# Declaration of Conformity
# Deklaracja Zgodności

Manufacturer:
*Producent:*

**ASPEL S.A**
**os. H. Sienkiewicza 33**
**PL 32-080 Zabierzów**
**Polska / Poland**

Digitally signed by Ceaicovschi Tudor
Date: 2021.06.30 15:37:16 EEST
Reason: MoldSign Signature
Location: Moldova

We declare under our sole responsibility that
*Deklarujemy na naszą wyłączną odpowiedzialność, że*

the medical device:
*urządzenie medyczne*:

**Long term, ECG signal recorder**
**Rejestrator długotrwałych zapisów EKG**

models:

**AsPEKT 712**

of class:
*klasa*

IIa, rule 10, paragraph 4 according to Annex IX of directive 93/42/EEC
IIa, reguła 10, akapit 4 zgodnie z Aneksem IX dyrektywy 93/42/EEC oraz zgodnie z Rozporządzeniem Ministra Zdrowia z dnia 5 listopada 2010 r. (Dz.U.2010, Nr 215, poz. 1416).

covered by production series:
*objęte serią produkcyjną:*

ZP/33/2019

and listed in:
i wymienione w:

.....

meets all provisions of the directive 93/42/EEC which apply to it.
*spełnia wszystkie postanowienia dyrektywy 93/42/EEC, ustawy z dnia 20 maja 2010 r. o wyrobach medycznych (Dz.U.2010, Nr 107, poz. 679) oraz wymagania załącznika 1 Rozporządzenia Ministra Zdrowia z dnia 19 lutego 2016 r. (Dz.U.2016,poz. 211), które go dotyczą.*

Conformity assessment procedure:
*Procedura oceny zgodności:*

Annex II without section 4 of directive 93/42/EEC.
*Annex II z wyłączeniem punktu 4 dyrektywy 93/42/EEC oraz załącznik nr 2 Rozporządzenia Ministra Zdrowia z dnia 19 lutego 2016 r. (Dz.U.2016, poz. 211).*

EC Certificate No.:
*Certyfikat EC nr:*

HD 60144443 0001

Notified Body:
*Jednostka notyfikowana:*

**Notified Body No. 0197**
**TÜV Rheinland LGA Products GmbH**
**Tillystraße 2**
**D-90431 Nürnberg**
**Germany**

CE 0197

Zabierzów, 2020-02-19

PREZES ZARZĄDU
dr Andrzej Mleśniowski

# Declaration of Conformity
# Deklaracja Zgodności

| | |
|---|---|
| Manufacturer:<br>*Producent:* | **ASPEL S.A**<br>**os. H. Sienkiewicza 33**<br>**PL 32-080 Zabierzów**<br>**Polska / Poland** |

We declare under our sole responsibility that
*Deklarujemy na naszą wyłączną odpowiedzialność, że*

| | |
|---|---|
| the medical device:<br>*urządzenie medyczne:* | **HolCARD 24W**<br>**HolCARD 24W** |
| models:<br>*modele:* | **Alfa System A712**<br>**Alfa System A712** |
| of class:<br>*klasa* | IIa, rule 10, paragraph 4 according to Annex IX of directive 93/42/EEC<br>IIa, reguła 10, akapit 4 zgodnie z Aneksem IX dyrektywy 93/42/EEC oraz zgodnie z Rozporządzeniem Ministra Zdrowia z dnia 5 listopada 2010 r. (Dz.U.2010, Nr 215, poz. 1416) |
| covered by production series:<br>*objęte serią produkcyjną:* | **ZP/00030/2020** |
| and listed in:<br>i wymienione w: | ..... |

meets all provisions of the directive 93/42/EEC which apply to it.
*spełnia wszystkie postanowienia dyrektywy 93/42/EEC, ustawy z dnia 20 maja 2010 r. o wyrobach medycznych (Dz.U.2010, Nr 107, poz. 679) oraz wymagania załącznika 1 Rozporządzenia Ministra Zdrowia z dnia 19 lutego 2016 r. (Dz.U.2016, poz. 211), które go dotyczą.*

| | |
|---|---|
| Conformity assessment procedure:<br>*Procedura oceny zgodności:* | Annex II without section 4 of directive 93/42/EEC<br>*Annex II z wyłączeniem punktu 4 dyrektywy 93/42/EEC oraz załącznik nr 2 Rozporządzenia Ministra Zdrowia z dnia 19 lutego 2016 r. (Dz.U.2016, poz. 211)* |
| Notified Body:<br>*Jednostka notyfikowana:* | **Notified Body No. 0197**<br>**TÜV Rheinland LGA Products GmbH**<br>**Tillystraße 2**<br>**D-90431 Nürnberg**<br>**Germany** |

CE 0197

Zabierzów, 12.02.2020

PREZES ZARZĄDU
dr Andrzej Wrzesiński

**Specificație Completată**
**Model: ASPEL HOLCARD-712 HLT v.301ALFA; Producător:ASPEL SA; Țara: Polonia.**

| Specificarea tehnică deplină solicitată de către autoritatea contractantă | Specificarea tehnică deplină propusă de către autoritatea contractantă |
|---|---|
| Monitor Holter ECG (caracteristici de baza)<br>Cod 260260<br>Descriere Dispozitivul înregistrează ECG in 12 derivații simultan, nictimeral monitorizind parametrii in timpul repaosului si la efort.<br>Parametrul Specificația<br>Tip pacient adult, pediatric<br>Numărul de canale de procesare 12<br>Configurația Portabil da<br>Derivațiile Tip înregistrare automat<br>Gama de frecvență ≥ 0.05-100 Hz<br>Impendanța de intrare ≥ 50 M Ohm<br>Gama de rejecție a modului comun la 50 Hz ≥ 85 dB<br>Detectare pacemaker da<br>Convertor analog-digital ≥ 12 bit<br>"Frecvența maximă de eșantionare (sampling rate)" de achiziție ≥ 1000 Hz<br>Frecvența ajustabilă da<br>Display LCD da<br>Lumină fundal da<br>Butoane pentru navigare în meniu da<br><br>Identificarea activității pacientului: mers/alergare/repaos prin buton evenimente sau senzor incorporat<br>Posibilitatea transmiterii datelor ECG la PC sau notebook USB / SD-Card / Wi-Fi / BT<br>Greutatea fără accesorii și baterie ≤ 100 gr<br>Protecție în potriva pătrunderii prafului, lichidelor da<br>Baterie Reîncărcabilă da<br>Tip baterie AA / AAA<br>Timp de înregistrare semnal ECG ≥ 72 h<br>Timp operare autonomă ≥ 72 h<br>Indicator deconectare electrod acustic sau vizual da<br>Indicatori vizuali contact slab sau lipsă de contact<br>statut sistem<br>statut baterie<br>deconectare alimentare<br>ora<br>Posibilități Soft PC de interpretare<br>Introducere date pacient ID da<br>Nume, prenume da<br>Data nașterii da<br>Gen da<br>Alte date da<br>Adnotare eveniment ECG da<br>Clasificarea de evenimente da | Monitor Holter ECG (caracteristici de baza) **DA**<br>Cod 260260<br>Descriere Dispozitivul înregistrează ECG in 12 derivații simultan, nictimeral monitorizind parametrii in timpul repaosului si la efort. **DA**<br>Parametrul Specificația<br>Tip pacient adult, pediatric **DA**<br>Numărul de canale de procesare 12 **DA**<br>Configurația Portabil **DA**<br>Derivațiile Tip înregistrare automat **DA**<br>Gama de frecvență ≥ 0.05-100 Hz **DA**<br>Impendanța de intrare ≥ 50 M Ohm **DA**<br>Gama de rejecție a modului comun la 50 Hz ≥ 85 dB **DA**<br>Detectare pacemaker **DA**<br>Convertor analog-digital ≥ 12 bit **DA**<br>"Frecvența maximă de eșantionare (sampling rate)" de achiziție ≥ 1000 Hz **DA**<br>Frecvența ajustabilă **DA**<br>Display LCD **DA**<br>Lumină fundal **DA**<br>Butoane pentru navigare în meniu **DA**<br>**și posibilitatea de navigarea.**<br>Identificarea activității pacientului: mers/alergare/repaos prin buton evenimente sau senzor incorporat **DA**<br>Posibilitatea transmiterii datelor ECG la PC sau notebook USB / SD-Card /BT **DA**<br>Greutatea fără accesorii și baterie - 130 gr **DA**<br>Protecție în potriva pătrunderii prafului **DA**, **lichidelor parțial nu este protecție complet**<br>Baterie Reîncărcabilă **DA**<br>Tip baterie AA **DA**<br>Timp de înregistrare semnal ECG - **maxim 7 zile**<br>Timp operare autonomă **DA 72 h dar de pinde de capitatea memorie si capacitatea acumulatoarelor**<br>Indicator deconectare electrod acustic sau vizual **DA**<br>Indicatori vizuali contact slab sau lipsă de contact **DA**<br>statut sistem **DA**<br>statut baterie **DA**<br>deconectare alimentare **DA**<br>ora **DA**<br>Posibilități<br>Soft PC de interpretare **DA**<br>Introducere date pacient ID **DA**<br>Nume, prenume **DA**<br>Data nașterii **DA** |

| | |
|---|---|
| Analiza ST da<br>QT da<br>PQ da<br>PM da<br>Aretmii da<br>Variabilitate ritm cardiac după timp da<br>Variabilitate ritm cardiac după frecvență da<br>Reprezentarea grafică a datelor da<br>Reprezentarea tabelară a datelor da<br>Raport prestabilit de utilizator da<br>Interfață presetabilită utilizator da<br>Posibilitatea printare raport Tabel da<br>Grafic da<br>Accesorii<br>Cablu ECG 10 fire 2 unități<br>Set de electrozi de unica folosinta adult 500 buc.<br>Set de electrozi de unica folosinta pediatric 500 buc.<br>Soft necesar pentru analiza Holter ECG pe PC inclus cu cheie de acces, licență cu un termen nelimitat de utilizare da<br>Geantă pentru fixarea dispozitivului Holter pe pacient da<br>Cablu pentru transmiterea datelor ECG da<br>Sursa de alimentare pentru reîncărcarea bateriei da | Gen **DA**<br>Alte date **DA**<br>Adnotare eveniment ECG **DA**<br>Clasificarea de evenimente **DA**<br>Analiza ST **DA**<br>QT **DA**<br>PQ **DA**<br>PM **DA**<br>Aretmii **DA**<br>Variabilitate ritm cardiac după timp **DA**<br>Variabilitate ritm cardiac după frecvență **DA**<br>Reprezentarea grafică a datelor **DA**<br>Reprezentarea tabelară a datelor **DA**<br>Raport prestabilit de utilizator **DA**<br>Interfață presetabilită utilizator **DA**<br>Posibilitatea printare raport Tabel **DA**<br>Grafic **DA**<br>Accesorii<br>Cablu ECG 10 fire 2 unități **DA**<br>Set de electrozi de unica folosinta adult 500 buc. **DA**<br>Set de electrozi de unica folosinta pediatric 500 buc. **DA**<br>Soft necesar pentru analiza Holter ECG pe PC inclus cu cheie de acces, licență cu un termen nelimitat de utilizare **DA fără calculator.**<br>Geantă pentru fixarea dispozitivului Holter pe pacient **DA**<br>Cablu pentru transmiterea datelor ECG **DA**<br>Sursa de alimentare pentru reîncărcarea bateriei **DA** |

**Specificație Completată**
**Model: ASPEL HOLCARD-712 HLT v.301ALFA; Producător:ASPEL SA; Țara: Polonia.**

| Specificarea tehnică deplină solicitată de către autoritatea contractantă | Specificarea tehnică deplină propusă de către autoritatea contractantă |
|---|---|
| Monitor Holter ECG (caracteristici avansate)<br>Cod 260270<br>Descriere Dispozitivul înregistrează ECG in 12 derivații simultan, nictimeral monitorizind parametrii in timpul repaosului si la efort.<br>Parametrul Specificația<br>Tip pacient adult, pediatric<br>Numărul de canale de procesare 12<br>Configurația Portabil da<br>Derivațiile Tip înregistrare automat<br>Gama de frecvență De diagnostic 0.05-100 Hz<br>Impendanța de intrare ≥ 100 MOhm<br>Gama de rejecție a modului comun la 50 Hz > 100 dB<br>Detectare pacemaker da<br>Frecvența maximă de eșantionare (sampling rate) de achiziție ≥ 1200 Hz<br>Frecvența ajustabilă da<br>Rezoluția ADC (Convertor Analog/Digital) ≥ 12 bit<br><br>Ecran LCD da<br>lumină fundal da<br>Date ecran ora da<br>statut baterie da<br>Indicator deconectare electrod acustic sau vizual da<br>Buton evenimente da<br>Buton navigare meniu da<br>Blocarea automată a butoanelor da<br>Posibilitatea transmiterii datelor ECG la PC sau notebook USB / SD-Card / Wi-Fi / BT<br>Baterie reîncărcabilă da<br>tip baterie AA sau AAA<br>Tip operare autonomă ≥ 72 h<br>Indicatori vizuali<br>contact slab sau lipsă de contact<br>status sistem<br>deconectare alimentare<br>baterie descărcată<br>Posibilități soft PC de interpretare<br>Introducere date pacient da<br>Adnotare eveniment ECG da<br>Clasificarea de evenimente da<br>Analiza ST da<br>Analiza QT da<br>Analiza PQ da<br>Analiza PM da<br>Analiza aretmiilor da<br>Variabilitate ritm cardiac după timp da<br>Variabilitate ritm cardiac după frecvență da | Monitor Holter ECG (caracteristici avansate) **DA**<br>Cod 260270<br>Descriere Dispozitivul înregistrează ECG in 12 derivații simultan, nictimeral monitorizind parametrii in timpul repaosului si la efort. **DA**<br>Parametrul Specificația<br>Tip pacient adult, pediatric **DA**<br>Numărul de canale de procesare 12 **DA**<br>Configurația Portabil **DA**<br>Derivațiile Tip înregistrare automat<br>Gama de frecvență De diagnostic 0.05-100 Hz **DA**<br>Impendanța de intrare ≥ 100 MOhm **DA**<br>Gama de rejecție a modului comun la 50 Hz > 100 dB **DA**<br>Detectare pacemaker **DA**<br>Frecvența maximă de eșantionare (sampling rate) de achiziție ≥ 1200 Hz **DA**<br>Frecvența ajustabilă **DA**<br>Rezoluția ADC (Convertor Analog/Digital) ≥ 12 bit **DA**<br>Ecran LCD **DA**<br>lumină fundal **DA**<br>Date ecran ora **DA**<br>statut baterie **DA**<br>Indicator deconectare electrod acustic sau vizual **DA**<br>Buton evenimente **DA**<br>Buton navigare meniu **DA**<br>Blocarea automată a butoanelor **DA**<br>Posibilitatea transmiterii datelor ECG la PC sau notebook USB / SD-Card / BT **DA**<br>Baterie reîncărcabilă **da**<br>tip baterie AA **DA**<br>Tip operare autonomă - **maxim 7 zile**<br>Indicatori vizuali<br>contact slab sau lipsă de contact **DA**<br>status sistem **DA**<br>deconectare alimentare **DA**<br>baterie descărcată **DA**<br>Posibilități soft PC de interpretare **DA inclus in set**<br>Introducere date pacient **DA**<br>Adnotare eveniment ECG **DA**<br>Clasificarea de evenimente **DA**<br>Analiza ST **DA**<br>Analiza QT **DA**<br>Analiza PQ **DA**<br>Analiza PM **DA**<br>Analiza aretmiilor **DA**<br>Variabilitate ritm cardiac după timp **DA**<br>Variabilitate ritm cardiac după frecvență **DA** |

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| Reprezentarea grafică a datelor da<br>Reprezentarea tabelară a datelor da<br>Raport presetabil de utilizator da<br>Interfața presetabilă utilizator da<br>Posibilitate printare raport da<br>Accesorii<br>Cablu ECG 2 unități<br>Set de electrozi de unica folosinta adult 500 buc.<br><br>Set de electrozi de unica folosinta pediatric 500 buc.<br>Soft necesar pentru analiza Holter ECG pe PC inclus cu cheie de acces, licență cu un termen nelimitat de utilizare da<br>Sursa de alimentare pentru reîncărcarea bateriilor da | Reprezentarea grafică a datelor **DA**<br>Reprezentarea tabelară a datelor **DA**<br>Raport presetabil de utilizator **DA**<br>Interfața presetabilă utilizator **DA**<br>Posibilitate printare raport **DA**<br>Accesorii<br>Cablu ECG 2 unități **DA**<br>Set de electrozi de unica folosinta adult 500 buc. **DA**<br>Set de electrozi de unica folosinta pediatric 500 buc. **DA**<br>Soft necesar pentru analiza Holter ECG pe PC inclus cu cheie de acces, licență cu un termen nelimitat de utilizare **DA fără calculator.**<br>Sursa de alimentare pentru reîncărcarea bateriilor **da** |

# Certificate

TÜVRheinland®

**Quality Management System**
**EN ISO 13485:2016**

| | |
|---|---|
| Registration No.: | SX 1032460-1 |
| Organization: | ASPEL S.A.<br>os. H. Sienkiewicza 33<br>32-080 Zabierzów<br>Poland |
| Scope: | Design and development, manufacture, distribution, installation and servicing for active medical devices for vital functions monitoring and related accessories |

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

| | |
|---|---|
| Report No.: | 84950650-20 |
| Effective date: | 2021-02-15 |
| Expiry date: | 2024-02-08 |
| Issue date: | 2021-02-15 |

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH

Maciej Ściera
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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# Certificate

TÜVRheinland®

**Quality Management System**
**EN ISO 13485:2016**

| | |
|---|---|
| Registration No.: | SX 1032460-1 |
| Organization: | ASPEL S.A.<br>os. H. Sienkiewicza 33<br>32-080 Zabierzów<br>Poland |
| Scope: | Design and development, manufacture, distribution, installation and servicing for active medical devices for vital functions monitoring and related accessories |

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| Report No.: | 84950650-20 |
| Effective date: | 2021-02-15 |
| Expiry date: | 2024-02-08 |
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DAkkS
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D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH

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Tillystraße 2 · 90431 Nürnberg · Germany



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# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 1032460-1

Manufacturer: ASPEL S.A.
os. H. Sienkiewicza 33
32-080 Zabierzów
Poland

Products:
- Multichannel Electrocardiographs
- Ambulatory Electronic Automatic Sphygmomanometers, Long Term Recorders
- Ambulatory Electronic Automatic Sphygmomanometers, Long Term Analysing Software
- Spirometers
- Mouthpieces for Spirometer
- Pneumotachographs for Spirometer
- Ambulatory ECG, Long Term Recorders
- Ambulatory ECG, Long Term Analysing Software
- Data Management Systems, ECG
- Physiologic Monitoring Systems, Stress Exercise, Cardiac
- Physiologic Monitoring Systems, Stress Exercise, Cardiac, Software

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 26300262 010

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24

TÜV Rheinland LGA Products GmbH

Maciej Ściera
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



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# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 1032460-1

Manufacturer:
ASPEL S.A.
os. H. Sienkiewicza 33
32-080 Zabierzów
Poland

Products:
- Ergometers, Stress Exercise, Cardiac
- Treadmills, Stress Exercise, Cardiac
- Multichannel Electrocardiographs with Pulsoximetry Module
- Physiologic Monitoring Systems, Stress Exercise, Pulmonary, Ergospirometers

Replaces EC Certificate number HD 60144443 0001

Report No.: 26300262 010

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24

TÜVRheinland LGA Products GmbH Zertifizierstelle

Maciej Ściera
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg Germany

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# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 1032460-1

Manufacturer: ASPEL S.A.
os. H. Sienkiewicza 33
32-080 Zabierzów
Poland

Products:
- Multichannel Electrocardiographs
- Ambulatory Electronic Automatic Sphygmomanometers, Long Term Recorders
- Ambulatory Electronic Automatic Sphygmomanometers, Long Term Analysing Software
- Spirometers
- Mouthpieces for Spirometer
- Pneumotachographs for Spirometer
- Ambulatory ECG, Long Term Recorders
- Ambulatory ECG, Long Term Analysing Software
- Data Management Systems, ECG
- Physiologic Monitoring Systems, Stress Exercise, Cardiac
- Physiologic Monitoring Systems, Stress Exercise, Cardiac, Software

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 26300262 010

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24

TÜV Rheinland LGA Products GmbH

Maciej Ściera
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# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 1032460-1

Manufacturer:
ASPEL S.A.
os. H. Sienkiewicza 33
32-080 Zabierzów
Poland

Products:
- Ergometers, Stress Exercise, Cardiac
- Treadmills, Stress Exercise, Cardiac
- Multichannel Electrocardiographs with Pulsoximetry Module
- Physiologic Monitoring Systems, Stress Exercise, Pulmonary, Ergospirometers

Replaces EC Certificate number HD 60144443 0001

Report No.: 26300262 010

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24

TÜVRheinland LGA Products GmbH Zertifizierstelle

Maciej Ściera
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg Germany

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ASPEL

**ASPEL S.A.**
PL 32-080 ZABIERZÓW OS. H. SIENKIEWICZA 33
TEL. +48 12 285 22 22, FAX +48 12 285 30 30
WWW.ASPEL.COM.PL

CE
0197

# OPERATION MANUAL

## HOLCARD 24W GAMMA SYSTEM

## HOLCARD 24W ALFA SYSTEM
## A702 A800 A812 A903 A703 A712

# HOLCARD 24W

**SOFTWARE VERSION from 8.04.00**

**HOLCARD 24W COPYRIGHT © 2016 ASPEL**

**XVII Edition, Zabierzów, 30.08.2016**

# CONGRATULATIONS

♥ HolCARD 24W System for conducting an ECG Holter, long-term examinations is a result of years of researches and experiences gathered through close contact with our customers;

♥ HolCARD 24W was awarded with Gold Medal of Salmed 99 – International Poznań Fair;

♥ HolCARD 24W software complies with standards of Polish Cardiac Society applicable for Holter based tests;

♥ ASPEL offers a wide assortment of units electronic devices and accessories for ECG diagnostics, such as electrocardiographs AsCARD family, spirometry attachment SPIRO 31, ABPM system HolCARD CR-07, Exercise Stress Test Systems CardioTEST with treadmill B612 Ergometer CRG200, as well as ECG accessories, such as: bags, cables, electrodes and recording paper;

♥ Read this Manual carefully as it includes guidelines concerning the safe installation, proper use and several practical instructions how to optimize this system application;

Please keep this Manual for further consultation.

# TABLE OF CONTENTS

***Introduction*** ***5***
1.1 Doctor's responsibility 5
1.2 General Information 6
***Program operation*** ***14***
2.1 Starting Program 14
2.2 Starting a Holter test 15
2.3 Upload test from recorder 18
2.4 Analysis and Review of the Uploaded Test 19
***Increasing possibilities*** ***21***
3.1 Patient Database 21
3.2 Visits and tasks schedule 27
3.3 Quick WWW access 28
3.4 System tools 29
***Automatic analysis*** ***38***
4.1 Analysis configuration 38
4.2 Examination browse 39
***Test edition*** ***58***
5.1 Standard requirements 58
5.2 Reclassification of beats 59
5.3 Adding beats 60
5.4 Delete beats 61
5.5 Arrhythmia edition 62
***Report*** ***63***
6.1 Generating reports 63
6.2 Development of an individual summary 65
6.3 Setting report preferences 66
***Advanced analysis techniques*** ***67***
7.1 General 67
7.2 ST analysis 67
7.3 HRV analysis 70
7.4 QT analysis 76
7.5 Analysis of pacemaker operation 79
7.6 HRT Analysis 86
7.7 Prospective Analysis 90
7.8 Analysis of 12 channels examination 94
***Settings*** ***96***
8.1 Monitor AsPEKT 903 96
8.2 User's data 98
8.3 Preferences 99
8.4 Analysis parameters 105
***Monitor AsPEKT 700*** ***112***

9.1 General Info 112
9.2 Program operation 113
9.3 Setting work parameters 115
***Monitor AsLINK 118***
10.1 General Info 118
10.2 Starting program 118
10.3 Patient Data 119
10.4 ECG signal view 120
10.5 ECG test viewer 124
10.6 Printing 127
10.7 System Settings 129
***Safety precautions 133***

# Chapter 1

# Introduction

## 1.1 Doctor's responsibility

Holter analysis report is for exclusive use of physicians or the personnel under their direct supervision. Quantitative and graphic results should be analyzed referring to the whole medical image of a patient, with notes concerning preparation quality and general quality of the registered data, which may influence accuracy of the data covered by the report.

Physicians are responsible for correct management of ECG ambulatory reports, diagnosis or obtaining opinion of an expert on the results, and implementation of adequate treatment, if indicated.

**Note!!!** Information included in this manual may be changed without prior notice. ASPEL shall not be held liable for any technical or editorial errors in this manual or incidental damages or any damages arising from equipment or application of this manual.

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## 1.2 Purpose

HolCARD 24W (Alfa System, Gamma System) is intended to register and analyse long-term ECG recordings and is based on the Holter method. It allows you to create activity analysis reports and cardiac arrhythmia case reports.

Available HolCARD 24W Alfa System models:

- A702 - consists of HolCARD 24W software and AsPEKT 702 recorder,
- A800 - consists of HolCARD 24W software and AsPEKT 800 recorder,
- A812 - consists of HolCARD 24W software and AsPEKT 812 recorder,
- A903 - consists of HolCARD 24W software and AsPEKT 903 recorder,
- A703 - consists of HolCARD 24W software and AsPEKT 703 recorder,
- A712 - consists of HolCARD 24W software and AsPEKT 712 recorder.

HolCARD 24W Gamma System - the system consists of Medical Diagnostics Stand with Computer Workstation and the HolCARD 24W software.

HolCARD 24W software supports the following procedures: single-lead, double-lead, three-lead and twelve-lead, registered by the AsPEKT series recorders.

# 1.3 General Information

HolCARD 24W made by ASPEL is a powerful diagnostic instrument intended for use in everyday doctor's work.

HolCARD 24W is designed for loading and analysing ECG records lasting up to 48 hours, registered on PCMCIA card with the use of 3 or 12-channel digital AsPEKT recorders and for developing reports of activation analysis and heart arrhythmia events.

HolCARD 24W operates with IBM standard compatible PC computers. Microsoft Windows operational system is used for enhancing presentation and operation qualities of the system.

Holter can be operated after minimal technical training of operators. Moreover, an automatic Holter report may be obtained with little operator commitment. Soon after inputting patient data and inserting PCMCIA card with ECG record into the Holter system, the unit reads the data and automatically develops a report.

HolCARD 24W system complies with Polish Cardiac Society standards. It has all necessary functions for Holter examinations and report generating. Additionally, it has been provided with a system verifying results of Holter analysis, according to standards, to help user to meet necessary requirements.

System is able to detect, browse and generate reports of: arrhythmia, ST segment depression and elevation, ST episodes, maximal, minimal, and average heart rate, as well as percentage of artifacts in the record.

Marking QRSes with colours facilitate refusing or accepting computer analysis of abnormal QRSs.

Tabular presentation of numerical data allows for easy evaluation of Holter analysis results and find examples of the selected arrhythmia events. HolCARD 24W uses the newest algorithms of Holter analysis. Effectiveness of detecting QRSes is approximately 99,24%. The application of the newest digital technique for recording and analysing of ECG signals allows for making measurements with accuracy to 1 ms.

**HolCARD 24W is a trademark of Aspel company.**

## 1.3.1 Licence Agreement

The following terms and conditions are the binding Licence Agreement concluded between the Buyer - the end user and ASPEL S.A. hereinafter referred to as the Manufacturer. In case the Buyer does not accept terms and conditions of the Licence Agreement, the complete product shall be immediately returned to the Distributor where the product was purchased and money paid will be refunded.

**Licence object**

1. HolCARD 24 W hereinafter referred to as the Software is entirely the property of the Manufacturer and cooperating companies mentioned in associated materials. The Software is protected by Polish law (The Act on Copyright and Related Rights as published in Journal of Laws Dz.U. no 24 section 83) and international regulations referring to protection of intellectual property rights. Therefore the purchased Software shall be treated as any other element of the copyright law (i.e. book or music recording). The Manufacturer does not sell the Software to the Buyer but only licenses the Buyer to use the Software according to terms and conditions mentioned herein. The Manufacturer reserves all rights not directly expressed herein. The Buyer may not copy, lend, lease or other types of transfer the granted Licence and/or use it otherwise than provided for in this Licence without obtaining prior approval of the Manufacturer, expressed in writing.

2. The Manufacturer grants the Buyer the right to use the Software on only one computer at the same time. In order to obtain a multi-computer license, the Buyer shall apply to the Manufacturer or its authorized distibutor.
3. The Buyer is not entitled to copy, modify, recompile and/or introducing any other changes to the Software and associated documentation.
4. The Agreement and all rights attributed to the Buyer in connection with the Agreement shall terminate if the Buyer fails to comply with any term or condition of this Agreement. In such a case the Manufacturer will pursue its entitlement by virtue of relevant regulations. Claims arising from any breach of the Manufacturer's copyright will be in force also after the above Agreement is terminated.

**Limited Warranty**

1. The Manufacturer warrants that the Software will perform to significant extent in accordance with the documentation attached and that all materials such as floppy disks, documentation, etc. will be free from any defects in material.
2. The Manufacturer grants the warranty for products used under normal operational conditions and according to the purpose for one year period from the date of purchase documented with an invoice. All warranty claims are limited to one year period.
3. None of the distributors or persons representing the Manufacturer may extend or modify the above resolutions. The Manufacturer does not guarantee that the Software will meet expectations of the Buyer or that the operation of the Software will be entirely flawless. The entire risk whether the purchased Software is suitable for a specific purpose is attributed to the Buyer.

**Buyer Rights**

The Manufacturer is responsible for:

1. Repair or replacement of materials not meeting terms and conditions of this Agreement when returned to the Manufacturer or Manufacturer's authorised distributor supported with a copy of the relevant invoice,

   or

2. In case replacement of materials is not possible, the Buyer may return the goods and a copy of the bill to the Manufacturer or Manufacturer's authorized distributor and the Buyer will get money back. The way of satisfying the Buyer's claims is up to the Manufacturer.

**Exclusions from damage liability**

1. Neither the Manufacturer nor Manufacturer's authorized distributors are liable for any losses or damages arising directly or indirectly from the use or inability of use of the Software, including but not limited to loss of profit, downtime costs, loss of information and other circumstances and events not mentioned herein, even if the Manufacturer was notified about possibility of occurrence of such circumstances.
2. The liability of the Manufacturer will not exceed the sum of payment effected by the Buyer for the Software License.

### 1.3.2 AsKEY

AsKEY protects ASPEL software against illegal copying. Correct operation of the system is possible only when AsKEY is connected to the USB port of a computer with installed HolCARD 24W.

**Figure 1. AsKEY**

To ensure proper operation of the system HolCARD 24W, AsKEY must be continuously connected to the USB port. Do not remove the key when the program is opened. After inserting the AsKEY to the USB port please wait 1-2 minutes, until MS Windows finishes the driver initialization.

**The loss of security key results in loss of right to the software.**

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fax +48 12 / 285 30 30

### 1.3.3 System Elements

HolCARD 24W (Alfa System) system has to consist of the following elements:

- IBM compatible computer (according to EN 60950)
- Windows XP, Windows 7, Windows 8 operating system – 32 and 64 bits
- VGA 17” colour monitor
- PCMCIA card reader
- HP LaserJet printer
- IrDA interface
- Desk to put the whole system on.

**NOTE!** You can also use other printers, if only requirements connected with resolution and memory are met. The necessary information can be obtained at Aspel.

MS Windows operational system is required for correct operation of HolCARD 24W (c) Aspel program. There is a possibility of connecting wireless AsPEKT 800 and AsPEKT 812 recorders but a AsLINK 800 adapter and at least MS Windows XP SP2 are necessary.

### 1.3.4 Installation

Aspel recommends the installation of the program into an account belonging to the User Group (the so-called individual user account) in the folder c:\ASPEL. This folder should be authorized for reading and saving. Installation into a GUEST account is prohibited due to the numerous limitations of this account. It is also possible to install a program from the Administrator level and to allow access to the program by users. In this case, it is important to ensure that user access is properly authorized.

Limitations during installation into MS Windows system accounts:

1. folder names in the installation path may not contain spaces,
2. the program may not be installed into a GUEST account,
3. administrator access to a program may occur only after the first login of users into their own account.

The HolCARD 24W System © ASPEL is supplied on a CD-ROM disk. We begin the installation by placing the disk in the reader. On the monitor screen, the main board of the installation program will be displayed. It enables the installation of the HolCARD 24W program, the opening of the instructions for using the program, and access to the demonstration versions of ASPEL's program offerings.

**Figure 2. Main HolCARD 24W Installer Menu**

To begin installation, select the item <**HolCARD 24W**>. A window will open in which we can select the installation language:

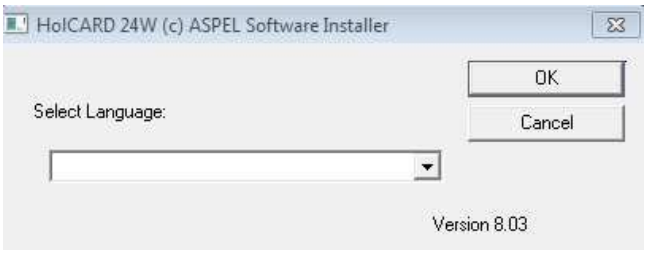



**Figure 3. Window for selecting installation language**

By pressing the <**OK**> button, we proceed to the welcome screen:

**Figure 4. Start of the installation program**

By selecting the <**Next**> button in this window, we begin the 5-step installation process.

## STEP 1

The HolCARD 24W program is a legally protected product and every user is obliged to familiarize himself with and abide by the license agreement. After reading the license and accepting the agreement, select the button, <**I agree**>.

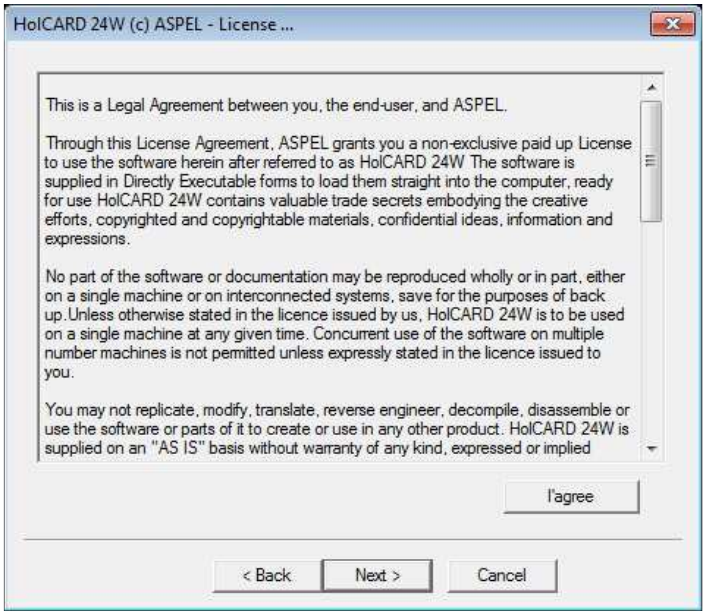



**Figure 5. License agreement window**

Selecting this button will activate the <**Next**> button, which will allow you to go to the next step.

## STEP 2

This step allows the user to enter identification data which will be placed in the header of printed reports. We accept the entered data with the <**Next**> button:

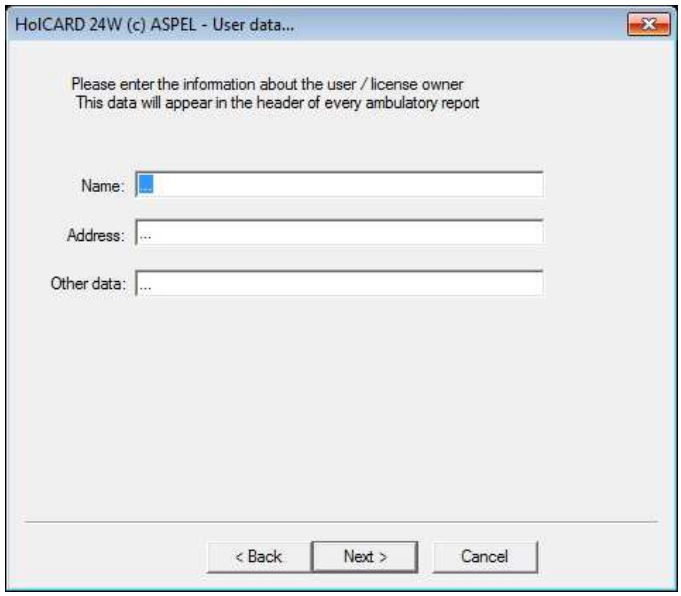



**Figure 6. User data window**

## STEP 3

Step 3 enables the installation of the required VC2005 libraries. The installation occurs with the aid of an additional program which will be activated when the <**Next**> button is pressed. Go through the entire installation process with the additional program activated and then return to the next installation step.

**Figure 7. Installation window for VC2005 libraries**

**STEP 4**

Step 4 enables the installation of the required AsKEY key controllers. The installation occurs with the aid of an additional program which will be activated when the <**Next**> button is pressed. Go through the entire installation process with the additional program activated and then return to the next installation step.

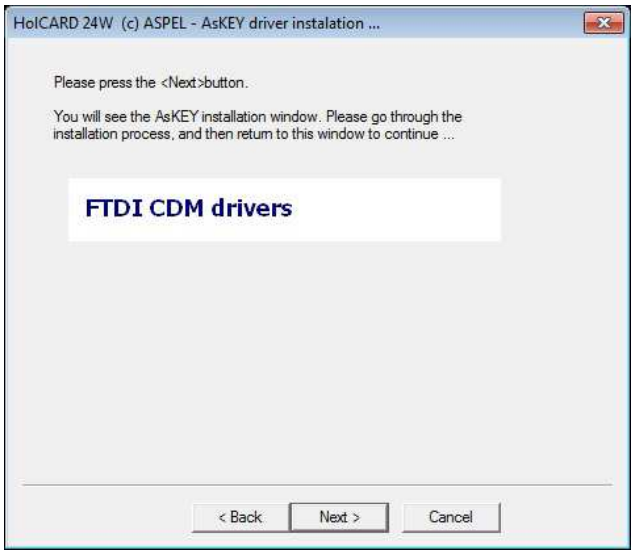



**Figure 8. AsKEY key installation window**

**STEP 5**

Step 5 is the final step of the installation, consisting of the proper downloading of the HolCARD 24W program. Selecting the <**START**> button initiates the process of copying the needed system files to the computer disk.

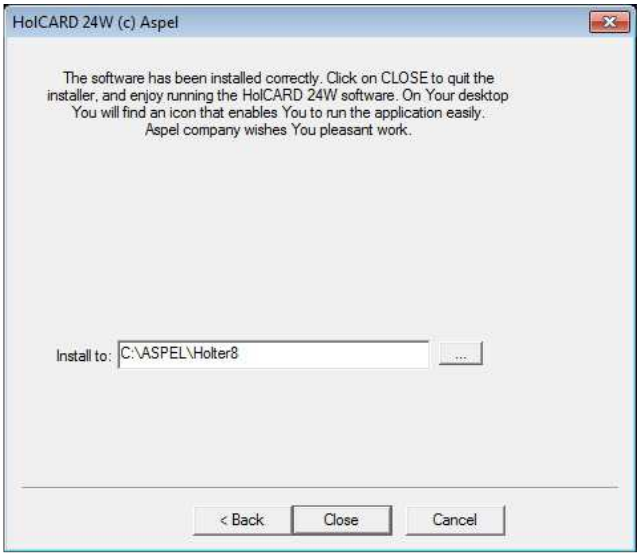



**Figure 9. Window for downloading program files**

Proper completion of the installation causes the appropriate information to appear in the window and the start icon of the program to display on the desktop.

Now place the AsKEY key which was supplied with the installation disk in the free USB port of the computer and wait (2-3 minutes) until the MS Windows system installs the key, which will be confirmed by the appropriate message in the lower part of the screen.

When all of the described actions are completed, the program is ready to run.

### 1.3.5 Basic operation principles

Holter HolCARD 24W is very easy to work with. After short edition operator can obtain high quality printout of an extremely accurate and detailed report.

High quality ECG records are very important. Read this Manual carefully and follow the instructions in order to get correct final reports of ECG recordings.

Electrodes placement is crucial for getting accurate results of Holter test. Mispositioning results in a large number of artefacts and base line drifts which influences negatively on ECG courses in Holter test.

Correct placing of electrodes is the most important point in patient's preparation in order to receive correct results.

Proper electrodes placement usually gives 99% of good quality ECG courses. Positioning of the electrodes is easily checked with Monitor AsPEKT software and printouts of full disclosure. However, recording device and displaying device cannot fully compensate defects caused improper placement of the electrodes.

Deformed ECG records should not be analyzed. To get good ECG you have to prepare patient's skin properly and use good quality disposable electrodes. Quality of analysis and fast development of Holter test depends on complying with the above principles.

# Chapter 2

# Program operation

## 2.1 Starting Program

After installing HolCARD 24W © Aspel, a start icon will appear on the screen (Figure 10). It is a shortcut, which allows starting the program quickly. Since Holter is protected against unauthorized access using a dongle, be sure to check whether it is placed in the computer's USB host. The program will not start without the correct key.

**Figure 10. HolCARD 24W ICON**

After starting the program (double-click on the icon), the main HolCARD 24W screen appears.

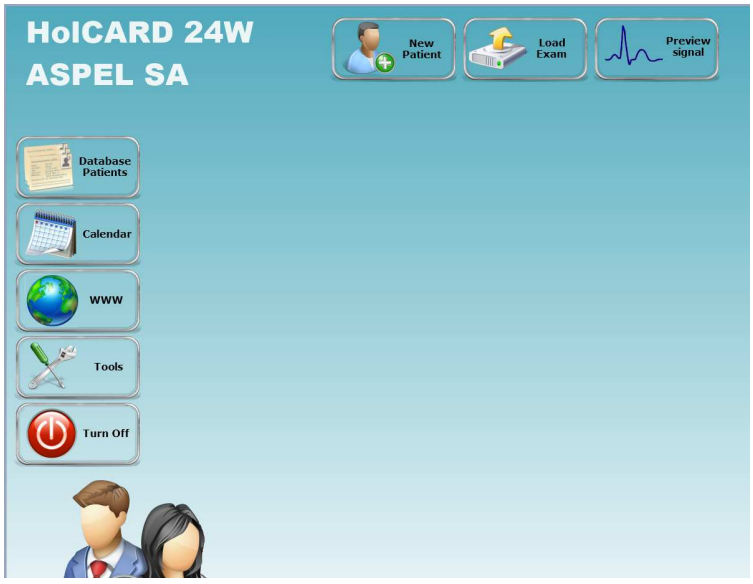



**Figure 11. Main screen in HolCARD 24W**

The main window in HolCARD 24W is divided into two parts. At the top, there are buttons related to running a Holter test – e.g. new patient registration, uploading previously performed tests, or quality control of the electrode connection to the patient. On the left, there are buttons for access to a variety of additional operations – e.g. access to the database of patients and their tests, to the visit schedule, to web pages or additional tools.

The first step after starting the program is uploading a new test from the recorder, or from a memory card removed from a recorder (depending on the version of the recorder you have). The following chapter introduces you to the easiest and fastest way to upload a new test and perform automatic analysis.

## 2.2 Starting a Holter test

All Holter recorders in the AsPEKT series have been designed to allow the start of test registration without having to communicate with a computer and with HolCARD 24W. Usually there is a special button for that – for details see the user's guide of the recorder.

### Preparing the AsPEKT 903 recorder

AsPEKT 903 recorders are equipped with an additional function – they store the data of the examined patient and the contact data of the doctor. Patient data stored in the recorder uniquely identify the patient with their record and allow for quick searching of that patient in HolCARD 24W © Aspel database while uploading the test. Contact details to the doctor can be displayed on the screen of the recorder. To store the patient's data in the recorder, proceed as follows:

**Step 1.** Connect the transmission cord of the recorder to the PC.

For details, see the AsPEKT 903 user's guide.

**Step 2.** Register a patient in the HolCARD 24W © Aspel system.

Patient registration is an operation of entering the basic information about the patient to the HolCARD 24W system; this information includes: name and surname, date of birth, ID number, address, contact data. To perform this step, click the top button with the description <**New Patient**>. The screen will display a window for entering the data – see Figure 12.

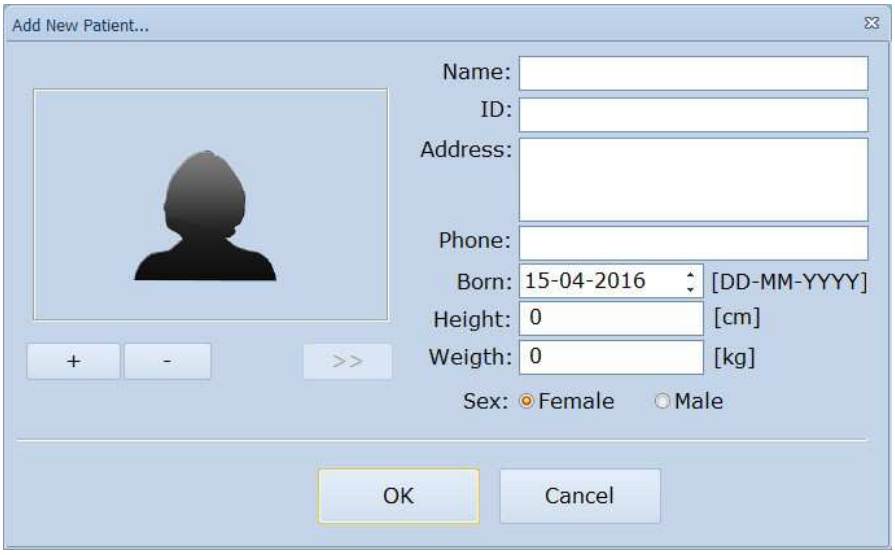



**Figure 12. Add New Patient**

**Note!!!** The patient number should be a unique number assigned to a specific person.

It is also possible to attach an image of the patient's ID to more easily identify the patient with the test and the recorder 2.3 Upload test from recorder.

After entering all patient data and verification, confirm the registration of a new patient by pressing the <**OK**> button. The data of the registered patient will be displayed in a new window – see Figure 13.

