tm="12:25" D="1"/>
<BG Val="1.7" Dt="2007-06-26" Tm="10:30" D="1"/>
<BG Val="4.6" Dt="2007-06-26" Tm="07:45" D="1"/>
<BG Val="2.8" Dt="2007-06-26" Tm="00:05" D="1"/>
<BG Val="10.0" Dt="2007-06-25" Tm="20:05" D="1"/>
<BG Val="6.0" Dt="2007-06-25" Tm="17:55" D="1"/>
<BG Val="2.7" Dt="2007-06-25" Tm="15:20" D="1"/>
<BG Val="3.0" Dt="2007-06-25" Tm="12:27" D="1"/>
<BG Val="14.4" Dt="2007-06-25" Tm="10:05" D="1"/>
<BG Val="14.3" Dt="2007-06-25" Tm="07:40" D="1"/>
<BG Val="3.3" Dt="2007-06-25" Tm="00:07" D="1"/>
<BG Val="8.3" Dt="2007-06-24" Tm="20:05" D="1"/>
<BG Val="6.7" Dt="2007-06-24" Tm="17:45" D="1"/>
<BG Val="4.4" Dt="2007-06-24" Tm="15:00" D="1"/>
<BG Val="3.5" Dt="2007-06-24" Tm="12:28" D="1"/>
<BG Val="16.6" Dt="2007-06-24" Tm="10:05" D="1"/>
<BG Val="18.5" Dt="2007-06-24" Tm="07:42" D="1"/>
<BG Val="14.8" Dt="2007-06-24" Tm="00:05" D="1"/>
<BG Val="10.0" Dt="2007-06-23" Tm="20:05" D="1"/>
<BG Val="5.3" Dt="2007-06-23" Tm="17:36" D="1"/>
<BG Val="3.5" Dt="2007-06-23" Tm="15:10" D="1"/>
<BG Val="2.1" Dt="2007-06-23" Tm="12:20" D="1"/>
<BG Val="10.9" Dt="2007-06-23" Tm="10:00" D="1"/>
<BG Val="13.0" Dt="2007-06-23" Tm="07:45" D="1"/>
<BG Val="8.3" Dt="2007-06-23" Tm="00:10" D="1"/>
<BG Val="10.0" Dt="2007-06-22" Tm="20:00" D="1"/>
<BG Val="6.7" Dt="2007-06-22" Tm="17:45" D="1"/>
<BG Val="4.7" Dt="2007-06-22" Tm="15:00" D="1"/>
<BG Val="3.5" Dt="2007-06-22" Tm="12:15" D="1"/>
<BG Val="6.0" Dt="2007-06-22" Tm="11:00" D="1"/>
<BG Val="12.2" Dt="2007-06-22" Tm="10:00" D="1"/>
<BG Val="12.3" Dt="2007-06-22" Tm="07:50" D="1"/>
<BG Val="7.6" Dt="2007-06-22" Tm="01:01" D="1"/>
<BG Val="8.6" Dt="2007-06-21" Tm="21:32" D="1"/>
<BG Val="9.0" Dt="2007-06-21" Tm="17:32" D="1"/>
<BG Val="4.5" Dt="2007-06-21" Tm="15:20" D="1"/>
<BG Val="2.6" Dt="2007-06-21" Tm="12:20" D="1"/>
<BG Val="13.9" Dt="2007-06-21" Tm="10:00" D="1"/>
<BG Val="16.8" Dt="2007-06-21" Tm="07:40" D="1"/>
<BG Val="7.8" Dt="2007-06-21" Tm="06:58" D="1"/>
<BG Val="14.3" Dt="2007-06-21" Tm="00:05" D="1"/>
<BG Val="7.8" Dt="2007-06-20" Tm="19:45" D="1"/>
<BG Val="2.8" Dt="2007-06-20" Tm="17:45" D="1"/>
<BG Val="2.6" Dt="2007-06-20" Tm="15:15" D="1"/>
<BG Val="6.0" Dt="2007-06-20" Tm="12:30" D="1"/>
<BG Val="2.8" Dt="2007-06-20" Tm="10:30" D="1"/>
</BGDATA>
```

```
<CHECK CRC="1F61"/>
</IMPORT>
```

XML File (Example Insulin Pump ACCU-CHEK Spirit)

File name : I2066053.XML

```
<?xml version="1.0" encoding="ISO-8859-1" ?>
<?xml-stylesheet type="text/xsl" href="ACSPIXIP.xsl" ?>
<!DOCTYPE IMPORT [
<!ELEMENT IMPORT (ACSPIX, IP, IPDATA, CHECK)>
<!ELEMENT ACSPIX  EMPTY>
<!ATTLIST ACSPIX
 Type  CDATA #REQUIRED
 SN  CDATA #REQUIRED
 Ver  CDATA #REQUIRED
>
<!ELEMENT IP (IPPROFILE*)>
<!ATTLIST IP
 Name  CDATA #REQUIRED
 SN  CDATA #REQUIRED
 Dt  CDATA #REQUIRED
 Tm  CDATA #REQUIRED
 RestUseDays CDATA #REQUIRED
 ActiveProf CDATA #REQUIRED
>