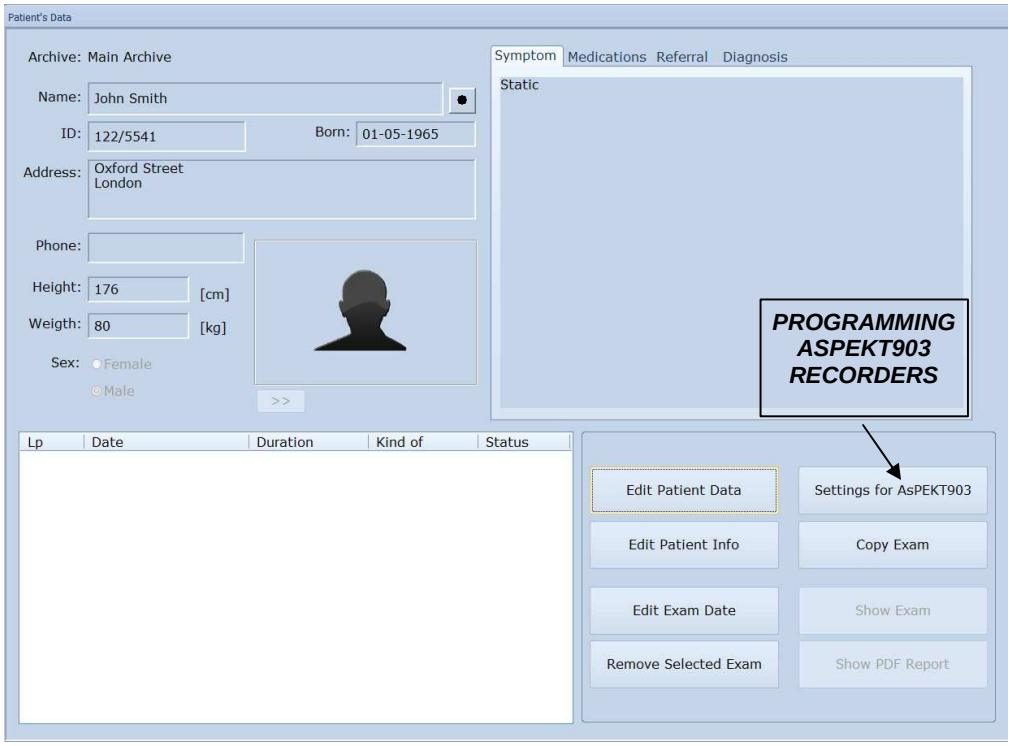



**Figure 13. Patient Data**

**Step 3.** Save the patient data, contact data and other settings in the recorder.

To save the data, proceed as follows:

- Select the save button <**Settings for AsPEKT903**>
- Set the required parameters in the window that will pop up – see Figure 14
- Save the settings by pressing <**Save**>

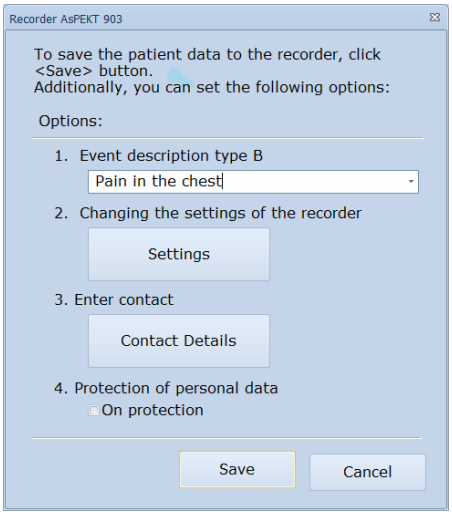



**Figure 14. AsPEKT 903 Configuration**

Note!!! In order to save the patient data only, you can click <**Save**> immediately, without changing any settings.

**Meaning of individual items:**

**<Event description type B> -** The AsPEKT 903 recorder allows storing two types of events. Pressing the button once generates a Type A Event. It is a general-purpose event similar to events in other recorders. Pressing the button twice generates a Type B Event. This event has an assigned description, which can be selected or entered in the box above. After uploading a test in HolCARD 24W, Type B events will be described under this assigned name.

**<Settings> -** the settings button opens a window, where you can set the recorder's working parameters – e.g. recording time in days, the number of recorded channels, test protection stored on the card, delayed recording start by 2 minutes, the ability to view the ECG while recording and before the start of the recording, etc. A detailed description can be found in Chapter 8.1 Recorder AsPEKT 903.

**<Contact Details> -** this button allows entering the doctor's contact details, which will be displayed on the screen – for details, see Chapter 3.4.5 User data.

**<Protection of Personal Data> -** if on, the recorder will not store the patients name, only saving their ID number instead. In that case, the patient's name does not appear on the display.

**<Save> –** saves all settings for the connected recorder.

## Monitoring the quality of electrode connections

The AsPEKT 903 recorder has a built in display, on which the ECG signal is presented. After connecting the electrodes to the patient, make sure that the signal quality is satisfactory. If necessary, adjust the connection of the electrodes. If the signal is correct, the test can be started.

Other Aspel recorders offer another possibility to check for signal quality. Such a recorder may have a built in **IRDA** – infrared data transmission or **AsLINK** – wireless radio transmission.

HolCARD 24W provides a <**Preview signal**> button at the top of the screen. Clicking this button will open a menu that allows choosing the type of preview. Depending on the recorder version you have, you must start the appropriate view (Monitor).

**Figure 15. Signal Preview**

In the case of recorders fitted with the ability to transmit **AsLINK**, the first step is to open the window with the data of the patient – <**Patient Data**>. Only then will the <**Monitor AsLINK**> item become available in the <**Signal Preview**> menu.

To do that:

- Click the <**Database Patients**> button located on the left side of the system window,
- Then find the patient on the list,
- Double-click the patient's name – a window will then open displaying their data.

After opening the <**Patient's Data**> window, click the <**Signal Preview**> button and select <**Monitor AsLINK**>. The screen will run a program that allows receiving ECG data via AsLINK – for details, see 10.1 Monitor AsLINK

## 2.3 Upload test from recorder

HolCARD 24W allows uploading ECG tests saved by AsPEKT recorders. Uploading tests involves copying the entire ECG signal from the device's memory to a computer and storing that information in the system's database. Immediately after uploading is completed, the recorder/card may be reused to record another test – it requires no additional preparation (e.g. deleting or demagnetizing).

### Uploading Test

1. Insert the card into the reader installed in your computer

   If you are using an **AsPEKT 903** recorder, you can upload the test without removing the card. Connect the recorder to the computer using a transmission cord.

2. Run the test uploading module

   - Click the <**Upload Test**> button, which is located at the top of the main screen
   - Then select <**Recorder**> (if not already selected)
   - Click <**Next**>

The screen will display a list of automatically found locations, where potential tests await uploading. Select the right test from that list and click <**OK**>

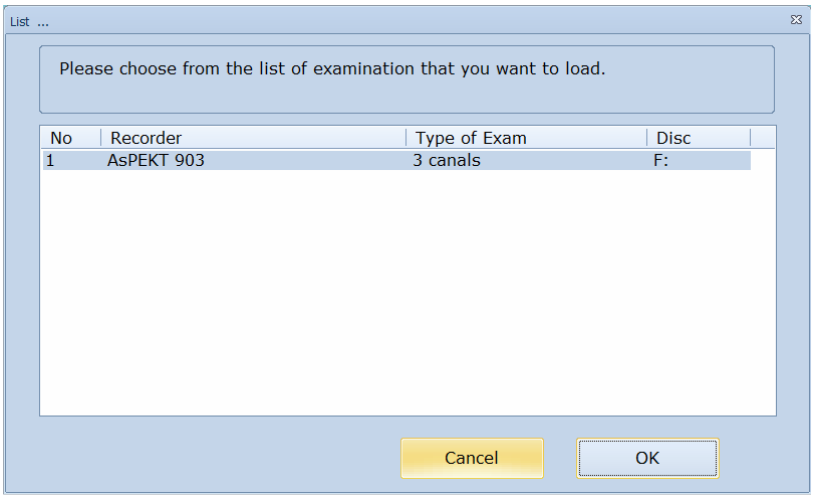



**Figure 16. List of founded tests**

After clicking <**OK**>, the program will start the procedure of uploading information regarding the test. If patient data has also been saved in the recorder, a window will pop up displaying that info and presenting the patient's image (if attached). Such a solution allows for the proper identification of the test's owner and prevents possible confusion.

If the owner of the test has been identified correctly, press <**OK**>. Otherwise, click the <**Cancel**> button and select the right owner from the displayed list of patients, or add a new one. After completing these operations, click the <**START**> button, which starts the procedure of reading the test from a recorder and copying it to HolCARD 24W.

Depending on the size of the test, the uploading process may take from several seconds to few minutes. Once this process is complete, the screen will display the <**Patient Data**> window together with a list of tests. Now simply select the uploaded test on the list and run the Analysis and Review Tool by clicking <**Show Exam**>.

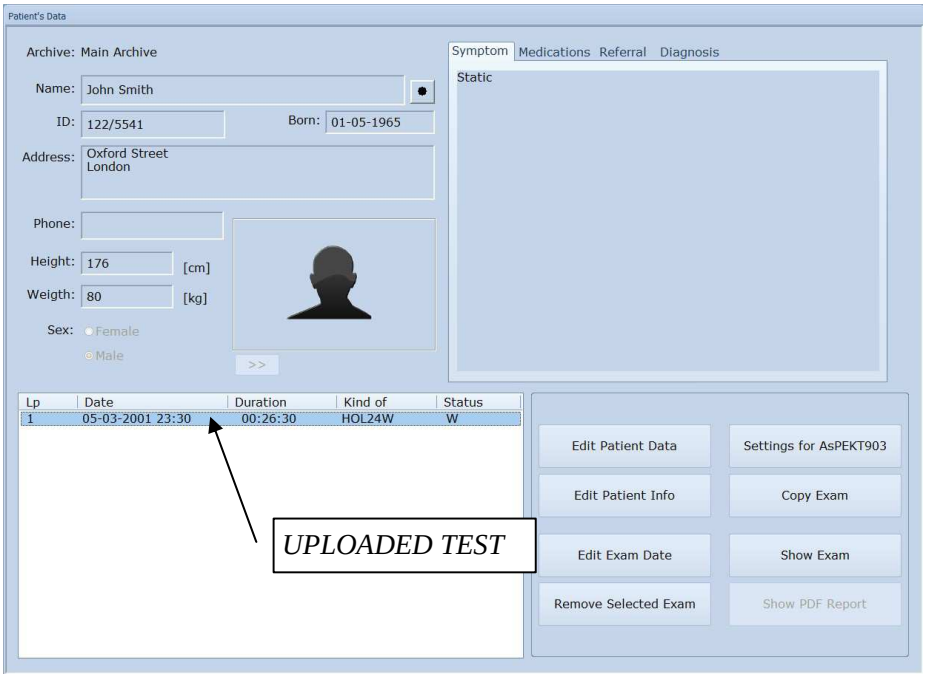



**Figure 17. List of uploaded tests**

If the recorder saved a test that takes longer than 24 hours, e.g. 48 hours, then that test will be divided into two separate parts. The List of Patient Tests in the <**Patient Data**> window will, therefore, display two items. The first one represents the first 24 hours of the test, the second will include the remaining 24 hours. Each of these tests should be analyzed separately.

## 2.4 Analysis and Review of the Uploaded Test

In the <**Patient Data**> window, there is the <**Show Exam**> button. It starts a module that allows you to run a Holter analysis of the test, review the ECG and generate reports.

To perform the analysis of the uploaded test, check it on the list of tests and click <**Show Tests**> – see Figure 18. The screen will display a new window and the system will automatically start the analysis.

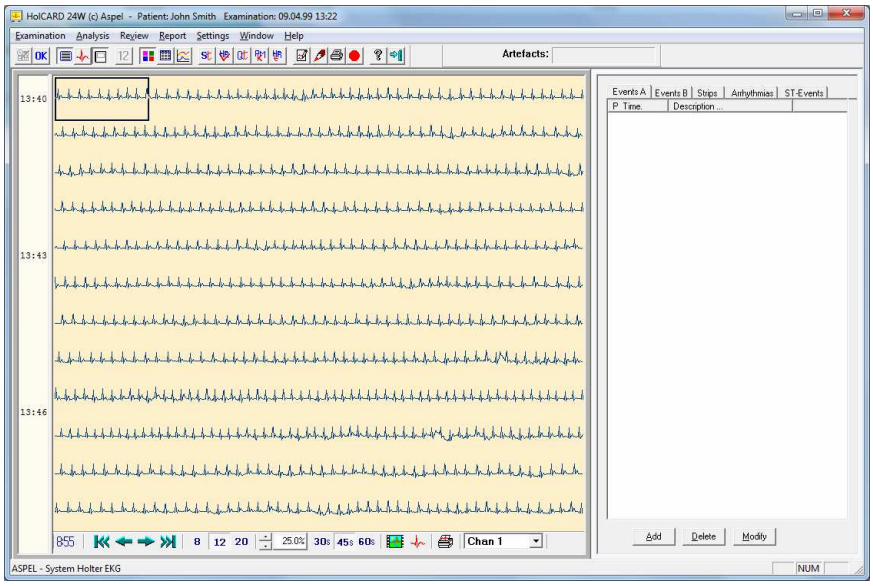



**Figure 18. Analysis Module Window**

To view the information on how to perform an analysis, the methods of reviewing Holter tests, the methods of analysis edition and the report-generating capability, please refer to Chapter 2 Program operation of this manual.

# Chapter 3

# Increasing possibilities

## 3.1 Patient Database

### 3.1.1 List of Patients

The HolCARD 24W © ASPEL database allows for the storage of any number of patients and tests (the only limit is the hard drive capacity of the computer, on which the system has been installed). Upon registering a patient in the system, they are automatically stored in the database. New tests are also stored in the system's database upon uploading.

To open a window displaying the list of all patients, click the <**Database Patients**> button, which is located on the left of the main screen. The list can be sorted by any column. When you click the <**Name**> column, patients will be arranged according to the order of the letters in the alphabet. When you click the <**ID**> column, patients will be arranged according to their ID numbers, from smallest to largest.

To open the window with detailed data on a patient together with their list of tests, double click the patient's name – the screen will then display the <**Patient Data**> window. To remove a patient from the list, right-click their name. **NOTE!!!** Removing patients is an operation that cannot be undone. It removes all information on that patient as well as all the patient's tests permanently.

Where many patients are involved, the patient find function may be convenient. Press the <**F7**> key on the keyboard and a window allowing entry of the beginning of the patient's last name or first name will open. After the <**Search**> key is pressed, a search of the list begins. The found patient is highlighted. When the same button is pressed again, the next patient beginning with the given phrase can be found.

In the lower part of the window are buttons allowing the above-noted actions to be performed.

Database

| No. | Name | ID | Born |
|---|---|---|---|
| 603 | Langrová Apolonie | 22-52-07/424 | 03.11.2009 |
| 604 | Blahutová Michalea | 92-52-06/5922 | 05.11.2009 |
| 605 | Marek Vladimir | 61-04-17/1777 | 06.11.2009 |
| 606 | Fusíková Drahomíra | 66-51-19/1965 | 06.11.2009 |
| 607 | Kaštovský Petr | 49-01-15/210 | 06.11.2009 |
| 608 | Biener Petr | 62-05-10/1320 | 10.11.2009 |
| 609 | Dehnerová Lenka | 84-51-30/5236 | 13.11.2009 |
| 610 | Richtarová Světlana | 64-51-22/2228 | 16.11.2009 |
| 611 | Aghová Tereza | 84-58-12/5247 | 18.11.2009 |
| 612 | Ostružlík Ladislav | 64-12-09/0344 | 19.11.2009 |
| 613 | Hanzelka Jaroslav | 40-03-27/457 | 23.11.2009 |
| 614 | Smoljar Theofan | 36-03-25/085 | 24.11.2009 |
| 615 | Blinková sabina | 74-54-29/5585 | 24.11.2009 |
| 616 | Břenek Roman | 74-05-3/5265 | 24.11.2009 |
| 617 | Stanková | | 27.11.2009 |
| 618 | Přádková Věra | 40-61-28/436 | 27.11.2009 |
| 619 | Beneš Eduard | 44-03-06/433 | 27.11.2009 |
| 620 | Klosová Miluše | 355528428 | 01.12.2009 |

**Figure 19. List of Patients**

### 3.1.2 Patient data and tests

The Patient Data Module presents information on the patient and their tests, as well as allows carrying out several important operations:

- <**Edit Patient Data**> – allows making changes to patient data
- <**Edit Patient Description**> - allows making changes to medical descriptions
- **<Edit Exam Date>** - allows you to change the date of a selected exam
- <**Remove the Selected Test**> – removes the selected test from the database
- <**AsPEKT 903 Configuration**> – saves patient data and working settings in the recorder
- **<Copy exam>** - allows you to copy a selected exam to a different storage or card
- <**Show Test**> – runs the Analysis and Review Tool
- <**Show PDF Report**> – displays a report on the test (if available)

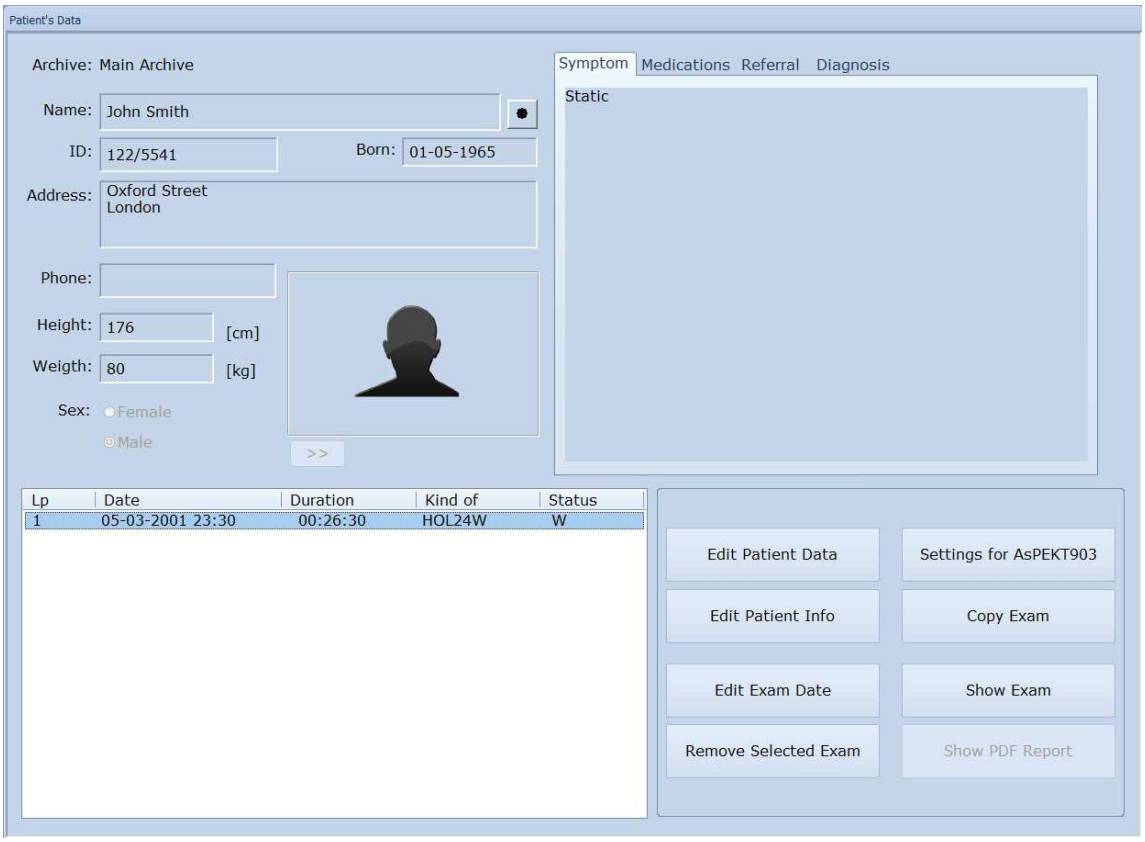



**Figure 20. Patient Data Module**

Information in the module has been divided into two major parts. The upper area of the module presents all the data stored by the program, directly related to the patient, i.e. passport data and medical data. The lower area contains a list of the patient's tests, information on these tests and buttons to perform various operations.

## Data on Patient

HolCARD 24W keeps the following passport data of every registered patiet:

| | |
|---|---|
| Name | Date of birth |
| Registration number | Height |
| Address | Weight |
| Phone number | Sex |

In order to modify the currently selected patient's data, proceed as follows:

1. Select the <**Edit Patient Data**> button.

   The screen will display a separate dialog box, which allows modifying individual patient data.

2. Enter new data.
3. Confirm operation by selecting <**OK**>.

Only selecting the <**OK**> button will save the changes you entered. Selecting the **<Cancel>** button or closing the window using the icon in the top title bar will restore previous settings.

In addition to the passport data of the patient, medical information can also be entered:

- Identification,
- Medication used.
- Referral
- Diagnosis

After selecting the **<Edit Patient Info>** button, the screen will display an additional window, which allows entering any text in identification and the information concerning the patient's medication. After confirming the changes by pressing <**OK**>, the program's database is updated automatically.

There are some restrictions on these descriptions. Referral and diagnosis are associated with a particular test. Therefore, they can only be entered when the test already exists. Every test has its own description regarding referral and diagnosis. The descriptions concerning identification and medications are related to the patient and can be entered at any time.

### Data on test

Every patient can have any number of uploaded and analyzed tests. All these tests are presented in the <**Test list**>. This list includes the following information:

- Test number (No.),
- Date of the test,
- Duration of the test,
- Type of the test
- Status of the test.

The type of the test provides information on the way the test has been recorded. A Holter test is described <**HOL24W**>. Tests made during quality control of electrode connections with the use of Monitor AsLINK are either described <**MANUAL>** or <**AUTO>**. The status of the test informs the user of the current status of the review and the correctness assessment of the results of a Holter analysis performed on that test.

| Status | Meaning | Next step |
|---|---|---|
| W | Uploaded. The test has only been uploaded. No Holter analysis has been performed so far. | A Holter analysis of the test must be performed. |
| AA | Automatic Analysis. The test has been uploaded and analyzed automatically. Analysis results have not yet been approved by the user. | The results of Holter analysis must be assessed and – if necessary – corrected. |
| OK | OK. Verified. Test results approved by the user as correct | |

Statuses **W** and **AA** are assigned automatically by the program, after carrying out an appropriate operation, i.e. after uploading the test (W) or after performing the firs automatic analysis (AA). The **OK** status is only assigned by the user, since it is associated with making a decision, whether the results of the analysis are correct. To do this, select the <**Mark as OK>** box in the <**Test>** menu**.** You can also use the <**OK**> icon on the toolbar.

### Removing test

The selected test can be removed from the database. To do this, select the test and press <**Remove selected exam**>. Every test occupies a lot of space on the computer (around 60-120 MB); they are frequently removed to release space and allow loading further records. Keep in mind that it is possible to store tests on a CD or DVD – see 3.4 System tools

## ID Image - scanning

Patient data can be complemented with an image of an ID card. If you have an appropriate scanner connected to your computer and installed properly, all you need to do is go to the <**Add New Patient**> window and select the button marked < + > – see Figure 21. In the menu that will expand, select <**Scan Obverse**>. Then insert the ID into the scanner, so that the page with the image faces down.

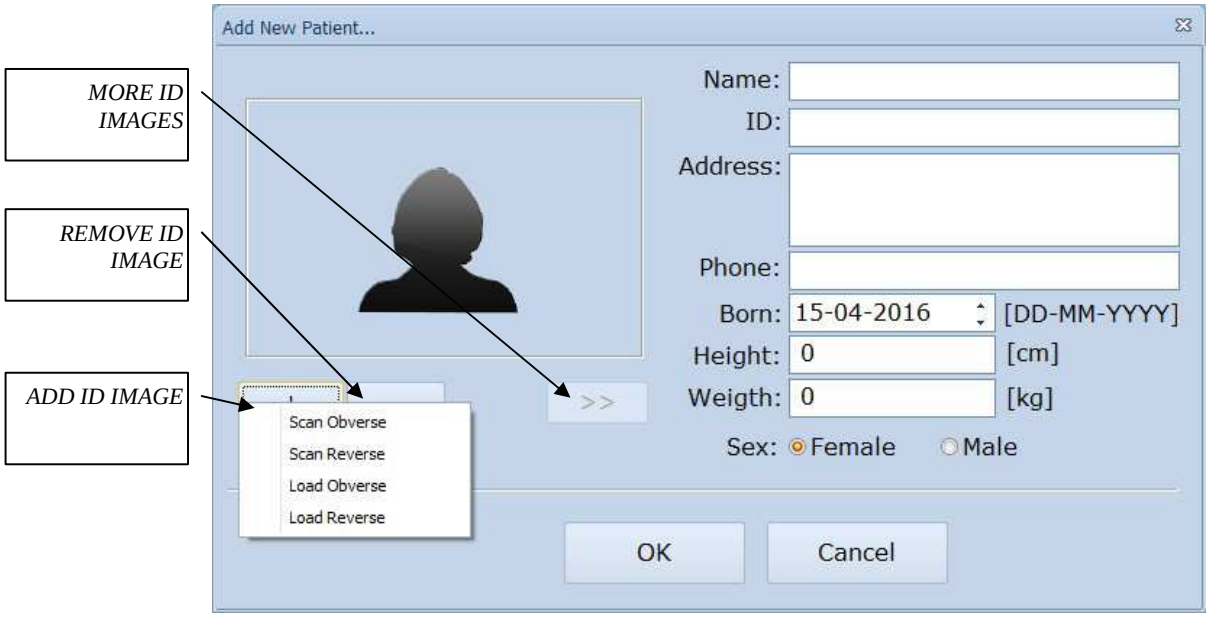



**Figure 21. Patient Data Window**

The screen will display a window that allows scanning the ID. Depending on the scanner you have, this window can take many forms. Below is an example of one such form.

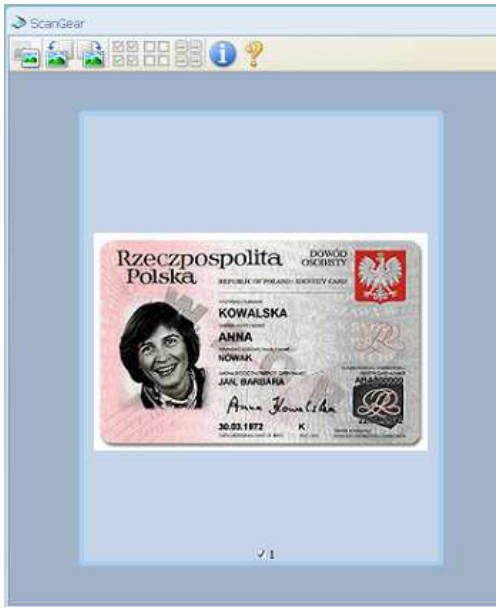



**Figure 22. ID scanning window**

The first step is to determine whether the ID has been inserted properly and, if necessary, make appropriate adjustments. To do that, you must run the initial scanning – click <**Preview**>. After completing the initial scan, a screen image of the ID will be displayed. If the ID has been inserted improperly, upside down, or crooked, it should be adjusted. This can be done by rearranging the ID properly in the scanner, or using appropriate functions available in the window. Then the proper scanning can be started – press <**Scan**>. After the scanning has been completed, the image will be sent directly to the patient data window.

In the same way you can scan the other side of the ID:

- Insert the ID into the scanner, so as to the side without the picture faces down
- Select the < + > button, and then <**Scan Reverse**> in the menu that appears
- Perform initial scanning – <**Preview**> button
- Check the correctness of the can; if necessary, make adjustments
- Perform the proper scanning – **<Scan>**

After the scanning has been completed, the image will be sent directly to the patient data window. Now you will have 3 ID images available:

- **Obverse** – the side of the ID with the photo
- **Reverse** – the other side of the ID card
- **Patient's photo** – cropped out from the obverse side of the patient's ID.

Using the < >> > button, you can view more images of the ID. To remove ID images, select < - >.

## ID Image – uploading e.g. from external data carrier

ID image can be uploaded from the hard drive or from an external data carrier, provided it has been saved in one of the following formats: BMP, JPEG, JPG, PNG or GIF. To upload an image:

- Select < + > in the Patient Data Window - Figure 21
- Then select <**Load Obverse**> or <**Load Reverse**> from the menu

The screen will display a window, which will allow choosing the right file with an ID image. After selecting the file, select the <**Open**> button and the ID image will be uploaded automatically to the patient data window.

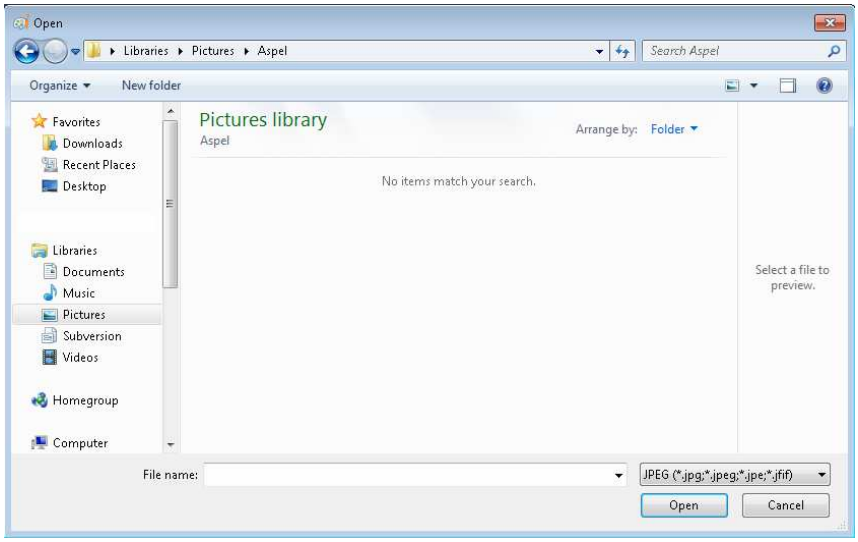



**Figure 23. Picture uploading window**

The uploaded ID image can be of any size – the program scales the image automatically to the required size (preferred size is 660x400, the minimum size is 260x160).

# 3.2 Visits and tasks schedule

The Visits and Tasks Schedule allows for planning the visits of subsequent patients and for entering the tasks that must be performed in the near future. It has three main views – a view on the current month with scheduled visits and tasks, a weekly view and a detailed daily view.

To start the Schedule, click <**Calendar**> located on the left side of the main window.

Adding visits and tasks is possible in any of these views. Move the cursor to a specific day and click that day; it is now selected, and then:

- You can start typing any text immediately and press <**Enter**> on the keyboard once you have finished.
- You can wait a moment until a bubble appears displaying the words "Click to add a visit", then click that bubble and enter the text to the window that will appear.

If you want to assign the entered text (e.g. name of the patient appointed for a visit) at a specific time, go to the <**Day**> view, then "catch" the text you have entered with your mouse and drag it to the desired hour. You can also book longer periods of time for specific appointments or tasks by extending the edge of the field with the entered text.

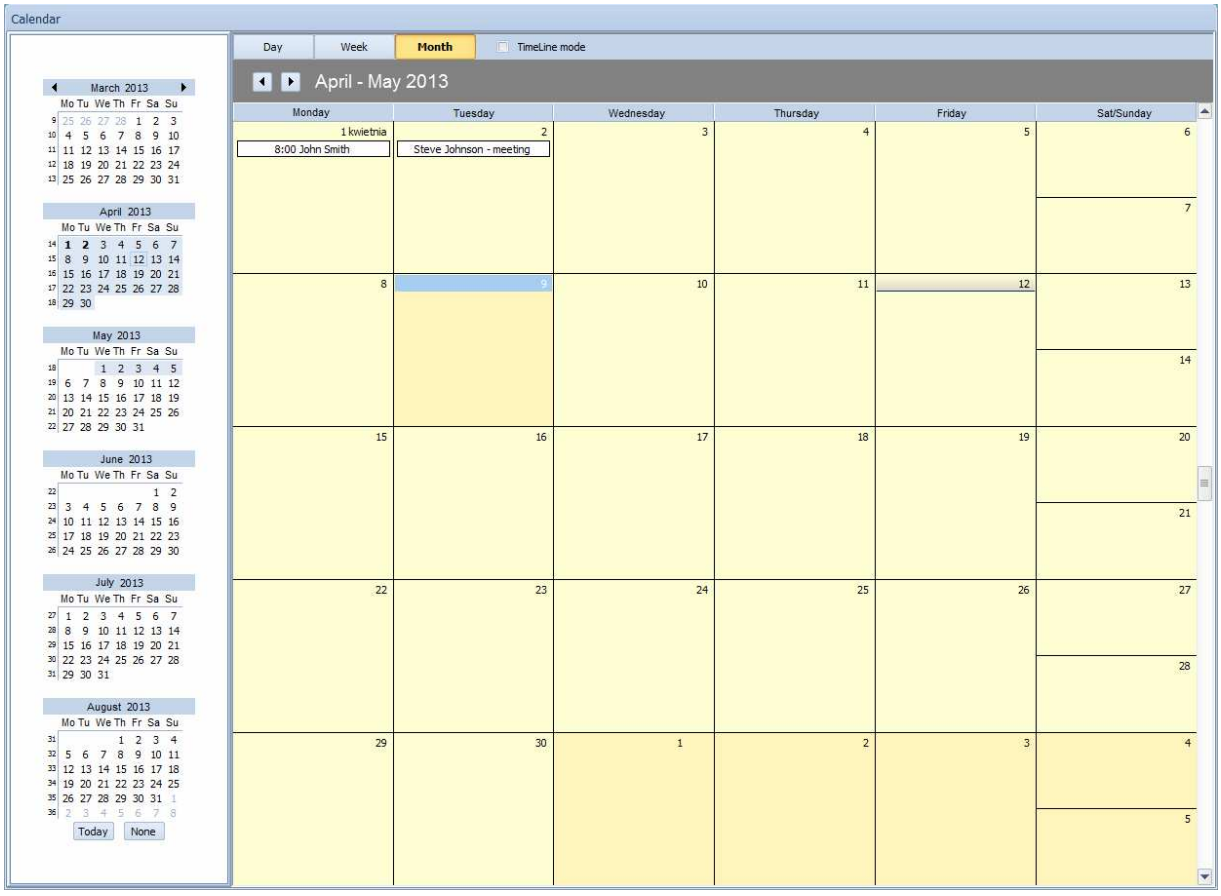



**Figure 24. Visits and Tasks Schedule**

In order to facilitate the planning of patient visits, a mechanism has been implemented that allows for easy transfer of patient names from the HolCARD 24W database to the Schedule. In the window <**Patient Data**>

next to the patient's name. There is a button with the symbol of a black dot. Pressing it will copy the patient's name to internal clipboard. In the Schedule module, you can add a visit by using the data stored this way. Simply right-click in the text entry mode (e.g. after clicking the bubble saying "Click to add a visit"), and when a menu appears, select <**Paste**>. The patient's name will be entered in the Schedule.

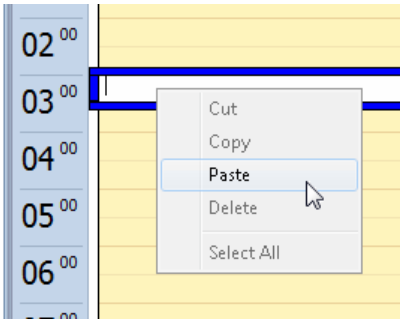



**Figure 25. Pasting patient's name in the Schedule**

## 3.3 Quick WWW access

Clicking the <**WWW**> button, which is located on the left side of the main window starts the websites review. It is a tool that allows quick access to important websites.

**Figure 26. Access to WWW**

You can enter the address of the website by selecting it from the list of entered websites, which is located at the top of the window (see Figure 26) or enter it via keyboard. When you enter a new address, click <**Go**> to load the page.

# 3.4 System tools

System tools allow you to perform some specific operations in HolCARD 24W. They enable:

- Performing storage archiving e.g. onto USB or CD/DVD
- Selection, setting up active exam storage
- Configuration of the PHOTO mode
- Defining the type of the included signal filtering from AsPEKT 903
- Setting user data

To run System tools, click the <**Tools**> button on the left side of the main window.

## 3.4.1 Archivization

The Archivization Module allows a security storage backup to be performed in the external memory (e.g. the USB memory, the external disk, the network disk) or on a CD/DVD disk. The archivization proceeds so that after it is performed, the archive performs the function of separate storage, which enables the efficient review of examinations immediately following the downloading from the medium.

To activate the process of archivization, click the <**Tools**> button. A dialogue window with various buttons will open on the screen – one of which is the <**Archivization**> button. When this button is selected, the main module for studies archivization will be displayed.

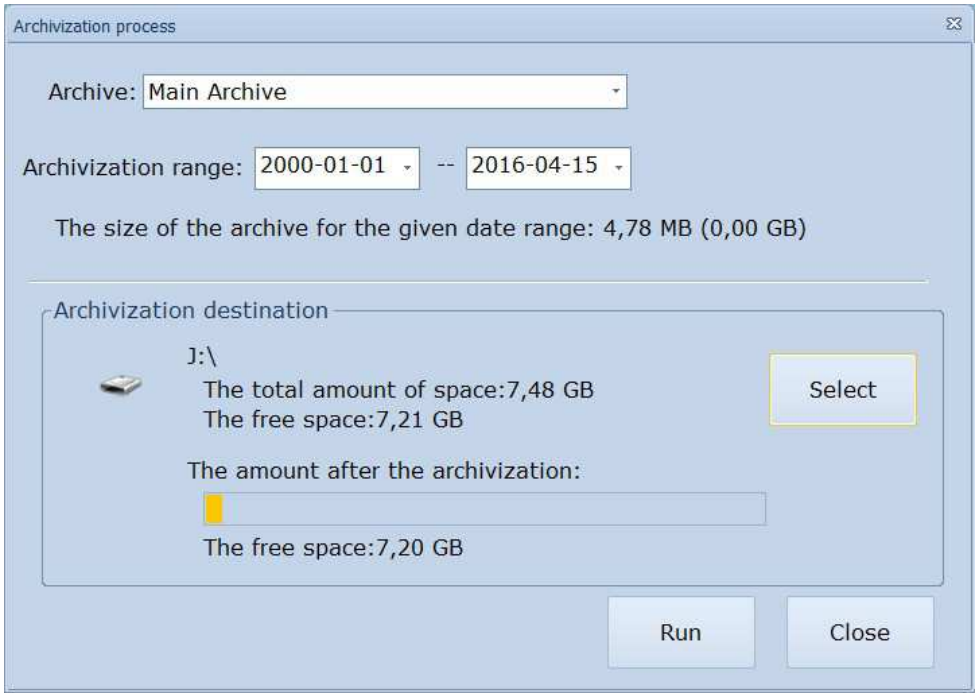



**Figure 27. Archivization process**

## Performing archivization

It is always only current storage which may be archivized. Only examinations from a given time interval – i.e., from the range of days listed in the window – are copied. Archivization occurs into the indicated medium. When archivization is completed, the system remembers the period of the last archivization and sets the date following the last archivization as the beginning date. The user may change these dates as desired.

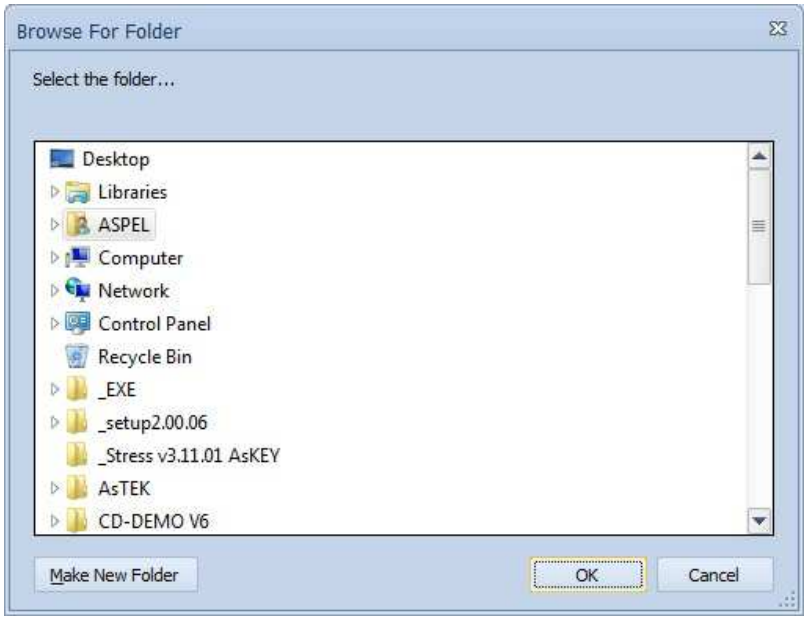



**Figure 28. Browse for archivization folder**

In order to perform an archivization:

1. Set the period of archivization.
    - Each change in the period of archivization causes an automatic re-calculation of the size of storage for the given period. In the event that the storage contains a very large number of patients and examinations, a window with information on ongoing calculations will display.
2. Select the archivization location.
    - The most recently given archivization location is always set as the default location. The <**Select**> button allows indicating another archivization location. By pressing this button, connect the external memory to the computer or insert a CD/DVD disk into the reader.
    - If a CD/DVD disc is not the selected archiving place, a folder may be selected to save data. The archive will be saved in a selected location in a folder named in the following configuration: A H24W_date_time - date_time of archiving in the format (yyyddmm_hhmmss);
    - If the selected place of archiving is a CD/DVD disc, the screen may display a system message regarding the recording; this should be cancelled. For further steps, please follow the guidelines provided in the “Recording tests on a disk” section;
    - The window shows basic information about the selected place for archiving and whether the archive will fit within the selected memory. If the progress bar is red, it means that the archive will not fit in the selected location. In this case, you should indicate a different archiving location (e.g. replace the USB memory with another one, insert an empty CD/DVD disc or reduce the size of the archive by limiting the date range).
3. Activation of the archivization process.
    - The archivization process is set in motion by clicking the <**Run**> button. If a mass memory is selected (e.g., USB memory, an external disk, or a network disk), a window reporting the progress

of archive creation will display. The conclusion of the archivization process will be noted with an appropriate message. For archivization onto CD/DVD disks, an additional window will display – see below.

## Recording tests on a disk

After the <**Run**> button is pressed, if a CD/DVD device has been selected as the archivization location, the following window will display on the monitor screen:

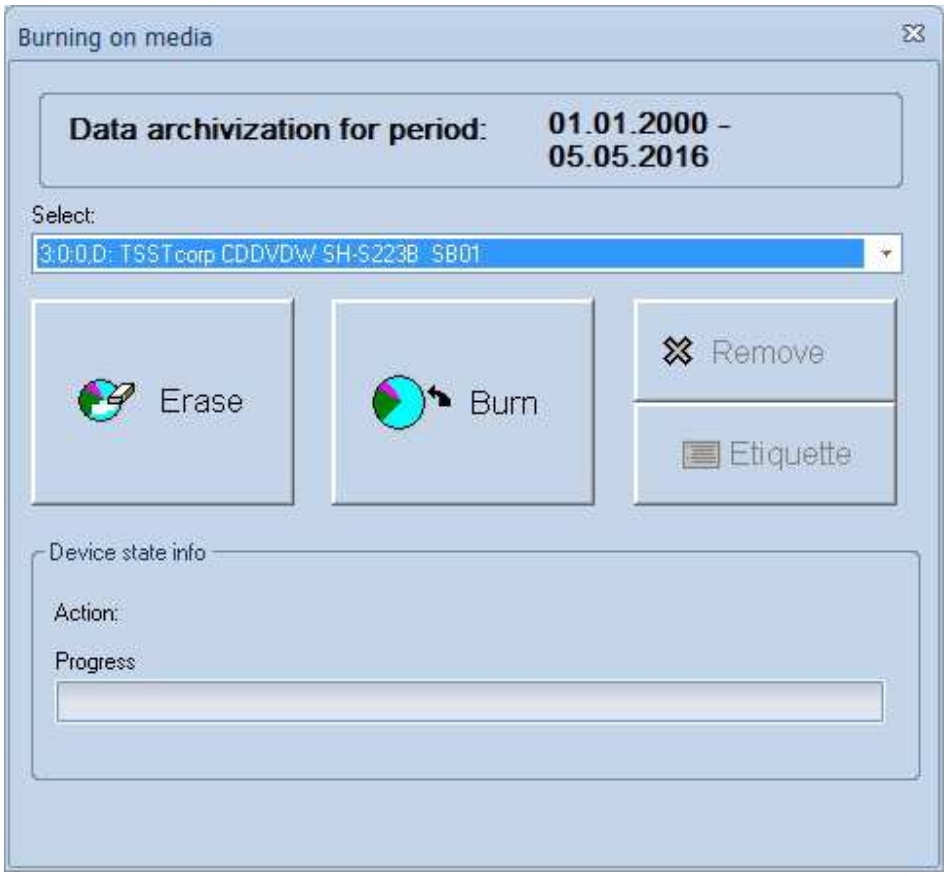



**Figure 29. Burning on media**

CD/DVD disc archiving window includes the following elements:

a) Recorder selection field

- This field allows you to select a device which will enable you to record the disc. If your computer has only one device, the recorder selection field will show only the name of that device and it will not be necessary to select it.

b) <**Burn**> button

- This button starts the process of saving the archive to the disc.

c) <**Erase**> button

- This button allows you to delete all data from a rewritable CD/DVD disc.

d) <**Remove**> button

- This button deletes the exams recorded on the disc from the computer hard disc.

e) <**Etiquette**> button

- Allows you to print on paper the contents of the recorded disc on a default printer, set up in MS Windows.

During the recording, the lower part of the window will display the status of this process. After the recording of tests on a specific CD is completed, the process of data verification will be started automatically. If the verification reveals any inconsistency, the backup process will be suspended. If the user replaces the CD with another and wishes to continue (a dialog box asking about that will pop up) then the process is resumed on another disk.

## Backup history

Insight into the backup history is enabled by the button in the main backup window <**History**>. Pressing it will open the history window. This window allows you to view what has been saved to the disc (i.e. patient's first and last name and his/her exams) as well as search for discs with the saved exams of a given patient.

The contents of this window:

1. Table with information regarding backups
   - the table displays the date of the backup, the name of the CD, on which the tests are stored, and – in case of standard backup mode – the period it covers.
   - Depending on the backup mode you selected, the name of the disk is generated accordingly:

     STD date of backup OKR period in the from – to format CD disk number.
     e.g. STD 12.12.2007 OKR 03.04.2006 – 07.07.2007 CD 1

2. <**Show contents**> button:
   - displays the contents of the disk selected in the table. The contents can be displayed by double-clicking the disk with your left mouse button.
3. <**Search**> button:
   - displays the search window for browsing patients or disks. The process of patient search allows displaying all disks, on which their tests have been archived. Searching CDs marks the backup on a particular disk in the history table.

4. <**Label**> button:
   - pressing this button start printing the contents of a CD (as a cover).

## Searching patients and disks

Clicking an appropriate button in the history window will open the search window.

To search all disks that store a particular patient's tests, choose the <**Patient search**> option, and then fill in the search fields with the patient's data. (Fig.82). The more detailed data you put in the search field, the more accurate the result. E.g. If you only enter the name "Adam", the program will find all patients with this name.

The results will be displayed in a window showing the names of CDs, on which the tests have been archived. The contents of the disks can be viewed as in the "History" window.

The system does not recognize the input sequence in Name – Surname; therefore, if you enter the letter A in the search window, then the program will find all patients, whose either name or surname starts with an A.

Pressing the <**Search**> button will open a window showing the list of disks containing a patient's tests. The contents of the disk can be viewed as in the <**History**> window. If a disk contains more than one patient that meet the search criteria, the window will display buttons for navigating the data of these patients.

To find a particular disk in the history, choose the <**Disk search**> option, and then enter the name, or part of the name of the disk. If you enter a part of the name, the search results will show all files that contain that name. E.g. entering "ZAAW" will result in finding all disks made in advanced backup mode.

**Additional information**

Archiving on CDs runs in single-session mode, which means that a CD is closed after recording and no other data can be added to it. This particularly applies to CD-RW disks. This principle has been adopted to prevent data overwrite.
The module supports backups in the following disks:

- CD - R
- CD - RW
- DVD - R
- DVD + R
- DVD - RW
- DVD double layer (DVD-DL)

Important: Data will be recorded to a disc, provided the computer has an installed device supporting the particular format.

Note: All custom-sized carriers, or partially overwritten CDs are not supported in this module.

**IMPORTANT**!!! Manufacturers usually provide a 10-year warranty for data carriers. We recommend that you back up your data on media with a longer life. All information is usually available on the manufacturer's website or in the point of sale.

## 3.4.2 Exams Archive

A Holter examination loaded by the HolCARD 24W System © Aspel is remembered on the computer disk in a strictly defined place – this location is known as the examination storage location. To facilitate managing a large number of loaded examinations, the possibility of creating many different storage locations has been introduced. Storage locations may be found on a physically connected computer disk or on any other medium which is interpreted by the MS Windows system as a disk e.g.: a CD-ROM reader, a CD-RW, magneto-optical disk or any other discretionary archivization device, or network disks.

Every storage location is identified by a discretionary name given during the creation of such storage and by the access path to the file where this storage is located. At any given time, one of such storage locations is the current storage location (in the Figure 30). New examinations, which can later be transferred to other places, are loaded into this storage.