<!ELEMENT IPPROFILE (IPTIMESLOT*)>
<!ATTLIST IPPROFILE
 Name  CDATA #REQUIRED
 Active CDATA #REQUIRED
 IUday CDATA #REQUIRED
>

<!ELEMENT IPTIMESLOT EMPTY>
<!ATTLIST IPTIMESLOT
 Number CDATA #REQUIRED
 IU  CDATA #REQUIRED
>

<!ELEMENT IPDATA ((BASAL|BOLUS|EVENT)*)>

<!ELEMENT BASAL EMPTY>
<!ATTLIST BASAL
 Dt  CDATA #REQUIRED
 Tm  CDATA #REQUIRED
 cbrf  CDATA #REQUIRED
 TBRdec CDATA #IMPLIED
 TBRinc CDATA #IMPLIED
 profile CDATA #IMPLIED
 remark CDATA #IMPLIED
>

<!ELEMENT BOLUS EMPTY>
<!ATTLIST BOLUS
 Dt  CDATA #REQUIRED
 Tm  CDATA #REQUIRED
 type  CDATA #REQUIRED
 amount CDATA #REQUIRED
 remark CDATA #IMPLIED
```

```
>

<!ELEMENT EVENT EMPTY>
<!ATTLIST EVENT


 Dt   CDATA #REQUIRED
 Tm   CDATA #REQUIRED
 shortinfo CDATA #IMPLIED
 description CDATA #IMPLIED
>

<!ELEMENT CHECK EMPTY>
<!ATTLIST CHECK
 CRC  CDATA #REQUIRED
>
]>

<IMPORT>
<ACSPIX Type="2106" SN="UI00100344" Ver="0.44.00"/>
<IP Name="Spirit" SN="02066053 " Dt="2003-01-08" Tm="21:52" RestUseDays="2200"
ActiveProf="1">
<IPPROFILE Name="1" Active="1" IUday="23.6" >
<IPTIMESLOT Number="1" IU="0.7"/>
<IPTIMESLOT Number="2" IU="0.7"/>
<IPTIMESLOT Number="3" IU="0.9"/>
<IPTIMESLOT Number="4" IU="1.2"/>
<IPTIMESLOT Number="5" IU="1.4"/>
<IPTIMESLOT Number="6" IU="1.3"/>
<IPTIMESLOT Number="7" IU="1.1"/>
<IPTIMESLOT Number="8" IU="0.8"/>
<IPTIMESLOT Number="9" IU="0.7"/>
<IPTIMESLOT Number="10" IU="0.7"/>
<IPTIMESLOT Number="11" IU="0.7"/>
<IPTIMESLOT Number="12" IU="0.7"/>
<IPTIMESLOT Number="13" IU="0.7"/>
<IPTIMESLOT Number="14" IU="0.8"/>
<IPTIMESLOT Number="15" IU="0.9"/>
<IPTIMESLOT Number="16" IU="1.0"/>
<IPTIMESLOT Number="17" IU="1.1"/>
<IPTIMESLOT Number="18" IU="1.2"/>
<IPTIMESLOT Number="19" IU="1.4"/>
<IPTIMESLOT Number="20" IU="1.5"/>
<IPTIMESLOT Number="21" IU="1.3"/>
<IPTIMESLOT Number="22" IU="1.1"/>
<IPTIMESLOT Number="23" IU="0.9"/>
<IPTIMESLOT Number="24" IU="0.8"/>
</IPPROFILE>
<IPPROFILE Name="2" Active="0" IUday="0.0" >
<IPTIMESLOT Number="1" IU="0.0"/>
<IPTIMESLOT Number="2" IU="0.0"/>
<IPTIMESLOT Number="3" IU="0.0"/>
<IPTIMESLOT Number="4" IU="0.0"/>
<IPTIMESLOT Number="5" IU="0.0"/>
<IPTIMESLOT Number="6" IU="0.0"/>
<IPTIMESLOT Number="7" IU="0.0"/>
<IPTIMESLOT Number="8" IU="0.0"/>
<IPTIMESLOT Number="9" IU="0.0"/>
<IPTIMESLOT Number="10" IU="0.0"/>
<IPTIMESLOT Number="11" IU="0.0"/>
<IPTIMESLOT Number="12" IU="0.0"/>
<IPTIMESLOT Number="13" IU="0.0"/>
<IPTIMESLOT Number="14" IU="0.0"/>
<IPTIMESLOT Number="15" IU="0.0"/>
```

```
<IPTIMESLOT Number="16" IU="0.0"/>
<IPTIMESLOT Number="17" IU="0.0"/>
<IPTIMESLOT Number="18" IU="0.0"/>
<IPTIMESLOT Number="19" IU="0.0"/>
<IPTIMESLOT Number="20" IU="0.0"/>
<IPTIMESLOT Number="21" IU="0.0"/>