**Reviewing the contents of an examination storage**

It is possible to review the contents of a selected examination storage. In a separate dialogue window, a list of registered patients in a given storage will display. To do this:

- Select a desired storage – mouse over the name of the storage and press the left key,
- Select the button <**Display**> – mouse over the button and press the left key,

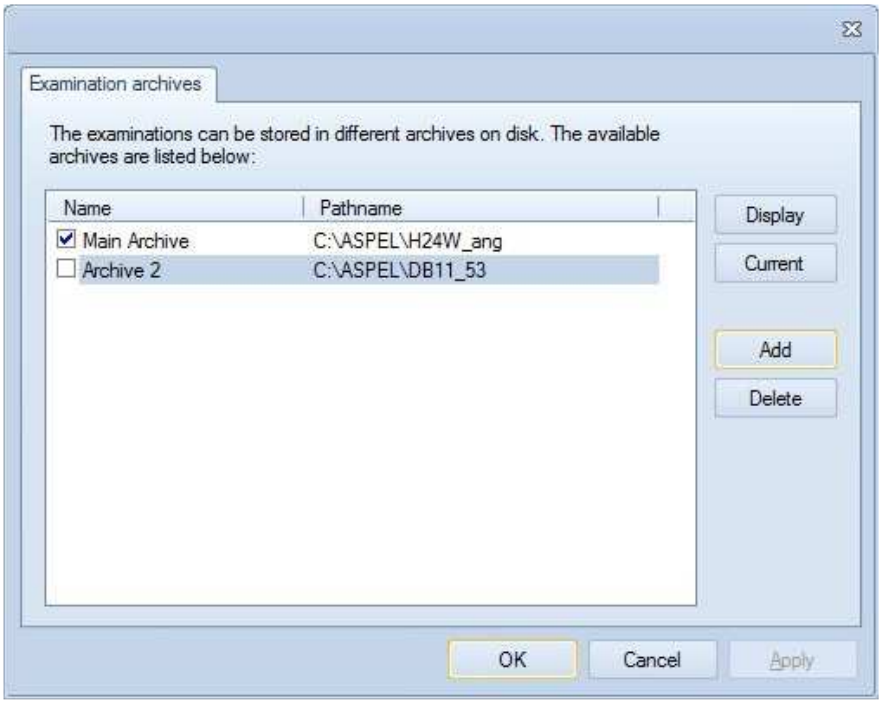



**Figure 30. Examination Archive**

## Selecting the current examination storage's location

One of the storage locations is designated as the current storage location – a 'tick' on the left side of the storage location name. The current storage differs from other storages only by virtue of the fact that new examinations are loaded into it (field <**Load Examination**>). To select another storage as the current storage, move the cursor into the area of the rectangle found next to the name of the storage and press the left mouse key or select the given storage and then use the button <**Current**>.

## Creating a new examination storage

A user of the HolCARD 24W System may create his own examination storage to store examination. To do this he/she should select the button <**Add**>.

On the monitor screen a dialogue window will appear which allows him/her to indicate the location for storing the examination (i.e., disk and file). This is a standard window of the MS Windows environment which is used to save or indicate files. If necessary, he/she can create a new file in the selected location by using the icon <**Make new folder**>. In the field <**Name**>, enter the name of the examination storage which has been created. If all the information has already been entered, confirm the operation by selecting the button <**OK**>. A newly added storage will be recorded in the system and will appear on the list of available storage locations.

## Removing an examination storage

Any desired examination storage may be removed from the system. However, the consequences of this operation must be remembered: all of the examination remembered in a given storage will be deleted irretrievably.

To delete a storage, indicate the given storage by moving the cursor into the area of the storage name and press the left mouse button, then select the button <**Delete**>. A message will appear on the monitor screen with a request to confirm the operation which has been performed.

## 3.4.3 PHOTO mode configuration

HolCARD 24W © ASPEL has the ability to attach images of every patient's ID. This option increases the level of security in identifying the patient with a test and recorder (2.3 Upload test from recorder). The way of uploading images has been described in detail in 3.1.2 Patient data and tests

PHOTO mode configuration allows you to specify, which of the available ID images is to appear in the patient data window as the starting image – see Figure 31. The remaining images are only available after pressing an appropriate button.

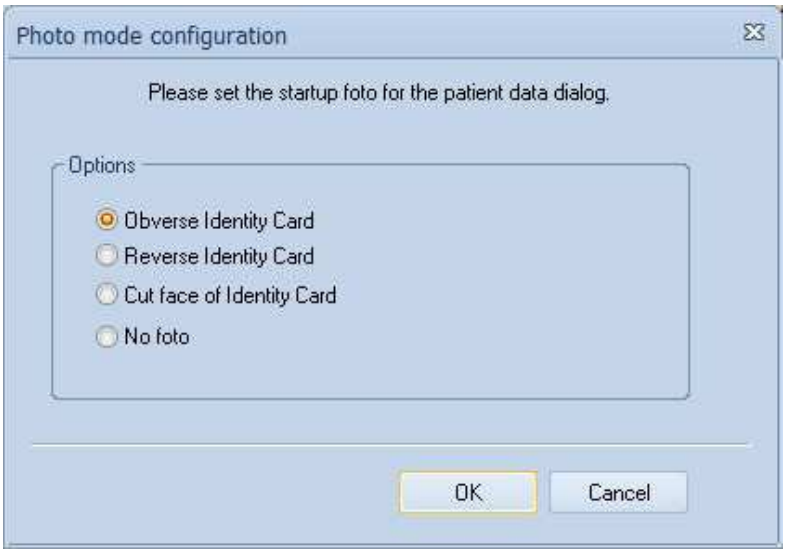



**Figure 31. PHOTO mode configuration**

## 3.4.4 Test filter in AsPEKT 903/703/712

Tests carried out by the AsPEKT 903, AsPEKT 703 i AsPEKT 712 recorder may be subject to filtration during uploading to the program in order to eliminate unwanted interference. The user has 3 types of filters at their disposal – the baseline filter prevents the baseline from wandering, and muscle artifact filters eliminate disturbances from muscle tension. It is recommended to connect the following filters to AsPEKT 903 recorders – <**Baseline filter**> and <**Muscle filter 2**>. In case of strong disturbances, you can switch on a heavier muscle artifact filter <**Muscle filter 1**>.

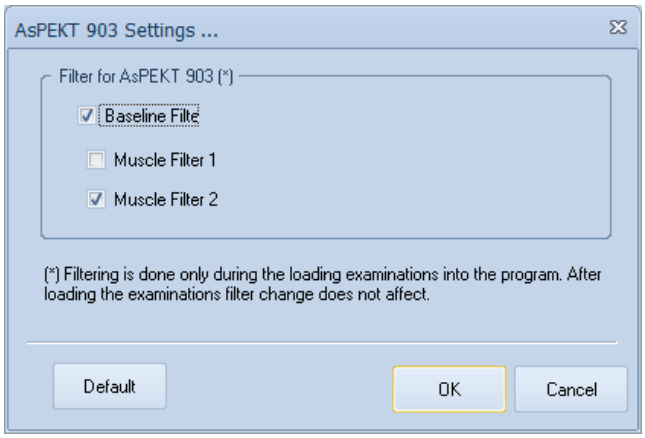



**Figure 32. Filter Settings**

Keep in mind that signal filtration is only done during test uploading. If the test is already in the HolCARD 24W database – which means it has been uploaded, then changing these filters have no effect on the ECG signal in that test.

## 3.4.5 User data

While generating reports on Holter tests, the first page of patient data in the printed headline shows user data found in HolCARD 24W © Aspel. That data include: the name of the facility performing the test, its address and other data, e.g. phone number. All this information may be set by selecting menu <**Tools**> field <**User data**>. On the monitor screen, a dialogue window will appear will which allow entry of the particular information.

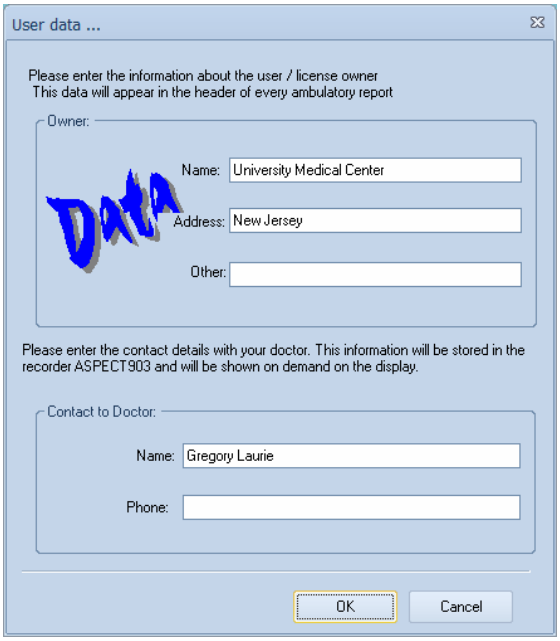



**Figure 33. User Data**

Additionally, you can enter information that will be stored in the AsPEKT 903 recorder – the name of the person the patient should contact in case of problems while wearing the recorder, and their phone number. These data will be available on the display of AsPEKT 903 after pressing the appropriate buttons.

After entering or editing individual fields, all changes should be confirmed by pressing <**OK**>. The data will be saved in the program.

In the case of changing the data of the office, the information included can be edited (corrected). Data edition is done in a standard way, as in most window-based programs under MS Windows. Characters can be removed using the <**Backspace**> key, switching between successive fields <**Name**>, <**Address**>, <**Other data**> is done using the <**TAB**> key or using a mouse.

# Chapter 4

# Automatic analysis

## 4.1 Analysis configuration

Initial analysis of the selected examination (so called automatic analysis) is based on settings arranged within the very first minutes of recording and eventual changes introduced by the user. These settings are of paramount importance for quality of the whole automatic analysis. Therefore it is important to have high quality and simple initial signal, which will provide:

- High value of QRS amplitude – between 1mV a 1.5 mV and more,
- Low noise level,
- Stable base line,
- No arrhythmia of the type: pause, tachycardia, etc.

### Selection of a channel for analysis

The most important thing is to decide which channels should be selected for analysis and which should be rejected. HolCARD 24W © Aspel program may analyze an examination in one, two or three channels. Channels with the highest QRS amplitude and channels containing important information on heart work should be selected for analysis. If channels are selected improperly it may result in lack of detection of ventricular beats or in false detection of beats, which actually do not exist (e.g. where noises appear), as well as generating a great number of templates.

Please note, that a channel which was the best at the beginning may eventually become worse because electrodes have been unfastened or loosen. Therefore it is important to browse the whole examination data to assess quality of the channels using Full disclosure and Strip modules, which are displayed on the screen. After making an assessment the channels should be highlighted in the analysis window (Figure 34). The window allows choosing separately the channels on which QRS detection will be conducted and separately the channels on which morphology will be assessed. To start the analysis press <**START**> button.

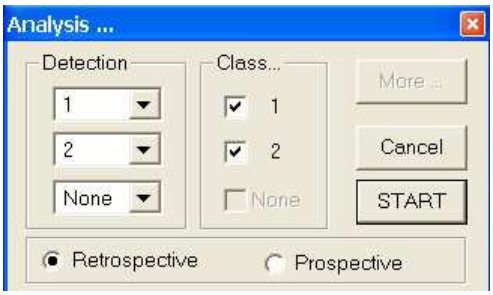



**Figure 34. Dialogue box for analysis setting**

**Other options**

Analysis settings window allows changing of an active channel polarization with <**Inverse Polarity**> button and set value of the ECG signal displayed in Full disclosure module. Controlling of the signal makes the presentation of the test better clear-cut and is set with <**Gain indicator**> scroll. All these options are available after choosing <**More...**> button.

**Remember**! Quality of ECG signal is of paramount importance. You must take care that patient's electrodes are properly connected to ensure minimal resistance of connection and high amplitude of beats. Monitor AsPEKT program and recorder will help you only to control the performed activities.

The loaded examination may be browsed in several ways. The next section will inform you about the most important modules, which will ensure fast evaluation of the examination and help to make the correct diagnosis.

## 4.2 Examination review

Several modules preset the test in several ways:

1. Full Disclosure,
2. Strip,
3. List of strips,
4. Templates,
5. Tables,
6. Trends,
7. HRV analysis (*Heart Rate Variability*),
8. QT analysis,
9. Cardiac pacemaker analysis.
10. HRT analysis,

Each module may be started from the program toolbar or <**Review**> menu. To end the work of a module click on an icon on the toolbar or an icon in the menu. Toolbar icons inform (on/off button) whether the given module is on or off.

The first three modules (Full disclosure, Strip, List of strips) allow to reach any part of the test and operate both in analyzed and non analyzed examinations. Other modules (Templates, Table, Trends, HRV, QT, pacemaker analysis, HRT) are dedicated to presentation of Holter analysis results. In case of not analyzed test these modules are not accessible (gray).

**Figure 35. General view of the menu and toolbar**

Figure 35 represents general view of HolCARD 24W © Aspel window that is content of the title bar, menu and toolbar. Pointing any of the icons with a mouse cursor you will see a short prompt explaining the meaning.

**Remember**! The modules are shown in the same sequence as they actually appear at the toolbar. This sequence is also suggested for browsing and editing the examination after the automatic analysis.

Other modules of examination browse and presentation of analysis results are described in next sections.

### 4.2.1 Full Disclosure

Full disclosure module allows to view the whole test in any channel selected by the user (HolCARD 24W © Aspel is a 3 or 12 channel system – depend on recorder) and print any part of or the whole examination.

All operations referred to this module are performed with the help of the toolbar located at the bottom part of the module (so called module toolbar).

**Examination reveiw**

There are three ways to browse the examination:

1. Go to the preset examination time.
   - Select an icon <**Go to specified time**>,
   - Set the time you want (remember to change the date if the time includes examination performed after the first day of recording),
   - Press <**OK**> to accept.
2. Browsing next pages of the examination
   - Select one of the buttons which allow to browse pages:
     – beginning of the examination,
     – back,
     – forward,
     – end of examination.
   - Repeat the operation as many times as needed to reach the place you want.
   - You can shift a frame on the screen with arrows (up, down, left, right).
3. Automatic browse (so called film)
   - Select <**Film**> icon. The program will automatically go to next pages of the examination after about 1 second. In this time you can use the above described buttons to shift to the preset time or manual browsing. In this way you may change the place of automatic browse. Select <**Film**> icon again. The program will end automatic browsing and remain at the place of browsing end. Select <**Film**> again to start automatic browsing starting at the place it has been previously stopped.

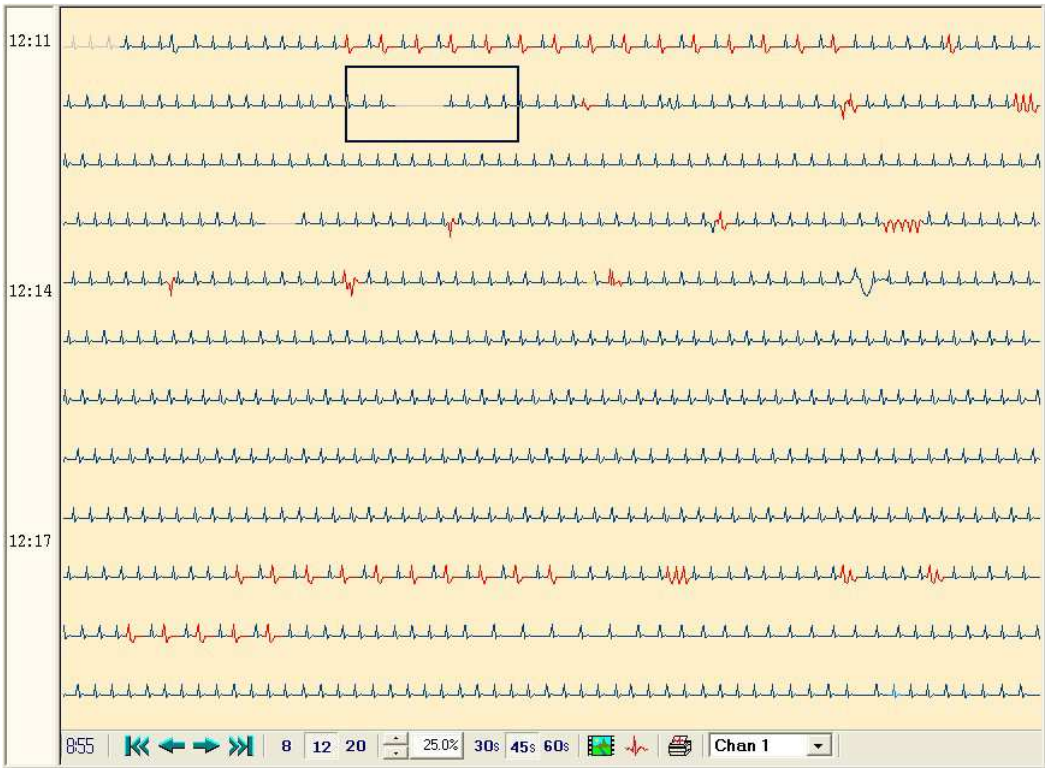



**Figure 36. Full Disclosure module**

## Other options

You may change a number of information displayed by the module any time you want – larger or smaller time interval or more or less information in one line. Use buttons <**Number of lines in the window**> and <**Seconds in the line**>. The program allows to set 8 lines on the screen, 12 or 20 lines, 30 sec, 45 sec or 60 sec, each. You may select the required time interval with those groups of icons, and check the time of examination at the <**Examination time bar**> on the left of the module window.

Example 1: 8 lines on the screen, 30 seconds each = 4 minutes of examination (minimal interval)

Example 2: 20 lines on the screen, 60 seconds, each = 20 minutes of examination (maximal interval)

In case the signal amplitude is very small and the course of examination is not distinctly visible on the screen you may strengthen it by pressing a special icon. Strengthening is only for visualization reasons and does not influence results of the analysis (i.e. ST level).

Beats detected in the analysis are coloured to facilitate verification of pathological states. It is very important when this module is displayed together with other modules showing concrete results of the analysis.

You can change classification of beats is a large part of ECG record:

1. Highlight ECG part:
   - Point the highlighted field with a mouse
   - Click the left button and drag a cursor to the end of the field.
2. Select morphology in the highlighted field.

A dialogue box for morphology selection will appear. Templates will be changed for all beats in the highlighted field.

To have exact view of the examination press <**Strip**>. The highlighted part will be enlarged and presented in three channels at the same time.

## 4.2.2 Strip

The strip shows a short part of the examination in all the channels. It is the most often used module also for presentation of beat templates and tables.

This module is operated from the toolbar in the bottom part of the module and the upper line of the strip description.

ECG course is drawn on the millimeter grid (1 grid = 1 cm) with 1 mV amplifying feature on the left. You may move along the whole examination – from the beginning to the end – with <**Strip reveiw**> button. Current location is signaled with <**Strip beginning time**>.

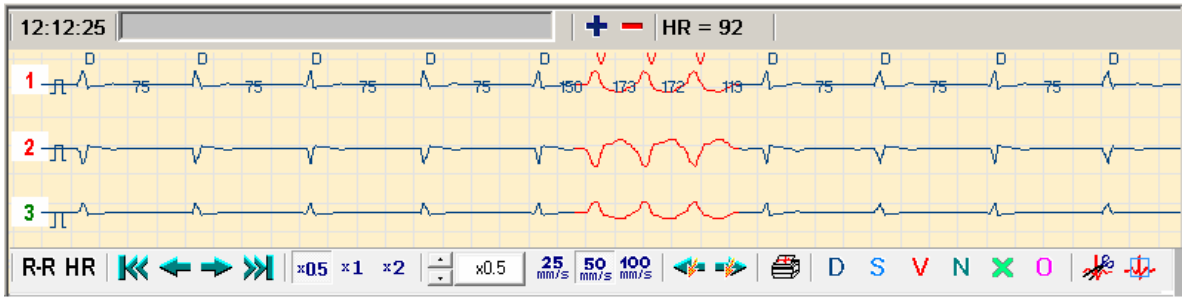



**Figure 37. Strip module**

### Beat description

Beat templates are displayed in the upper part of the strip. Information about RR (in ms) and HR is displayed between beats. RR and HR descriptions my be switched off with <**HR**> and <**RR**> on/off buttons.

### Amplifying and recording speed

The displayed signal may be set in one of three standard positions: x0.5, x1, x2 or smoothly controlled. A change in amplification does not change the value of the represented signal, which is always 1 mV, despite the settings. It allows initial evaluation of QRS.

The strip presents a section of the examination depending of the selected <**Signal display speed**>:

| Speed | Time |
|---|---|
| 25 mm/s | 16 s |
| 50 mm/s | 8 s |
| 100 mm/s | 4 s |

Tool tip displays accurate information about the length of the strip. The size of displayed information does not change even after a module window size changing.

### Description of the strip

Each strip may be described and saved in the Strip List module. This module (see details in section 4.2.3 Strip List) gives fast access to chosen parts of the examinations and print them while the report is being generated. Description is placed in <**Strip description line**> and accepted with < + > button. A green arrow, which will appear on the strip informs that this part of the examination has already been saved and described.

A description may be freely modified by deleting the existing description or a part of it with <**Backspace**> or add your own text. Modifications are also saved with < + > button.

The saved and described strips may be removed by pressing < - >. Strip description and arrow will be removed from the screen, and information will be erased from the Strip List.

You can move to the next or previous event with <**Next event**>, <**Previous event**> buttons. The place of event occurring is signaled with an arrow – the red arrow informs about a patient's event, and the green arrow informs about strips saved by the user.

If a part of examination has been saved twice, two arrows are displayed. The description seen in <**Strip description line**> always refers to the first arrow. To read the next description move the beginning of the examination in such a way that the first arrow disappears and the second arrow is at the beginning. For accurate shifting of a strip by 1 sec use left and right arrows of the keyboard.

## Strip printing

Strips may be printed:

- directly,
- through a list of strips (output queue).

Press <**Strip printing**> for direct printing. Before printing you may enter your own description in a window which will appear on the screen. Printing starts 10 seconds before the strip is displayed and contains 20 seconds of the examination. The printout encompasses the surroundings of strip begining 10 sec from the left and 10 sec from the right.

In case of an option of the output queue, save a part of the examination with <**Save**> button in the upper line of the strip and then Print in Report menu. Each printed page contains 3 strips. For the detailed description see section 6.1 Generating reports.

## Reclassification

Each detected beat is coloured and signals the position of R peak with a relevant abbreviation. Morphologies are marked as follows:

| Morphology | Abbreviation | Colour |
|---|---|---|
| Dominant | D | Yellow |
| Ventricular | V | Red |
| Supraventricular | S | Blue |
| Artefact | X | White |
| Unknown (Other) | U | Green |
| Non-classified | N | Grey |
| Pacemaking | P | Purple |
| Summarised | F | Purple |
| Block | B | Purple |
| Own | 1, 2 or 3 | Purple |

Each detected beat may be reclassified. To do this:

1. Indicate a beat or a group of beats:
   - To highlight a single beat click QRS field with the left mouse button (near R peak). A red frame appears.

- To highlight a group of beats click with a left mouse button the filed of the first beat and keeping the key pressed move to the last highlighted beat (near R peak) and release the button. QRS beats you have selected will be red framed.

2. Select new morphology.
   - Press <**Reclassification**> button. When the button is released, the program will automatically change the morphology of the selected complexes and change a colour.

Buttons of colours are the same as colours of morphologies to facilitate the operation. Additionally, after moving mouse cursor in the field of whichever reclassification button an explanation of the meaning of particular abbreviation appears.

**Measurements**

<**RR intervals display**> button is at the beginning of the module toolbar. When pressed, it displays RR intervals between consecutive QRS in [ms].

Strip module shows a selected part of the examination with full information about ECG course, that is correct amplitude and duration of beats, those values may be measured for any QRS complex.

Measurement of amplitude and duration of the signal:

1. Press and hold **<Ctrl>**
2. Move mouse cursor to the beginning of the measurement (e.g. R peak of QRS complex).
3. Press and hold the left mouse button.
4. Drag the cursor to the end of measurement (e.g. level of the next QRS base line). You will see a rectangular frame indicating the field of measurement.
5. Read the deflection value and duration in the window which will appear in the left top corner of the strip window.
6. After measurement ending release <Ctrl> and mouse cursor.

**Remember**! Full Disclosure and Strip modules are very often displayed together. A change of position of the frame in ECG module automatically changes the content of the Strip. A change in the examination part displayed in the Strip module will automatically change the position of the frame in ECG module.

## 4.2.3 Strip List

Strip list module is designed to save important lists. You can print strips and attach to the report. The list also allows fast access to parts of the examination.

**Strip categories**

This module distinguishes 4 categories of strips:

1. (Patient's) events A
2. (Patient's) events B – AsPEKT 903, AsPEKT 703, AsPEKT 712
3. Strips
4. Irregularities of rhythm
5. ST episodes

Events button is built in AsPEKT recorder. A patient should signal any not typical situations by pressing this button. The recorder saves the moment of such event and HolCARD 24W © Aspel system presents it as a strip. Events category contains all the signaled events of the examination.

For the detailed description see section 4.2.2 Strip.

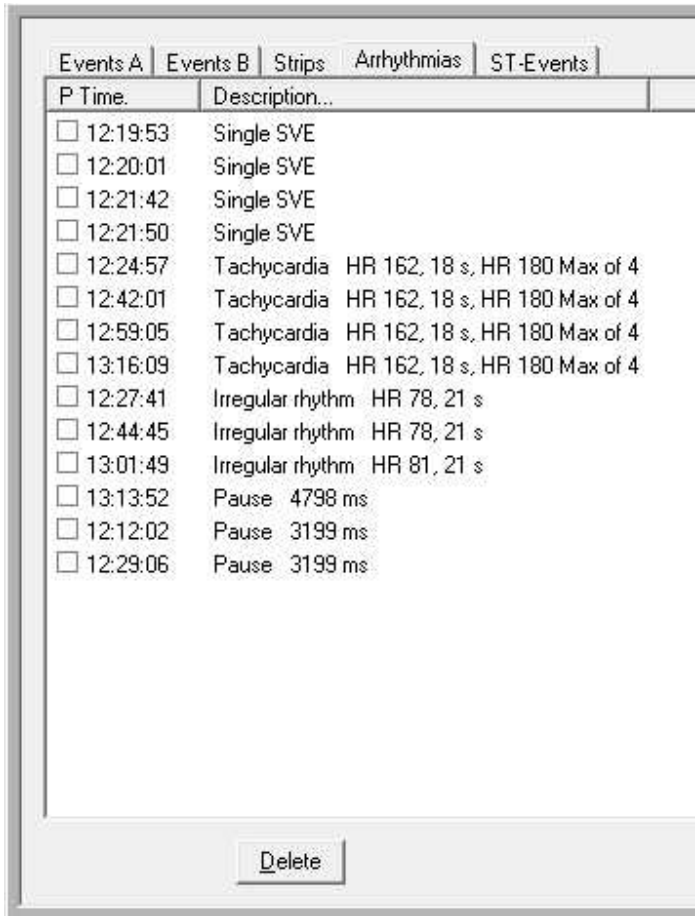



**Figure 38. Strip List module**

Automatic analysis is followed with rhythm irregularities and ST episodes generated by the system. Each type of rhythm irregularity is documented on the list with one strip. It is always the longest irregularity of the given type or the first irregularity if duration time is not significant for the given disorder. All episodes detected during the examination are included in ST episodes.

## List Edition

The first column includes the time of strip beginning and additional information whether the strip is to be printed when the report is generated. If a small square is ticked, it means that the examination is to be printed (left click on the square). To print the highlighted strips select <**Print**> in <**Report**> menu. The detailed description is in section 6.1 Generating reports.

The second column contains a description of the strip. The description is easily modified:

1. Select a strip. Left click on the strip start time.
2. Press <**Modify**>.
   - A window will be displayed to modify a description by adding or deleting any part of the test. You may also delete a description with **<Backspace>**
   - Confirm the entered modifications with <**OK**>
3. Repeat the same action for any strip, if required.

Patient's event program automatically introduces an initial description like: "Patient event no ...". This description should be followed by a patient's comment rewritten from a patient's diary and doctor's notes. Only then it makes the complete documentation of atypical events.

You can also add or delete new events. Adding new events is particularly useful when a patient entered an atypical situation in the diary but has forgotten to signal it with he event button. Add doctor's strip in Strip module. To delete an event, highlight it on the list and press <**Delete**>.

**Remember**! Strip list interacts with Full Disclosure and Strip modules. It is recommended to activate all three modules at the same time because in case of choosing any event from any category Full Disclosure and Strip frames will be at the beginning of the time that event occurred. Full Disclosure allows to evaluate what happened in the close vicinity of the event, and the Strip allows accurate investigation of the event itself.

### 4.2.4 Templates

Upon completion of a Holter analysis each QRS will have its morphology. HolCARD 24W © Aspel system differentiates six types of morphology:

- Dominant,
- Supraventricular,
- Ventricular,
- Other – unknown morphology,
- Artifact,
- Own (Pacemaker, summarized, blocks).

QRSs may have different templates. Each detected group of templates is called a class, and a representative of the class is called a standard. A representative is a QRS which reflects best templates of all other QRSs in a given class.

**Figure 39. Template module**

The Templates module presenting all the detected templates in the given morphologies allows to browse particular beats qualified to a given template and edit templates.

The window of this module consists of three parts:

- **Morphology selection buttons**. Each button contains a number of QRS beats in a given morphology and a number of detected templates.
- **Template selection buttons.** Each button contains templates and related number of beats in brackets. Additionally a representative of a template is drawn on the button. Here you will find only buttons of templates of previously selected morphology.
- **Strips**. It is a standard Strip module which allows browsing of all beats in the template.

The Strip module has the same functions as the one described in Section 4.2.2 Strip. The only difference results from replacing <**Next, Previous Event**> buttons with <**Next, Previous Template**> buttons.

To select morphology or template click the left key of the mouse on the selected button.

## Group buttons selection

Edit operations in Template module refer to all the QRS classified to currently chosen Template (dimmed button). In Template module you can highlight more than one button at the same time and reclassify the whole group.

- Press and hold **<Ctrl>**,
- Select the next template (left click of the mouse).

You can repeat the whole operation many times by creating a new template and drag it to another morphology or template. There is also o possibility of marking off any element in the template. Hold <**Ctrl**> pressed and select again the highlighted button.

Alternatively, you can highlight a certain group of buttons:

- highlight the first key,
- press <**Shift**> and hold it pressed,
- highlight the last key.

All the keys, from the first to the last, will be highlighted as selected ones. Such group may be dragged to another morphology or connected to another class.

### Class Survey

When the module is activated, dominant morphology class is presented as default option. To browse classes of other morphologies do the following:

- Select one of the buttons of available morphologies. This button will be shifted to the left to indicate which morphology has been selected.
- Hitherto class buttons will be replaced with new ones, according to groups of shape of the selected morphology.
- The most numerous class (first on the list) of given morphology will be marked out because classes are always placed by the number of QRS. The selected class is indicated with a colour changing of the button which will be the same as a colour of the strip (see Figure 39).
- Strip content is changed in such a way that a frame indicates a part of test where a representative of the class appears. This allows to see a template in all three channels at the same time.

To see a representative of a different class on a strip, click the left button of the mouse. A selected class will be highlighted and a strip will be automatically displayed.

### Change of amplitude and displayed channel

In order to change amplitude of a displayed signal in class buttons it is enough to use buttons on the toolbar. You can also use:

- < + > (numeric keypad) – amplitude increasing
- < - > (numeric keypad) – amplitude decreasing

On screen information will be automatically updated. A change of amplitude often helps in evaluation of morphology group.

Buttons of subsequent classes display representatives of a given class (groups which reflect nature of the whole class the best). To change a channel select <**Channel change**> button or a key: <**1**> channel 1, <**2**> channel 2, <**3**> channel 3.

### Classes connecting

Classes of the same morphology may be connected into one class. When a user finds two classes identical from the medical point of view or with negligible differences, such two classes may be merged. Such operation depends on “throwing” a reference class into the second class called target class. Size of the target class is increased by a relevant number of groups contained in the reference class, the representative, however, remains unchanged.

In order to merge two classes of the same morphology, do the following:

1. Select a reference class.
2. Move the cursor above the reference class once again. Press the left button of the mouse and hold it pressed. The cursor will change its shape –a plus sign appears next to the arrow.
3. Hold the key pressed and move the cursor above the target class.
4. Release the mouse key. You have just entered the reference class into the target class.

### Beat browse

To browse subsequent elements of the class, that is beats, two browse methods are applicable.

**Method one** (with a Strip):

- Select a class. The strip will be automatically set at the representative of that class.
- Select <**Next element**> button on the toolbar in Strip module. The strip content will be changed and a frame will be placed at the first beat belonging to the selected class.
- Select <**Next element**> again to move from the second to the third beat in this class, etc. Beats are presented in the same order they appeared during the test.

Press <**Previous element**> button to return to the previous beat classified in the same morphology. Use <**SPACE**> to make your work easier. <**SPACE**> functions same as <**Next element**>. If you want to browse all elements and verify the analysis, just press <**SPACE**>.

**Method two** (page mode):

- Select class you want to browse.
- Press <**Page mode**> button. Instead of morphologies and classes, subsequent QRSs of this class will be displayed. On the toolbar you will see <**Page mode end**> button.

To return to the previous screen (close browse) select <**Elements browse button**> on the toolbar or press <**ESC**>.You may also move to class element browse mode with double mouse click above the button of a selected class.

Generally, elements browse is the same as classes browse. Subsequent groups are divided into pages. You can change pages in the same way as described above or you can change amplitude and select another channel.

Additionally, two operations have been introduced:

1. Highlight all groups on a given page with <**A**> key (All)
2. Invert the meaning with <**I**> key (Inversion)

### Class of ”unknown” type

In case of manual QRS reclassification (detailed information in 4.2.2 Strip), changed beats are placed in a special class called <**Unknown**>. Such class is created for each morphology separately, if needed. <**Unknown**> class does not have to contain all identical beats – it depends on kind of operations performed by a user. This class also contains beats added manually. Therefore this class does not possess a representative and selection button of this class does not have any image of QRS. This class may be treated as a kind of bag for beats edited by a doctor, but always of one and the same morphology.

### ”Other” morphology

At the beginning of this chapter morphologies detectable by HolCARD 24W © Aspel are indicated. One of those morphologies is described as <**Other**>. Of course, it is not morphology in the medical sense. It should be understood as a group of those classes where accurate definition of morphology based on analysis is impossible.

To avoid mistakes which may influence the diagnosis adversely, the system prefers to leave the decision to the user.

**The basic task of a user browsing class division is:**
a) Verification of classification,
b) Definition of morphology classes contained in ”Other” group.

**Remember !**

Important notes:

- <**Unknown**> type class is just a bag with beats with morphology changed by you.
- Green beat is ”Green light for you to act” – define the correct morphology. The program prefers not to take any decision than making an error- it needs your help.
- Browse all classes in <**Other**> morphology.
- Go to the next element of the selected class by pressing <**SPACE**>.

Division into classes module interacts with Full Disclosure. You may see beats not only on the Strip but also on Full Disclosure. It allows to evaluate a larger section of the test. Start both modules at the same time, and the frame will be placed on a given beat <**Next, Previous element of the class**> both in Strip and Full Disclosure modules.

Function keys:

| Key | Meaning |
|---|---|
| Home | First page (beginning) |
| End | Last page (end) |
| Page Up | Previous page |
| Page Down | Next page |
| + | Increase amplitude |
| - | Decrease amplitude |
| 1 | Display channel 1 |
| 2 | Display channel 2 |
| 3 | Display channel 3 |
| **Module browsing class elements** | |
| A | Highlight all groups |
| I | Highlight inversion |

## 4.2.5 Tabularized List

Tabularized List module displays results of Holter analysis in digital form giving consideration to examination dividing into subsequent full hours.

The table consists of two parts:

1. Table of hours,
2. Strips.

Table of hours presents:

a) Maximal, minimal, and average value for 24h rhythm,
b) Maximal, minimal and average value for dominant rhythm,
c) Table of supraventricular irregular rhythms,
d) Table of ventricular irregular rhythms,
e) ST episodes in subsequent channels,
f) ST maximal elevation and depression.

The strip is mainly used for documenting which parts of ECG signal were the basis for calculating values arranged in the table. This strip is a standard one, as described in Chapter 4.2.2, and functions in the same way. The only difference is in replacing <**Next, Previous event**> buttons with <**Next, Previous irregular rhythm**> buttons.

## Abbreviations

Names of values and irregularities contained in the table are abbreviated because of limited space. The table below presents these abbreviations.

| Abbreviation | Full name |
|---|---|
| HR for 24h/basic rhythm | |
| Max | Maximal HR |
| Min | Minimal HR |
| Avg | Average HR |
| #QRS | Total number of analysed beats |
| Artef % | % of artifacts |
| Supraventricular rhythm irregularities | |
| S'SVE | Number of single premature supraventricular beats |
| PSVT | Number of supraventricular paroxysmal tachycardia |
| Tachy | Number of tachycardia |
| Brady | Number of bradycardia |
| IRR | Number of irregular rhythms |
| Pause | Number of pauses |
| Ventricular irregularities of rhythm | |
| S'VE | Number of single premature ventricular beats |
| VT | Number of ventricular tachycardia |
| IVR | Number of active ventricular rhythms |
| Salvo | Number of cluster beats |
| Bigem | Number of bigeminies |
| Trigem | Number of trigeminies |
| Couplet | Number of pairs |
| R on T | Number of Rna T episodes |
| ST elevation / depression | |
| Max ST 1+ | Maximal ST elevation in channel 1 |
| Max ST 1- 1 | Maximal ST depression in channel |
| ST Episodes | Number of ST episodes |

## Table content

On the left of the 'Table of Hours' there are periods for which particular values are calculated. The first line, 'Total' sums up the whole period of the test, the next line (brown line) allows definition of any period of time for which the values will be calculated. Other lines comprise one hour periods from the beginning to the end of the test.

The upper part of the module contains two lists for selection:

1. List of rhythm selection:
   - 24h rhythm – calculated values of HRs include all the detected beats,
   - Basic rhythm – calculated values of HR include only dominant beats.
2. Tables of irregular rhythms or ST present:
   - SVE - detected supraventricular rhythm irregularities,
   - VE – detected ventricular rhythm irregularities,
   - ST episodes – ST episodes in subsequent channels of the tests,
   - ST – maximal elevation and depression of ST in subsequent channels.

Click an arrow to select a list and then select any item you want. The table content will be automatically renewed.

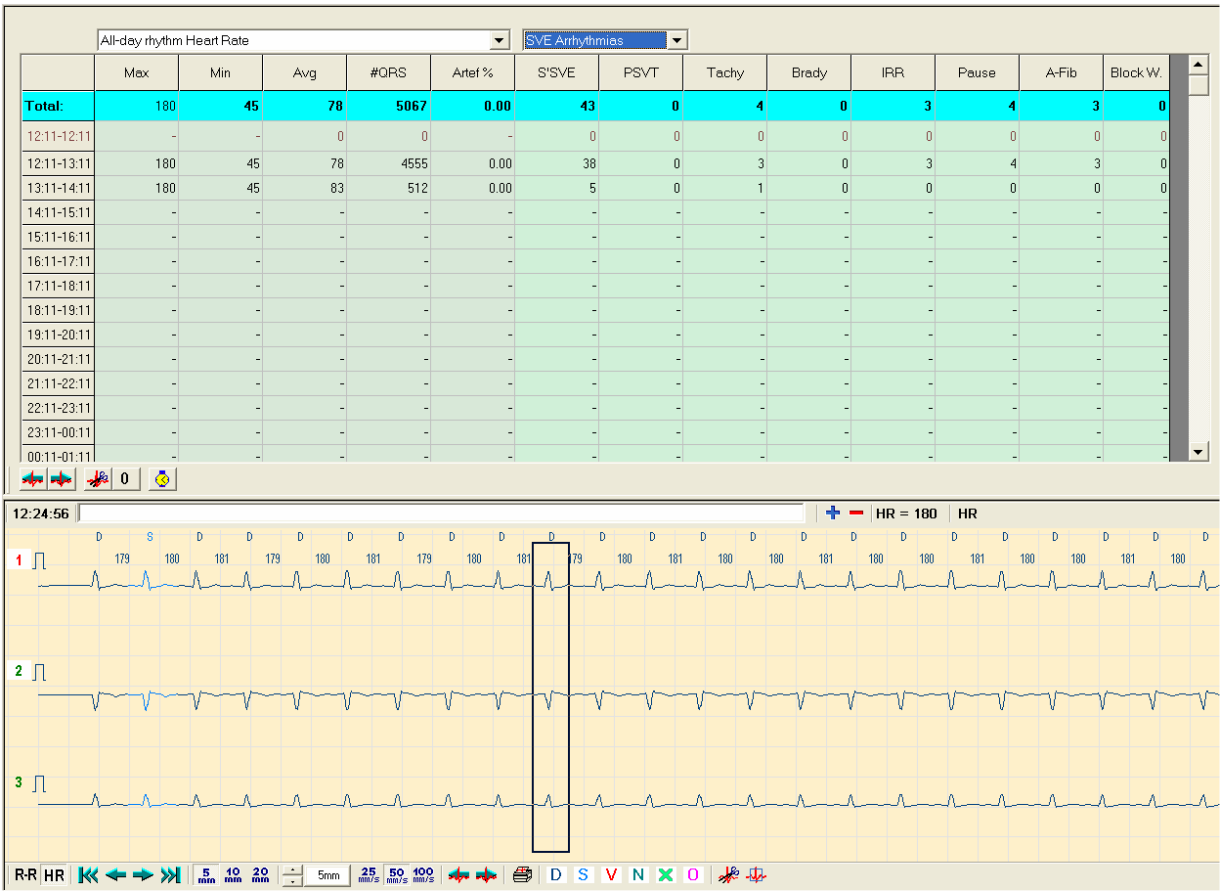



**Figure 40. Module of tabular lists**

## Table browse

To browse a part of the test which is the basis for calculation of the indicated value, click a left mouse button into a relevant cell of the table. The selected cell will be coloured yellow.

The following columns are the exception:

- Average HR,
- # QRS,
- Artef %,

These columns cannot be selected, because a short part of the test referring to these values does not exist.

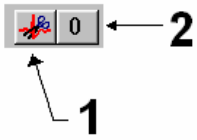
Following the selection of other columns the Strip content will be automatically modified. In case of columns referring to HR, a frame will show a beat with the indicated HR value. Maximal irregularity of rhythm is the one which lasted the longest in the given period and when time is not important (e.g. Pairs, S'SVE and S'VE) is the first which appeared counting from the beginning of the period.

All parameters of the indicated rhythm irregularity are displayed in description line. To see the next irregularity press <**Next irregularity**> on the toolbar of Strip module or <**SPACE**>. Description line will additionally inform about irregularity being browsed. Subsequent irregularities are presented in the same order as during the test. If a test was shorter than 24h, a part of lines in the table will be empty (marked as "-").

## Edition of irregularities table

Buttons for edition are in the bottom part of the table. You can:

- Delete mistakenly detected episodes (1),
- Neutralize the whole column of the table (2).




## Irregularity parameters

Detected irregularities are described with a certain set of enumerated parameters. List of parameters depends on nature of a given irregularity.

1. Irregularities without parameters:
   - Single SVE
   - Single VE
   - Pair
2. Irregularities with full list of parameters:
3. Various combinations of parameters:
   - Max Tachycardia
   - Max Salva
   - Max Irregular Rhythm
   - Max. Active Rhythm
4. Irregularities with defined time of duration:
   - Max Pause

5. Each detected ST parameter is also described with a set of parameters:
    - Number of QRSs forming PSVT
    - PSVT time
    - HR value
    - Max HR value from 4 QRSs

**Own Time interval**

Tabular List module allows to define any time interval (within the limits defined by the beginning and the end of a test) which will include all values contained in the table. The second line in the table (brown line) presents these values. This line is always cancelled when the module is started.

If you want to define your own time interval do the following:

1. Click left mouse button on the clock icon at <**Time interval**> column. Or click a brown button of time interval,
2. A dialogue window will appear where you can set any time interval you want,
3. Confirm the setting with <**OK**>.

The content of the second line of the table will be automatically changed and particular columns will show values calculated for the given time interval.

**Remember**! Tabular List module interacts with Full Disclosure module. You can see the irregularities with the help of Strip and on Full Disclosure pages. It is a very useful option which allows to view a wider history of a given irregularity. Just start these two modules simultaneously and <**Next, Previous irregularity**> frames will appear at subsequent irregularities both in Strip and Full Disclosure modules.

### 4.2.6 Trends

Trends Module displays Holter analysis data in the graphic form. It is represented with digital values in Tabular List in the form of linear or bar diagrams. Fast and easy transition from the diagram to a given part of the test highly facilitates the work.

The module window consists of two parts:

1. Permanent field of HR trend diagram,
2. Variable field where one of the following diagrams may be placed:
    - ST level and slope diagram,
    - Histogram of any ventricular rhythm irregularity,
    - Histogram of any supraventricular irregularity.

All operations in this module are conducted with the help of the toolbar at the bottom part of the module (so called module toolbar).

**HR trend diagram**

HR trend in the upper part of the module shows changes in HR recorded during the whole examination. It consists of two diagrams: a blue one and a red one (placed on the blue one).

The blue diagram shows HR variability averaging from 10 second course and the red one shows a diagram averaging from 60 seconds. Those two diagrams provide a lot of information about HR.

The blue diagram should be interpreted as value of deviation from standard deviation showed on the red diagram. The higher peaks on blue diagram, the larger HR variation was in given moment of test, the lower peaks – the temporary HR variation was HR closer to standard deviation. This diagram helps to evaluate rhythm irregularity during the whole examination.

## Diagrams change

The module toolbar contains four buttons for changing a category of the diagram.

1. ST button,
2. VE irregularities button,
3. SVE irregularities button,
4. ST3D button.

After choosing suitable button, a list of available marker is changed. The first marker is always the implicit one. Abbreviations on the markers are the same as in tabular List module. Additionally, the abbrevation development is available in Diagram description line.

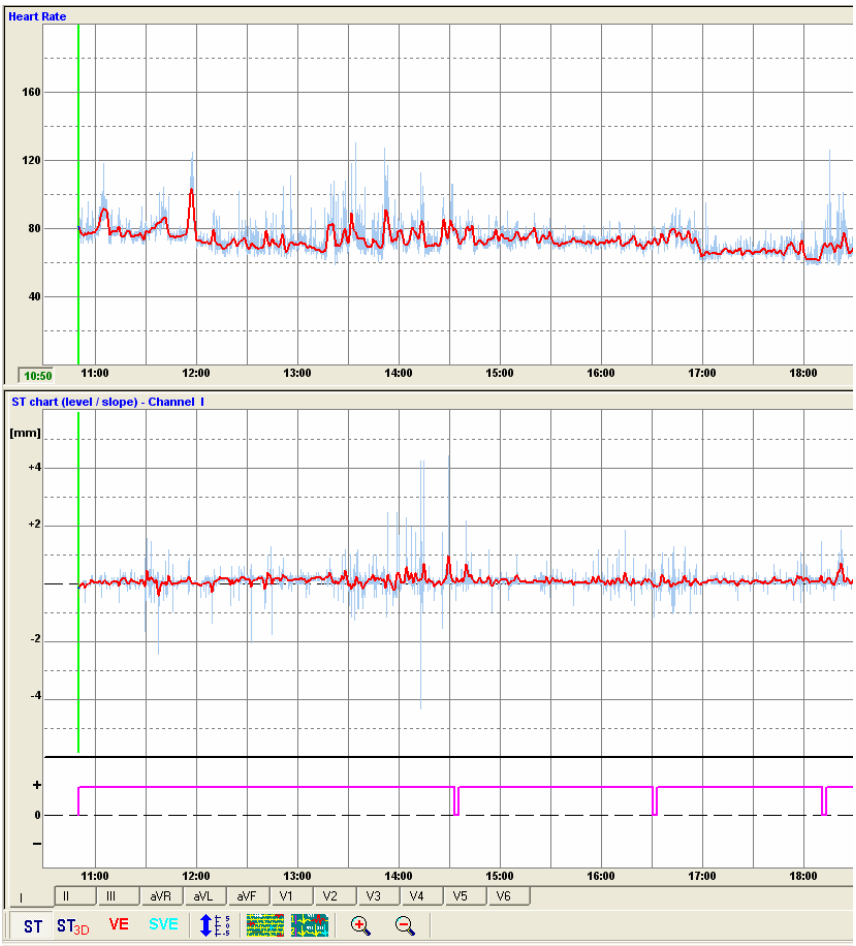



**Figure 41. Trends module**

## Other options

Trends module interacts with Full Disclosure and Strip. Change location of a frame in Full Disclosure and Strip from HR trend Browse bar you will accelerate accession to the desired part of the examination (e.g. find maximal HR).

Browsing the test with HR trend:

1. Start **Trends** module.
   - Select Trends icon from the program toolbar (see Figure 35) or start the module with **<Review>** menu **<Trends>** field.
2. Start Full Disclosure module.
   - Select Full Disclosure icon from the program toolbar (see Figure 35) or start the module with left double click on HR trend diagram. Full Disclosure module will be automatically set at the beginning of the selected hour.
3. Shift <**Browse bar**> on HR trend.
   - Method A. Left click on any part of the trend. Browse bar will automatically move to the selected place.
   - Method B. Shift the mouse cursor over the browse bar until it changes into two-direction arrow. Now press the left button of the mouse. Hold it pressed and move the bar to the left or to the right. Release the left button when you have reached the selected place.
   - Method C. You can also move the bar with the keyboard: left arrow or right arrow.
4. The content of Full Disclosure module will be modified in such a way that the frame will indicate the same beginning of the test as the trend browse bar.

The same procedure may be repeated for Strip module. However, it is useful to remember that Full Disclosure module has a button in a toolbar which allows to “magnify” the required part of the test by indicating Strip module. Therefore it is more convenient to start from Strip level.

## ST3D diagram

HolCARD 24W © Aspel system enables displaying of ST trends for all channels on one diagram with the ST3D module. This module has many useful functions: gain changing, time axis slope changing, filters, printing. With the use of cursor and upper bar it is possible to investigate ST values for each examination moment.

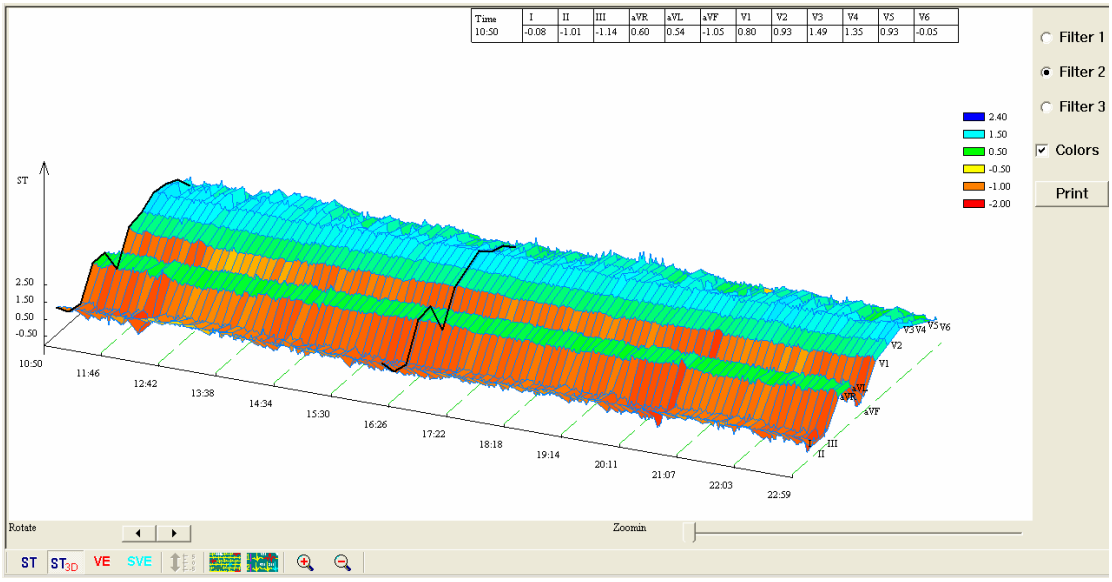



**Figure 42. ST3D diagram**

## 4.2.7 End of program operation

When the examination is loaded and Holter analysis completed, results will be saved automatically in the computer. Reloading of the examination (from the system base) allows to reproduce the test from before the last closure of the system.

To end operation select <**Examination**> menu and <**Close**> field. Or press <**Exit**> icon (Figure 43) on the upper toolbar.

**Figure 43. Exit icon**

Before closing the program confirm your decision with <**OK**> or give up pressing <**Cancel**>.

# Chapter 5

# Test edition

## 5.1 Standard requirements

When Holter analysis is completed you have to review the results presented by subsequent modules in order to verify and adjust, if needed.

*Results of automatic evaluation should be always verified by a doctor.*
*(Polish Cardiac Society Standards – page 11)*

Important requirements concerning Holter tests:

1. Morning hours must be covered by the test,
2. Number of artefacts cannot exceed 5% of recorded QRSs.

Holter examination which does not meet the above requirements should be repeated. Holter EKG © Aspel system checks the requirements and informs about possible dangers displaying a dialogue window after the first analysis has been completed. Additionally, a bar of artifacts is placed by the main toolbar of the program. This bar displays a current number of artifacts in the test.

| Description | Information [Chapter] |
|---|---|
| Check identification of dominant, supraventricular, ventricular QRS and adjust if needed. | 4.2.4 Templates |
| Check identification of artifacts and correct if needed. | 4.2.4 Templates |
| Verify HR and irregularities on the basis of ECG parts. | 4.2.5 Tabularized List |
| If you are sure that you are not mistaken (on the basis of 1, 2 and 3 above), you may carry out:<br>• Qualitative and quantitative characteristics of the basic rhythm,<br>• Qualitative and quantitative evaluation of the fastest and the slowest rhythms,<br>• Analysis of significant elongations of R-R distances 9 so called pauses),<br>• Confrontation of data from the patient's diary with ECG record | 4.2.5 Tabularized List<br>4.2.6 Trends<br>4.2.5 Tabularized List<br>4.2.3 Strip List |
| In case of diagnostic difficulties, poor record from the technical point of view, or doubts as to reliability of the analysis, it is advisable to use page mode option. | 4.2.1 Full Disclosure |
| Check setting of ST measurement points and adjust, if needed. | 4.1 Analysis configuration |
| Check analysis of ST segment | 4.2.5 Tabularized List |
| Check analysis of ST episodes | 4.2.5 Tabularized List |

The above table shows description of what should be done and refers to chapters where you can find information about the modules, which allow evaluation and verification of analysis results. The chapters below deal with edition, that is adjustment of those results.

## 5.2 Reclassification of beats

The basic task in relation with test edition is adjustment of QRS identification, so called reclassification of beats. As the average number of QRSs in 24h examination reaches 120 thousand, a user would rather not browse all of them to find out whether morphologies are correct. To facilitate the evaluation we have introduced Templates module. This module connects QRSs of the same shape and morphology into one group. Templates may be browsed and edited, so you can change morphology of all QRSs belonging to the same template. Detailed information is included in 4.2.4 Templates Section. Here we will only discuss editorial capabilities of the module.

**Reclassification of the whole class of beats**

In case the whole class of QRS should be included in another morphology, for instance, a certain group of QRS with a lot of noises have been classified as artifacts and not as dominant beats, as it should be. It is very easy to rectify such errors.

1. Select the template with wrong definition.
2. Move it to the relevant morphology.
   - Method A. Move a mouse cursor over the selected template. Press the left button and hold it pressed. The cursor will change its shape – a plus symbol will appear next to the arrow. Holding the button pressed shift the cursor over the button of correct morphology.
   - Method B. Move a mouse cursor over the selected template. Press the right button of the mouse. You will see menu on screen. Select a symbol of the correct morphology from the menu.
   - Method C. Press the button of the correct morphology on the toolbar of templates module.

Change in morphology will outdate some of the existing results of the Holter analysis so Reanalysis is required. It is the best to reanalyze after all adjustments have been completed.

Template module has an “artificial” morphology - Other. It is a group of templates which could not have their morphologies defined with initial analysis. To avoid mistakes which could influence diagnosis, the system prefers to leave the decision for a user.

All templates in this morphology should be moved to one morphology: dominant, supraventricular, ventricular morphology or artifacts. The peculiar case is ‘Unknown’ class which should be interpreted as a group of various beats. It should not be moved to another morphology in whole because we do not know if QRSs are of the same shape. It is recommended to browse the whole class and reclassify manually.

**Single beat reclassification**

Single beats is always reclassified from Strip module level. This module is attached to Templates module. It may also operate separately and constitute a part of other modules.

Detailed information on reclassification is described in Chapter 5.2 Reclassification of beats.

Indicate QRS: one or more with a Strip module frame. Then select a button of a defined morphology on the Strip toolbar. Reclassification will be automatic. The indicated QRS or a group of QRSs will change its colour for a colour of the new morphology.

**Examination reanalysis**

Change of morphology outdates some results of Holter analysis. For instance, changing two adjacent beats classified by the system as ventricular ones into artifacts you will reduce a number of detected pairs which may influence the maximal and minimal 24h HR. Therefore reanalysis is required.

To reanalyze, select <**Start**> from <**Analysis**> menu. You can also use <**Analysis/reanalysis**> icon on the toolbar.

Reanalysis following changes in morphology always refers to:

- Detecting maximal, minimal, and average rhythm,
- Detected supraventricular and ventricular irregularities,
- Results of ST analysis,
- Detected ST episodes.

HolCARD 24W © Aspel system informs about user's conditions displaying "Reanalyzing necessary" on the program title bar – upper part of the program above the menu and toolbar (see Figure 35).

The optimum solution is to enter all adjustments in templates module and then perform reanalysis. Closing templates module or starting another module, e.g. Tabularised List will automatically start reanalysis. This provides accuracy of the displayed data.

**Exclusion of beats from analysis**

It is possible to exclude the whole class of beats from Holter analysis. QRSs indicated as excluded will not be reanalyzed.

How to exclude the whole class from analysis:

1. Select the class.
2. Mark it as excluded.
   - Method A. Move the mouse cursor over the class. Press the right mouse button. The menu will be displayed. Select **<Exclude>** from the menu.
   - Method B. Move the cursor over the class. Press **<N>** on the keyboard.

All QRSs will be automatically marked with gray colour.

Any QRS may be marked as non-classified, that is excluded from the analysis. You may do it from the Strip module with <**Non-classified**> button from the toolbar. You may mark any part of the examination (for example the deformed one).

## 5.3 Adding beats

If ECG signal is of poor quality (e.g. low amplitude, a lot of disturbances), a number of QRSs may not be detected with Holter analysis. Such beats may be added manually and their target morphology may be defined. Beats are added with Strip module attached to another independently operating module.

All detected beats have the mark of current morphology at the place of R wave (e.g. D, S, V, X). Lack of such mark and frame inform the user that such beat has not been detected.

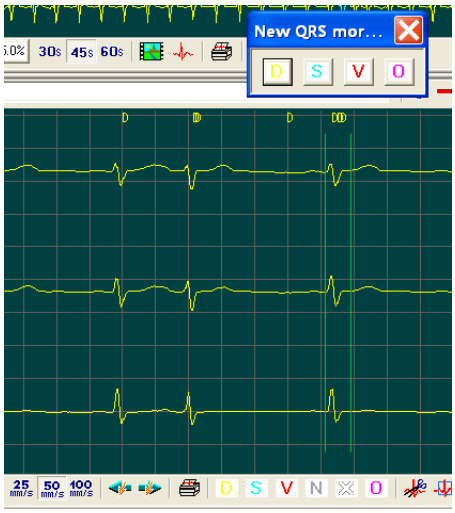



**Figure 44. Manual adding of QRS**

In order to add new QRS, do as follows:

1. Move the mouse cursor over the undetected QRS.
2. Press the right mouse button.
   - You will see two green lines on the screen to indicate the field of searching a new QRS. Holding the button pressed move the lines to the left or to the right placing them in such a way that the undetected QRS is within. You don't have to be 100% accurate because the system will find the indicated field to define the location of R wave.
3. Release the right button of the mouse when new QRS is set properly.
   - You will see <**Select new QRS morphology**> window. It will help to define morphology of the added beat. When you press a suitable button the window will be automatically closed and adding procedure will be completed.

To give up adding, close a morphology selection window without defining its type. You can do it in two ways:

1. Press <**ESC**> on the keyboard.
2. Use < **x** > button at the level of title bar.

The most convenient is to add QRS if speed of signal display is 100 mm/s because it facilitates definition of the search field with vertical lines.

If a given examination has a large number of undetected QRSs check whether channels (or one of the channels) used for analysis are disturbed. Very often wrong detection or no detection is caused by poor quality ECG signal.

Try to switch off the worst channel and/or switch on a channel with good quality signal (menu <**Analysis**> field <**Settings**> – description Chapter 4 Automatic analysis) and reanalyze the examination.

## 5.4 Delete beats

Sometimes QRS may be detected in a wrong place. Very often noises are understood as beats. In such situation delete such QRS because it can influence determination of maximal minimal, and average HR.

Do it with Strip module. Indicate a beat with a frame and delete it with <**QRS delete**> button at the end of the module toolbar.

In case there are too many excessive detections, browse the detected templates in Templates module to check whether they have not been grouped together. If such a template is found and we are sure it contains only wrong detected beats we may delete it:

1. Select a template with wrong detected QRSs.
2. Delete it.
   - Method A. Move the mouse cursor over the template. Press the right button. You will see menu. Select <**Delete**> from the menu.
   - Method B. Move the cursor over the template. Press **<DEL>** on the keyboard.
   - Method C. Select scissors button from the toolbar of the template module.

All QRSs belonging to the indicated template will be deleted. Remember to follow the changes with reanalysis.

## 5.5 Arrhythmia edition

Correct analysis of arrhythmia is based on correct identification of QRSs. Tabular List module presents all detected arrhythmia and reference parts of the test which allow verification of results.

3 possible ways of adjusting the detected arrhythmia:

1. Adjustment of identification of QRSs belonging to a given arrhythmia:
   - Adding an undetected QRS,
   - Deleting a wrong indicated QRS,
   - QRS reclassification.
2. Change of parameters of arrhythmia analysis (menu <**Settings**> field <**Analysis Parameters**>, <**Arrhythmia**> marker).
3. Direct edition of the table
   - Deletion of episode from the table
   - Zeroing the column from the table

Each of the above activities should be followed by reanalysis of the test.

# Chapter 6

# Report

## 6.1 Generating reports

Standards of Polish Cardiac Society specify the content of a Holter test report (see: Standards – Documentation of Holter test). This chapter tells us how to generate a report meeting these requirements.

**Report elements**

Reports generated by HolCARD 24W © Aspel are not limited only to standard requirements but they allow obtaining other important summations. It may consist of the following elements:

1. **Patient's data**
   - Patient's data include his/her passport and medical data, that is diagnosis and a list of applied medicines, data concerning his/her examinations and user's comments. Additionally in the bottom part of the report information about ECG signal and channels selected for Holter analysis is printed.
2. **Examination summary**
   - Examination summary is a description of Holter analysis results developed with Summary module. It is an easy text editor where you can develop a pattern describing tests according to your own requirements. Detailed information is included in Section 6.2 Development of an individual summary
3. **Tables**
   - Tables of hours containing information about HR, detected irregularities and results of ST analysis in particular hours of the test.
4. **24h list**
   - This list includes information about maximal and minimal rhythm throughout the examination, place of its occurrence and information about maximal irregularities (the longest ones), together with calculated parameters. Additionally it give information about maximal elevation and depression of ST throughout the examination and the longest ST episodes in particular channels.
5. **Saved strips**
   - This report option allows to print all strips saved in Strip list module and designated for printing. The strips document events signaled by the patient, parts of the examination selected by the user for printing and detected irregularities and ST episodes (see Chapter 4.2.3 Strip List).
6. **Trends**
   - Trends selected by a user are printed Selection button. A list of printed diagrams may include HR, St level and slopes, histograms of supraventricular and ventricular arrhythmia.
7. **HRV index**
   - HRV report may contain tables of time indices and spectrum in particular frequency ranges for subsequent hours of the examination as well as diagrams selection button.
8. **Results of evaluation of QT**
   - Printouts of tabular lists and trends
9. **Results of cardiac stimulator evaluation**
10. **ECG examination**

- Additionally you may attach full printout of ECG or a selected part. In the window for selection of elements for the report you will see a selection button next to ECG test field. When you press this button you will display a dialogue window for defining a type of the examination and a channel.

Printing may be started form Report menu Print field or with <**Report**> icon on the upper toolbar of the program. Before the report is generated, a dialogue box will be displayed to determine elements of the printout.

How to indicate elements to be printed:

1. Move a mouse cursor over the white square on the left of the selected report element.
2. Press the left button of the mouse.
3. The square will be ticked.
4. If you want to exclude a given element of the report, click the square again.

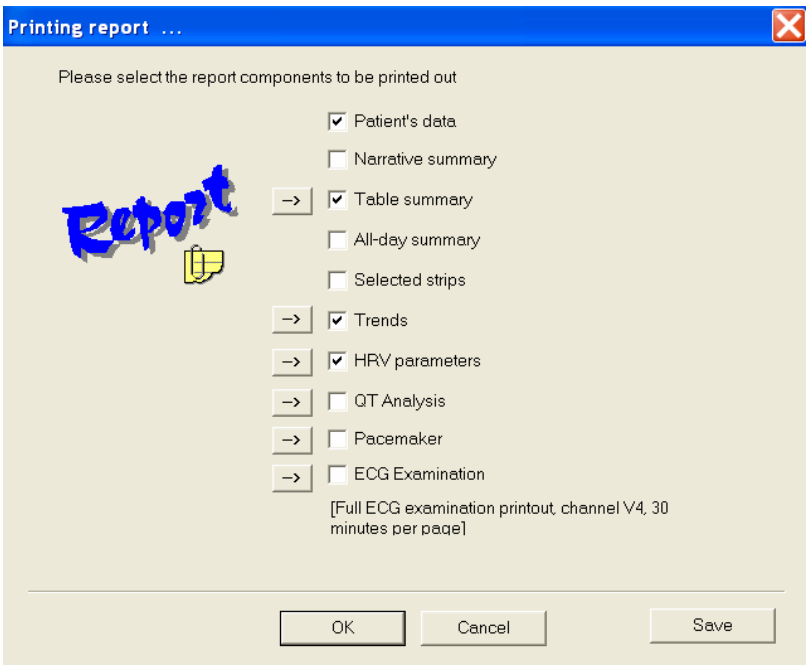



**Figure 45. Report print module**

## Requirements of Standards of polish Cardiac Society

The table below shows how HolCARD 24W © Aspel meets requirements of Polish Cardiac Society. Implementation column informs which elements of the report should be printed.

| Requirement | Implementation |
|---|---|
| Patient's data (name, surname, date of birth, sex, address, diagnosis, medicines taken). | Patient's data |
| Indications for tests | Patient's data |
| Test time (from – to) | Patient's data |
| Duration of artifacts | Patient's data |
| Results of quantitative and qualitative analysis of HR and ST | Tabular lists Trends |
| Parts of ECG | Saved strips |
| Comment | Patient's data or test summary |
| In case of doubts: 24h ECG record | ECG test |

**Data concerning a surgery**

The first page of the printed report (patient's data) contains user's data in the header:

- Name of surgery,
- Address,
- Other data.

**<Other data>** for instance information about reception hours, telephone number.

These data may be entered into the system from Settings menu User's data field. A dialogue box displayed on the screen will allow for introduction or modification of such information.

**Other options**

Reports are directed to default printer. You may also define another printer as the target printer. You can do it from <**Settings**> menu <**Printer**> field. The displayed dialogue window will allow you to select a printer from the list. The changed setting is valid only during program work. When the program is restarted printouts will be directed again to the default printer.

Program HolCARD 24W © Aspel allows to print reports with any type of printer (ink, laser) installed in MS Windows environment.

**Remember**! Each result of the test must be signed by a technician or a doctor responsible for the report. Report which is not signed is not reliable. There is a special blank left on the first page for your signature.

## 6.2 Development of an individual summary

This module serves for generating reports complying with requirements of a user. The report is based on previously prepared pattern containing the text and micro definitions. Micro definitions are a special set of signs closed in brackets which will be replaced with one of Holter analysis results (e.g. <MAX_C_HR> this a maximal 24h HR).

HolCARD 24W system is equipped with several ready patterns but you can easily create your own patterns. A pattern may additionally include drawings or other graphics (e.g. surgery logo).

A pattern is filled with Holter analysis values upon the module start. If a user wants to add a text for a test just loaded, he/she should remember about saving the changes. A pattern will be modified only for the current examination.

This module is operated in the same way as simple text editors (e.g. WordPad). Reports may be generated from this module or Report menu Print field.

## 6.3 Setting report preferences

Strip List module automatically fills category of Arrhythmia and ST episodes with strips documenting the detected irregularities. Every strip has a marker defining whether it is to be printed or not. You may define strips to be indicated automatically when attached to the module list.

In order to define strips of arrhythmia to be printed, do the following:

1. Start <**Report**> menu <**Report preferences**> field.
2. A dialogue box will be displayed (see Figure 46).
3. Tick arrhythmia to be default documented
4. Mark those you do not want to be default documented.

Of course you can include or exclude a tick in all categories in Strip List module. The described settings are standard values – initial for each examination. Detailed information about categories and Strip List module are included in 4.2.3 Strip List.

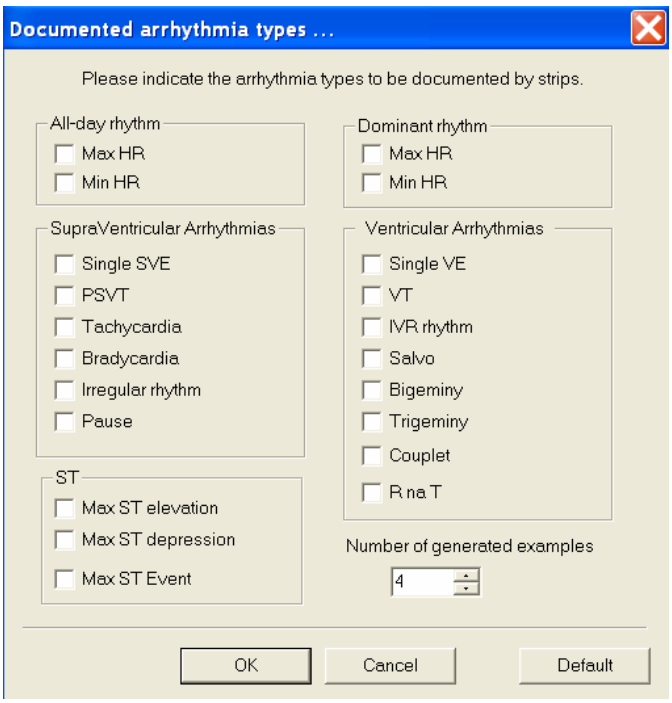



**Figure 46. Window of default arrhythmia definitions**

If you highlight <**Saved strips**> option when generating the report for arrhythmia selected from the above window, parts of the examination will be printed.

# Chapter 7

# Advanced analysis techniques

## 7.1 General

New methods of ECG record analysis are being added to standard ones because of fast development of knowledge. Basic Holter analysis covered analysis of rhythm irregularities and changes in ST segment. Now, very often new techniques are applied to interpret the data. Increasing number of patients with pacemakers require HRV analysis and evaluation of QT interval. All the modern methods have been implemented to HolCARD 24W by ASPEL.

The advanced analysis options are accessible from the toolbar in the main window of the program. There are 5 buttons opening relevant options:

- ST analysis
- HRV analysis
- QT analysis
- Pacemaker operation analysis
- HRT analysis

Point a button with the mouse cursor and press left button of the mouse to start the selected option.

**Figure 47. Icons of additional analyses**

**Remember!**

Additional ST, HRV, QT, PMK and HRT analyses may be started after standard Arrhythmia and ST analyses are completed.

## 7.2 ST analysis

ST analysis module calculates ST elevations and ST depressions for each dominant beat and marks ST episodes on all channels. The analysis results are presented in Trends module or Tabular list module.

In case of ST analysis it is important to set the ST measuring points correctly (ST analysis configuration). After choosing ST icon from the upper toolbar the dialogue window appears enabling to perform this action.

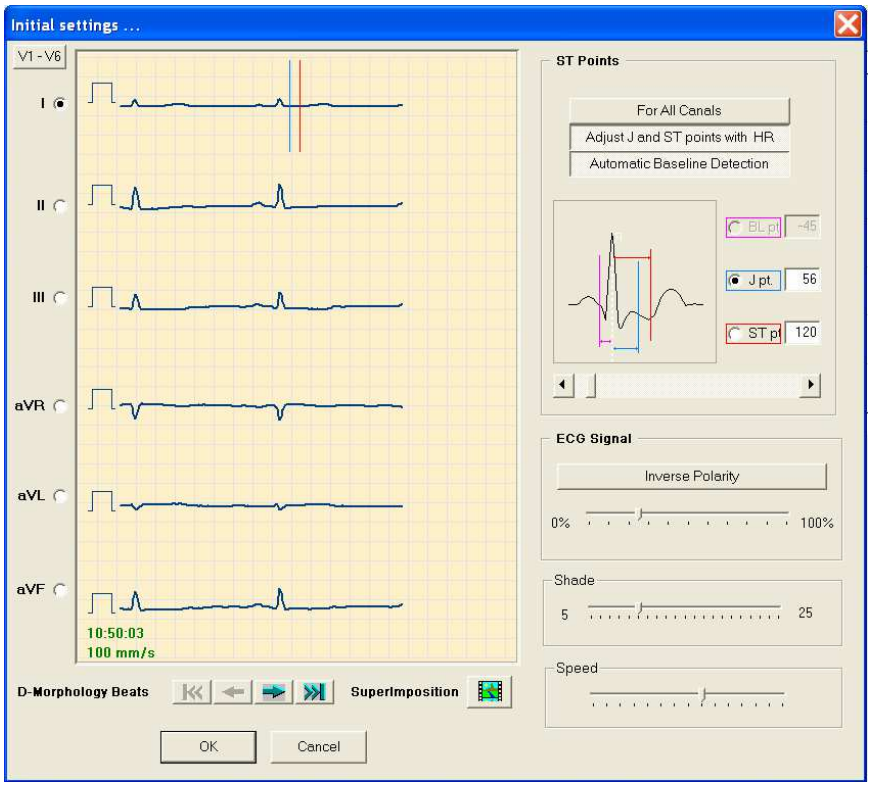



**Figure 48. ST analysis configuration window**

## ST analysis configuration

Default values of measuring points:

- BL point (Base Line) – 45 ms,
- J point – 56 ms
- ST point – 120ms.

Given values are calculated in regard with R wave. You can control position of these points regarding other QRSs by moving with the <**QRS navigation button**>. Automatic QRSs survey mode – <**Film**> button is also available. QRSs are presented in succession beginning with the first one till the last one with the given change of speed on the screen. It allows to quick visual verification of ST and J points setting.

In order to introduce changes do as follows:

1. Choose channel for which you want to change settings. Press the button with <**1**> or <**2**> or <**3**> situated on the left side of the window used for active channel choosing,
2. Choose the type of set measuring point (BL, J or ST). Click with the mouse button one of the chosen points in the section <**ST measuring points**>,
3. Set the required value. You can smoothly regulate the R walve with the use of Measuring points position slide valve.

Remember that you can change ST measuring points of these channels only which were chosen to analyze. During changing, vertical lines signaling current location of the measuring point are displayed on the screen.

ST analysis is always carried out in 3 channels.

The above described method allows to set ST measuring points on one chosen channel. If you want to do it for all channels press <**All channels fitting**> and repeat the procedure. Vertical lines will appear on analyzed channels and changes will be carried out simultaneously.

It is possible to mark BL point automatically by using analysis algorithm. It is recommended option created to improve the analysis quality. Other way is to condition the position of measuring points for each QRS from the actual value of heart beat frequency. With the HR increase the J and ST measuring points are moved to the right and with the HR decrease – to the left. Both options are switched on with the first analysis start.

## QRSs navigation description

To navigate QRSs five buttons are used:

1 – FIRST QRS,
2 – PREVIOUS QRS,
3 – NEXT QRS,
4 – LAST QRS,
5 – MOVE REVIEW

**Figure 49. QRSs navigation buttons**

After pressing SuperImosition <**Film**> button automatic QRSs survey starts. You can set the speed of survey with <**Film speed**> slide valve. <**Shadows quantity**> slide valve allows to set the number of previous QRSs which are displayed in the form of disappearing shadows (Superimposition mode) on the screen.

## Edition of ST analysis results

ST analysis results – level, slope, episodes – depend mainly on correctly determining the measuring points. Measuring points correction takes place always from window level <**ST analysis configuration**> activated from <**Analysis**> menu <**Setting**> field with <**More**> button.

In case of edition ST episodes results it is possible to change parameters connected with analysis settings – <**Setting**> menu <**Analysis**> parameters field <**ST episodes**>.

It may happen that maximal elevation or depression is marked on QRS which was wrongly determined or with noise. Therefore you can make use of correction of QRSs identification, similarly to edition of heart beat artifacts.

## Remember!

A few important notices:

- Remember about standards – examination must cover morning hours and can not exceed 5% of artifacts. Otherwise it must be repeated.
- Green beat is ”Green light for you to act”. Look through all “Other” classes and determine their morphology.
- If the particular part of ECG signal is of bad quality you can exclude it from Holter analysis by marking it as non-classified.
- Lack of morphology designation in the place of R wave occurrence gives you information that it was not detected. You can add the beat manually and determine its morphology.
- If the morphology designation occurs in wrong place it is possible that wrong QRS was detected. You can remove that beat.
- Carry out automatic analysis without HRV and ST evaluation. It will accelerate the speed of work. Without verification of automatic results the HRV and ST evaluation is less than reliable. Only after introducing proper changes switch on the HRV and ST evaluation in Initial settings module.

- If you have done the examination edition check whether next reanalysis is necessary – toolbar in the upper side of the window.
- To achieve the best effect, introduce all modifications and then start the reanalysis again.

## 7.3 HRV analysis

HRV Analysis module presents evaluation of Heart Rate Variability. The module consists of 4 parts representing results of HRV analysis:

- Time and spectrum diagrams,
- Time indices,
- Frequency indices,
- Spectrum diagram 3D.

HolCARD 24W © Aspel automatically edits the test removing all beats other than dominant and replacing them with simulated beats. A user doesn't have to prepare the signal before starting HRV analysis what is usually laborious.

"Reliable analysis of HRV must be based on correct qualification of all QRSs and artifacts. Analysis must be preceded with accurate procedure of HR evaluation" – Standards of Polish Cardiac Society: HRV, page 30.

Therefore it is recommended to edit the examination for verification of automatic analysis and entering adjustments, if needed, before you start HRV analysis.

**Time analysis**

HRV analysis indices are calculated for hourly intervals starting from the beginning of the test to the full test (Total line). The table below explains meaning of particular indices.

| Designation | Meaning (time) |
|---|---|
| Average RR | Average value of all RR intervals in sinus rhythm |
| RR variability | Variability of subsequent RR intervals of sinus rhythm |
| SDNN | Standard deviation of all RR intervals in sinus rhythm in [ms] |
| rMSSD | The square root of the average of the sum of squared differences between subsequent RR intervals in (ms) |
| SDNN | index Average SDNN of 5-minute segments |
| SDANN | Standard deviation of average RR intervals in 5-minute segments |
| p50NN | Percent of differences between subsequent RR intervals exceeding 50 ms in [%]. |
| Triangular index | Number of bars (7.8125 ms) in the base of the triangle of RR histogram. |
| TINN | Length of the triangle base in [ms] approximating histogram of next RR intervals. |

A part of the examination which was the basis for calculation of a given parameter is displayed from Full Disclosure if you select a cell from the table of indices.

Time and Frequency Analysis of Heart Rate Variability (HRV)

Plots | Time | Frequency | 3D Graph

| | #QRS | #QB | Average RR | Variance | SDNN | SDNN-ix | SDANN | rMSSD | p50NN | Triang-ix | TINN |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Total:** | **99654** | **77645** | **842** | **16557** | **128** | **90** | **80** | **110** | **22.58** | **62** | **514** |
| 10:50 - 11:50 | 4550 | 3847 | 742 | 5780 | 76 | 58 | 43 | 72 | 16.24 | 29 | 240 |
| 11:50 - 12:50 | 4533 | 3727 | 794 | 10684 | 103 | 73 | 60 | 89 | 20.09 | 34 | 294 |
| 12:50 - 13:50 | 4497 | 3383 | 801 | 14591 | 120 | 102 | 53 | 127 | 30.78 | 44 | 357 |
| 13:50 - 14:50 | 4663 | 3841 | 772 | 9860 | 99 | 75 | 55 | 90 | 19.59 | 43 | 340 |
| 14:50 - 15:50 | 4522 | 3870 | 796 | 5481 | 74 | 63 | 33 | 77 | 14.78 | 27 | 221 |
| 15:50 - 16:50 | 4446 | 3755 | 810 | 4376 | 66 | 55 | 36 | 64 | 11.77 | 24 | 207 |
| 16:50 - 17:50 | 4152 | 3348 | 867 | 7777 | 88 | 75 | 41 | 88 | 17.74 | 26 | 252 |
| 17:50 - 18:50 | 4155 | 3052 | 866 | 15194 | 123 | 105 | 53 | 129 | 30.11 | 52 | 409 |
| 18:50 - 19:50 | 4467 | 3541 | 806 | 13162 | 114 | 93 | 58 | 119 | 26.94 | 54 | 387 |
| 19:50 - 20:50 | 4594 | 3966 | 784 | 11477 | 107 | 64 | 73 | 79 | 16.46 | 32 | 318 |
| 20:50 - 21:50 | 4201 | 3472 | 858 | 8875 | 94 | 70 | 53 | 83 | 14.49 | 27 | 278 |
| 21:50 - 22:50 | 4531 | 3734 | 795 | 9447 | 97 | 73 | 54 | 90 | 19.79 | 32 | 283 |

**Figure 50. Time of HRV analysis**

Time indices are supplemented with time diagrams presenting RR histograms in the whole test and differences between RR intervals, as well as Lorenz's diagram.

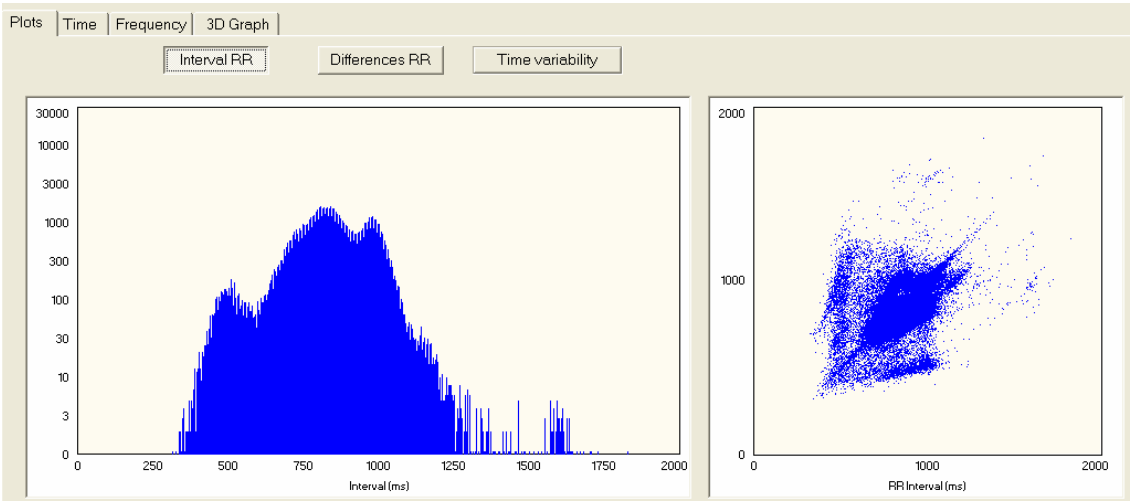



**Figure 51. Time diagrams of HRV analysis**

To display the diagram of differences press <**Differences RR**>. Lorenz's diagram can also represent variability in time. Selecting <**Time variability**> button results in displaying simulation of drawing of the diagram. It allows to get oriented in time distribution of diagram points.

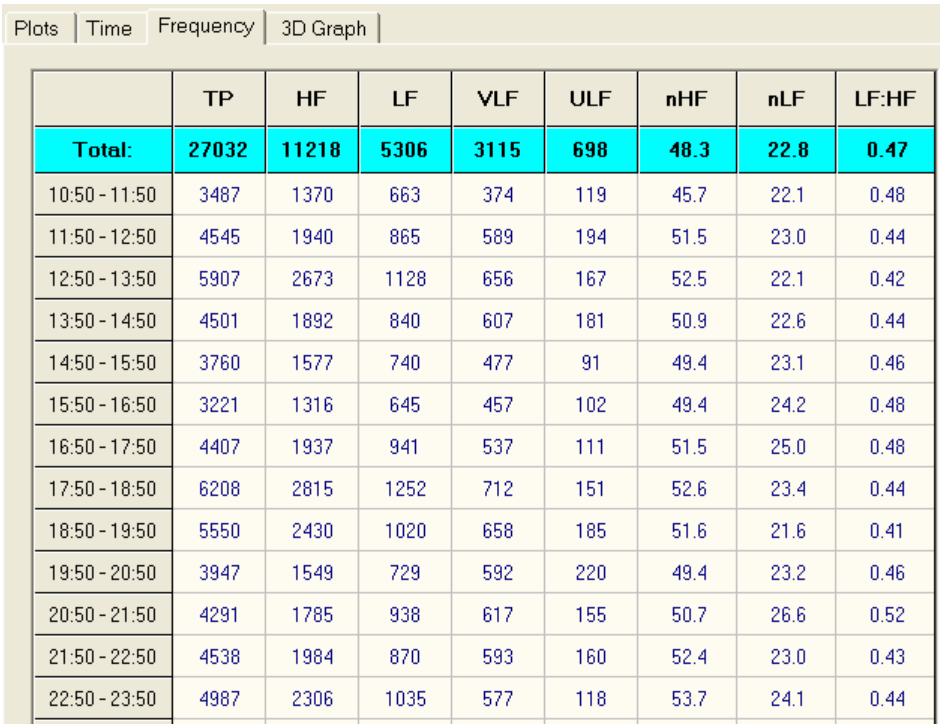
## Frequency analysis

HRV frequency analysis indices are calculated for hourly intervals starting from the beginning to the full test (Total line).

The table below shows the meaning of particular indices.

| Designation | Meaning of the index (frequency) |
|---|---|
| TP | Total power [$ms^2$] |
| HF | High frequency [$ms^2$] |
| LF | Low frequency [$ms^2$] |
| VLF | Very low frequency [$ms^2$] |
| ULF | Ultra low frequency [$ms^2$] |
| NHF | Normalized high frequency [%] |
| NLF | Normalized low frequency [%] |
| LF/HF | LF/HF rate |

Selecting any cell from the indices table results in displaying, with the use of Full disclosure module, the part of examination on which basis the given parameter was set.




| | TP | HF | LF | VLF | ULF | nHF | nLF | LF:HF |
|---|---|---|---|---|---|---|---|---|
| **Total:** | **27032** | **11218** | **5306** | **3115** | **698** | **48.3** | **22.8** | **0.47** |
| 10:50 - 11:50 | 3487 | 1370 | 663 | 374 | 119 | 45.7 | 22.1 | 0.48 |
| 11:50 - 12:50 | 4545 | 1940 | 865 | 589 | 194 | 51.5 | 23.0 | 0.44 |
| 12:50 - 13:50 | 5907 | 2673 | 1128 | 656 | 167 | 52.5 | 22.1 | 0.42 |
| 13:50 - 14:50 | 4501 | 1892 | 840 | 607 | 181 | 50.9 | 22.6 | 0.44 |
| 14:50 - 15:50 | 3760 | 1577 | 740 | 477 | 91 | 49.4 | 23.1 | 0.46 |
| 15:50 - 16:50 | 3221 | 1316 | 645 | 457 | 102 | 49.4 | 24.2 | 0.48 |
| 16:50 - 17:50 | 4407 | 1937 | 941 | 537 | 111 | 51.5 | 25.0 | 0.48 |
| 17:50 - 18:50 | 6208 | 2815 | 1252 | 712 | 151 | 52.6 | 23.4 | 0.44 |
| 18:50 - 19:50 | 5550 | 2430 | 1020 | 658 | 185 | 51.6 | 21.6 | 0.41 |
| 19:50 - 20:50 | 3947 | 1549 | 729 | 592 | 220 | 49.4 | 23.2 | 0.46 |
| 20:50 - 21:50 | 4291 | 1785 | 938 | 617 | 155 | 50.7 | 26.6 | 0.52 |
| 21:50 - 22:50 | 4538 | 1984 | 870 | 593 | 160 | 52.4 | 23.0 | 0.43 |
| 22:50 - 23:50 | 4987 | 2306 | 1035 | 577 | 118 | 53.7 | 24.1 | 0.44 |

**Figure 52. HRV frequency analysis module**

Frequency indices are supplemented with spectrum diagram. Frequency analysis is made with Fourier's transform.

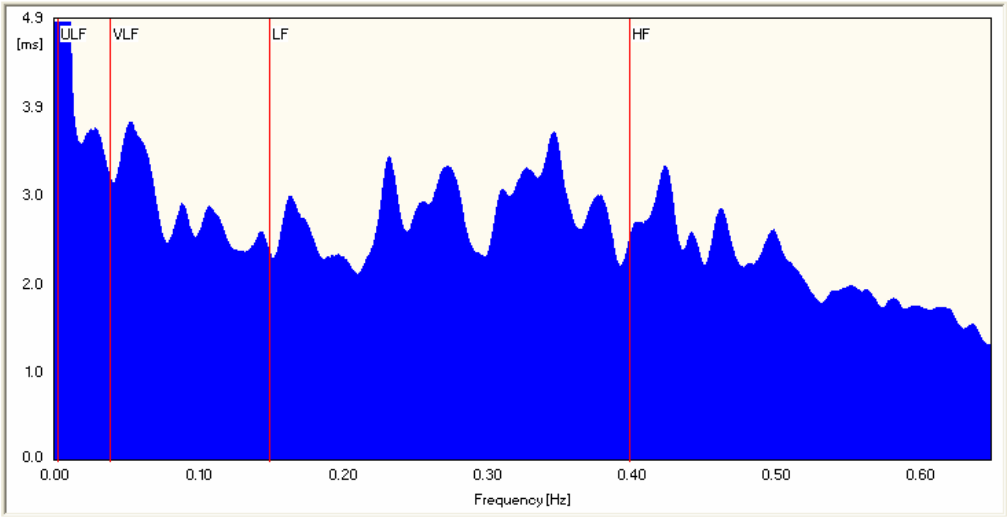



**Figure 53. Diagram of HRV spectrum**

## Selection of a period to be analyzed

Normally HRV module makes calculations for the whole test. You may also choose calculation for a selected period only.

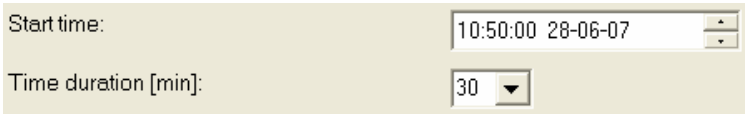



**Figure 54. Selection of a period for analysis**

## Spectrum 3D diagram

System HolCARD 24W enables carrying out HRV analysis for whole examination and presenting the results in one diagram. Below exemplary spectrum 3D diagram is presented:

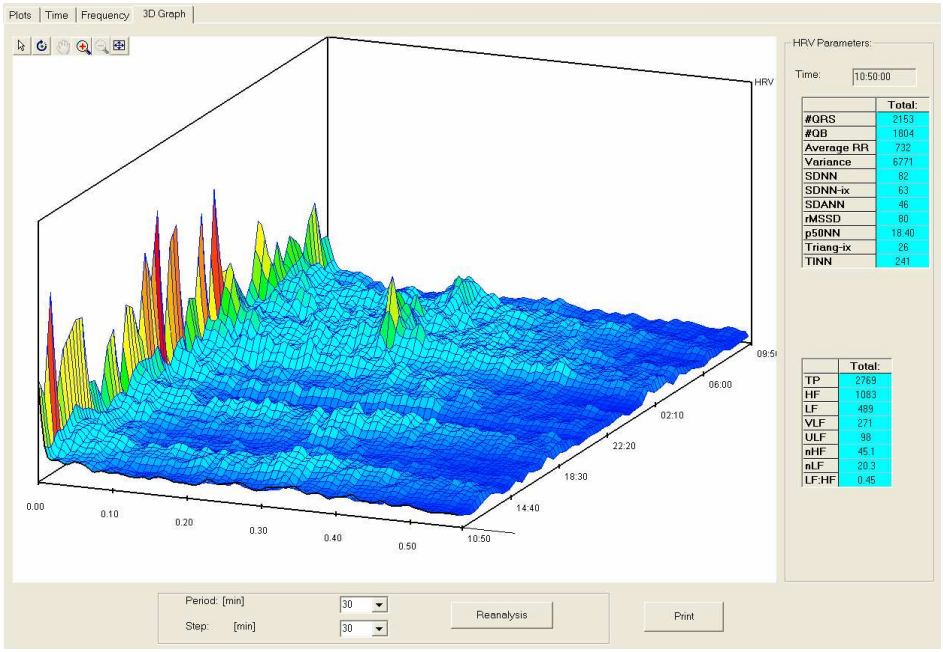



**Figure 55. HRV 3D diagram**

The above diagram is drew based on results acquired from analysis of 20 minutes fragments from whole examination. System enables carrying out HRV analysis for different periods (5 minutes, 10 minutes, ..., 60 minutes). For each analysis you may set “step” – the space between analyzed periods.

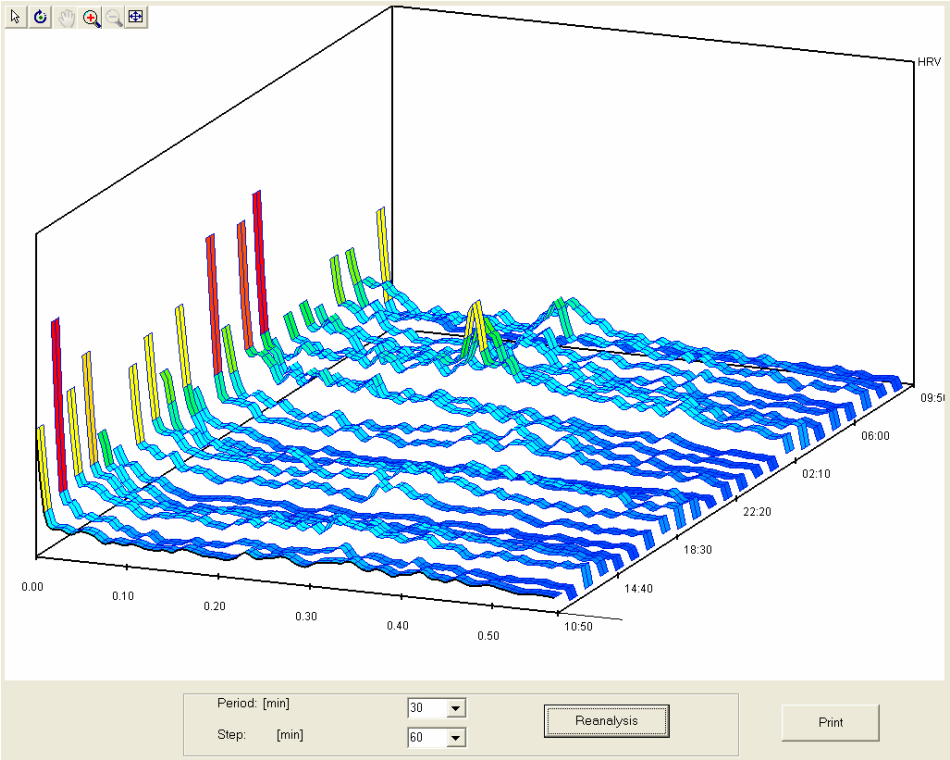



**Figure 56. HRV 3D diagram with the step greater than analysis period**

## 3D diagram navigating

To navigate 3D diagram 6 buttons are used. With the use of these buttons you can format a diagram presentation on the display. Functions of particular buttons are presented below:

1 – change of cursor – to show an actual time on the diagram
2 – change of cursor – to rotate the diagram
3 – change of cursor – to move the diagram
4 – increase of the diagram
5 – reduction of the diagram
6 – setting the diagram at the start position

# 7.4 QT analysis

## 7.4.1 General

QT analysis belongs to a group of advanced ECG techniques. On the basis of raw record of the signal in chosen epoch averaging P-QRS-T is created. Results of measurements are presented in graphic form as diagrams and in numerical form as a table. Analysis for each channel is carried out independently.