<IPTIMESLOT Number="22" IU="0.0"/>
<IPTIMESLOT Number="23" IU="0.0"/>
<IPTIMESLOT Number="24" IU="0.0"/>
[…]
</IPPROFILE>
<IPPROFILE Name="5" Active="0" IUday="0.0" >
<IPTIMESLOT Number="1" IU="0.0"/>
<IPTIMESLOT Number="2" IU="0.0"/>
<IPTIMESLOT Number="3" IU="0.0"/>
<IPTIMESLOT Number="4" IU="0.0"/>
<IPTIMESLOT Number="5" IU="0.0"/>
<IPTIMESLOT Number="6" IU="0.0"/>
<IPTIMESLOT Number="7" IU="0.0"/>
<IPTIMESLOT Number="8" IU="0.0"/>
<IPTIMESLOT Number="9" IU="0.0"/>
<IPTIMESLOT Number="10" IU="0.0"/>
<IPTIMESLOT Number="11" IU="0.0"/>
<IPTIMESLOT Number="12" IU="0.0"/>
<IPTIMESLOT Number="13" IU="0.0"/>
<IPTIMESLOT Number="14" IU="0.0"/>
<IPTIMESLOT Number="15" IU="0.0"/>
<IPTIMESLOT Number="16" IU="0.0"/>
<IPTIMESLOT Number="17" IU="0.0"/>
<IPTIMESLOT Number="18" IU="0.0"/>
<IPTIMESLOT Number="19" IU="0.0"/>
<IPTIMESLOT Number="20" IU="0.0"/>
<IPTIMESLOT Number="21" IU="0.0"/>
<IPTIMESLOT Number="22" IU="0.0"/>
<IPTIMESLOT Number="23" IU="0.0"/>
<IPTIMESLOT Number="24" IU="0.0"/>
</IPPROFILE>
</IP>
<IPDATA>
<BOLUS Dt="2005-06-08" Tm="" type="" amount="1.50" remark="Bolus Total"/>
<BOLUS Dt="2005-06-08" Tm="" type="" amount="3.74" remark="Bolus+Basal Total"/>
<BASAL Dt="2005-06-08" Tm="02:57" cbrf="0.00" remark="power up"/>
<BASAL Dt="2005-06-08" Tm="02:56" cbrf="0.00" remark="power down"/>
<BASAL Dt="2005-06-08" Tm="02:56" cbrf="0.00" remark="Stop"/>
<BOLUS Dt="2005-06-08" Tm="02:56" type="Std" amount="1.50"/>
<EVENT Dt="2005-06-08" Tm="02:54" shortinfo="A2" description="battery low"/>
<BASAL Dt="2005-06-08" Tm="02:00" cbrf="0.90" profile="1"/>
<BASAL Dt="2005-06-08" Tm="00:00" cbrf="0.70" profile="1"/>
<BOLUS Dt="2005-06-07" Tm="" type="" amount="13.00" remark="Bolus Total"/>
<BOLUS Dt="2005-06-07" Tm="" type="" amount="36.60" remark="Bolus+Basal Total"/>
<BASAL Dt="2005-06-07" Tm="23:00" cbrf="0.80" profile="1"/>
<BASAL Dt="2005-06-07" Tm="22:00" cbrf="0.90" profile="1"/>
[...]
<BASAL Dt="2005-05-03" Tm="17:05" cbrf="0.00" remark="changed 1"/>
<BASAL Dt="2005-05-03" Tm="17:02" cbrf="0.00" remark="changed 1"/>
<BASAL Dt="2005-05-03" Tm="15:59" cbrf="0.00" remark="changed 1"/>
<BASAL Dt="2005-05-03" Tm="15:43" cbrf="0.00" remark="changed 1"/>
<BASAL Dt="2005-05-03" Tm="14:52" cbrf="0.00" remark="changed 1"/>
<BASAL Dt="2005-05-03" Tm="14:51" cbrf="0.00" remark="changed 1"/>
<BASAL Dt="2005-05-03" Tm="14:51" cbrf="0.00" remark="time/date set"/>
<BASAL Dt="2005-05-03" Tm="14:51" cbrf="0.00" remark="time/date corrected"/>
<BASAL Dt="2005-05-03" Tm="14:50" cbrf="0.00" remark="time/date set"/>
<BOLUS Dt="2003-01-01" Tm="" type="" amount="0.00" remark="Bolus Total"/>
```

```
<BASAL Dt="2003-01-01" Tm="14:04" cbrf="0.00" remark="time/date corrected"/>
<EVENT Dt="2003-01-01" Tm="14:02" shortinfo="E10" description="cartridge error"/>
<BASAL Dt="2003-01-01" Tm="14:02" cbrf="0.00" remark="time/date set (time shift
back)"/>
</IPDATA>
<CHECK CRC="1A18"/>
</IMPORT>
```

XML File – User Friendly View (Example bG Meter ACCU-CHEK Aviva)

File name : G8009222.XML