## 7.4.2 Start analysis

First you should complete a standard arrhythmia analysis. To open a module for QT analysis press button.

**Figure 57. Main window of QT analysis module**

The main window (Figure 57) shows:

- Hr trend, QT and QTc,
- Channel selection buttons,
- 3 windows with averaged P-QRS-T with marked measurement points and results of measurements,
- Edition field for defining length of epochs.

**P-QRS-T window**

3 windows with averaged P-QRS-T are displayed at the lower part of the window. Positions of measurement points are shown against the background of P-QRS-T.

There are:

- Measurement point – Q,
- Measurement point of T –peak,
- Measurement point of T wave end.

The window displays also such data as:

- Analyzed period,
- Number of averaged beats,
- Q wave position (in relation to R wave),
- T wave peak position,
- T wave end position,
- QT value,
- Distance of Q from T-peak,
- Adjusted QTc value,
- Average RR interval.

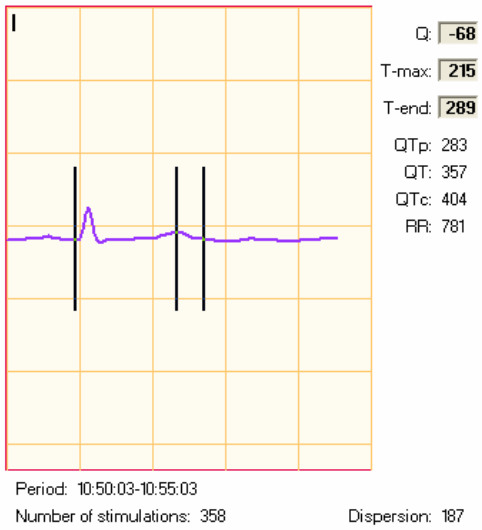



**Figure 58. P-QRS-T window**

These 3 windows allow to verify positioning of measurement points. In case automatically determined point positions are wrong, you can set them manually.

## Setting measurement points

In case of wrong position adjust the points manually:

- Indicate a measurement point line with the mouse cursor. The line becomes thicker,
- Press the left button of the mouse and drag a line to the proper position.
- Release the left button of the mouse.

When the operation is completed, the system will automatically recalculate results of measurements.

**Figure 59. Change in positions of measurement points**

## Selection of a displayed epoch

There are two ways to display an epoch for displaying averaged P-QRS-T.

1. By trend

Indicate a proper place in the trend area and click with the left mouse button to have the data from the indicated place displayed automatically by the system.

2. With the keyboard

Left and right arrows move cursor in the area of the trend in one epoch.

## Definition of epoch length

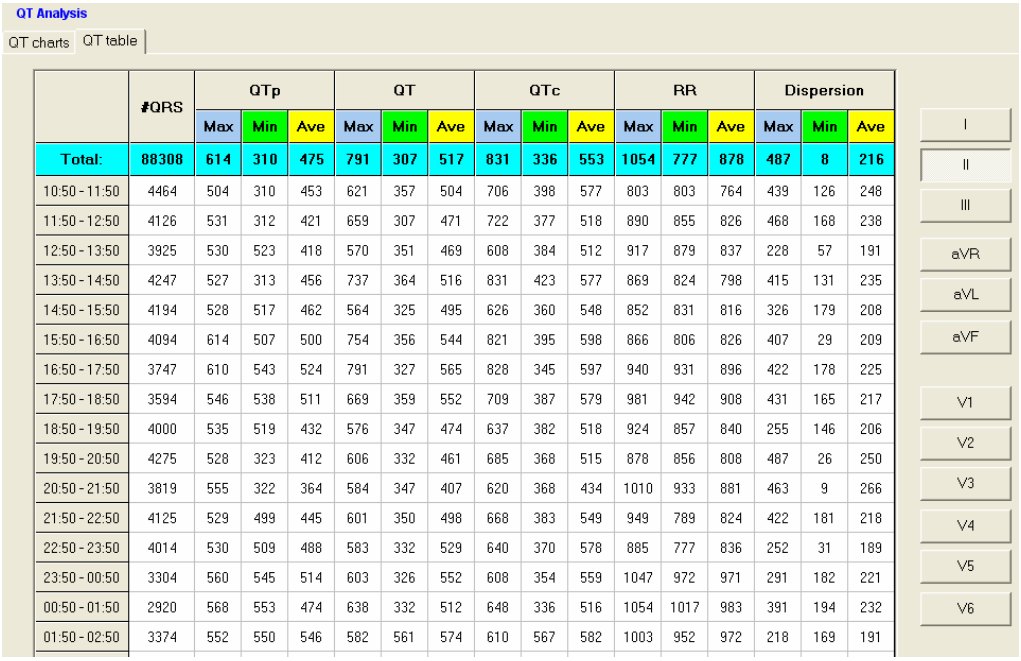
A field on the right is for entering length in [min] of the epoch. When you change the length of epoch, the system will automatically recalculate the data for the whole test and analyze the trend, and tabular list.

## Tabular list

”QT table” opens a window with the table containing results of QT calculations. The table develops statistic results from the whole test and hourly sub periods. The table contains data concerning:

- The analyzed period
- Number of P-QRS-T in the period
- QTp values (minimal, average and maximal)
- QT values (minimal, average and maximal)
- QTc values (minimal, average and maximal)
- RR values (minimal, average and maximal)
- QT dispersion values (minimal, average and maximal)

The table is created independently for each channel. On the right 3 buttons for changing a lead are displayed.




| | #QRS | QTp | | | QT | | | QTc | | | RR | | | Dispersion | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Max | Min | Ave | Max | Min | Ave | Max | Min | Ave | Max | Min | Ave | Max | Min | Ave |
| **Total:** | **88308** | **614** | **310** | **475** | **791** | **307** | **517** | **831** | **336** | **553** | **1054** | **777** | **878** | **487** | **8** | **216** |
| 10:50 - 11:50 | 4464 | 504 | 310 | 453 | 621 | 357 | 504 | 706 | 398 | 577 | 803 | 803 | 764 | 439 | 126 | 248 |
| 11:50 - 12:50 | 4126 | 531 | 312 | 421 | 659 | 307 | 471 | 722 | 377 | 518 | 890 | 855 | 826 | 468 | 168 | 238 |
| 12:50 - 13:50 | 3925 | 530 | 523 | 418 | 570 | 351 | 469 | 608 | 384 | 512 | 917 | 879 | 837 | 228 | 57 | 191 |
| 13:50 - 14:50 | 4247 | 527 | 313 | 456 | 737 | 364 | 516 | 831 | 423 | 577 | 869 | 824 | 798 | 415 | 131 | 235 |
| 14:50 - 15:50 | 4194 | 528 | 517 | 462 | 564 | 325 | 495 | 626 | 360 | 548 | 852 | 831 | 816 | 326 | 179 | 208 |
| 15:50 - 16:50 | 4094 | 614 | 507 | 500 | 754 | 356 | 544 | 821 | 395 | 598 | 866 | 806 | 826 | 407 | 29 | 209 |
| 16:50 - 17:50 | 3747 | 610 | 543 | 524 | 791 | 327 | 565 | 828 | 345 | 597 | 940 | 931 | 896 | 422 | 178 | 225 |
| 17:50 - 18:50 | 3594 | 546 | 538 | 511 | 669 | 359 | 552 | 709 | 387 | 579 | 981 | 942 | 908 | 431 | 165 | 217 |
| 18:50 - 19:50 | 4000 | 535 | 519 | 432 | 576 | 347 | 474 | 637 | 382 | 518 | 924 | 857 | 840 | 255 | 146 | 206 |
| 19:50 - 20:50 | 4275 | 528 | 323 | 412 | 606 | 332 | 461 | 685 | 368 | 515 | 878 | 856 | 808 | 487 | 26 | 250 |
| 20:50 - 21:50 | 3819 | 555 | 322 | 364 | 584 | 347 | 407 | 620 | 368 | 434 | 1010 | 933 | 881 | 463 | 9 | 266 |
| 21:50 - 22:50 | 4125 | 529 | 499 | 445 | 601 | 350 | 498 | 668 | 383 | 549 | 949 | 789 | 824 | 422 | 181 | 218 |
| 22:50 - 23:50 | 4014 | 530 | 509 | 488 | 583 | 332 | 529 | 640 | 370 | 578 | 885 | 777 | 836 | 252 | 31 | 189 |
| 23:50 - 00:50 | 3304 | 560 | 545 | 514 | 603 | 326 | 552 | 608 | 354 | 559 | 1047 | 972 | 971 | 291 | 182 | 221 |
| 00:50 - 01:50 | 2920 | 568 | 553 | 474 | 638 | 332 | 512 | 648 | 336 | 516 | 1054 | 1017 | 983 | 391 | 194 | 232 |
| 01:50 - 02:50 | 3374 | 552 | 550 | 546 | 582 | 561 | 574 | 610 | 567 | 582 | 1003 | 952 | 972 | 218 | 169 | 191 |

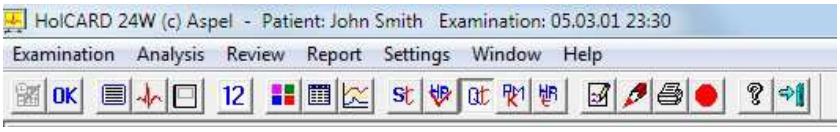
**Figure 60. Table with results of measurements**

**Development of results**

A user has to verify measurement results obtained from automatic analysis. First of all, it refers to positions of measurement points. Observing trends, it is easy to catch epochs (unexpected peaks on the diagram) where the system determined positions of measurement points as the result of artifacts. In such situation adjust positioning manually.

# 7.5 Analysis of pacemaker operation

Pacemaker (PMK) module is a part of HolCARD 24W © Aspel system which is used for Holter tests and analysis. Before start-up you must start the whole system, load the test and perform automatic analysis (see HolCARD 24 W service manual). Only then a Pacemaker PMK icon on the toolbar will be activated.




If a loaded examination does not contain information about operation of cardiac stimulator, the system will not open Pacemaker – PMK module and display information: ”This ECG examination has not detect any cardiac stimulator beats”.

Otherwise, after selecting <**PMK**> icon or start menu <**Review**> field <**Pacemaker**> a PMK window will be displayed.

This window consists of four parts:

a) Trends window,
b) Histograms window,
c) Interval statistics window,
d) Error statistics window.

### 7.5.1 Trends window

Trends window shows number of cardiac stimulator beats for each subsequent minute of the test in the graphic form. You can indicate any point on the trend with the mouse cursor. You will see a vertical blue line – position indicator, and a trend module in the lower part of the of the screen presenting a selected part of ECG record. Position indicator may be moved with arrows as described below:

| Key | Meaning |
|---|---|
| Left arrow | Move 4 seconds forward |
| Right arrow | Move 4 seconds backwards |
| Down arrow | Move to the next point of diagram |
| Up arrow | Move to the previous point of diagram |

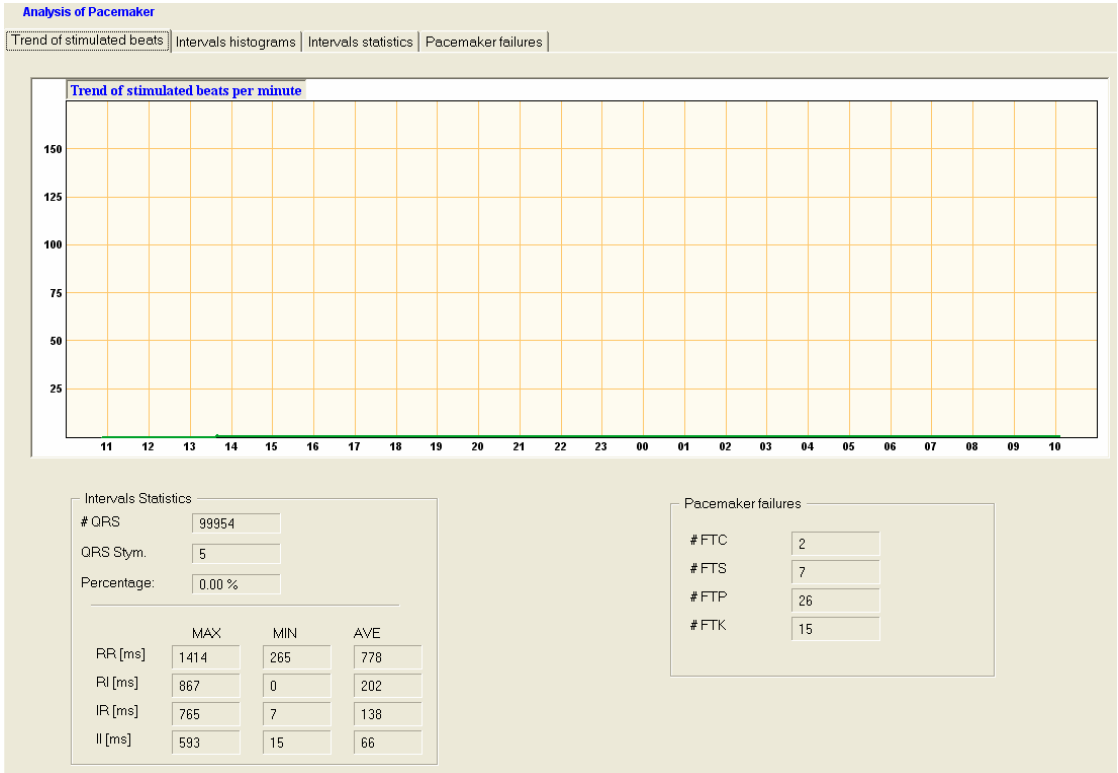



**Figure 61. Trends window**

### 7.5.2 Histograms window

Histograms window consists of 4 diagrams. Each diagram contains information about intervals:

a) Between QRSs (**R-R intervals**),
b) Between QRS and cardiac stimulator impulse (**R-I intervals**),
c) Between cardiac stimulator and QRS (**I-R intervals**),
d) Between subsequent cardiac stimulator impulses (**I-I intervals**).

Interval length in [ms] is in X axis of each histogram, and number of intervals in Y axis. Each histogram window is operated in the same way. With left mouse button you select any bar of the histogram. The colour of the indicated bar will change and a strip in the lower part of the screen will display an interval with the given length.

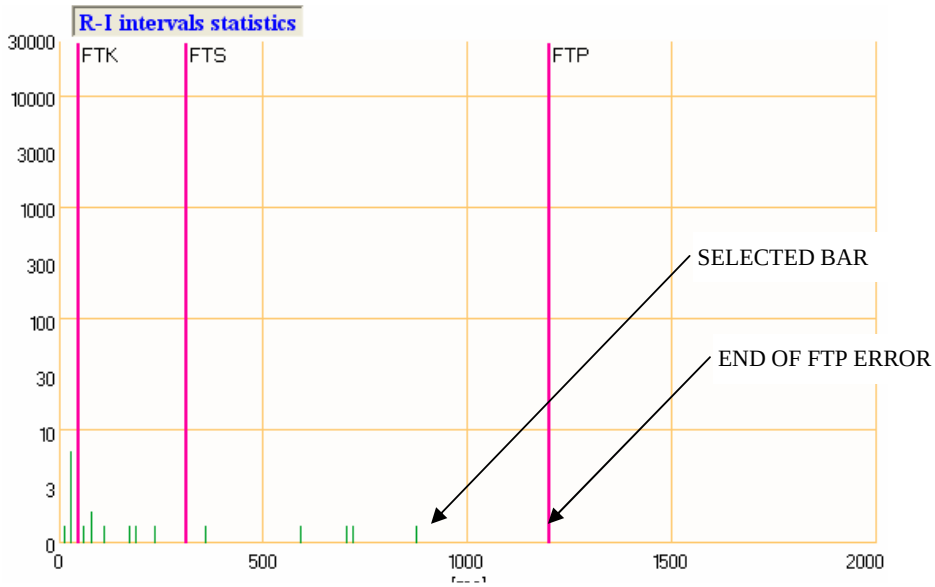



**Figure 62. R-I histogram window**

Use arrows and space to move to the next, previous interval or bar. The table below explains meaning of the arrows.

| Key | Meaning |
|---|---|
| Up arrow | Next interval |
| SPACE | Next interval |
| Down arrow | Previous interval |
| Right arrow | Next bar |
| Left arrow | Previous bar |

In this way you may reach any interval and find out if the cardiac stimulator worked correctly or if any irregularities were detected. At the same time, you may edit wrong classified beats, if any. The strip contains a set of tools needed for this purpose (see Strip Module description).

Thicker vertical red lines determine limits of cardiac stimulator errors on the histogram. They are basis for calculation of stimulation errors – FTS, FTC, FTP and FTK. Values of those limits may be changed in Analysis setting window accessible from Settings-parameters of analysis – PMK.

Strip module displays the place of occurrence of cardiac stimulator impulses registered by AsPEKT recorder with stimulation option. „^" marker is used for this purpose.

When a histogram bar is selected, the strip also displays information on types of intervals, number of intervals found by the system which interval is being displayed, starting from the beginning of the examination.

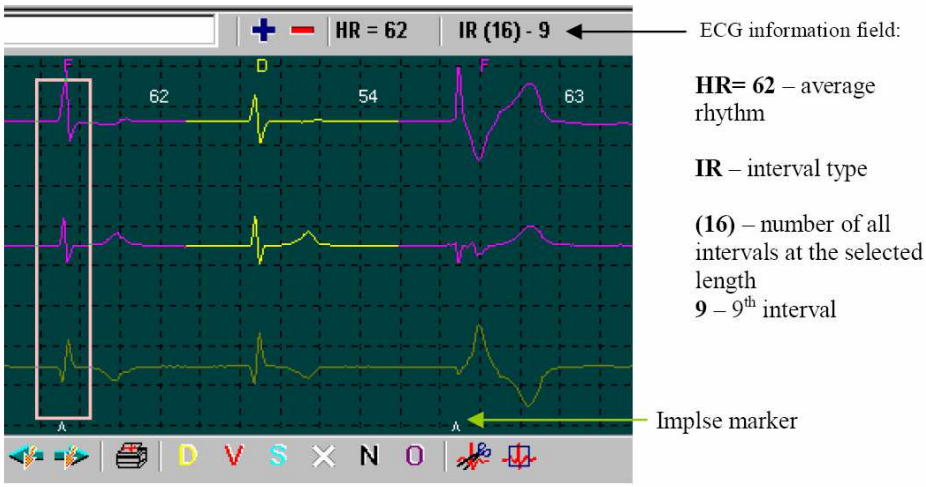



**Figure 63. ECG Strip**

## 7.5.3 Interval statistic window

Interval statistics window represents maximal, minimal and average interval of a given type, divided into hours and presented in tabular form. Select a cell, and the strip below will present the selected interval.

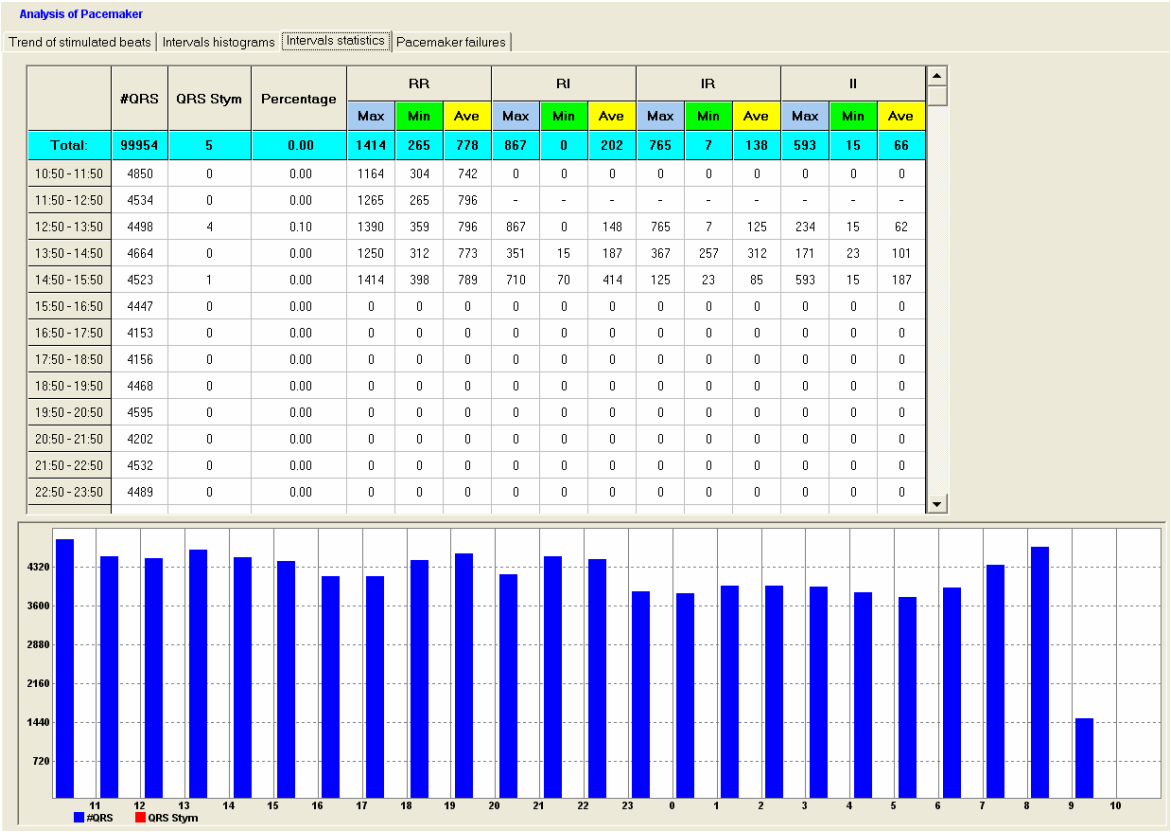



**Figure 64. Interval table**

Using toolbar situated in Strip module you can edit the displayed interval in case of wrong classification made by the system. You may also reach next intervals from a given hourly and type period. Do it with the following keys:

| Key | Meaning |
|---|---|
| Up arrow | Next interval |
| SPACE | Next interval |
| Down arrow | Previous interval |

Intervals are presented as follows:

a) **max** column – in descending order in relation to the interval length,

b) **min** column – in ascending order in relation to the interval length,

c) **average** column – as occurred starting from the beginning of a given hour.

Strip module displays also information on a currently selected interval (Figure 65).

**Figure 65. ECG Strip**

## 7.5.4 Error statistic window

A table of statistic errors shows the following errors: FTC, FTS, FTP and FTK in hourly interval. Table cells presents number of errors for a given hours interval.

Analysis of Pacemaker

Trend of stimulated beats | Intervals histograms | Intervals statistics | Pacemaker failures

| | #QRS | QRS Stym | Percentage | FTC | FTS | FTP | FTK |
|---|---|---|---|---|---|---|---|
| **Total:** | **99954** | **5** | **0.00** | **2** | **7** | **26** | **15** |
| 10:50 - 11:50 | 4850 | 0 | 0.00 | 0 | 0 | 1 | 0 |
| 11:50 - 12:50 | 4534 | 0 | 0.00 | 0 | 0 | 14 | 0 |
| 12:50 - 13:50 | 4498 | 4 | 0.10 | 1 | 5 | 9 | 13 |
| 13:50 - 14:50 | 4664 | 0 | 0.00 | 1 | 0 | 1 | 1 |
| 14:50 - 15:50 | 4523 | 1 | 0.00 | 0 | 2 | 1 | 1 |
| 15:50 - 16:50 | 4447 | 0 | 0.00 | 0 | 0 | 0 | 0 |
| 16:50 - 17:50 | 4153 | 0 | 0.00 | 0 | 0 | 0 | 0 |
| 17:50 - 18:50 | 4156 | 0 | 0.00 | 0 | 0 | 0 | 0 |
| 18:50 - 19:50 | 4468 | 0 | 0.00 | 0 | 0 | 0 | 0 |
| 19:50 - 20:50 | 4595 | 0 | 0.00 | 0 | 0 | 0 | 0 |

**Figure 66. Table of errors**

Meaning of particular columns:

| Column | Meaning |
|---|---|
| #QRS | Total number of QRSs |
| QRS Stym | Total number of stimulated QRSs |
| Percentage | Percentage of stimulated QRSs |
| FTC | Stimulation failure |
| FTS | Control failure |
| FTP | No stimulator impulses |
| FTK | Competitive beat |

After selecting a given cell, the first wrongly generated by cardiac pacemaker impulse for given interval will be presented on the strip in the lower part of the screen.

You can reach other impulses generated with errors. Use the following keys:

| **Key** | **Meaning** |
|---|---|
| Up arrow | Next interval |
| SPACE | Next interval |
| Down arrow | Previous interval |

Reviewing succeeding errors, a user may check whether cardiac stimulator operates correctly or not.

### 7.5.5 Report

A report generated by the system summaries up the evaluation of cardiac stimulator operation. It consists of 3 parts:

a) Diagrams – four histograms of (R-R, I-R, R-I, I-I) intervals and beats trend stimulated in a minute.

b) Interval table containing statistics of R-R, I-R, R-I, I-I intervals divided into hours.

c) Table of stimulator errors – a table containing FTC, FTS, FTP and FTK errors divided into hours.

Printouts are generated with any printer connected to the PC and interacting with MS Windows. A user may select one of three elements of the printout (Figure 67).

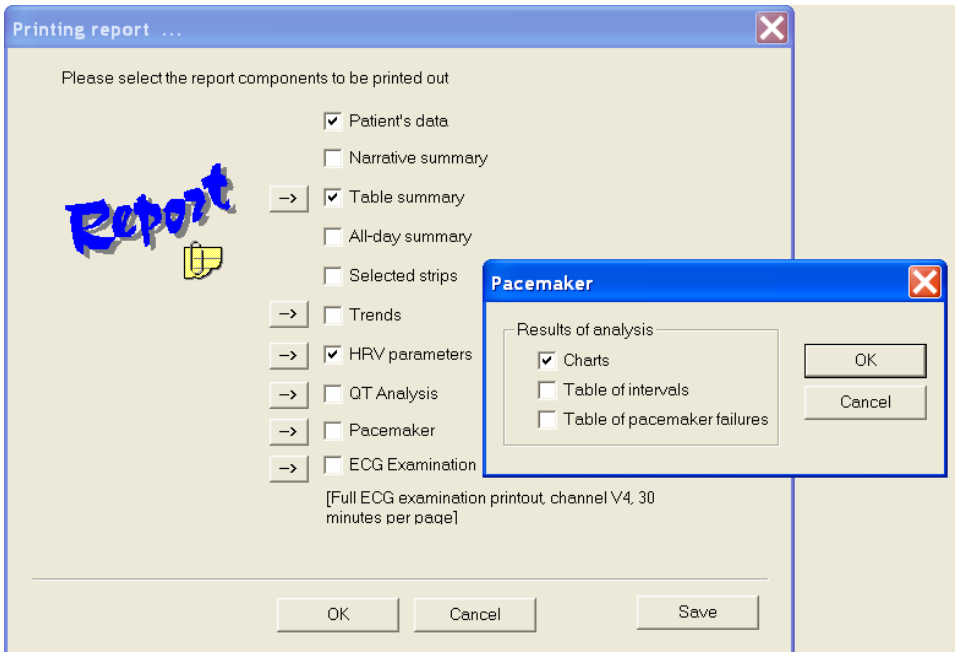



**Figure 67. Report window**

**NOTE!** The best method in PMK operation is entering all parameters of cardiac stimulator, automatic analysis and adjustment of beat classification, and finally starting PMK module to verify operation of a cardiac stimulator.

## 7.6 HRT Analysis

HRT Analysis Module allows you to exam the heart rate turbulences. You can start the module by clicking on HRT button in top toolbar. Remember to perform arrhythmia analysis before you start the turbulences analysis.

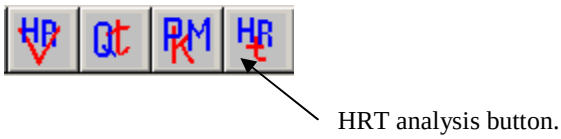



**Figure 68. Analysis setting**

After starting the module, on the screen you will see the information about current study.

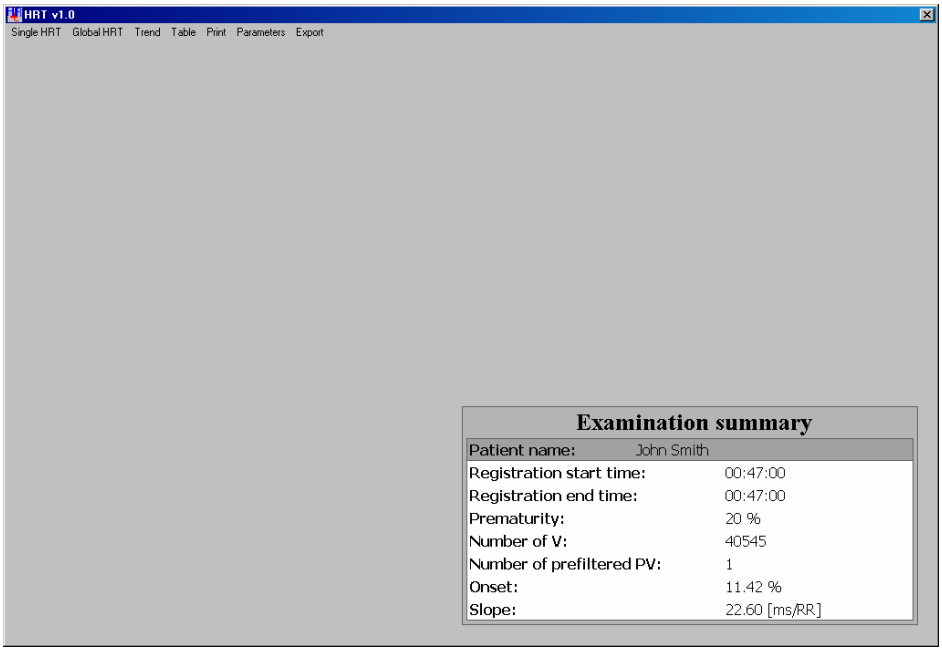



**Figure 69. Main window of HRT module.**

In the right corner there is a table which contains information about:

- Name of the patient.
- Registration start time.
- Registration end time.
- Prematurity parameter.
- Total number of ventricular contractions.
- Total number of ventricular contractions which comply with the HRT conditions.
- The onset value for whole examination.
- The slope value for whole examination.

The main menu with all functions is located in the top of the module.

**<Single HRT>** – This function shows the changes of the RR interval after a single ventricular contraction.

**<Global HRT>** – This function shows the changes of the RR interval based on the averaged tachogram.

**<Trend>** – RR interval trend.

**<Table>** – Results presented in a table.

**<Print>** – Report printout.

**<Parameters>** – This function allows you to change the main parameters of the HRT analysis program.

**<Export>** – This function allows you to export analysis results to oher programms.

### 7.6.1 Single HRT

During the analysis, the HRT module search for a premature ventricular contractions of ECG which comply with HRT conditions. After clicking the <**Single HRT**> function, you will see a window with RR interval near the first ventricular contraction. In the window, there is information about: number of HRT onset value, slope value and RR values before and after the ventricular contraction.

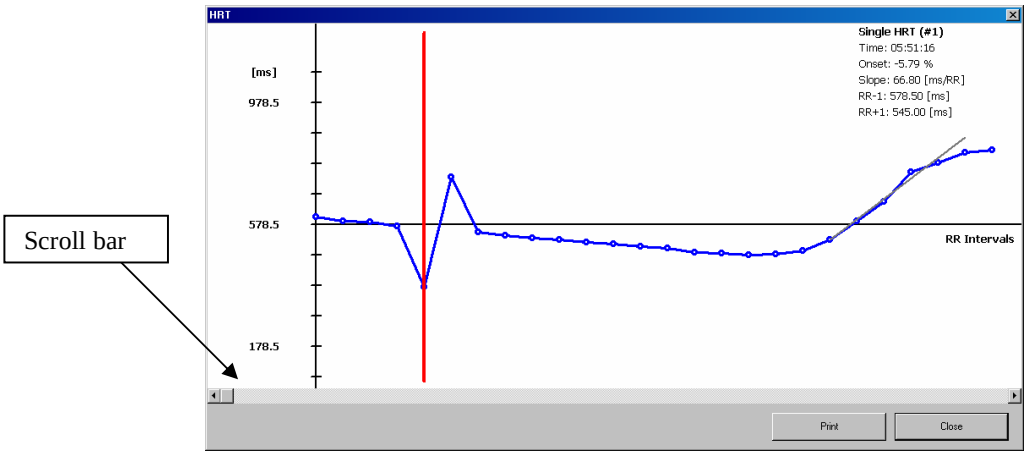



**Figure 70. Single HRT window.**

Scroll bar allows you to view diagrams for other ventricular contractions. The <**Print**> button allows you to print a report for the current view.

## 7.6.2 Global HRT

During the analysis, the HRT module prepares an averaged tachogram for RR values as a base for onset and slope calculations for the entire study. The print button allows you to print a report for the current view.

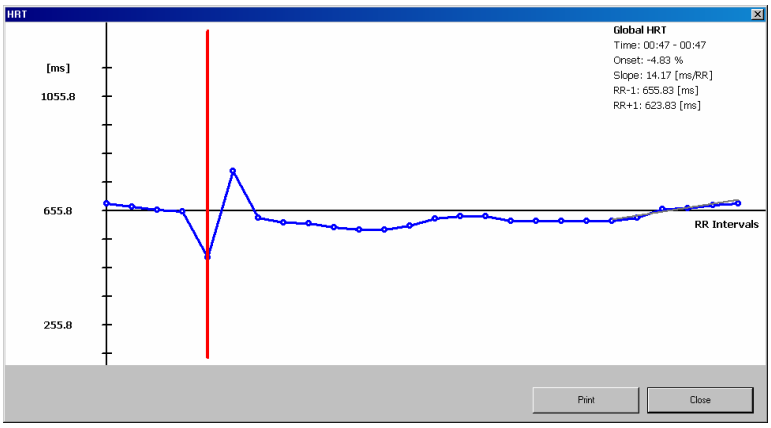



**Figure 71. Global HRT window**

## 7.6.3 Table

The results of the analysis can also be presented in a table. The table contains nine columns. The first column shows the time of analysis. The remaining columns contain information such as:

- Total number of ventricular contractions in the analyzed period.
- Total number of filtered ventricular contractions in the analyzed period.
- Onset value.
- Slope value.
- RR values before and after the ventricular contraction (RR-1, RR+1).
- Prematurity time.

- Post-extrasystole interval.

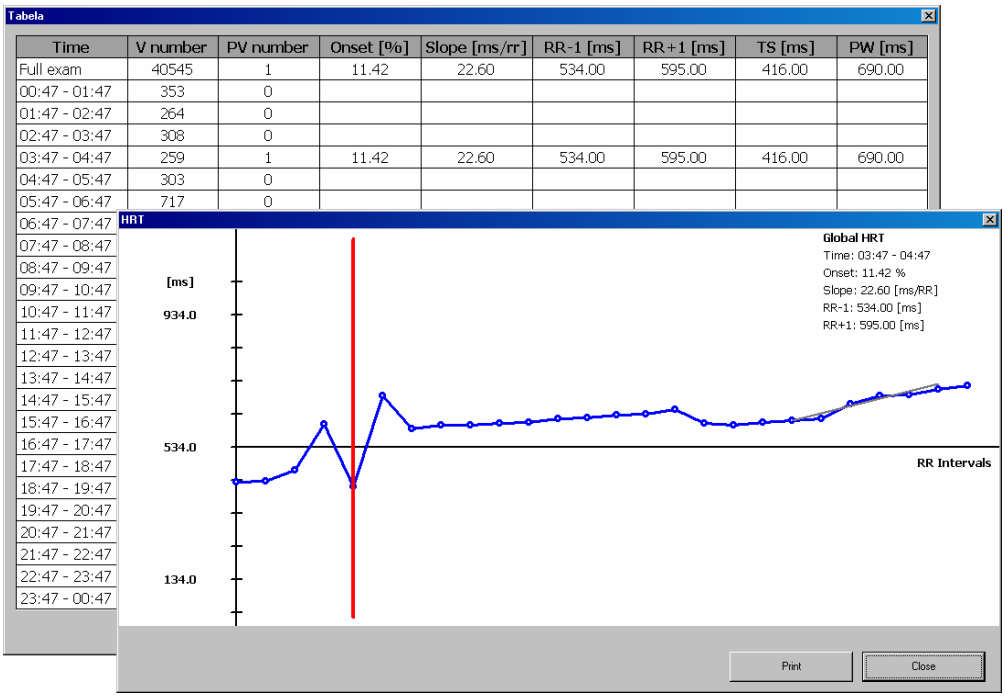



**Figure 72. Table with analysis results.**

When you select a row and click the right mouse button, you see the averaged chart for selected time period.

## 7.6.4 Trend

RR interval can be presented in bar graph. You can change the current position of the time by moving the scrollbar. When the Single HRT window is open, the cursor shows the time of selected ventricular contraction.

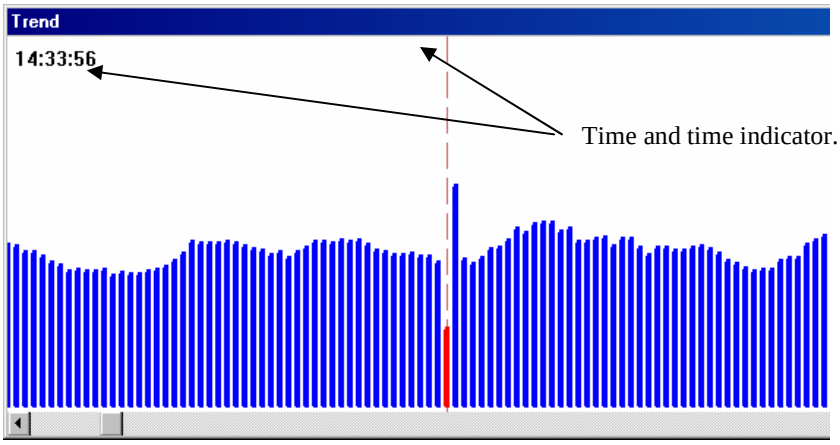



**Figure 73. Trend window.**

The trend view is very useful for verifying the classifications.

### 7.6.5 Parameters

The Parameters function allows you to modify the parameters of the analysis. You can change following parameters:

- **Prematurity** – percentage value of required prematurity.
- **Post-extrasystole interval** – percentage value of required Post-extrasystole interval.
- **Number of intervals after PVC** – The number of intervals after PVC to be taken in analysis.
- **Supraventricular** – If checked, then supraventricular contractions are treated as dominant. This may increase the number of found HRT.

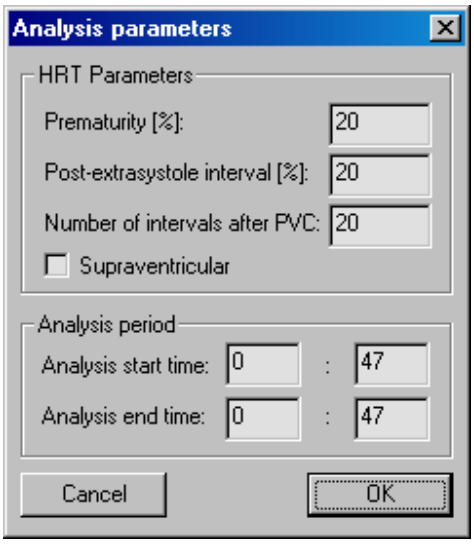



**Figure 74. Analysis parameters window.**

### 7.6.6 Export

This function allows you to export the examination results to a file. This function generates a formatted text file. This file can be imported by other applications (e.g. Matlab, Excel) to perform additional calculations.

## 7.7 Prospective Analysis

Prospective analysis is an alternative for Retrospective analysis. Prospective analysis results can be edited with the use of HolCARD 24W Aspel system modules like Retrospective Analysis (Standard analysis) results.

ECG signal is analyzed gradually – with the step every QRS complex. Every detected QRS complex is displayed in <**Control panel**> and RR interval values of a few last QRS complexes are displayed in <**RR interval windows**> vertical histograms. Additionally, on a <**Strip**> current QRS with its nearest environment is presented. At the same time the complex is classified and in case of new class opening a user defines its morphology and conditions of arrhythmia occurrence are verified. In case of arrhythmia detection it is currently signaled.

Start Prospective analysis module with <**Analysis**> window, choosing required analysis type and then press <**Start**> button. See picture below.

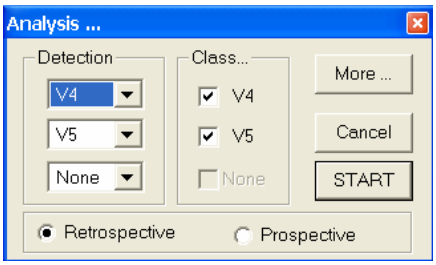



**Figure 75. Analysis setting**

After choosing <**START**> button a window enabling analysis carry out appears.

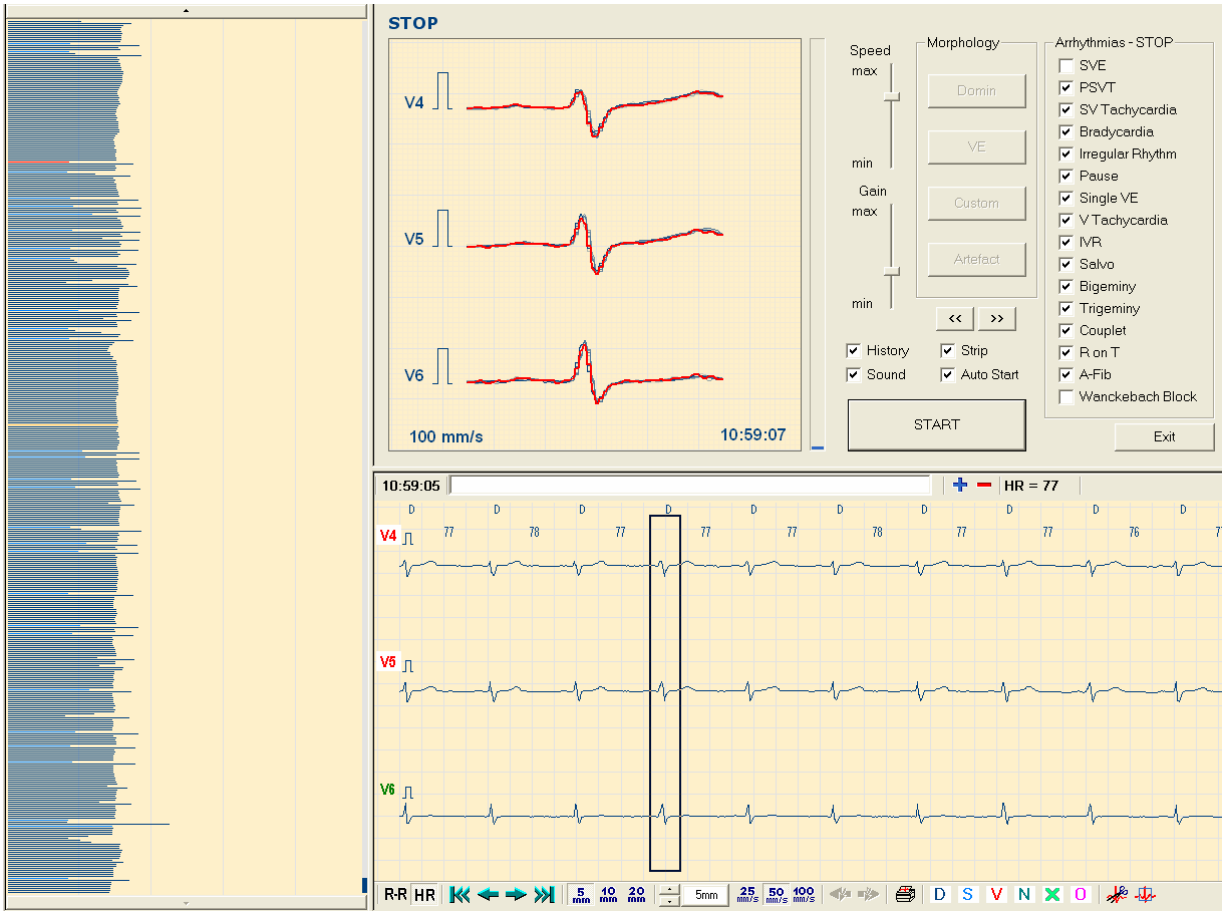



**Figure 76. Prospective analysis module**

## Control panel

<**Control panel**> is a main window situated in the upper right side of the module. On the left succeeding QRS complexes are presented. The current complex is presented in the background of its previous 10 complexes. The current complex is indicated with intensive colour whereas previous complexes are in neutral colour. QRS complexes are drawn on the millimeter net with the speed of 100 mm/s and the gain smoothly regulated with the use of <**Speed**> slide valve. The current gain can be evaluated based on 1 mV pattern regulated from the left side of diagram.

On the diagram complexes from 3 channels, chosen to analyze, are presented. In the diagram area current examination time is displayed. On the right there is an analysis progress bar of a currently loaded examination.

Information for the user is displayed over QRS complexes.

| | |
|---|---|
| Lasting analysis... | in the analysis duration |
| STOP | analysis stopped on a user's request or after morphology evaluation with the "Auto start" option on |
| Determine morphology | a question to the operator after new class establishing |
| Arrhythmia type – name of arrhythmia | information about detected arrhythmia |
| Interrupted analysis | interrupted analysis on the operator's request |
| Ended analysis | whole examination was converted |

During analysis the amplitude change of the displayed ECG signal is possible with the use of <**Gain**> slide valve. The analysis speed (speed of succeeding QRS complexes presentation) is regulated with the <**Speed**> slide valve or with the < **+** > and < **-** > buttons on the numerical keyboard. Minimal analysis speed is one QRS complex per second, maximal speed depends on the computer's processor capacity.

After prospective analysis beginning and detecting first QRS complex the module is stopped. Evaluation of QRS morphology complex is required. To determine morphology use the following buttons:

**Supraventricular** – <**D**>

**Ventricular** – <**V**>

**Own** – <**W**>

**Artifact** – <**X**>

After morphology determining and depending on "Auto Start" parameter system continues analysis or goes to the <**STOP**> mode. Analysis can be stopped/continued by pressing <**STOP**>/<**START**> button or <**SPACE**> button.

In the <**STOP**> mode it is possible to view hitherto analyzed examination fragment. To view examination with the step every QRS complex use following buttons:

- previous QRS < << > or < ↑ >,
- next QRS < >> > or < ↓ >.

Prospective analysis can be stopped on request before ECG recording by pressing <**Exit**> button.

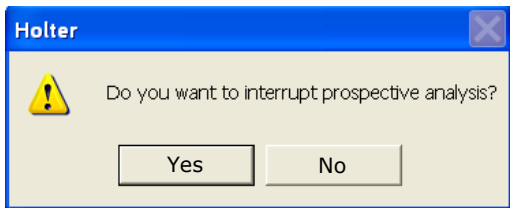



**Figure 77. Confirmation of Prospective analysis interruption**

**NOTE!!!** In case of prospective analysis interruption one has to remember that presented analysis results refer only to the analyzed examination fragment.

## RR intervals window

For the succeeding analyzed QRS complexes, in the left side of the window, in the form of vertical histogram, RR intervals are displayed. Spaces between vertical net lines equal 500ms. During analysis current RR interval is presented at the bottom of histogram. Additionally current histogram is indicated with the colour depending on HolCARD 24W system. Similarly RR intervals with complexes of morphology different than the dominant are indicated with suitable colours.

In <**STOP**> mode RR intervals window enables easy and effortless viewing of hitherto analyzed examination fragment. Clicking <**RR interval**> results in presentation of next QRS complex in <**Control panel**> and <**Strip**> windows. RR interval diagram can be rewinded with the use of buttons situated above and below diagram, accordingly with arrows. Current position of RR interval examination fragment regarding whole analyzed examination is signaled with the slide velve being on the right side of diagram. The slide velve is also used for quick move into any fragment of examination. It is done by clicking and keeping pressed left mouse button on the slide velve which allows for moving into desired position.

RR interval diagram moving buttons:

< ↑ > – previous QRS

< ↓ > – next QRS

<**Page Up**> - poprzednia strona

<**Page Down**> – next page

<**Home**> – examination beginning

<**End**> - examination ending

## Strip

<**Strip**> is the third window of Prospective Analysis window. On the strip current QRS complex is presented together with surroundings. Strip's description is in Chapter 4.2.2.

In <**STOP**> mode Strip allows to view and edit hitherto analyzed ECG recording fragment. It is possible to: add, delete ventricular captures, morphology change. See the exact description in Chapter 5 Test edition. Examination editing during the prospective analysis causes automatically arrhythmia reanalysis.

**Note!!!!** While stopping prospective analysis to determine morphology, in strip's window some of the buttons are unavailable. In this moment it is impossible to add or delete QRS complexes and change the morphology of previously detected QRS complexes.

In case of analysis of 12 channels ECG recording, in <**STOP**> mode, after pressing <**12**> icon it is possible to view, in neighborhood of current QRS complex, all 12 channels. In case of attempt to close HolCARD 24W program during prospective analysis following message will be displayed:

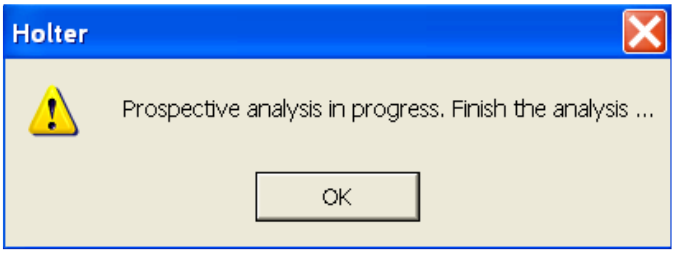



**Figure 78. Closing of HolCARD 24W program during prospective analysis**

Before program closing it is required to end the prospective analysis.

# 7.8 Analysis of 12 channels examination

HolCARD 24 W system, starting with 6.10.00 version, enables reading in and analysing 12 channels Holter examinations carried out with the use of e.g. AsPEKT 712 or AsPEKT 812 recorders. General scheme connected with proceeding with these examinations complies with the established presumptions for 3 channels examinations. In this chapter only differences and new options concerning analysis of 12 channels examinations will be described.

**Figure 79. Strip 12 module start-up**

**Strip 12 module**

Operating of Strip 12 module is similar to Strip module (see Chapter 4.2.2 Strip). The new thing is the lower part of the module which presents greater examination fragment – surroundings of signal viewed from upper part.

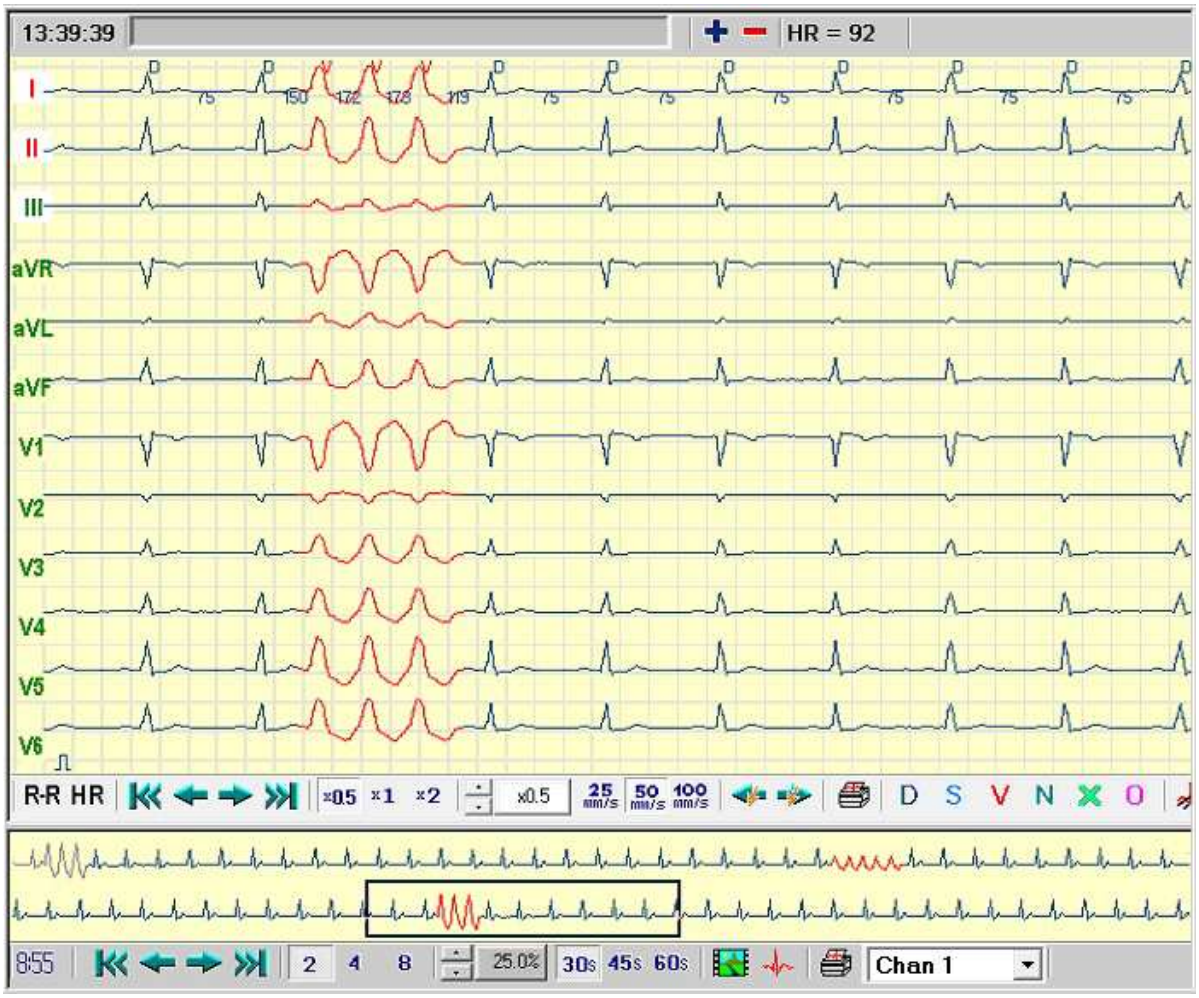



**Figure 80. Strip 12 module**

To turn Strip 12 module off press <**12**> icon on toolbar and all the system's modules are available. In the moment of Strip12 module operating the other modules are unavailable.

## Examination analysis

Examination analysis including 12 channels takes place based on 3 chosen channels. To start analysis choose <**Analysis**> from <**START**> position. <**Analysis**> window, will be displayed on the screen. In case of loading the examination from memory card this window appears automatically on the screen and in the background Strip12 module is started. Viewing the examination choose the channels upon which detection of QRS complexes will be carried out and morphology determined. General rules of channels selection are the same as in case of 3 channels examination.

After analysis (prospective or retrospective) the results can be viewed in all available modules. It should be remembered that <**Full disclosure**> and <**Strip**> modules present only 3 from 12 channels which have been chosen to analyze. To view the chosen beat in all 12 channels a Strip 12 module should be used. To facilitate user's work Strip 12 module reads itself the number of indicated QRS complex and presents it in its window.

## Expanded analysis

In case of 12 channels examinations ST and QT analyses take place in all 12 channels. Thus, windows enabling to view analysis results have been expanded with buttons which allow to change current leads.

# Chapter 8

# Settings

## 8.1 Recorder AsPEKT 903

The AsPEKT 903 recorder has a wide range of parameters, which can be set via **HolCARD 24W**. To do that, connect the recorder to a computer through a transmission cord. These settings can also be modified from the recorder itself.

By pressing the <**Load**> button, you can read the current parameters of the connected recorder. After changing the settings, remember to save them in the recorder by pressing <**Save**>.

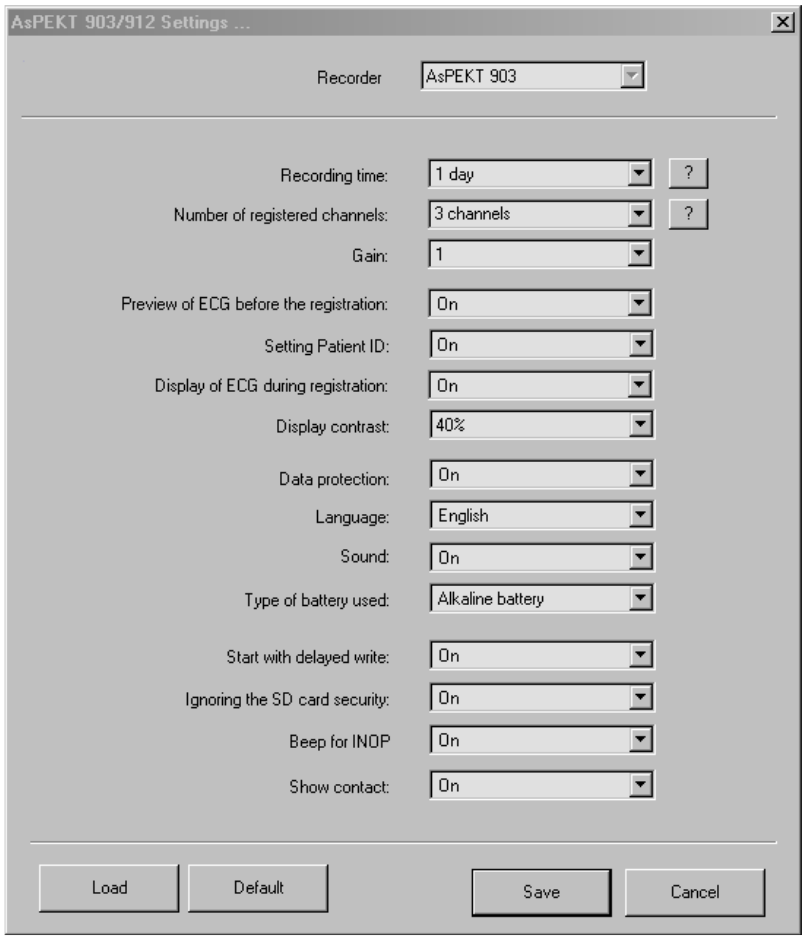



**Figure 81. AsPEKT 903 recorder settings**

The available parameter values depend on the recorder you are using –AsPEKT 903. If the recorder is connected to the computer while opening the settings window, HolCARD 24W will automatically read the type of recorder. If the recorder is not connected, then the type of the recorder in use can be changed by choosing one from the <**Recorder in use**> list.

Meaning of individual parameters:

| ***PARAMETER*** | ***PARAMETER'S MEANING*** |
|---|---|
| Recording time | It is the time, after which the ECG recording will stop automatically. Various values are available depending on the recorder. For AsPEKT 903, you can choose a value between 1 day and 7 days of operation, or select <**Next**>, which means the recorder will work for up to 14 days or until reaching critical battery level. The recording time also depends on the selected number of recorded channels – as presented in the table below. |
| Number of recorded channels | The AsPEKT 903 recorder allows choosing between recording 1, 2 or 3 ECG channels. |

| ***RECORDER*** | ***NUMBER OF RECORDED CHANNELS*** | ***RECORDING TIME – DAYS*** |
|---|---|---|
| AsPEKT 903 | 1 | 1,2,3,4,7, NEXT |
| | 2 | 1,2,3,4, NEXT |
| | 3 | 1,2,3,4, NEXT |

| ***PARAMETER*** | ***PARAMETER'S MEANING*** |
|---|---|
| Amplification | It is possible to set the value of amplification for the ECG signal at 0.5, 1 or 2. This means that the amplitude of the ECG signal received from the patient's body prior to saving on the card will be weakened by half in case of 0.5, saved without changes in case of 1, and doubled in case of 2. It is recommended to set this value to 1. Then check the ECG signal value on the screen. Should the amplitude turn out very small, the recorder settings should be changed to 2, and if it is very large, amplification should be at 0.5. The proper setting of amplification has an impact on the quality of the ECG record. |
| Patient ID settings | If this parameter is on, then before the test starts recording, the display will show the current patient ID number and their name. Setting the patient's number and their name has been described in chapter 2.2 Starting a Holter test. If the patient number has not been specified, then it can be defined in numerical values using buttons on the recorder. If this parameter is off, the recorder will start the recording immediately. |
| ECG display during recording | If this parameter is on, then during the test the recorder screen will allow viewing the ECG signal on the selected channel. To switch to this mode, use a special combination of keys. If this parameter is off, then it is not possible to view the ECG record during the test. |
| Screen contrast | By adjusting this value, you can change the brightness of the subtitles on the screen. The following values are available: 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% and 100%. |

| | |
|---|---|
| Data protection | If this parameter is on, then the recorder will not start the next test until the last one has been read by HolCARD 24W. The recorder must be connected to a computer and the test must be uploaded into the program. This way the data on the card are protected against accidental deletion e.g. by starting another test. If this parameter is off, the data will not be protected, and every time a new recording starts, the data on the previous test will be erased from the card regardless of whether it has been uploaded to HolCARD 24W or not. |
| Language | It is possible to choose between Polish and English as the language used by the AsPEKT 903 recorder. |
| Sounds | If this parameter is on, a short sound signal will be generated whenever a button is pressed. If this parameter is off, the signal will not be generated when a button is pressed. |
| Type of battery used | It is possible to choose between <**Ni-MH battery**> or <**Alkaline battery**>. This parameter should be set in accordance with the battery used – depending on whether an alkaline battery or a Ni-MH battery is currently used. The correct battery type setting is very important because it affects the decision when to stop the test due to low battery – see description of the parameter Recording time. |
| Delayed record | If this parameter is on, then the recorder starts recording the ECG signal on the card with a delay of 2 minutes from the start of the test. This option is very helpful, e.g. because it gives the patient time to dress up after attaching the recorder. In that case, ECG is not recorded for 2 minutes, which helps avoid massive disruptions to the record that might have a significant impact on the analysis of the entire test. If this parameter is off, the ECG starts recording on the card immediately after starting the test. |
| SD card lock check | If this parameter is on, then the recorder checks whether the card has enabled lock preventing recording. If the lock is on, the recording will not be started. If the parameter is off, the recorder does not check this lock. |
| Sound alarm upon INOP | If this parameter is on, then the recorder monitors the condition of electrode connections to the patient during the test. If it detects bad electrode connection (the so-called INOP), then will signal it by generating a stable, continuous sound alarm. If this parameter is off, then the recorder does not check the condition of electrode connections while working. |
| Presentation of contact data | If this parameter is on, then the recorder screen can display the doctor's contact data during the test – this includes their name and phone number. How to set these data has been described in chapter 2.2 Starting a Holter test. If this parameter is off, then such data cannot be displayed. |

After pressing <**Default**> in specific fields are set to default parameter values.

## 8.2 User's data

When generating reports from a Holter examination, on the first patient information page, in the header of the printout, the user data of the HolCARD 24W System © Aspel is also located. This information includes: the name of the office performing the examination, the address of the office and other information, e.g.: a contact

telephone. All this information may be set by selecting menu **Settings** field **User data**. On the monitor screen, a dialogue window will appear will which allow entry of the particular information.

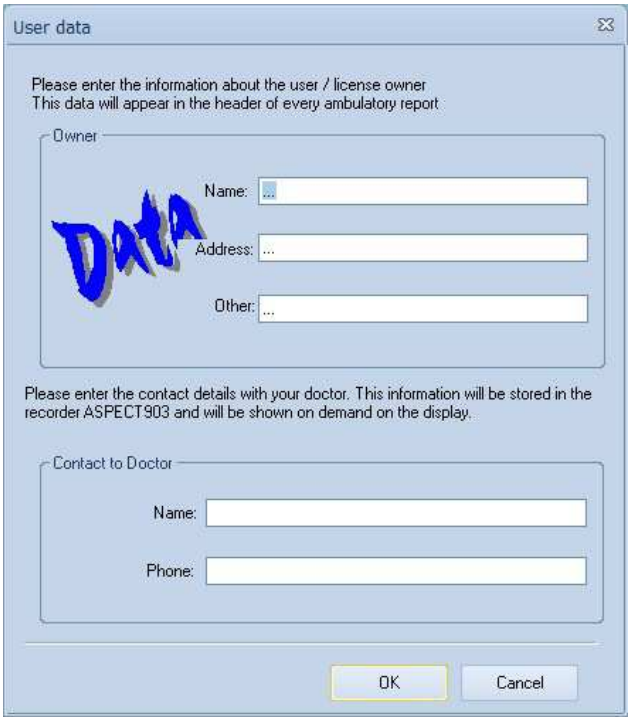



**Figure 82. User's data window**

In addition, it is possible to enter information which will be recorded in the AsPEKT 903 recorder – the name of the person with whom the patient is to make contact if problems occur during the wearing of the recorder and the contact number. This information will be available on the AsPEKT 903 display by pressing the proper buttons.

After entering or possibly editing the particular fields, any changes should be confirmed by selecting the button <**OK**>. The information will be remembered by the program.

For changes in office information, edits (corrections) may be made of the information entered here. Editing of information occurs in the standard manner, just as it occurs in the majority of program windows in operation in the MS Windows environment. A character may be deleted with the use of the <Backspace> key, moving between subsequent fields <**Name**>, <**Address**>, <**Other data**> takes place with the use of the <**TAB**> key or by using the mouse.

## 8.3 User Preferences

HolCARD 24W © Aspel is a modern program to operate under MS Windows. Operating is easy and fast. A lot of settings may be defined by a user depending on his/her needs. All options are available from <**Settings**> menu <**User Preferences**> field.

Preferences window displays <**OK**> and <**Save**> buttons. If you confirm changes with <**OK**>, they will be available only until loading the next examination. Each subsequent examination will have global settings again. If you press <**Save**> new parameters will be saved and applied to all the examinations – as global ones.

### 8.3.1 Automatic Windows Arrangement (AWA)

Working with HolCARD 24W © Aspel relies mainly on starting particular modules illustrating the recorded ECG examination and results of Holter analysis (see Chapter 4.2 Examination ). This operation is usually performed from a toolbar or the main menu. A new window with content depending on a module is displayed.

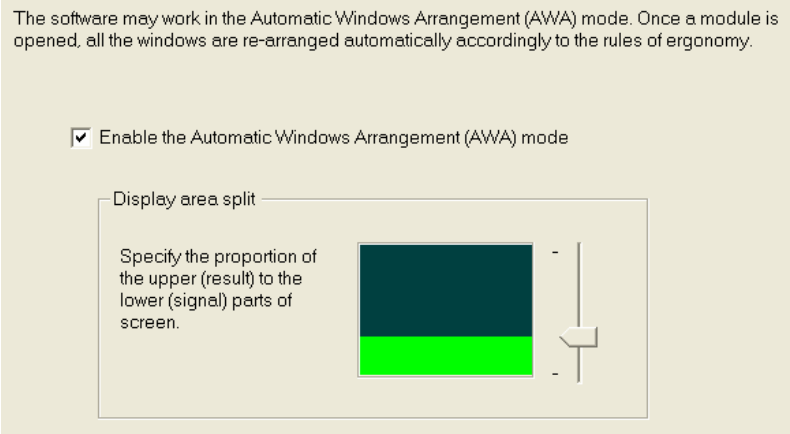



**Figure 83. AWA mode window**

If several windows are displayed at the same time it will be difficult to view all information. Some modules will be invisible and you will have to arrange them manually.

That is why Automatic Windows Arrangement mode (abbreviation - **AWA**) has been introduced. This mode arranges windows in such a way that all windows are visible. It may happen that previously opened window will be closed because putting two modules together may turn out useless.

Generally, the principle is as follows: Holter analysis windows: templates, tabular list, trends, HRV are always displayed separately. They are not automatically arranged one by one. To these windows following examination module may be added: Strip or Full disclosure in the bottom part of the screen. Such arrangement (Holter analysis up the screen and examination module down the screen) is very useful as you may verify results of Holter analysis against the test module.

In a dialogue box (see Figure 83) you may define the size of upper module and the lower module. Modules are indicated with different colours. Modification of this division is done with a scroll located next to a square of <**Display area split**> section.

In AWA mode there is no title bar in particular modules. Such solution leaves more space for displaying important information and makes manual shifting of module windows impossible.

If you want a different arrangement of windows, switch AWA mode off. Move the mouse cursor to <**Enable the Automatic Windows Arrangemnt (AWA) mode**> and click the left button. A tick should disappear and the mode is switched off.

Module windows will have again title bars and you we will be able to arrange them manually as usually under MS Windows. You can use standard options arranging the windows – <**Windows**> menu and fields like <**Cascade**>, etc.

### 8.3.2 Start settings of Full Disclosure and Strip

Strip and Full Disclosure modules display recorded ECG examination of a patient. A number of information may be adjusted with buttons on module toolbars, e.g. seconds of the displayed test in one line (see: Chapters

4.2.1 Full Disclosure, 4.2.2 Strip). You may present a larger area of the examination less precisely or a smaller area more accurately.

Start values of Strip and Full Disclosure modules allow definition of how to set a module immediately upon its start. If a user prefers a Strip with 50 mm/s ECG record, he/she may preset this parameter and avoid setting this speed every time.

A dialogue window is divided into two groups – settings for Full Disclosure and settings for Strip. Adjust setting selecting a required parameter from the list. Confirm changes with <**OK**> button.

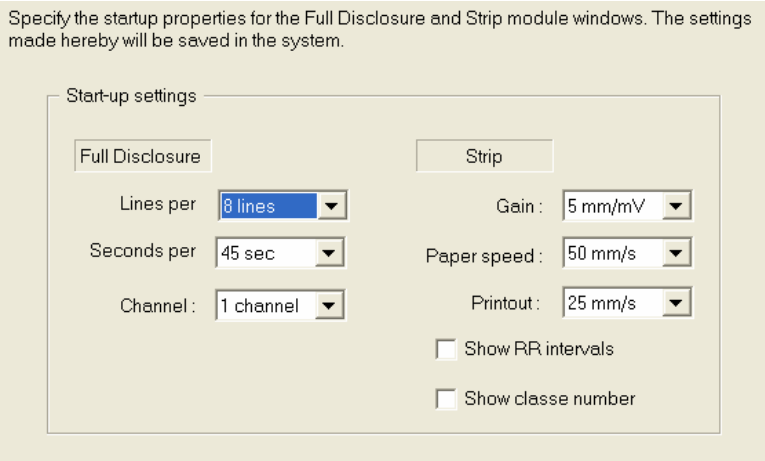



**Figure 84. Start value settings for Strip and Full Disclosure**

## 8.3.3 Standards of Polish Cardiac Society

In order to meet Polish Cardiac Society requirements a Holter test must be correctly recorded covering morning hours and a number of artifacts cannot exceed 5% of the examination time.

After loading the examination and performing the first automatic analysis, control procedure for Polish Cardiac Standards is activated. If requirements are not met, a user gets informed and has to repeat the examination. The examination may be continued without any limitations. Control warning is only information for the user.

Control procedure may be deactivated:

- Move the mouse cursor to <**Enable the PCS Standard Recommendations checking**> button,
- Press the left mouse button. A tick will disappear and the function will be deactivated.

Should control procedure check whether the test covers full 24h, the definition of morning hours is deactivated.

If the examination does not have to cover full 24 hours, you can define morning hours. Remember that you write in the following order: **hour:minute:second** in digits. In case of error, relevant information will appear. Accept with <**OK**>.

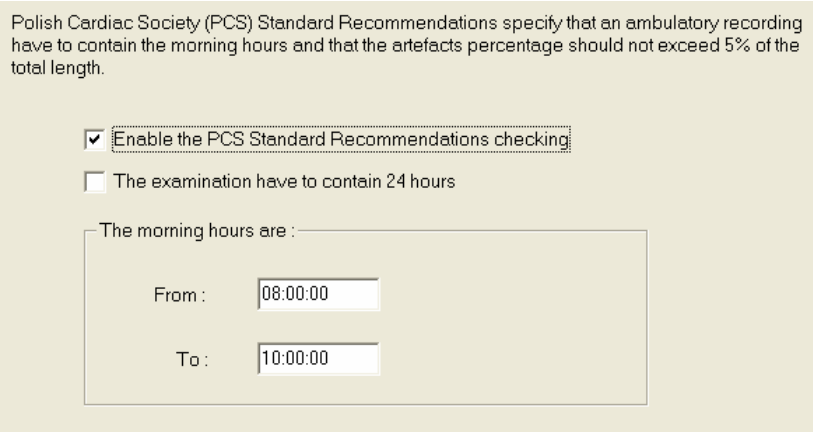



**Figure 85. Polish Cardiac Society Standards window**

## 8.3.4 QRS colours

HolCARD 24W © Aspel system enables defining colours of various program elements. The most important is possibility of defining own colours for particular QRS morphologies, Full disclosure's and Strip's background colour window, Strip net. You can adjust colours to your own preferencies. Additionally, you can define colours in which HR, RR values will be displayed as well as description of numbers or channels's names.

<**Standard**> button allows to load preset colours sets: City by night and Yellow Desert. After choosing this button a menu will be displayed enabling to choose required set of colours for loading. The colours range will be automatically presented in the window's view.

To change the colour choose the button with right description situated on the left side of the window. Description which is displayed after indicating it with the cursor may be also helpful. It gives information about colour in which element will be changed. After choosing the button, a window allowing to choose proper colour appears. The introduced colours changes are visble at once on window's view.

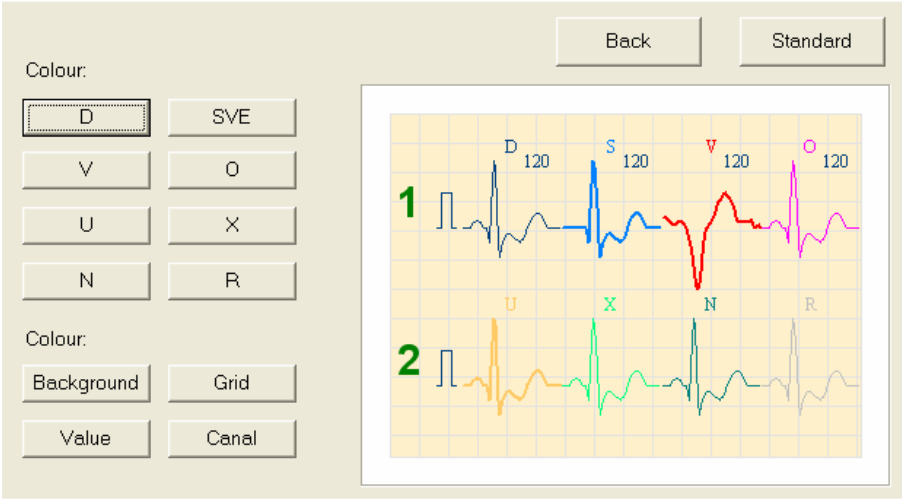



**Figure 86. QRS Colours setting**

Remember to confirm introduced changes with <**Save**> button. If you want the changes to be temporary just choose <**OK**> button. <**Back**> button cancels the introduced changes up to the last colour change.

## 8.3.5 Prospective analysis

<**Prospective**> allows to set initial parameters of analysis's results presentation in the Prospective analysis module's window. Parameters are set in <**User preferences**>. These are the same parameters which reflect to retrospective analysis.

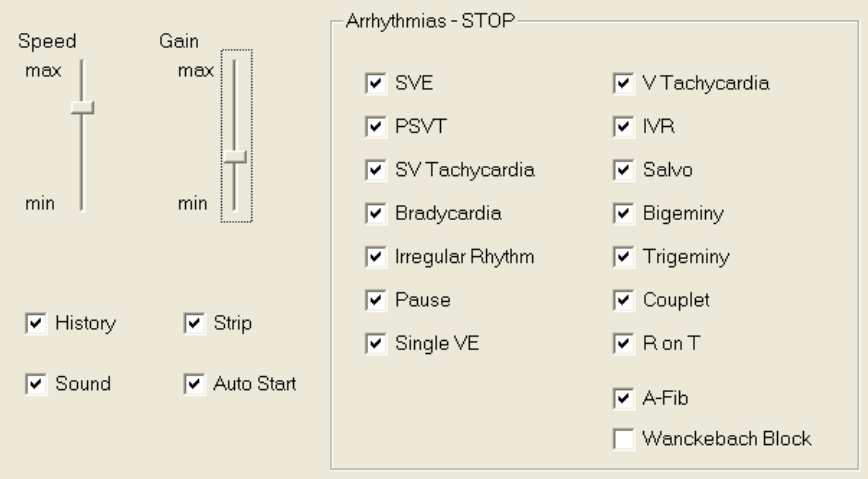



**Figure 87. Prospective Analysis module setting**

<**Speed**> - slide valve allows to set the speed of Analysis course (the speed of following QRS processing). Min position is the analysis of one QRS per second. Max position depends on the computer's processor capacity.

<**Gain**> - slide valve is to smooth regulation of gain presented during signal analysis. 1 mV changes in direct proportion with the gain increase.

<**History**> - switching on/off the background projection of 10 QRS preceding currently analyzed QRS. It is recommended to switch this option on because QRS are displayed on the screen for longer time what prevents from overlooking the improper QRS.

<**Strip**> - switching on/off the permanent renewal of Strip's view. Switching this option off means that Strip is renewed only during the suspension of Prospective analysis. It takes place, for example, during question about morphology occurrence, arrhythmia signaling and stopping the analysis by the user. Switching this option off accelerates the analysis course.

<**Sound**> - switching on/off the sound signaling of situations when the user's reaction is necessary for morphology evaluating or restarting the analysis after arrhythmia detection.

<**Auto Start**> - switching on/off the automatic analysis restart after evaluating morphology by user. In case of switching this parameter off after morphology evaluation the analysis is still stopped and may be continued after pressing <**Start**> button.

The group of settings <**Arrhythmias – STOP**> allows to qualify which arrhythmia type is to be currently signaled by module to the operator. In that case analysis is stopped and the proper information is displayed. If the system detects already marked arrhythmia it is stated in the final analysis results but it is not signaled to operator during Prospective analysis.

## 8.3.6 Other settings

Other settings are a set of several minor, not interconnected settings in the program operations. Each of them is switched on/off in the same way. Click a given inscription with the left mouse button. If the tick inside a square disappears, it means that this option is switched off. If the square is ticked it means that the option is on.

Confirm changes of the settings with <**OK**> button.

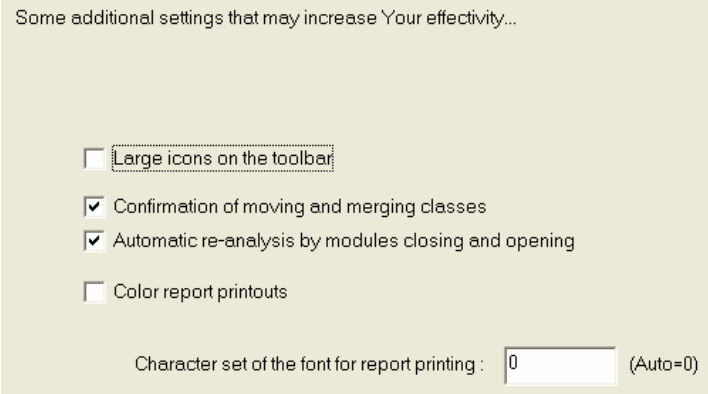



**Figure 88. Other settings window**

## Big icons on toolbar

The upper toolbar consists of icons which accelerate starting of an available operation of Holter system. Standard size of icons is 16x16 points. Icons may be enlarged to the size of 32x28.

Activate <**Large icons on the toolbar**> option, confirm changes with <**OK**> button and restart HolCARD 24W © Aspel program. You must restart the program to have large icons, activation of the option only is not sufficient.

A larger toolbar reduces operational area of the program where subsequent modules are displayed to illustrate the test and analysis results. That is why this option is recommended only for 17” and 20” monitors with resolution at least 1024x768 pixels.

## Confirmation of moving and merging classes

Templates module has an option to join classes of the same morphologies or transfer to other classes. During this operation, the program always asks if the user is sure that he/she wants this operation. This protects inexperienced users from accidental actions.

Such questions make working longer because answering takes time, so move the mouse cursor to a new place, press the left button and return to the previous position, very often to QRS on the strip. You may deactivate this option. The program will ask questions any longer.

This option is recommended to experienced users of HolCARD 24W system.

## Automatic reanalysis

After changes in results of Holter automatic analysis, reclassification of QRSs or adjustment of measurement points program informs about necessary reanalysis. The information is displayed at the top of a window on the title bar.

Normally if such information is displayed, reanalysis is started automatically. It ensures correctness of information displayed in modules. For instance, if two neighboring QRSs are deemed ventricular they will be reclassified as artifacts, the reanalysis is necessary to determine a number of ventricular QRSs, artifacts, pairs, maximal, minimal HR, etc.

You may deactivate this option. In such situation, reanalysis will not be automatic. At every beginning of a new module, the program will ask if you want to activate reanalysis. However, you must be aware of consequences of reanalysis deactivation.

This option is useful if your PC has low processor capacity. In such situation it is better to start reanalysis manually from the toolbar.

**Color report printouts from Holter examination.**

After switching this option on HolCARD 24W system will print the reports out using colours:

- Full disclosure printout (coloured QRSs of diferent morphology)
- HR and Trends diagrams
- QT, HRV, PMK diagrams

# 8.4 Analysis parameters

Holter analysis module is an advanced program utilizing modern knowledge on analysing ECG signals. This module is responsible for correct diagnosis, identification of beats, detection of arrhythmia, controlling ST level.

This module has a wide range of parameters for configuration analysis operations by a user of HolCARD 24W © Aspel system. Basic parameters depending on a specific examination are located in Initial Settings – selected channels for analysis, ST measurement points. Other parameters depending on a user needs, are grouped in <**Settings**> menu <**Analysis Parameters**> field – ST episode definition, parameters of arrhythmia.

Parameters analysis dialogue box have <**OK**> and <**Save**> buttons. If you confirm the setting with <**OK**> it will be available only until a new examination is loaded. Each subsequent examination will have global settings. If you select <**Save**> button, new parameters will be saved and applied to all examination loaded from that moment (including currently loaded examination).

## 8.4.1 ST episodes

HolCARD 24W © Aspel system differentiates four (4) basic types of ST episodes. Two first types detect ST elevation, the next two detect ST depression. Each type is defined by qualification of ST level value (ST threshold) and by showing direction of ST section slope.

Definition of ST episode contains also determination of minimal time of duration of ST level, data about the slope and minimal distance between subsequent recorded episodes.

If QRSs have ST depressed below 1 mm for time shorter than 60 seconds, it will be not registered as ST episode. Also when the next episode starts after more than 60 seconds it will be not recorded by the system.

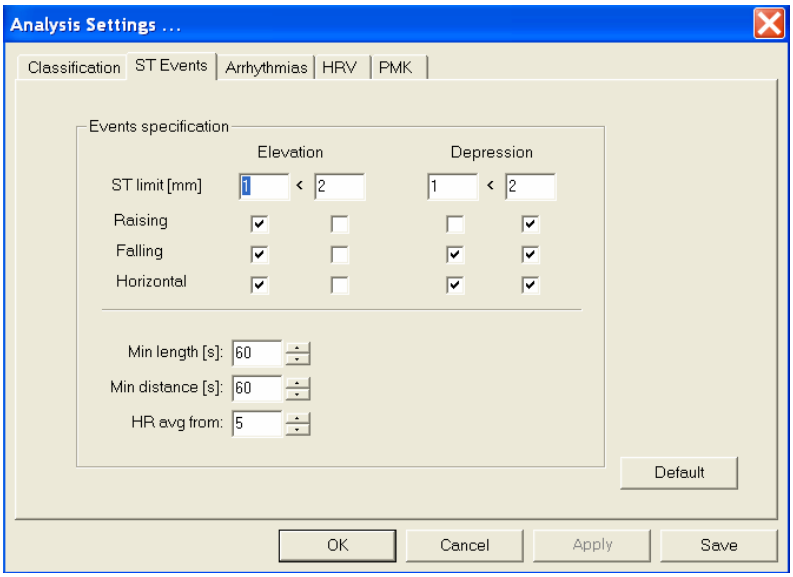



**Figure 89. ST episode parameters setting window**

HR value at the beginning, in the middle and at the end of the episode is displayed on a list of detected ST episodes in Tabular List module. It is possible to define how many QRS are needed for averaging HR values.

## 8.4.2 Arrhythmias

<**Arrhythmias**> allows to definite of detected arrhythmia presented in Tabular list module. It has four categories of parameters. Such division into four categories facilitate the work. Selection of a required category displays a new list of parameters possible for modification.

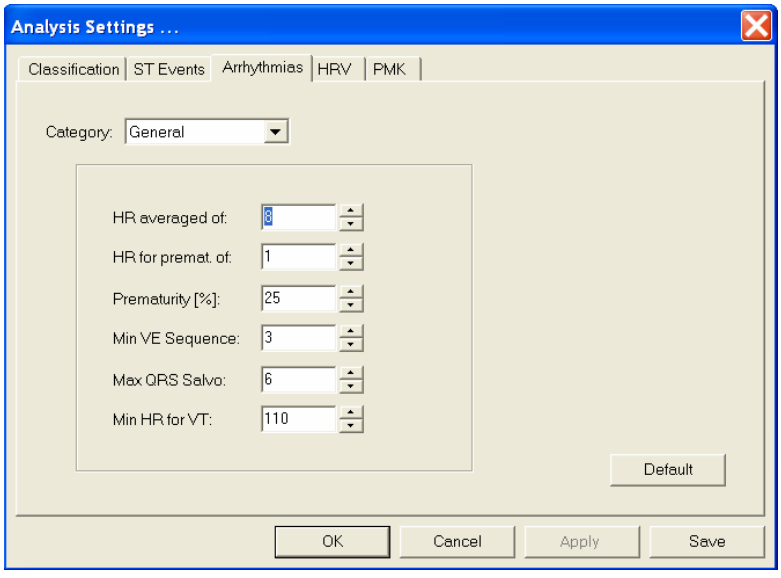
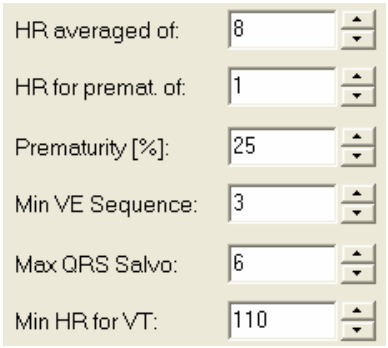


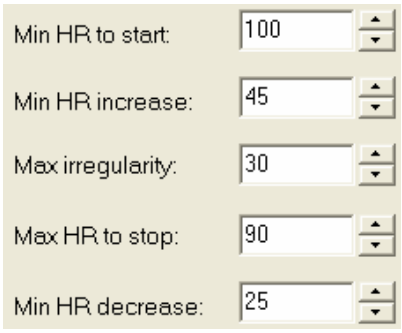

**Figure 90. Arrhythmia parameters setting window**

General Category:



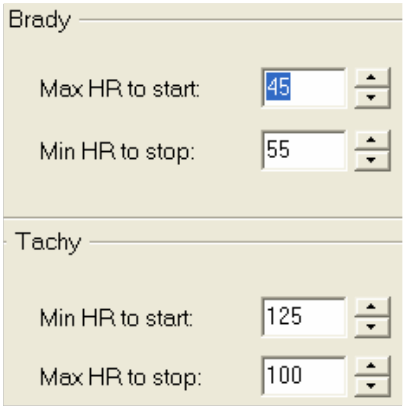

| |
|---|
| **HR averaged of:** HR value of a given QRS is averaging on the basis of previous 8 RR intervals between QRSs |
| **HR for premat of**: HR value for premature supraventricular QRSs is averaging on the basis of 1 QRS. |
| **Prematurity [%]:** Supraventricular QRS is premature when its HR was shorted by 25% in relation to previous HR. |
| **Min VE Sequence :** Minimal number of ventriular QRSs diagnosed as arrhythmia. |
| **Max #QRS Salvo:** maximal number id ventricular WRS diagnosed as Salvo (a number of cluser beats) beats. |
| **Min HR for VT:** Min. HR value recognized as VT and Salvo. |

PSVT Category:




| |
|---|
| **Min HR to start:** Mini HR value a the beginning of PSVT |
| **Min HR increase:** Min. Hr growth [%] a the beginning of PSVT |
| **Max irregularity:** Max. HR irregularity [%] during PSVT |
| **Max HR to stop:** Max HR value at the end of PSVT |
| **Min HR decrease:** Min. drop of HR [%] at the end of PSVT |

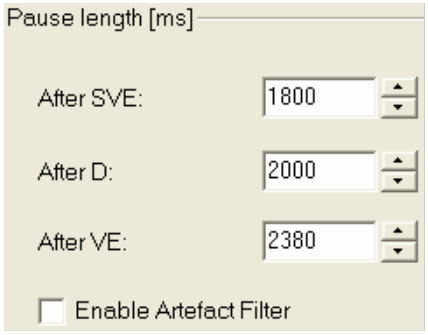
Brady/Tachy Category:




| |
|---|
| **Max HR to start:** Max HR value at the beginning of bradycardia |
| **Min HR to stop:** Min. HR value at the end of bradycardia |

| |
|---|
| **Min HR to start:** Min. HR value at the beginning of tachycardia |
| **Max HR to stop:** Max HR value at the end of tachycardia |

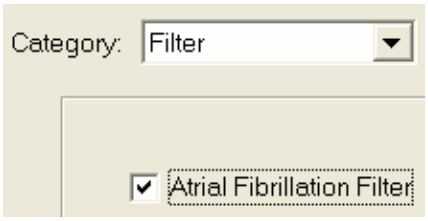
Pause Category:




| |
|---|
| **Pause after SVE:** Min. RR interval in [ms] after SVE recognized as a pause |
| **Pause after D:** Min RR interval in [ms] after D recognized as a pause |
| **Pause after VE**: Min RR interval in[ms] after VE recognized as a pause. |

| |
|---|
| **Artifact filter: Activated filter allows occurrence of artifacts during a pause** |

Filters:




In this option atrial fibrillation filters may be switched on/off.
This filter facilitates analysis of records from atrial fibrillation.

## 8.4.3 HRV analysis

Set parameters:

| | |
|---|---|
| Interpolation type:<br>• linear<br>• cubicle | Filter window:<br>• Hamming's<br>• Hann's<br>• Triangular<br>• Blackman's<br>• Harris's |
| Filter length | Width of ULF,VLF,LF,HF bands |

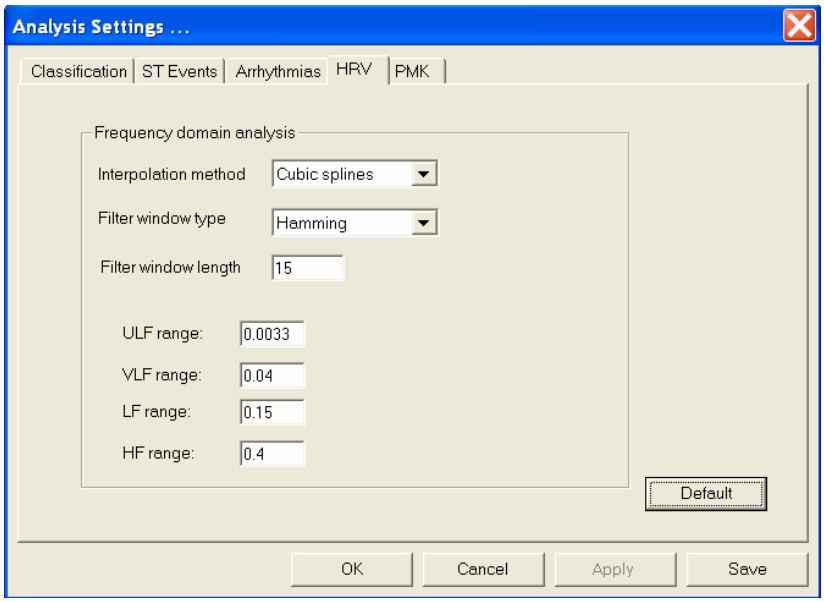



**Figure 91. Analysis Settings – HRV**

## 8.4.4 Pacemaker analysis

In order to identify QRSs correctly, Pacemaker module must have some additional information of operation of used cardiac stimulator. These parameters should be set in the window below available form <**Settings**> menu – <**Analysis parameters**>, <**PMK**>.

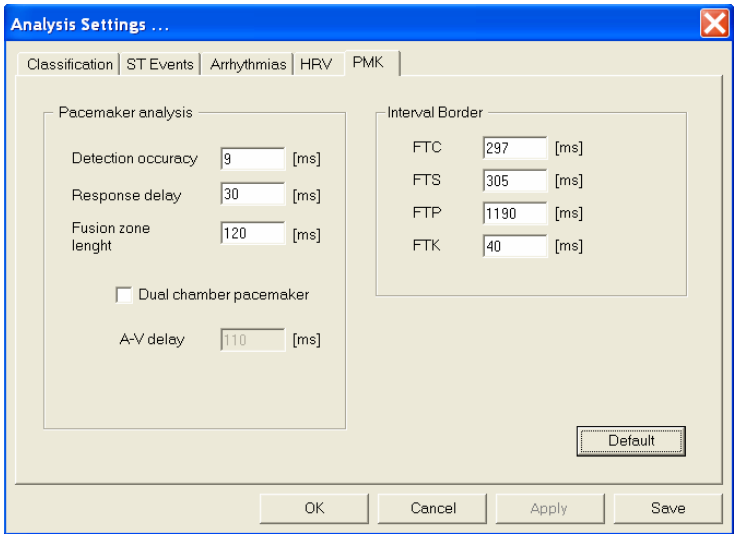
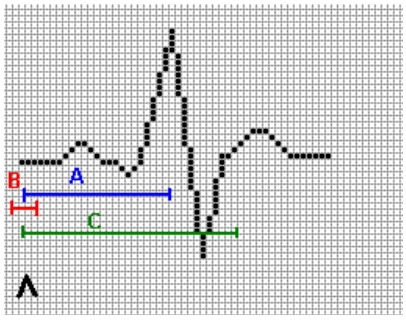



**Figure 92. Analysis Settings – PMK**

| Parameter | Meaning |
|---|---|
| Detection accuracy | Detection accuracy is defined by the width of time interval before QRS where pacemaker Impulse is interpreted as a reason of systole. The value is expressed in milliseconds, typically 9 and takes into account accuracy of readout of spike position and accuracy of locating maximal QRS. |
| Response delay | Response delay is defined with time interval before QRS where pacemaker impulse is interpreted as the reason for the systole. Time is measured from the spike to the top of QRS. The value is expressed in milliseconds, typically 78. |
| Fusion zone length | Fusion zone length is a definition of time interval where occurrence of pacemaker impulse is interpreted as summation beat. This interval starts after a segment determined with response delay and is longer than feedback time also beyond QRS peak. The value is expressed in milliseconds, typically 120. |
| Dual chamber pacemaker | Dual chamber pacemaker activates correct interpretation of pair of spikes of a dual chamber pacemaker. In such a case, an earlier spike (atrial stimulation) is neglected, and the later is the basis for evaluation correctness of pacemaker operation. |
| A-V delay | A-V delay is time interval between stimulation of atria and ventricles by a dual chamber. Correct positioning of pacemaker based on documentation allows correct interpretation of bilocular pacemaker spike pair. The value is expressed in milliseconds, typically 110. |
| FTC | FTC – IR type time intervals, which when exceeded will be interpreted as Failure to Capture. The value is expressed in milliseconds, typically 297. |
| FTS | FTS – RI type time interval when not reached may be interpreted as Failure to Sense. The value is expressed in milliseconds, typically 305. |
| FTP | FTP – time intervals of RR, IR, RI and II types, when exceeded interpreted as failure to Pace. The value expressed in milliseconds, typically 1190. |
| FTK | FTK – IR and RI time intervals when not reached may be interpreted as occurrence of a competitive beat. The value expressed in milliseconds, typically 40. |




A – Response delay
B - Detection accuracy
C - Summation beat

To return to standard values press <**Default**> button. Confirm the modified parameters with <**OK**> button. The changes are memorized only for this test.

If you want to change parameters globally for all tests press <**Save**>. After change of parameters, in case the examination is loaded, perform Holter analysis. Information will be displayed on the title bar of HolCARD 24W system.

### 8.4.5 AsPEKT 903/703/712 Filtration

Examinations performed through the AsPEKT 903, AsPEKT 703 and AsPEKT 712 recorders may be subjected to filtration to eliminate unwanted disruptions while being loaded into the program. The user has 3 types of filters at his/her disposal one isoline filter which eliminates the flow of the course over time and two muscle filters which eliminate disruptions resulting from muscle tension. It is recommended that for AsPEKT 903, AsPEKT 703, AsPEKT 712 recorders the following filters be turned on - <**Baseline filter**> and <**Muscle filter 2**>. For severe disruptions, a stronger muscle filter <**Muscle filter 1**> can be turned on.

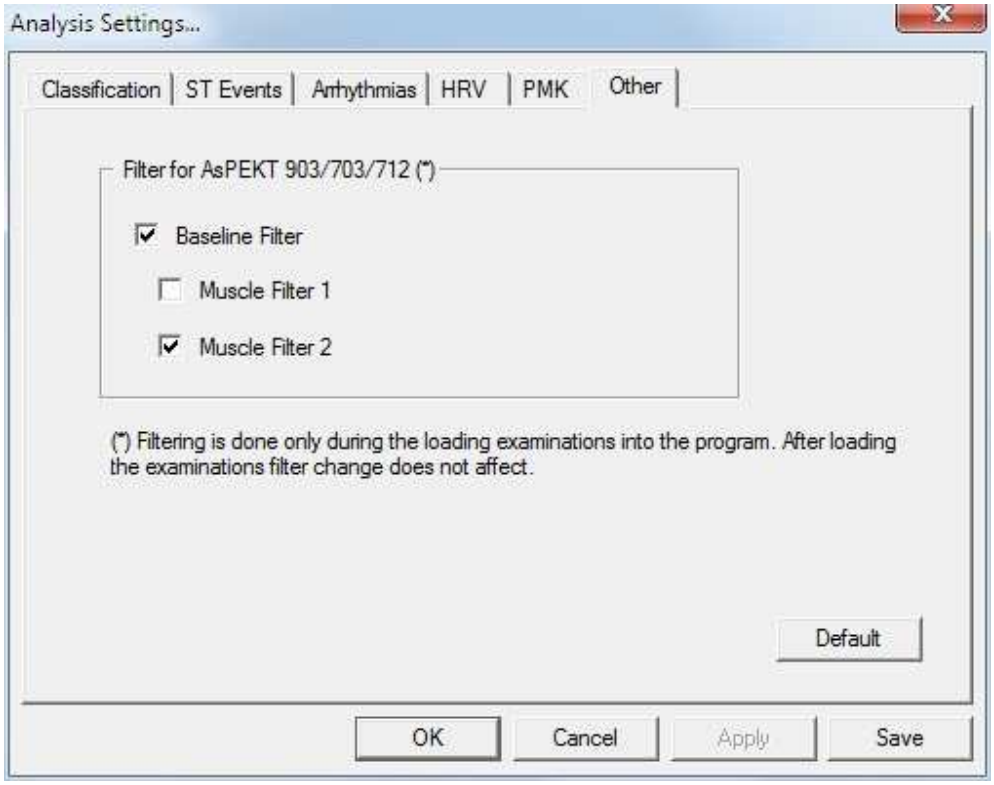



**Figure 93. Filtration of an examination being loaded for AsPEKT 903/703/712**

Keep in mind that the filtration of a signal occurs only while an examination is being loaded. If the examination is already in the HolCARD 24W program base, i.e., if it has already been loaded, changing the above filters will not impact the ECG signal of this examination.

# Chapter 9

# Monitor AsPEKT 700

## 9.1 General Info

Monitor AsPEKT 700 © Aspel (also referred to as Monitor IRDA) cooperates with AsPEKT recorders equipped with an IRDA transmitting LED. The main purpose of the program is to help connect the LEDs to the patient accurately. Such connection provides a high quality of record, which is crucial to the correctness of Holter analysis.

All information from the recorder is transmitted via an infrared transmitter. The rear part of the recorder contains a transmitting LED, to which the receiver is applied. The receiver is connected to a computer via standard COM port – serial connection.

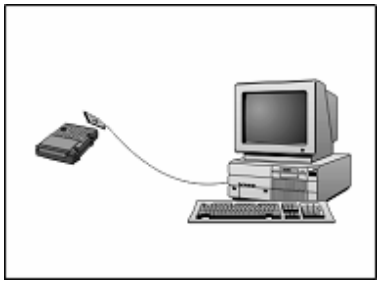


**Figure 94. Connection of the data receiver in an AsPEKT 700 recorder**

**Starting program**

Monitor AsPEKT 700 © Aspel can be started in the HolCARD 24W toolbar.

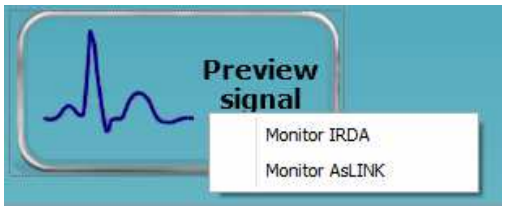



**Figure 95. Toolbar in HolCARD 24W**

Clicking the <**View signal**> button in HolCARD 24W (see Figure 95) expands a menu that allows choosing a Monitor – select <**Monitor IRDA**>

## 9.2 Program operation

The screen in Monitor AsPEKT 700 is divided into three separate parts. Each of them displays a different ECG channel – the first one shows channel no. 1, the second shows no. 2, and the third one shows no. 3. In the absence of data for display, a dashed red line is shown, e.g. after removing the receiver from the transmitting LED. Every channel also has its own millimeter grid, which allows assessing the size of the signal from electrodes, i.e. the QRS amplitude.

The ECG signal is always displayed at a fixed speed of 50 mm/s. Amplification depends on recorder settings. In the ECG data transmission mode, the patient event button takes over the control of amplification. The amplification changes each time you press the button. Along with the changing amplification, the height of the 1mV peak changes as well.

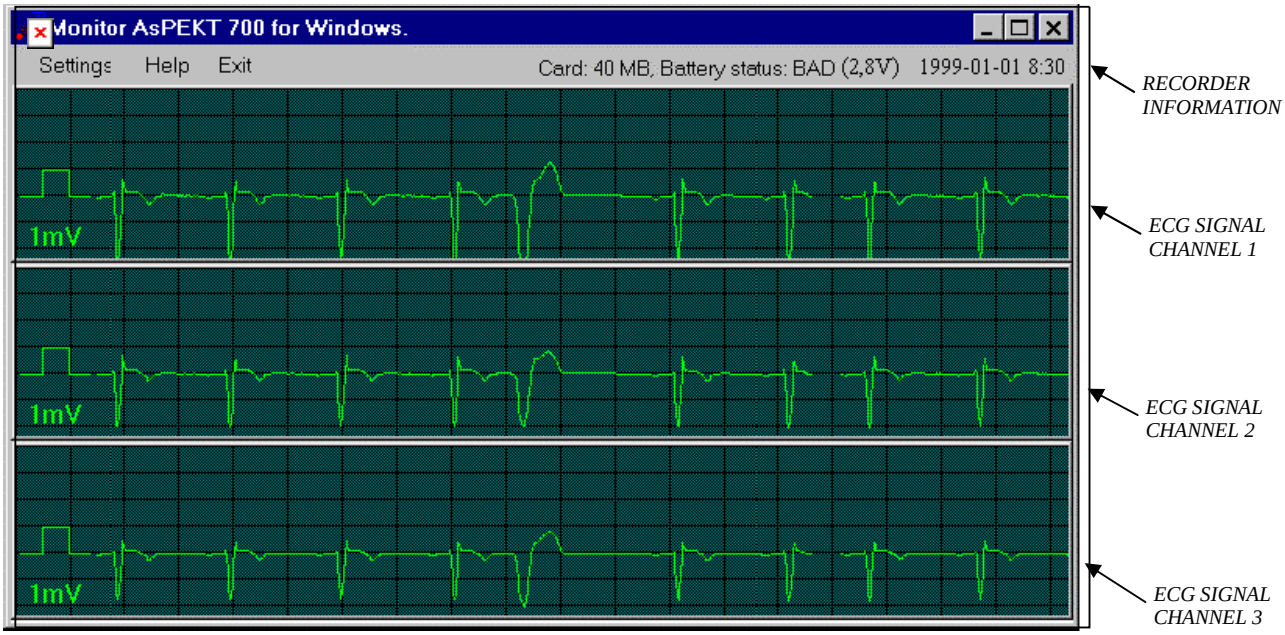



**Figure 96. Monitor AsPEKT 700 © Aspel window**

The <**Recorder information field**>, which is located in the upper part of the window at the level of the program menu, displays information on the technical conditions of AsPEKT 700 operation:

- Memory card size – in order to record 24 hours of ECG testing, the system requires a memory card of 40 MB. You can use smaller cards, e.g. 20 MB, to record shorter periods – 12 hours.
- Current battery status – displays information on whether the batteries are GOOD, i.e. whether they will suffice for the full length of the test, of BAD, partially depleted. Continuing recorder work with bad batteries will result in early termination of the record.
- Current hour on the recorder – the AsPEKT 700 recorder has a "built in watch", which is used to store the time and date of the start and of every time the patient event button is pressed.

Before starting the recording, it is worthwhile checking the parameters described above. Particular attention should be paid to the current battery status, whether the batteries are good, and the current time set in the recorder, which guarantees the correctness of storing the hour of the beginning of the test. This information is read by HolCARD 24W © Aspel, and therefore does not require manual input.

During the program operation, the screen may display various dialog boxes that will provide information on the current status of the recorder's work, e.g.:

1. No PCMCIA card in AsPEKT recorder.
2. Assessing correct installation of the recording set and preparing patient for test.
3. Electrodes improperly connected to patient.

The message saying **No PCMCIA card in AsPEKT recorder** will appear if there is no properly inserted memory card in the recorder. It often happens that the card has been inserted in the recorder socket, but has not been tightened properly. After applying an infrared receiver, the screen will display this exact message. The recorder indicates correct insertion by generating two short sound signals (see Table B-1 Indication of recorder work, Appendix B).

The message saying **Assessing correct installation of the recording set and preparing patient for test** announces the launch of a control procedure for electrode connection resistance. The procedure takes around 30 seconds, then in the event of non-compliance (INOP, resistance higher than 50kΩ), detailed information is displayed specifying as to which electrodes are to be corrected. At the time of the control, the transmitting LED in the recorder blinks red.

The message: **Electrodes improperly connected to patient**, informs that pairs of electrodes have failed to meet the requirements of resistance control (>50kΩ). After adjusting the connection of electrodes to the patient's skin, the information in the window is automatically updated (dynamically). If all electrodes meet the criteria of the resistance control, the window will disappear, and the screen will show the ECG progress.

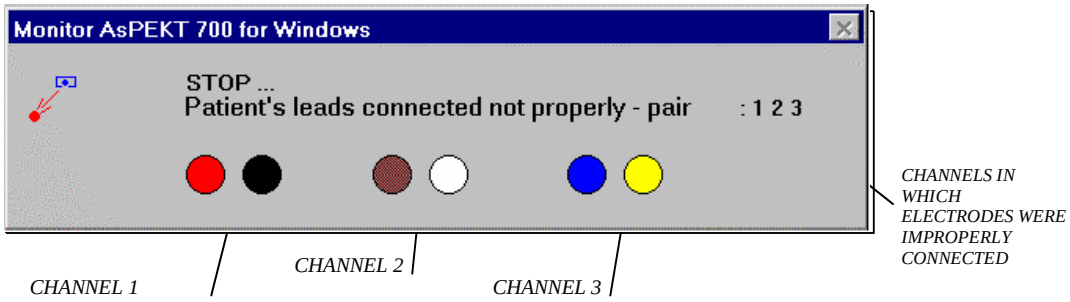



**Figure 97. Sample window signaling electrode connection control**

Note! At the time of these procedures, AsPEKT 700 does not display ECG signal. Only after a successful completion of resistance control in electrode connections.

To exit the program, select the box <**End**> from the menu.

## ECG signal amplification

Amplification of the ECG signal, which is set in AsPEKT 700 © Aspel determines the dynamics of the recorded signal. The correct setting of that amplification provides a very good quality of the ECG, which affects the efficiency of automatic analysis. This is the second factor (after the correct connection of electrodes to the patient – low resistance), which plays a crucial role in analysis, and that is affected by the person who puts on the Holter recorder.

**What is the dynamics of the ECG signal?**

Since computers are digital devices, the ECG signal provided for Holter analysis also has a digital form. It is sampled with a frequency of 256 Hz – i.e. the signal value (amplitude) is designated every 0,00390625 second and is stored in the form of a number between 0 and 255.

If the ECG signal is very weak (has a low amplitude), then only the values from the middle section – between 100 and 150 – are used; then we may say that the signal has low dynamics, because it changes within a small range of only 50 units.

If the amplitude of the same signal is doubled, prior to the recording, using a button in AsPEKT 700, then the amplitude will fit in a wider range, e.g.: from 80 to 180. The signal's dynamics has become higher, as it now has 100 units.

The figure below presents the same QRS, recorded on a memory card with different amplifications – different signal dynamics. With higher amplification, the highlight of various small yet medically significant details is clearly visible. Amplification of the basic signal in a Holter program after reading the card would not reveal these elements, since they would not appear in the digital record.

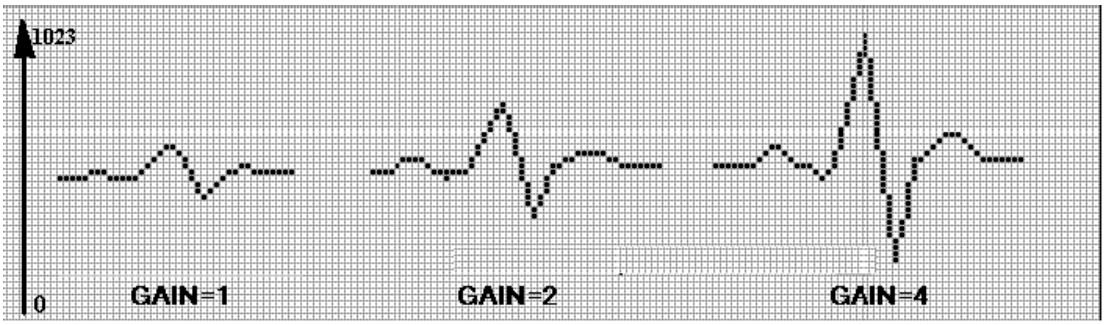



**Figure 98. The appearance of the QRS with various signal amplifications**

We can amplify this signal once more. We will then obtain the desired effect, since the amplitude will change in the entire range from 0 to 255. In practice, using Monitor AsPEKT 700 © Aspel, we choose such amplification with the patient event button, to make the signal span throughout its entire range, without exceeding it. This way, we obtain the maximum dynamics of the recorded ECG.

**What are the benefits of such setting compared to the original one?**

1. During analysis, it is easier to distinguish between the set that has the amplitude of 250 and the one that only has 50 amplitudes, especially if there are disturbances in the form of artifacts. Such disturbances often reach over 50 units.
2. We can more accurately determine the peak of the R-wave and calculate the RR interval, as it becomes steeper and less rounded. This is crucial to HRV analysis.
3. P-waves and T-waves are clearly recorded. We can see their shape and the direction of their slope. The case with bad amplification may be that they would "get lost", because their amplitudes would be very small – not much different from the isoelectric line.

## 9.3 Setting work parameters

**Setting the data receiver port**

An I-Red receiver is connected to a standard COM port in a computer. Computers usually have two such ports marked COM1 and COM2.

Using the <**Port COM**> field in the <**Settings**> menu, you can inform the program as to where the receiver has been connected. The screen will display a dialog box, which allows choosing the right port.

If you select the COM port, to which the receiver is not connected, or which is occupied by another device, then a warning will appear: "Driver Ekg I-Red not responding. Set the correct COM port number". Monitor AsPEKT

700 © Aspel remembers the port settings, so this option is usually used at the beginning of installation, or following the change in the receiver's location.

**Figure 99. Window that allows you to specify the COM port number for the receiver**

## Setting lead colors

When the signal has too high resistance in electrode connections, a dialogue box will display information as to which channel should be adjusted (e.g.: Channel 1 and 3) and the appropriate electrode colors are drawn.

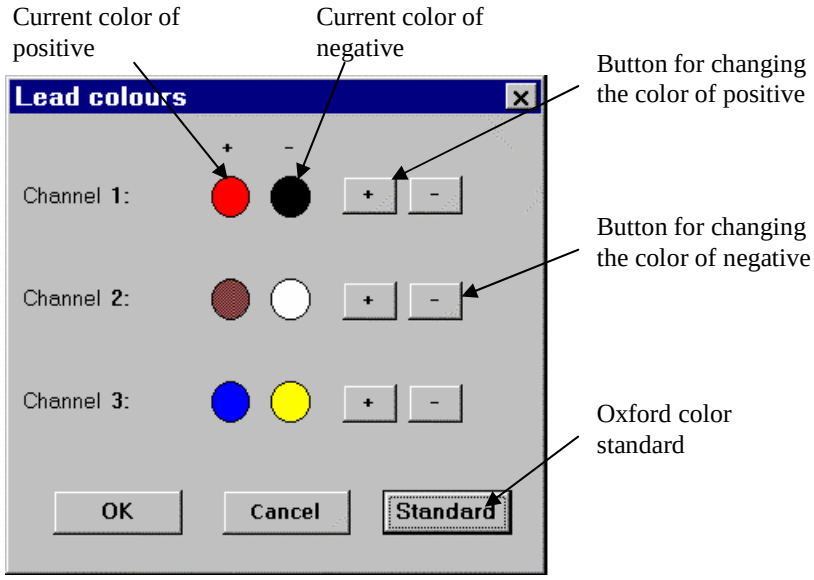



**Figure 100. Window for defining electrode colors in individual channels**

Using the Leads field in the Settings menu, you can inform the program as to which electrode colors are used for the first, second and third channel. These settings depend on the standards adopted by the user and may differ in various facilities.

To change the colors assigned to a specific pair of electrodes, proceed as follows:

- Select the button for changing the colors of positive and negative electrodes for the appropriate channel – move your mouse cursor to the button and left-click with your mouse.
- The screen will display a window with various colors – select the appropriate color and confirm by pressing <**OK**>.

- Repeat these operations for other electrodes.
- At the end, press <**OK**> to save your changes in the program.

Color definitions are stored by Monitor AsPEKT 700 © Aspel. The next run of the program no longer requires re-defining these settings.

# Chapter 10

# Monitor AsLINK

## 10.1 General Info

Monitor AsLINK © Aspel is used for viewing and archiving ECG signals recorded by AsPEKT 500, 522, 523, 703, 712 recorders made by Aspel. Archiving involves storing the records on a computer hard drive; these records can then be viewed and printed.

## 10.2 Starting program

Monitor AsLINK © Aspel can be started from the HolCARD 24W toolbar.

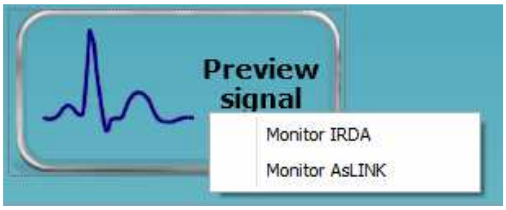



**Figure 101. Toolbar in HolCARD 24W**

Clicking the <**Preview signal**> button in HolCARD 24W (see Figure 101) will open a menu with a choice of Monitor – select <**Monitor AsLINK**>. This item is available after opening the window with patient data, because Monitor AsLINK is started for a selected patient from the database.

After starting, the screen will display a window containing the Main Menu, allowing performing all the functions provided in the system.

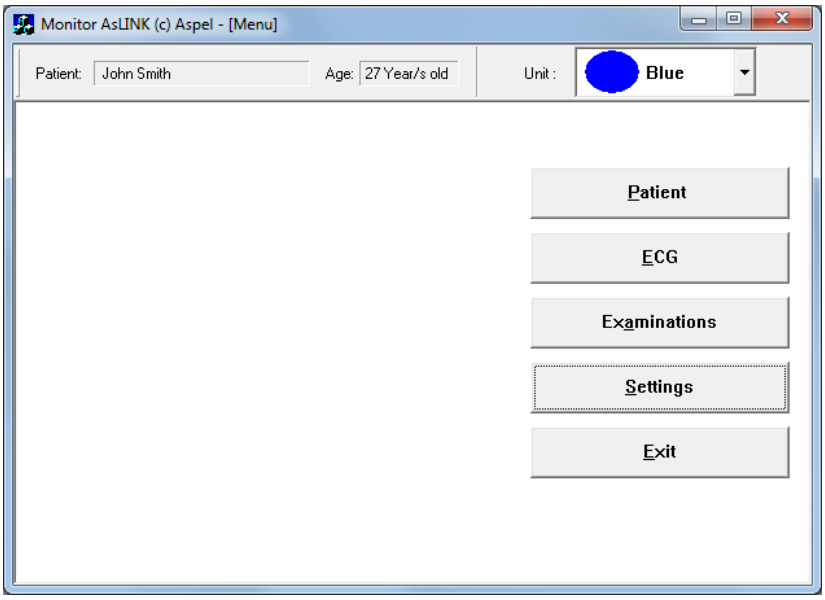



**Figure 102. Basic window in Monitor AsLINK**

The top bar of the window contains information on:

- Currently selected patient (i.e. their name, surname and age),
- A list of devices with which you can connect.

The meaning of items in the menu:

- **<Patient>** – allows viewing the data of the selected patient and their tests.
- **<ECG>** – view of ECG signal.
- **<Examinations>** – review and printing of a examination stored in Monitor AsLINK.
- **<Settings>** – allows choosing system work settings (preferences, equipment configuration).
- **<End>** – exit system.

# 10.3 Patient Data

The <**Patient**> button in the main menu allows displaying information on the selected patient as well as their list of tests performed with the use of this program.

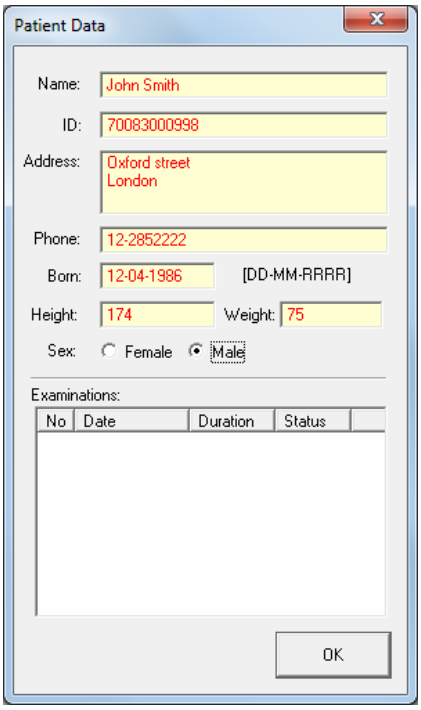



**Figure 103. Patient data window**

# 10.4 ECG signal view

The basic task of Monitor AsLINK © Aspel is to allow viewing ECG signals recorded by Aspel equipment, and storing these signals – saving on a computer. For this purpose, the ECG Viewer module is provided; it is started from the main menu with the <**ECG**> button.

Before pressing <**ECG**>, select the device you want to read the ECG signal with.

To select a device, with which you want to read the signal, use the <**List of Devices**>. This list is located in the upper part of the program window. It contains all the registered devices, which the program is able to communicate with.

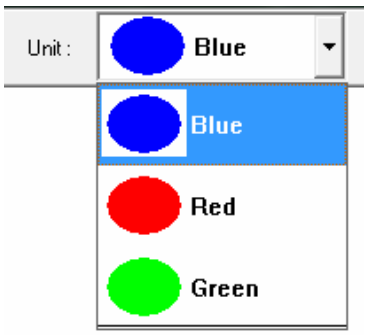



**Figure 104. List of Equipment (colors and names defined by user)**

After selecting a device, press the <**ECG**> button to view the signal transmitted to the program on your screen.

## Module Description

The window's title bar in the ECG Viewer module contains information on the currently selected patient. It is possible to change the patient after entering the module using the <**Help**> button, which is located in the upper right corner of the window. After a menu expands, select <**Patient**>.

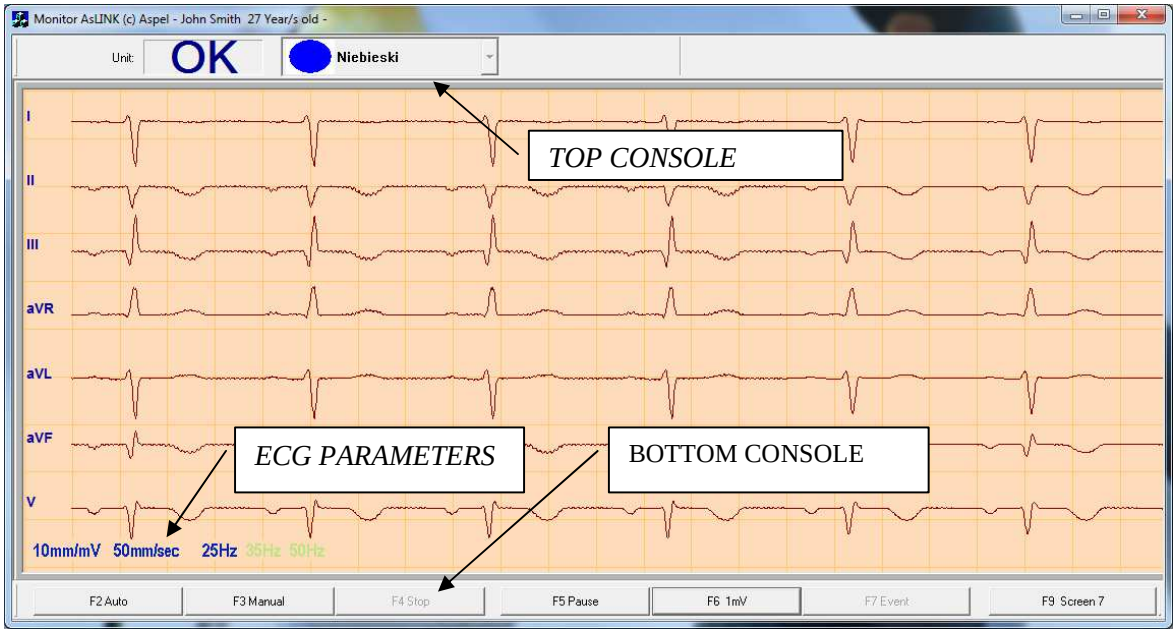
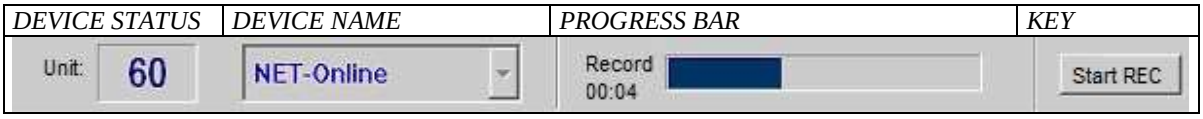



**Figure 105. ECG viewer module**

- Top console – information on the device you are using to read the ECG signal
- Bottom console – line containing buttons for controlling the module
- ECG parameters – line with information on the recording of an ECG signal
  - Signal amplification (2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV)
  - Shift (25 mm/s, 50 mm/s, 100 mm/s),
- ECG window – area of the screen where the ECG signal is drawn

## Top console description

In the upper part of the screen there is a console with a description of the currently connected device.



Information displayed in the device status field:

| STATUS | MEANING |
|---|---|
| OK | Patient is properly connected |
| INOP | Poor electrode contact with the patient |
| 60 | HR rhythm value determined by the connected device.<br>**Note**!!! Not all devices determine the HR value. |

The progress bar appears whenever the test is being saved, both in <**AUTO**> and <**MANUAL**> modes. It provides a graphic and numerical representation of the amount of data saved. In the <**MANUAL**> mode, the system allows you to save an ECG record of any length (only limited by hard drive capacity), and in the <**AUTO**> mode, 11 seconds (3 seconds preceding the moment of choosing a command and 8 seconds after choosing the command).

## Bottom console description

The user controls the course of the test using the buttons that are located in the bottom console. Each key is associated with function keys in a computer keyboard (description on buttons). Thus, the user can quickly run a specific function of the program during the test. The appearance of the bottom console has been presented below.

**Description of function keys:**

- <**F2 Auto**> - Starts the test in automatic mode (AUTO)
- <**F3 Manual**> - Starts the test in manual mode (MANUAL)
- <**F4 Stop**> - Finish recording
- <**F5 Pause**> - Stop the ECG waveform on the screen
- <**F6 1mV**> - 1 mV calibration pulse and adjustment of the isoelectric line
- <**F7 Event**> - Introduction of a marker in the recorded ECG
- <**F8 Print**> - Printing ECG signal
- <**F9 Screen X**> - Selecting the ECG display
- <**F10 Group X**> - Changing the lead group displayed on the screen
- <**F11 Leads**> - Selecting specific leads displayed on the screen
- <**End**> - Ends the test

## ECG window description

The main part of the screen is used for presenting the actual course of the patient's ECG. Taking into account the diagnostic requirements, the ECG signal can be drawn in several modes (3, 6, and 12 leads).

The figure below presents the various modes of drawing ECG, depending on user requirements. The display can be changed by pressing <**F9 Screen X**>. When the screen displays less than 12 leads, pressing <**F10 Group X**> allows changing a previously defined group of leads. The <**F11 Leads**> button allows selecting specific leads presented on the screen.

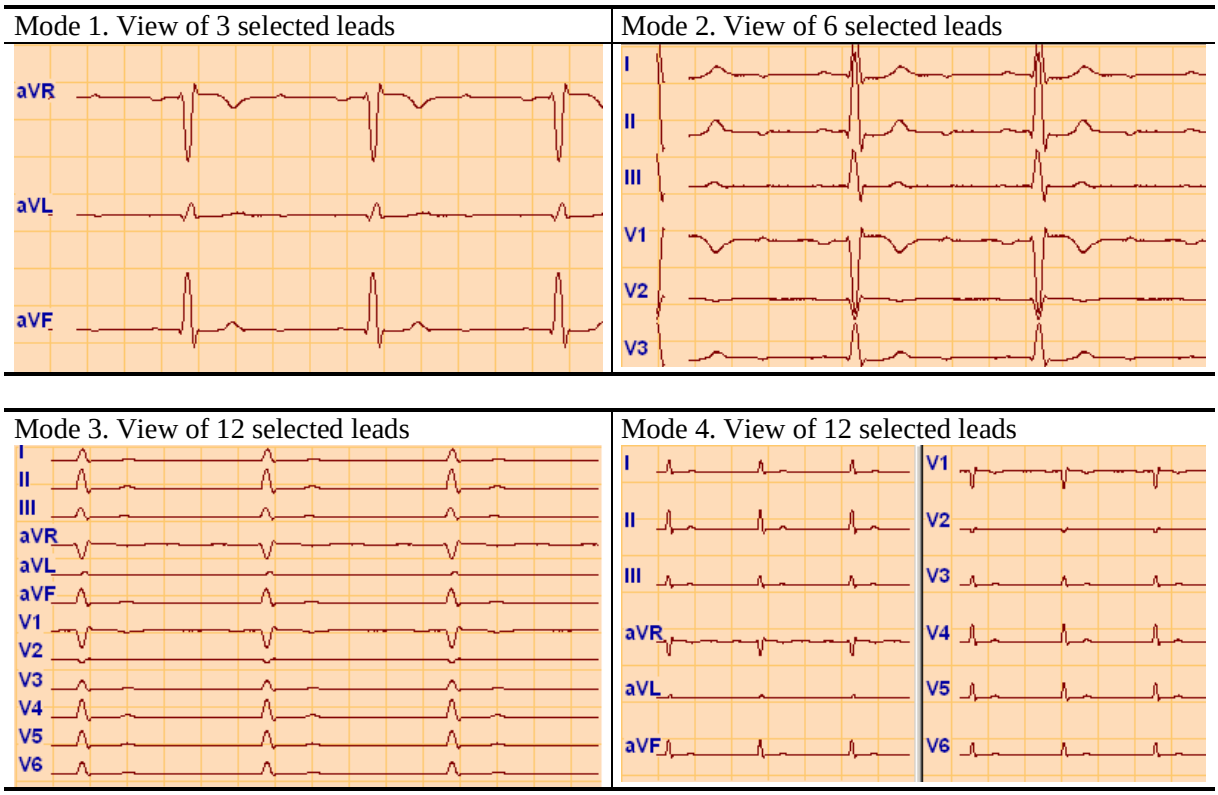



**Figure 106. ECG Viewer**

## Changing recording parameters

Changes in the speed and amplification are made by moving the mouse cursor and left-clicking on the text at the bottom of the screen. You can also use shortcut keys:

<**Speed**> - left and right arrows (or +/- on numeric keypad)
<**Amplification**> - up and down arrows

## ECG recording

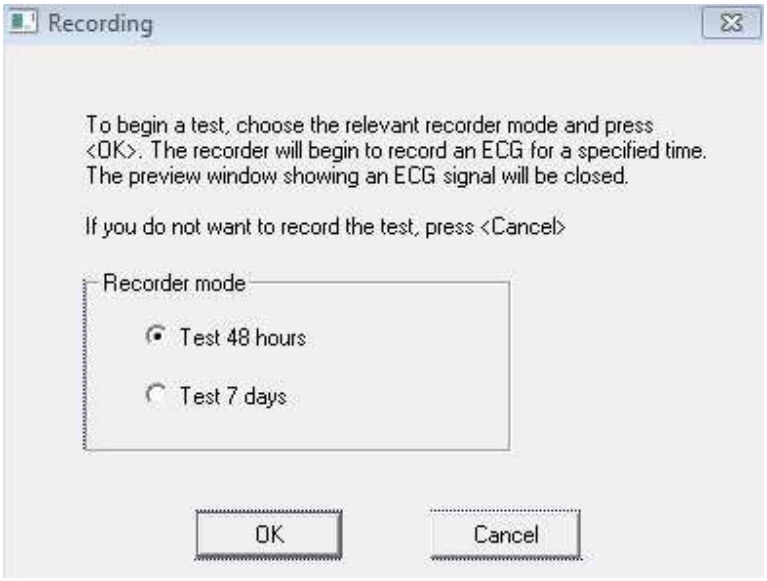
The ECG module starts by displaying the signal in a continuous manner. Recording the test for the database can be done in two modes: <**AUTO**> and <**MANUAL**>. All operations are performed using the bottom console (the so-called ECG console).

<**AUTO**> mode – saves 11 seconds of the signal (3 seconds before pressing + 8 seconds after pressing the <**AUTO**> button) and allows printing the test with a printer. By default, the print presents the leads that are visible in the screen, but these can be changed – in the window that will appear after 11 seconds have passed on the screen. This window allows choosing whether to save the test or to print it.

<**MANUAL**> mode – allows saving ECG signals of any length. The record can be stopped at any time by pressing <**F4 Stop**>. Automatic printing is not available after finishing the recording in this mode. To print the record, go to the Tests module.

**Start registration for AsPEKT 712**

If AsPEKT 712 recorder has been selected as the device from which the ECG signal is received, a window allowing you to select the recorder work mode will appear after pressing the <Start REC> button.




**Selecting the AsPEKT 712 recorder work mode**

If the recording is going to last up to 48 hours, you should select the <**Test 48 hours**> option; if the recording is going to last more than 48 hours, you should select the <**Test 7 days**> option. You should then confirm your selection by pressing the <**OK**> button to start recording the exam.

Data of the currently selected patient is sent to the recorder. The data is used later to identify the patient while the exam is being loaded. After this, the recorder switches to the exam saving mode and disconnects from the Monitor AsLINK program.

# 10.5 ECG test viewer

The recorded ECG test can be viewed in the Test Viewer module in two ways. The first way is to present a short section of the record, the so-called strip. The strip can present the selected 3, 6, or even all 12 leads at the same time. Using the control panel located in the bottom of the module, you can navigate the record forward, backward, to the beginning, or to the end. The second way involves presenting a large section of the record on a single page (2 minutes), but only allows viewing a single selected lead, the so-called page (full disclosure). The control panel allows you to change the lead to another.

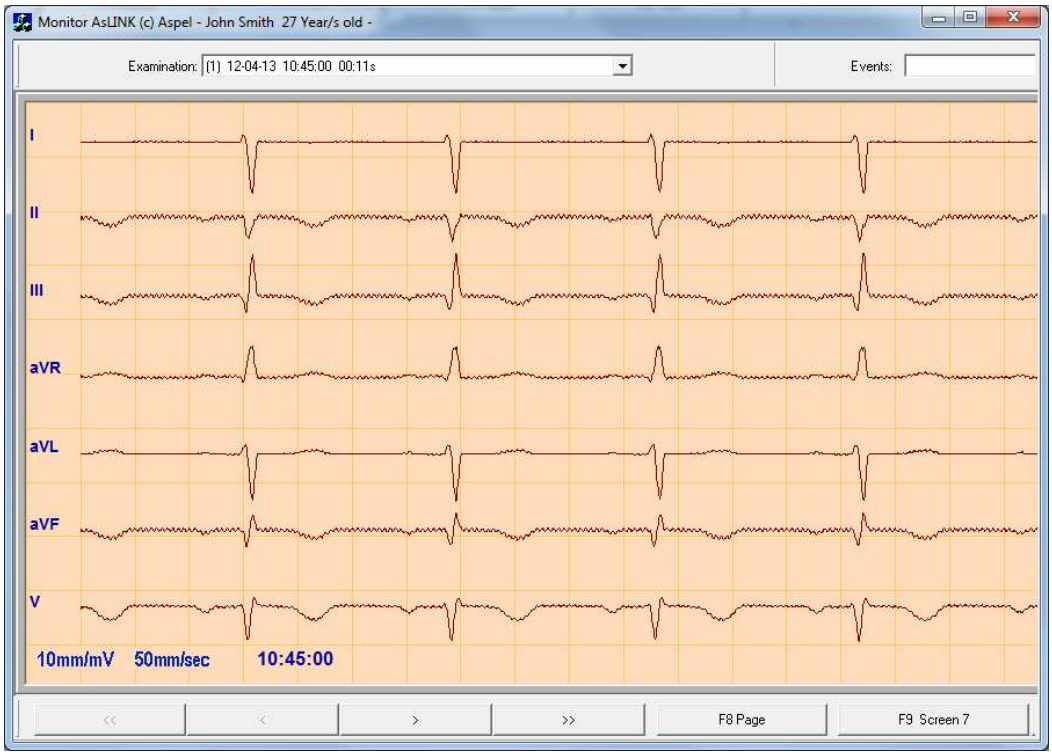
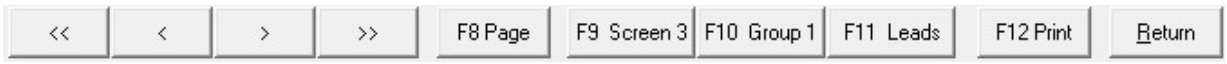



**Figure 107. Test viewer – strip mode**

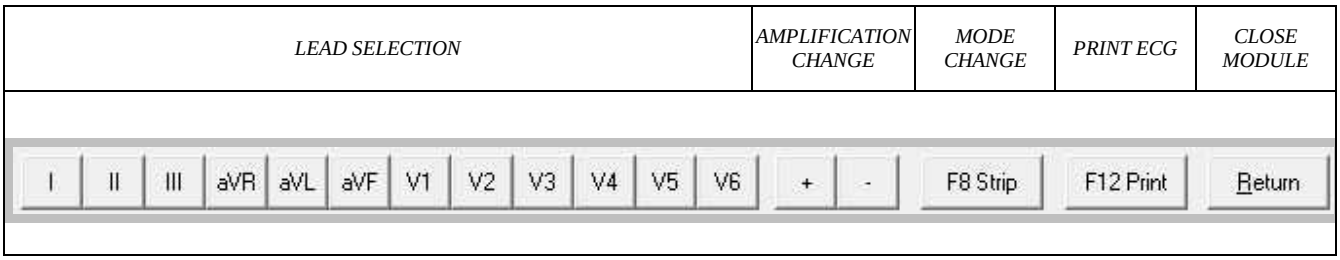
## Bottom console – strip mode

The bottom console allows viewing the recorded tests.




- **<<** - Move to the beginning of the test
- **<** - Previous strip
- **>** - Next strip
- **>>** - Move to the end of the test
- <**F8 Page**> - Change display
- <**F9 Screen xx**> - Select the number of displayed leads
- <**F10 Group x**> - Select a group of leads
- <**F11 Lead**> - Individual selection of leads
- <**F12 Print**> - Print ECG
- <**Report**> - Print report
- <**End**> - Exit viewer

## Bottom console - page




## Top console

The list of tests includes all tests of the selected patient. Each test has a subsequent number, date of recording and duration. The button allows you to remove the current test. The button allows viewing and editing the test description.

The list of events includes markers entered by the system operator. Events in the Strip mode are marked with the marker , and in Page with a navy blue dot.

To move to the next event, you can select it from the list, or press <**SPACE**>. Pressing the button again takes you to the next event. It is also possible to add a new event, remove an event selected in a list and edit information about that event.

## Amplitude-time measurements

The ECG Viewer module in the Strip mode allows performing manual amplitude-time measurements. Time measurements, e.g. of the interval between subsequent R peaks in QRS is presented in Figure 108

To perform a measurement:

- Place the mouse cursor at the beginning of the measurement location (point A)
- Press and hold <**Ctrl**> located on the computer keyboard
- Move the mouse cursor to the right, to the end of the measurement location (point B)
- Release (drop) the mouse button and the <**Ctrl**> button on the keyboard

After performing these operations, the screen will display a measurement arrow together with a numerical value. The measurement arrow can be extended, narrowed and moved to another location.

To change the position of one of the measuring points, move the mouse cursor over the arrowhead until the cursor changes its appearance. Then left-click your mouse and hold it while moving the cursor to another position. After establishing a new location, release (drop) the mouse button.

You can also move the entire measurement arrow to another location – e.g. to compare the RR interval with the interval between other sets. To do this, move your mouse cursor near the middle of the arrow (on the line of the measurement arrow) until the cursor changes its appearance. Then left-click and hold it while moving the cursor to another location. After establishing a new location, release (drop) the mouse button.

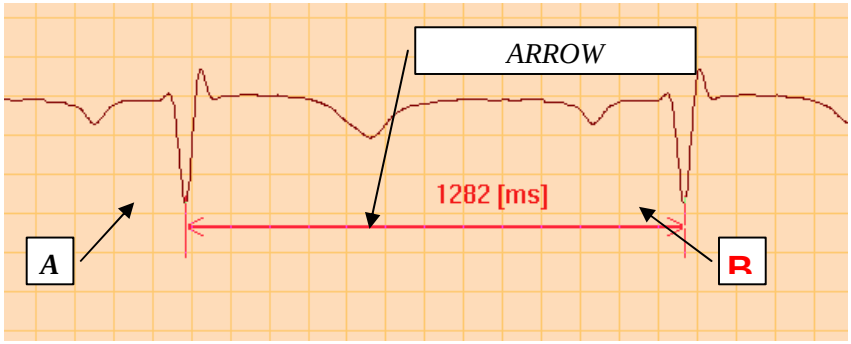



**Figure 108. RR interval measurement**

The signal amplitudes are measured similarly. To start measuring an amplitude, press the <**Shift**> button located on the computer keyboard and move your mouse cursor down the screen. The screen will display a vertical measurement arrow. This arrow can also be expanded, narrowed and moved – in the same way as a horizontal arrow.

**Shortcut keys in the "Test" module**

General keys:

| | |
|---|---|
| [-] (delete test) | DEL |
| [...] (about the test) | INSERT |
| [Patient] | Alt + 'P' |
| [Preferences] | Alt + 'R' |
| [ECG page/Strip] | ENTER |
| [Next event] | SPACE |
| [End] | 'Z' |

Strip Mode:

| | |
|---|---|
| [Beginning of test] | HOME |
| [End of test] | END |
| [Next page] | PgDn |
| [Previous page] | PgUp |
| [1 second left] | Left arrow |
| [1 second right] | Right arrow |
| [Speed] | Only gray +/- |
| [Amplification] | Up, down arrow |

ECG Page Mode:

| | |
|---|---|
| [Amplification+] | gray + |
| [Amplification -] | gray – |
| [Move frame] | Up/down, left/right arrows |
| [Lead] | Keys from '1' to '=' in sequence I, II, III, aVR, aVL, aVF, V1 ...V6 |

# 10.6 Printing

ECG signal is printed in the ECG Viewer module. If the module is in the Strip mode, the strip that is currently presented will be loaded. If the module is in the ECG Page mode, there are two ways to choose the fragment for printing.

## Choosing ECG fragment for printing in the Page mode

The first way is to set the position frame in the appropriate location in the record. The frame can be moved using arrow keys. You can also quickly set the frame by clicking it with your mouse cursor on the appropriate spot on the screen. After pressing <**Print**>, the fragment indicated by the frame will be printed.

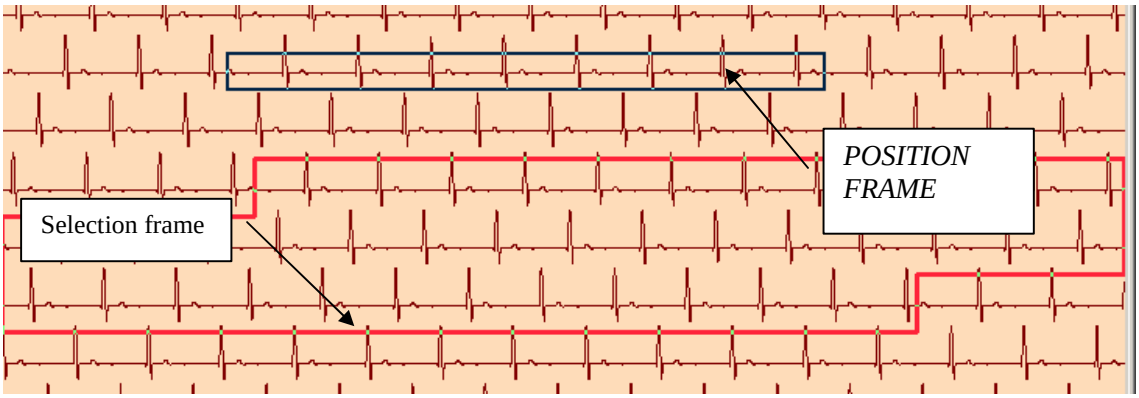



**Figure 109. ECG page, selecting the fragment for printing**

The second way involves selecting a larger area for printing with your right mouse button. After right-clicking with your mouse, the screen will display a small red selection frame, which can be expanded by moving the mouse downward (while still holding the left button). After releasing the mouse button, a larger area will be selected for printing.

## Print parameters

Selecting the <**Print**> button on the screen will open a dialog box that allows you to set the desired print parameters.

Subsequent tabs allow determining:

a) **<Basic>** – the beginning and the end of the print, printing format.

b) **<ECG strip>** – the type of the millimeter grid (full, simplified, or none), the speed of printing (25 mm/s, 50 mm/s 100 mm/s), format of patient data (full, simplified) and the comment (on, off).

c) **<Leads>** – the number of leads (3, 6, 12), type of leads (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6).

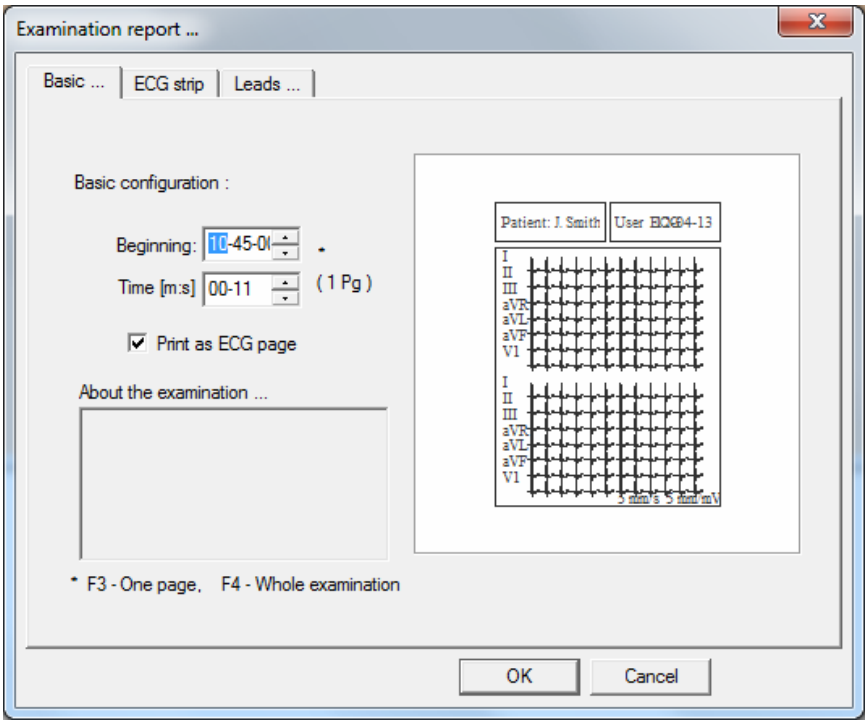



**Figure 110. Print parameter selection window**

All these changes result in changing the expected appearance of the print, which is presented on the right side of the window. This allows for accurate design of the generated report. If the default settings for printing are different than the ones applied by the user, they can be changed in System Preferences.

# 10.7 System Settings

Settings in Monitor AsLINK © Aspel consist of the following elements: settings related to devices that will be connected to the program <**AsPEKT**> and the work settings of the system itself <**Preferences**>.

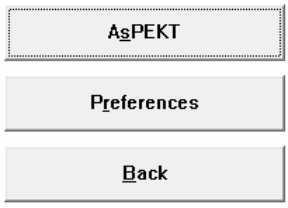



**Figure 111. Menu – Settings**

## Menu <AsPEKT>

AsPEKT recorders perform wireless communication with the computer using the AsLINK © Aspel protocol. On the part of the computer the connection is supported by the ASLINK 800 adapter. This adapter should be placed in a visible location, and should not be covered – in such conditions the recorder maintains correct connection in a distance of up to 10 meters in a straight line.

A dialog box that appears on the screen after selecting the <AsPEKT> button in the menu allows registering devices supported by the program.

**Note**! Every device that communicates with the computer must be registered in the list of devices supported by the system. During registration, enter the number of the device, which is specified on the back of the recorder, and give it a unique name that will be used when choosing a recorder.

**Note**! Every AsPEKT 703 and AsPEKT 712 recorder, before being registered, must be configured for MS Windows. Configuration process has been described in "Configuration of wireless communication of AsPEKT 703/712 recorder". This document is available on Aspel website (www.aspel.com.pl) in the section describing this recorder under the link „Files for downloading".

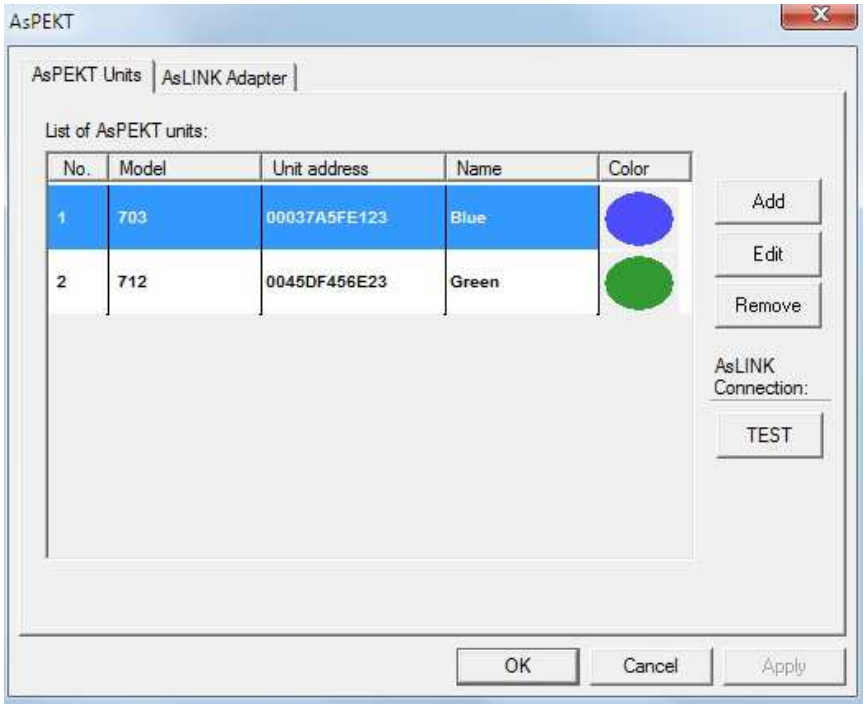



**Figure 112. AsPEKT window**

In order to register a device, please follow the following steps:

- Select the <**Add**> button in the window, and a new window will appear (Figure 113);
- From the drop-down menu, select the correct recorder model (model type is listed on the back panel of the recorder);
- Enter the address of the recorder (address is located on the back panel of the recorder - AN);
- Enter the name of the recorder;
- Select the colour for the recorder;
- Accept adding a new recorder by pressing the <**OK**> button, which will add the recorder to the list of AsPEKT devices that work in the system.

**Figure 113. Adding a new AsPEKT device window**

In order to distinguish which device the system will communicate with, we suggest using colour covers for the event button on the recorder. When adding a recorder, you need to select from the list of machines served by the system a colour which has not yet been used, and place the key cover of that colour on the button with the same colour. Additionally, each device may be given its own name and use it to describe the recorder.

The <**TEST**> button allows you to test the communication with the device. In order to do that, please select the desired device from the list and press the <**TEST**> button. The test result will be displayed in a window. If the connection test result is correct, the window will also display information about the software version of the recorder.

## AsLINK Adapter

In order to implement wireless communication with AsPEKT recorders, it is necessary to connect an AsLINK 800 adapter to the computer; its function is to receive data sent by these devices and passing them on to the program. A detailed description of installation can be found in the manual “Installing a USB AsLINK 800 adapter”.

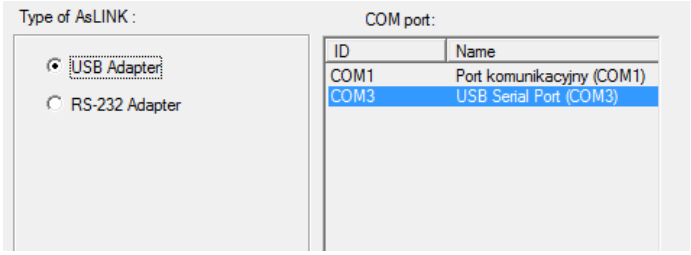



**Figure 114. Type of AsLINK 800 adapter**

The dialog box presented above is used to set the type of the adapter in use. Aspel provides two types of adapters. These are the USB adapter, which is recommended by Aspel, and the RS-232 adapter. When using an RS-232 adapter, set the number for the COM port, on which the adapter has been installed – see the installation manual for details.

## Menu <Preferences>

Preferences are a collection of settings related to the work of the program, which have been assigned a name by the user. By choosing such a set of settings, you can quickly change the conditions, under which the system operates, according to the user's expectations. The basic settings are:

- **<ECG>** – settings for the display of ECG (speed, amplification, filters, color).
- **<Report>** – ECG printout parameter settings.
- **<User>** – user data printed on the report
- **<Groups>** – editing ECG lead groups.

To launch the preferences module, press <**Settings**> in the main menu, and then the <**Preferences**> button. The screen will then display the main window of the module:

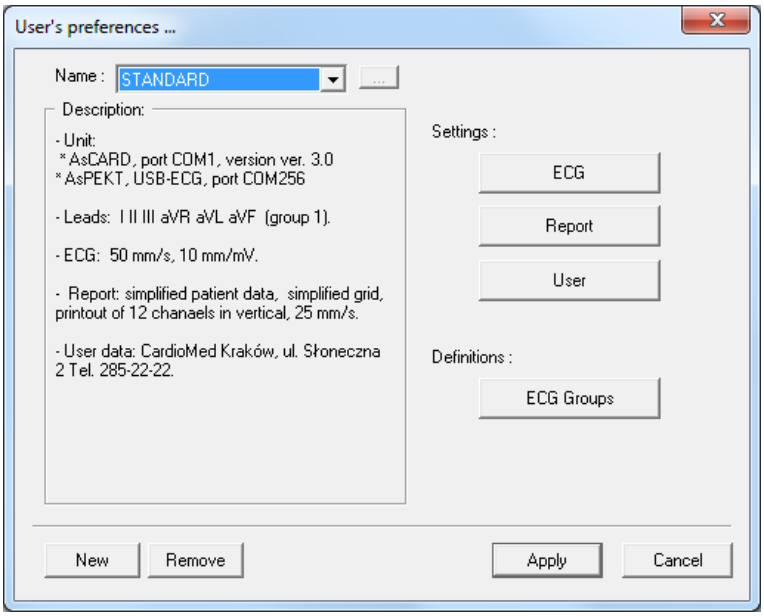



**Figure 115. Main window of the preferences module**

The system allows creating any number of such preferences, naming them and giving them short descriptions, as well as deleting the created preferences (only the <**STANDARD**> preferences cannot be removed). The user can quickly change their preferences, adjusting the system's operating conditions to their specific needs.

# Chapter 11

# Safety precautions

## Requirements for the user

HolCARD 24W program installs itself within MS Windows operation system environment. From the user it is required to know how to operate within MS Windows, since the proper use of the program depends on good command of MS Windows.

All the MS Windows system errors and the defects related to the improper system operating or destructive working of other programs will affect the HolCARD 24W program operating. Therefore it is not allowed to run other programs on the computer where Aspel software is installed. It is also recommended to carry out systematic antivirus control.

## Conditions of System operation

During the system installation, the requirements of the PN-EN 60601-1:2011 standards must be ensured with regard to electrical medical equipment, in particular – the computer on which the HolCARD 24W program is installed must be located more than 1.5 m outside the patient's area and it should operate under such conditions so as not to affect the proper operation of the entire system negatively. Detailed information may be obtained in the instructions for operating the computer and auxiliary equipment.

Possible sources of radiation and magnetic field which may disrupt operation must be noted. Places in which an entire system is located must be safeguarded against vibrations, dust, corrosive agents, agents which may cause explosions, major and sudden temperature changes, and excessive humidity.

For a Holter system to operate properly, it must have the proper air temperature in its environment. Exceeding the required temperature range may cause equipment damage. For this reason, the central computer and the monitor should be located in a space in which the free flow of air is ensured to enable the cooling of the entire system.

| | |
|---|---|
| Temperature: | 0-40 °C |
| Humidity: | <= 80% |
| Altitude: | -500 m to 4600 m |

## Warnings

**Earthing**. To protect personnel running the system, the computer have been equipped with a 3-wire power cable which should be connected to a 3-power socket ensuring grounding. If the installation site does not have the proper socket, the technical department must be contacted.

**Power**. Since temporary disruptions in power supply may occur in any power network, the use of UPS power outage equipment is recommended. This will guard against damage to the entire system and loss of data.

**Utilization**. Before system operation is begun, the following actions should be performed:

- Check to ensure that the equipment has no mechanical defects

- Check to ensure that the system is connected properly
- Check to ensure that the printer is connected
- Check to ensure that the acoustic system in the computer is operating properly

**Attention**! You may not begin operation if any sort of damage to the equipment has been detected. In such a situation you should contact the technical department. All inspection and servicing must be performed by qualified service personnel.

## Minimum hardware requirements

- Computer compatible with IBM (**EN 60950**),
- MS Windows XP/7/8 operating system,
- PENTIUM processor 1 600MHz,
- 256 MB RAM,
- Hard disk 40 GB,
- SVGA 17" colour monitor,
- HP LaserJet Printer.

Preferred printers:

- HP LaserJet 1010,
- HP LaserJet 1000,
- OKIPAGE 14ex.

Given requirements are minimal and are necessary to provide proper system working.

In computer's manual there are parameters relating to usefulness of respective computer subassemblies. After exceeding this time there is a possibility of errors occurring and computer's break-down which may affect the program's operating.

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CE 0197

# Operation Manual

Long-term ECG recorder

# AsPEKT 712

v.2xx, v.3xx

Zabierzów, 31.07.2020, Edition I

***We are pleased that you have chosen the AsPEKT 712 long-term ECG recorder, which is a result of years of surveys and experiences gathered through close contact with our customers. You have chosen quality, durability and high efficiency, as these are the features of AsPEKT 712 recorder.***

***ASPEL also offers a wide range of accessories for Holter recorders, electrocardiographs and their accessories such as: trolleys, carry bags, ECG cable and electrodes, and ECG paper, as well as non-invasive recorders of arterial blood pressure, spirometers, stress test systems, cardiac rehabilitation systems, EEG systems. For details visit our website: www.aspel.com.pl.***

***Please read this operation manual carefully, as it includes guidelines concerning safe installation, use and maintenance, as well as several practical instructions on how to optimize this recorder application.***

***Store this Operation Manual for reference.***

# Contents

**1. SAFETY INFORMATION ..... 4**

1.1. MANUFACTURER GUIDELINES ON SAFETY OF USE ..... 4
1.2. OPERATING, HANDLING AND STORAGE CONDITIONS ..... 8
1.3. MEANING OF SYMBOLS ..... 9

**2. RECORDER DESCRIPTION ..... 10**

2.1. INTENDED USE ..... 10
2.2. GENERAL DESCRIPTION ..... 10
2.3. DESIGN AND LOCATION OF FUNCTIONAL COMPONENTS ..... 11
2.4. KEY FUNCTIONS ..... 12
2.5. BASIC TECHNICAL AND PERFORMANCE PARAMETERS ..... 13
2.6. FUNCTIONAL FEATURES ..... 14
2.7. ACCESSORIES ..... 14
2.8. OPTIONAL ACCESSORIES ..... 15
2.9. MANUFACTURER AND RECORDER DESIGNATION ..... 15

**3. ECG TEST ..... 16**

3.1. TEST PREPARATION ..... 16
3.2. ELECTRODE LAYOUT ..... 17
3.3. STARTING THE RECORDING ..... 20
3.4. PATIENT INFORMATION ..... 21
3.5. FINISHING THE RECORDING ..... 21

**4. USING THE RECORDER ..... 23**

4.1. REPLACING THE BATTERY ..... 23
4.2. MICROSDHC CARD USAGE ..... 23
4.3. STARTING THE RECORDER ..... 24
4.4. CONFIGURATION MODE ..... 24
4.5. TEST RECORDING MODE ..... 27

**5. MAINTENANCE AND TECHNICAL SUPPORT ..... 30**

5.1. CLEANING THE RECORDER AND PATIENT CABLE ..... 30
5.2. ENVIRONMENTAL PROTECTION ..... 31
5.3. CUSTOMER SERVICE ..... 31
5.4. HOW TO DEAL WITH COMMON PROBLEMS ..... 31

**6. ELECTROMAGNETIC COMPATIBILITY DECLARATION ..... 32**

# 1. Safety Information

## 1.1. Manufacturer guidelines on safety of use

**Operation Manual**

- **The operator of this recorder should read the Operation Manual and Warranty Card carefully before starting the unit operation.**
- **Users are advised to store this Operation Manual along the recorder, to assist in operating it and solving related issues.**
- **The Operation Manual will help the user operate and maintain the recorder correctly.**
- **Complying with the guidelines and instructions provided by this Manual ensures safety of use, efficient functioning, reliability and fulfilling the tasks expected from the recorder.**

**Staff**

- **The recorder should be used under supervision of qualified and trained healthcare professionals.**

**Patient**

- **For the sake of safety and confidentiality of patients' data, keep unused recorders in a safe place, remove patient data from the microSDHC card after reading exam by the HolCARD 24W, instruct the patient to protect the recorder during registration.**
- **The recorder cannot be used for children below 10 kg.**
- **In patients with pacemakers, keep a proper distance between the recorder and the pacemaker, according to the pacemaker's manufacturer instructions.**

**AsPEKT 712 recorder**

- **The recorder is a medical device with internal power source with CF type application part and ABS plastic type casing. The patient is in no way exposed to the risk of electric shock from the recorder.**
- **The results of ECG measurements from the recorder serve as reference only. The final diagnosis should come from a doctor.**
- **Should the essential performance of the recorder be lost, or should primary safety problems occur, the unit should be withdrawn from service until repaired.**
- **The useful life of the device depends mainly on the efficiency of its**

**elements which, in normal conditions, should maintain performance for 5 years. After the lapse of the above-mentioned time limit, there is increased risk of damage due to the ageing of individual elements, which may lead to a breakdown of the unit.**

- **Every repair ought to be made by authorized service point of ASPEL S.A.**
- **Any modification of the recorder is not allowed.**

**Use Environment**

- **The recorder is not suited for places with the presence of combustible gases or fumes of flammable substances, and is not suited for use in oxygen-rich environment.**
- **Do not use the device in wet places, directly exposed to sunlight or precipitation, in dust and close to flammable or explosive material, or in the atmosphere polluted with corrosive agents.**
- **In order to obtain correct ECG signal recording, the patient should be advised to avoid close proximity of high-power electrical devices or other sources of electromagnetic interference, such as electric blanket, electric pillow, etc.**
- **Portable RF communication equipment such as mobile phones (including peripheral devices such as antenna cables and external antennas) should be used not closer than 30 cm (12 inches) to any part of the recorder, including cables specified by the manufacturer. Otherwise, the operation of the device may be degraded.**
- **Avoid using the recorder close to or stacked with other equipment, because it may cause inappropriate operation.**
- **The doctor should be aware of possible false detection of pacemaker impulses. False pacemaker impulses can result from incorrect connection of electrodes, or the recorder operating in high-interference environment. The lack of impulse detection can result from weak pacemaker signal on patient's skin in the case of using bipolar pacemakers.**
- **Do not place the recorder, including accessories, directly near heat sources such as stoves, radiators etc.**

**Batteries**

- **The recorder requires alkaline batteries, Ni-MH rechargeable batteries or Li-Fe batteries.**
- **Improper use of the recorder may lead to overheating, fire, explosion or decrease in the capacity of batteries. Therefore, please acquaint yourself carefully with this Operation Manual and pay attention to the warning messages.**
- **Leaving the batteries in unused recorder or using deficient or faulty batteries may cause recorder damage and loss of its warranty.**
- **Do not heat the battery or put it into fire or water.**

- **If a leak occurs or you feel unpleasant smell from the battery, stop using it immediately. If the skin or clothing comes into contact with battery electrolyte, rinse it with clean water. If electrolyte leak gets into the eyes, do not wipe them; instead, rinse with plenty of clean water and consult a doctor immediately.**

**Accessories**

- **The recorder should only be used with accessories from its manufacturer.**
- **The use of accessories and cables other than those specified or provided by the manufacturer may cause the increase of the electromagnetic emission or the decrease of the electromagnetic immunity of the recorder and cause inappropriate operation.**
- **Disposable purses for placing the recorder in them during the examination and disposable electrodes should be used only once during the examination and on the completion of the examination, they should be disposed of in accordance with applicable law.**

**Use**

- **Improper use of the recorder may cause the accident.**
- **The recorder is not suited for direct use over the heart.**
- **The recorder is not suited for operation with high-frequency surgical units.**
- **The recorder should not have contact with the skin.**
- **Protect the device against contact with water or dampness.**
- **Conducting parts of electrodes, including ground electrode, should not touch conducting parts.**
- **The recorder must not be used with devices producing defibrillation pulses. Combined use of a defibrillating device and the recorder may result in damage to the recorder, for which the manufacturer shall not be liable. Disconnect the device from patient before defibrillating.**
- **The recorder's wireless connection to other devices may cause yet unknown risk for patients, operators or third parties, which should always be identified, analyzed, assessed and managed before executing the connection.**
- **Periodically check the performance of accessories and the recorder itself. If you notice any issues with the recorder's operation, please contact an authorized service point.**
- **When reviewing the ECG data, the values of pacemaker signals amplitude on ECG printout should not be interpreted as the true value of pacing impulses amplitude.**

**Environmental protection**

- **There is potential risk of environment pollution related to the removal of the unit and cords after their useful life. The device and accessories should be disposed of in accordance with applicable provisions of law.**
- **Disposal of used batteries and rechargeable batteries should conform to applicable law.**

**General**

- **Failure to abide by the rules above may cause safety problems, for which the manufacturer shall not be responsible.**
- **The manufacturer shall not be held responsible for injuries to people or damage to elements of the recorder or other objects caused by:**
  - **failure to read and abide by this Manual,**
  - **improper power supply,**
  - **improper operation,**
  - **improper maintenance,**
  - **repairs performed by unauthorized services,**
  - **using parts and accessories that are not original or not recommended by the manufacturer,**
  - **operation in improper conditions.**

## 1.2. Operating, handling and storage conditions

AsPEKT 712 is intended to operate under the following conditions:

- ambient temperature 0 °C ÷ +45 °C,
- relative humidity 10% ÷ 95% (non-condensing),
- atmospheric pressure 70 kPa ÷ 106 kPa.

AsPEKT 712 should be kept and handled under the following conditions:

- ambient temperature -20 °C ÷ +60 °C,
- relative humidity 10% ÷ 95% (non-condensing),
- atmospheric pressure 70 kPa ÷ 106 kPa.

Air should not be strongly contaminated with corrosive agents.

**If the recorder was stored or handled at temperatures exceeding the operating conditions, remove the device from the packaging and leave it aside for a period of time necessary for the device to adapt to the ambient conditions at the premises where it is to be operated.**

## 1.3. Meaning of symbols

Significant manufacturer's comments.

Refer to the instruction for use (operation manual).

General warning sign.

Production date.

Manufacturer's address.

Applied CF part.

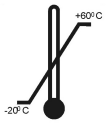
Device cannot be used for children below 10 kg.

Transport packaging should be protected against moisture.

Indicates proper vertical setting of the transport packaging.

The content of the transport packaging is fragile so it should be transported with care.

Indicates the maximum number of identical packaging boxes which may be piled up.




Indicates temperature range in which the transport packaging should be stored and transported.

Disposing waste equipment along with other waste is forbidden.

# 2. Recorder description

## 2.1. Intended use

AsPEKT 712 recorder is a diagnostic device intended for performance Holter ECG examinations in adult and pediatric patients >10 kg, in all health care facilities by trained personnel.

AsPEKT 712 recorder is a battery-powered digital device designed to record and save on a microSDHC card a 12-channel and 3-channel Holter monitor test (with 4, 7 or 10 electrodes) within the period of 24 hours, 48 hours or 7 days.

Saved ECG tests are read and analyzed by HolCARD 24W software. The recorder may record stimulation and two types of events.

## 2.2. General description

The recorder was developed with the use of micro-processing technology. It is equipped with a patient's button and a three-coloured control. Light weight, small size and battery power supply allow for a convenient use of the recorder during the test. The housing of the device is made of plastic, which facilitates the maintenance of its hygiene by the user.

The recorder is equipped with a wireless communication system, which enables review and evaluation of the ECG signal.

The event button is used for commencing the ECG test in configuration mode and for signalling events during ECG signal recording.

The recorder saves ECG data, which is analysed by HolCARD 24W software, on a microSDHC memory card.

The recorder is powered by one AA or Li-Fe alkaline battery or a Ni-MH battery. Li-Fe battery is designated to record ECG signal for a period of 7-days recording mode.

An optimised patient's cable, which reduces potential interferences during ECG signal recording, was used in the recorder.

AsPEKT 712 v.3xx is additionally equipped with a colour display and a capacitive keyboard for initial configuration of the recorder and preview of ECG quality.

## 2.3. Design and location of functional components

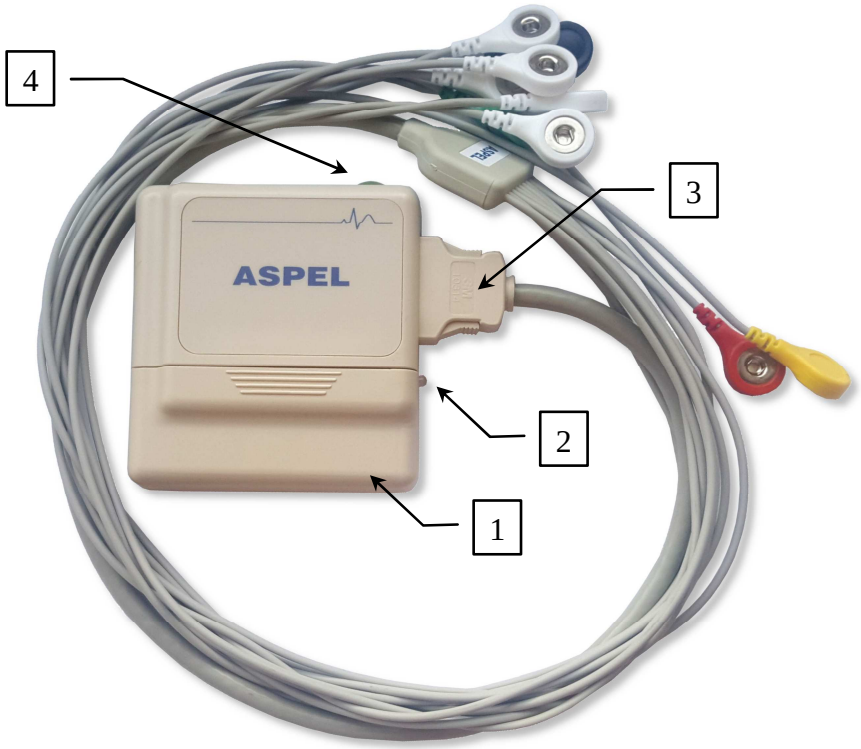



*Fig. 1. AsPEKT 712 v.2xx recorder – general view*

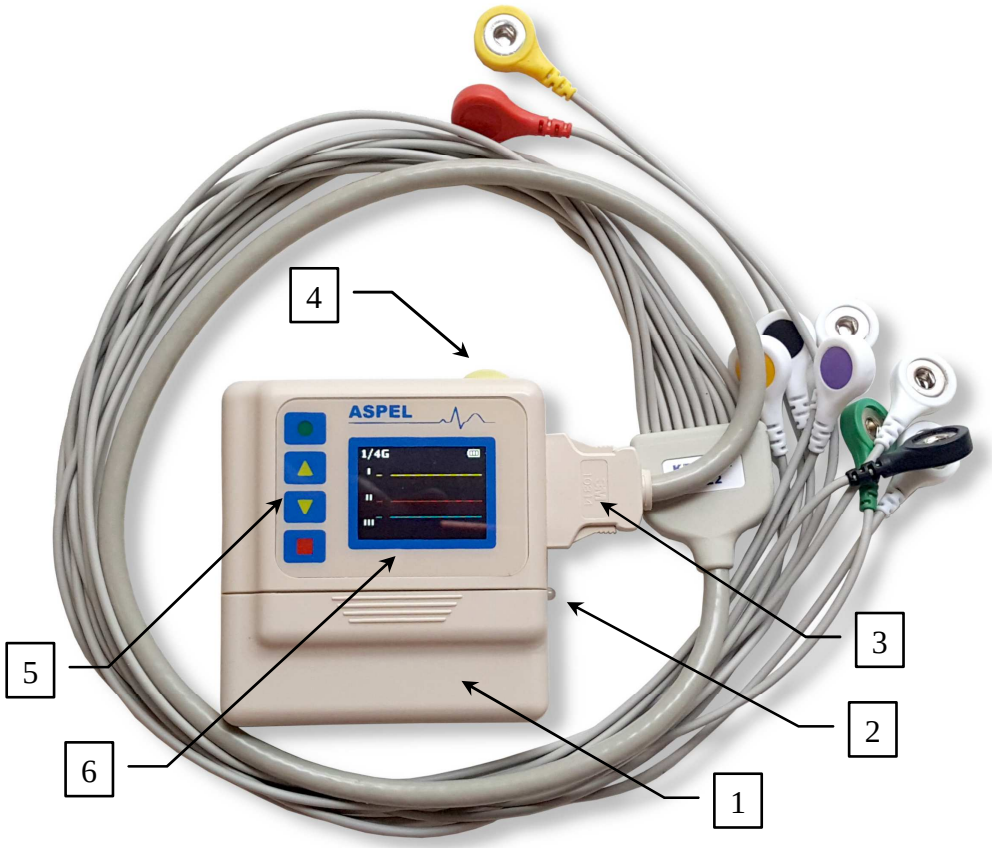



*Fig. 2. AsPEKT 712 v.3xx recorder – general view*

1. Battery cover.
2. Control LED - (description of signalling in chapters 4.4 and 4.5).
3. Patient's cable.
4. Event button.
5. Capacitive keyboard (AsPEKT 712 v.3xx).
6. Colour display (AsPEKT 712 v.3xx).

*Fig. 3. AsPEKT 712 v.3xx recorder – card slot and battery socket view*

1. MicroSDHC card slot with card.
2. AA battery socket with battery.

## 2.4. Key functions

Entry to the menu, approval of changes.

Move one position up, selection of the previous item.

Move one position down, selection of the next item.

Exit from the menu, cancel changes. Change the display mode of the signal.

## 2.5. Basic technical and performance parameters

| | |
|---|---|
| Dimensions: | 76 x 72 x 23 mm (length x width x height) |
| Weight: | 86 g ± 15 g without a battery |
| Power supply: | LR6 (AA) alkaline battery, Li-Fe, Ni-MH rechargeable battery |
| Electricity consumption: | < 33 mA in recording mode<br>< 200 mA in wireless communication mode |
| ECG – signals: | 3 leads (4 or 7-electrode cable)<br>12 leads (10-electrode cable) |
| Display | Colour display OLED, 1.27" screen size, 128x96 resolution, 262 144 colours (AsPEKT 712 v.3xx) |
| Sampling frequency: | 2000 samples/s per channel (proportionate sampling) |
| A/C converter resolution: | 24 bits |
| ECG signal range: | ±5 mV (10 mVpp) |
| Stimulation impulse detect band: | Up to 10 kHz |
| Wireless transmission power: | Maximum 2,5 mW |
| Wireless transmission band: | 2,402 GHz ÷ 2,480 GHz |
| Data rates: | (SPP mode) 240 kbps |
| Type of modulation | FHSS/GFSK, 79 channels with 1MHz spacing |
| Electric shock protection type (EN 60601-1): | Internal power supply |
| Applied part (EN 60601-1): | CF (4, 7, or 10 electrodes – patient connections) |
| Device class and group according to EN 55011: | Class B, group 1 |
| Medical device class: | IIa (rule 10) |
| IP protection class: | IP X0 |
| Use safety: | EN 60601-1, EN 60601-2-47 |
| Electromagnetic compatibility: | EN 60601-2 |
| Software version: | 1.0.xx |
| Directive | Aspel S.A. hereby declares that AsPEKT 712 v.2xx, v.3xx complies with Directive 214/53/EU. The full text of the declaration of conformity is available at the following e-mail address: techniczny@aspel.com.pl. |

## 2.6. Functional features

1. Recording 3 standard ECG leads.
2. Recording 12 standard ECG leads.
3. View of the ECG test course in wireless communication mode.
4. Detection of a disconnected electrode in configuration mode.
5. MicroSDHC card to save ECG data.
6. Touch keyboard with function keys (AsPEKT 712 v.3xx).
7. On-screen menu for easy keyboard operation (AsPEKT 712 v.3xx).
8. Attaching patient's full name to the ECG test recording.
9. Ability to view patient data (AsPEKT 712 v.3xx).
10. Option to change parameters such as: group display mode, single lead display mode, test type (24-hour, 48-hour, 7-day), date and time, Online mode (wireless connection option), language (AsPEKT 712 v .3xx).
11. Choice of operating mode: Optimal (sampling frequency 250 Hz) or Extended (sampling frequency 2000 Hz) (AsPEKT 712 v.3xx).
12. Three-coloured diode and sound signalling of a recorder status.
13. Signalling microSDHC card damage, flat battery and INOP.
14. Launching the recording by pressing the event button or automatically after 10 minutes.
15. Launching the recording by means of wireless communication via HolCARD 24W software or AsPEKT Configuration program.
16. Recording ECG signal for 48 hours or 7 days (AsPEKT 712 v.2xx).
17. Recording ECG signal for 24, 48 hours or 7 days (AsPEKT 712 v.3xx).
18. Recording two types of events.
19. Contour line filter 0,05 Hz.
20. Battery energy saving function.
21. Interoperability with HolCARD 24W software.

## 2.7. Accessories

| | | |
|---|---|---|
| 1. | Disposable electrodes | 50 pcs. |
| 2. | AA alkaline battery | 1 pc. |
| 3. | MicroSDHC card | 1 pc. |
| 4. | 7-electrode EKG cable - standard size KRH-703 v.422 | 1 pc. |
| 5. | 10-electrode EKG cable - standard size KRH-712 v.322 | 1 pc |
| 6. | Disposable purse for the recorder | 10 pcs. |
| 7. | Reusable puree for the recorder | 1 pc. |
| 8. | Operation Manual of the recorder | 1 pc. |
| 9. | Quick start guide of the recorder | 1 pc. |
| 10. | Operation manual of the ECG cable | 1 pc. |

## 2.8. Optional accessories

1. 4-electrode EKG cable KRH-703 v.331 1 pc.

All accessories are always available at ASPEL S.A. www.aspel.com.pl.

**Company ASPEL S.A. offers training for using AsPEKT 712 v.2xx, v.3xx recorder.**

## 2.9. Manufacturer and recorder designation

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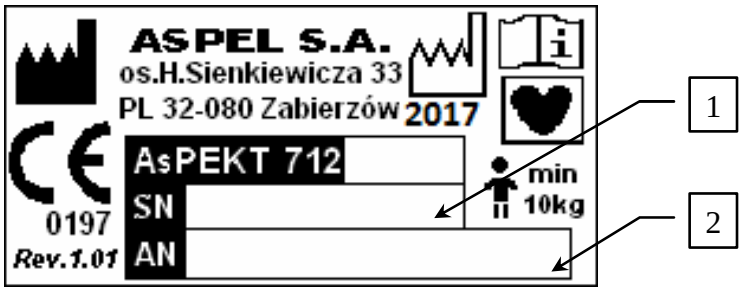



*Fig. 4. AsPEKT 712 designation*

1. Device serial number.
2. AsLINK Number (AN) – unique address of a wireless communication device.

# 3. ECG test

## 3.1. Test preparation

Patient's skin should be properly prepared before attaching electrodes to the patient's body. In order to perform a high quality test, the following recommendations concerning patient's preparation should be followed in an order given below:

1. If necessary, shave the skin hair by way of dry shaving the places to which the electrodes will be attached.
2. Clean the places to which the electrodes will be attached from dirt and epidermis sebum by rubbing them with a gauze damped with 99% isopropanol or acetone (do not use alcohol).
3. Places on the skin to which the electrode connection will be attached should be rubbed forcefully with a gauze with abrasive paste in order to remove the surface layer of dead cells.
4. Before fixing the electrodes in place, remove the remaining abrasive material and exfoliated epidermis with a gauze. This will improve the electric contact between the skin surface and the electrode, which ensures a high quality signal.
5. Connect coloured tips of the patient's cable with disposable parts of electrodes.
6. Remove protective film from the electrode and attach it to the patient's skin in a manner that will ensure that it fits tightly and it does not press out the electrolyte gel placed between the skin and the metal part of the electrode. Do so with other electrodes, one by one, taking into account the colour allocation set forth in the Operation Manual.
7. A proper skin cleansing has a considerable influence on the quality of monitoring. Therefore, electrodes should be attached with particular care.
8. A proper electrodes connection should be verified during the ECG signal acquisition time after turning the device on.

**The condition of the patient's skin should be monitored during the examination. If the skin is irritated, disconnect the electrodes for 24 hours.**

**It is recommended that electrodes should be placed on the patient's body by qualified healthcare professionals.**

**Connecting a patient to several devices requires pre-assessment of any possible risks stemming from leakage current aggregation of each device.**

**While attaching electrodes please ensure that the conductive parts of the electrodes and of the patient cable do not touch one another or other metal parts, including the earthing.**

## 3.2. Electrode layout

Standard indications and colours, presented on the figure below, were used to identify each of the electrodes.

Each electrode consists of a clip in a particular colour, fixed to the disposable part of the electrode. The clip is permanently fixed to the patient cable. A disposable part of the electrode attached to the body consists of a self-adhesive collar covering the electrode and a metal centre covered with electrolyte gel.

The figures below present electrode layout for 3-channel and 12 channel ECG. The cardiologist may slightly modify the layout, depending on the suspected condition of the patient or other factors. Importantly, connecting a patient to several devices requires pre-assessment of any possible risks stemming from leakage current aggregation of each device. While attaching electrodes please ensure that the conductive parts of the electrodes and of the patient cable do not touch one another or other metal parts, including the earthing. It is recommended to place the electrodes on the skin above ribs or cartilages to avoid disturbances due to soft tissue movement.

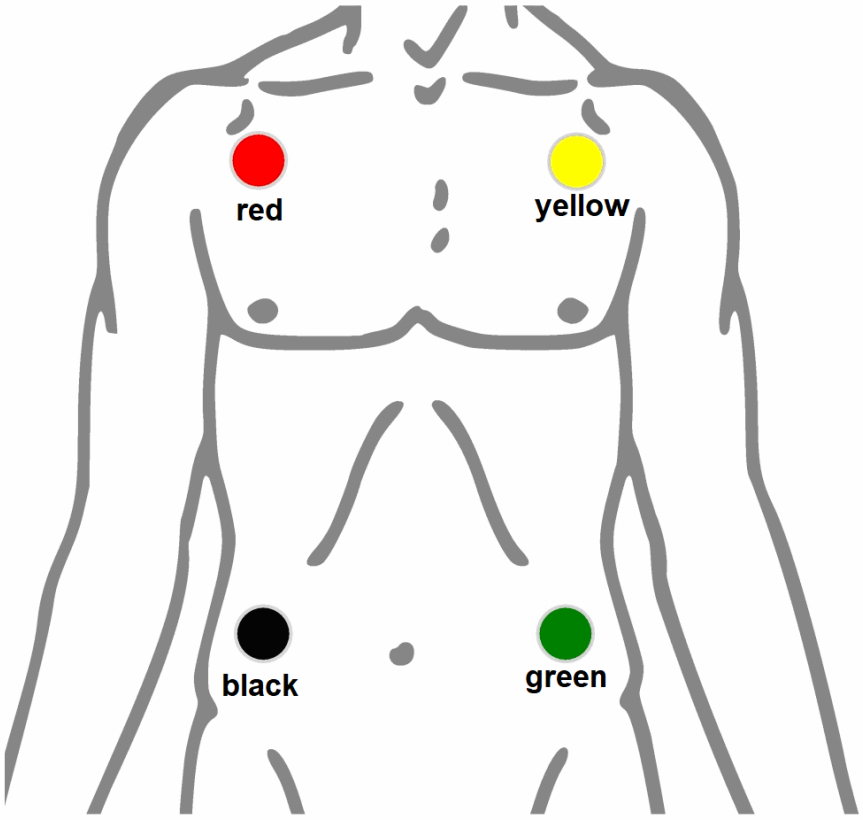
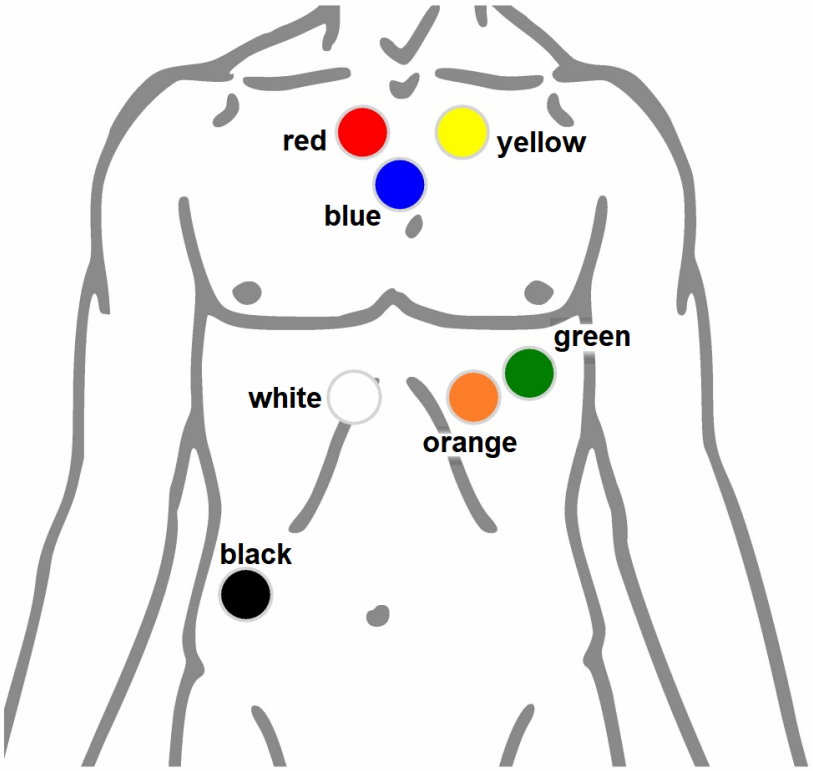



*Fig. 5. Electrode layout for 3 channel (4 electrodes)*

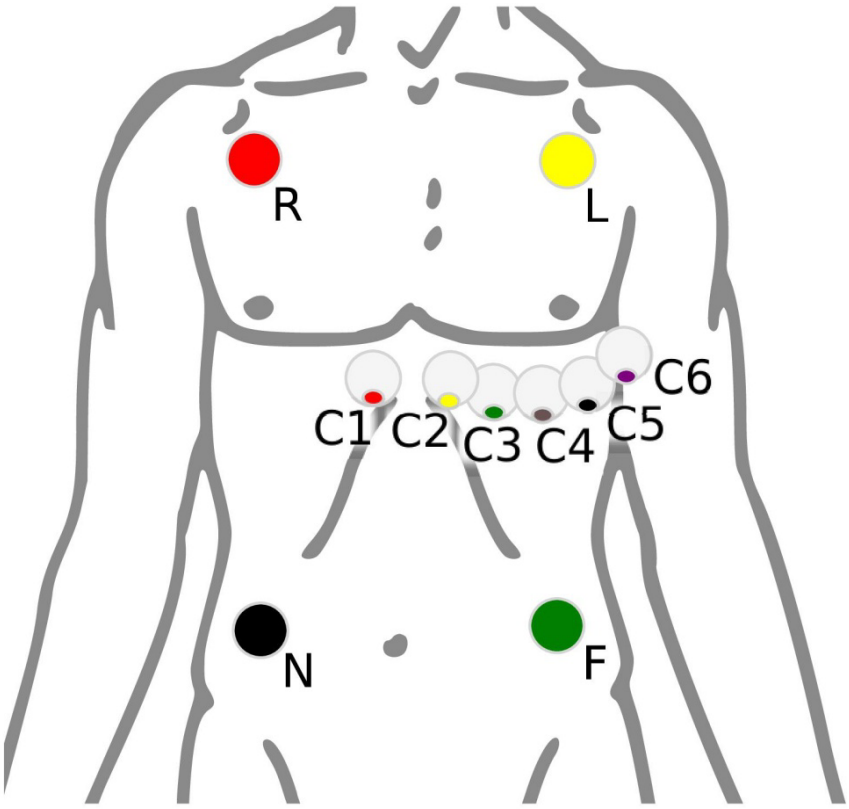
| **Limb electrodes:** | **Description** |
|---|---|
| red | - right subclavicular area, |
| yellow | - left subclavicular area, |
| green | - left hip, |
| black | - right hip. |

| **Channels** | **+** | **–** |
|---|---|---|
| **CH1** | - yellow electrode | - red electrode, |
| **CH2** | - green electrode | - red electrode, |
| **CH3** | - yellow electrode | - green electrode. |




*Rys. 6. Electrode layout for 3 channels (7 electrodes)*

| **Channel** | **Electrode** | **Description** |
|---|---|---|
| **(CH1+)** | - green | - sixth rib in the left anterior axillary line, |
| **(CH1-)** | - red | - the right end of the upper part of the sternum, |
| **(CH2+)** | - white | - approximately 2,5 cm to the right of the xiphoid process (the lowest bone of the sternum) at the rib level, |
| **(CH2-)** | - yellow | - the left end of the upper part of the sternum, |
| **(CH3+)** | - orange | - the sixth rib in the left medial clavicular line, |
| **(CH3-)** | - blue | - the middle upper part of the sternum. |
| **(RL)** | - black | - the right lower costal arch above the bone, |




*Rys. 7. Electrode layout for 12 channels (10 electrodes)*

| **Limb electrodes:** | | **Description** |
|---|---|---|
| **R** | - red | - right subclavicular area, |
| **L** | - yellow | - left subclavicular area, |
| **F** | - green | - left hip, |
| **N** | - black | - right hip. |

| **Precordial electrodes:** | | **Description** |
|---|---|---|
| **C1** | - white-red | - the fourth intercostal space on the right side of the sternum, |
| **C2** | - white-yellow | - the fourth intercostal space on the left edge of the sternum, |
| **C3** | - white-green | - half way between C2 and C4, |
| **C4** | - white-brown | - the fifth intercostal space in the left central clavicular line, |
| **C5** | - white-black | - straight line from the C4 point perpendicularly to the left front auxiliary line in the intersection point with this line, |
| **C6** | - white-purple | - at the same level as C5, but in left central auxiliary line. |

## 3.3. Starting the recording

1. Attach electrodes to the patient's body.
2. Connect patient cable to ECG recorder.
3. Insert the microSDHC card into the recorder.
4. Insert a new AA battery into the recorder. An internal test of recorder is signalling by fast blinking green led and next one long green control light signal and a long acoustic signal of the recorder confirm the proper start. After starting AsPEKT 712 v.3xx recorder, it has the ability to preview the ECG signal on the display.

**Data from the previous recording on the microSDHC card are deleted after few seconds from the moment inserting the batteries.**

5. In version v.2xx of the recorder within 3 minutes from starting the recorder, it is possible to make a wireless connection with the recorder and then for 10 minutes the possibility of viewing the ECG signal on the computer by means of communication wireless in the programs: HolCARD 24W, Configurator AsPEKT.
6. In version v.3xx of the recorder within 10 minutes from the starting the recorder, there is a preview of signal on the display and possibility of establishing a wireless connection with the recorder, in order to view the ECG signal on the computer in the programs: HolCARD 24W, Configurator AsPEKT.

**In the AsPEKT 712 v.3xx recorder, in order to be able to connect to the programs: HolCARD 24W, AsPEKT Configurator, the Online mode should be enabled in the recorder menu.**

7. During signal preview you can improve the fixing of the electrodes. Condition unplugged / bad conductive - the INOP – is signalled with intermittent acoustic signal.

**ECG curves can only used to assess the signal quality. They can not be used for diagnostic purposes.**

**In the AsPEKT 712 v.3xx version both the display and keyboard are only active in configuration mode. After starting the recording, the display will be turned off and the keyboard will remain inactive until the end of the record.**

8. To start the recording for a period of 48 hours, press the event button for about 4 seconds until you hear and see the ECG test start signal (3 short and one long audible signal and the green signalling diode).
9. If the recording has not started, the recorder will enter the automatic recording mode after 10 minutes of the signal preview (in version v.2xx without signal preview after 3 minutes).

**Recording is signalled with a short green light flashing every 10 seconds. If the control does not blink, no signal is registered. Once the recording has commenced, the healthcare professional should ensure that the recorder is in the recording mode.**

10. Once the recording has commenced, place the recorder in the purse. Attach the purse with the recorder on the chest of the patient.

**It is possible to hang the purse with the recorder on the side of the patient over his hip. In this case, use a large size 4-electrode cable.**

**In order for the recorder to work in a stable position and not cause discomfort to the patient and that the recorded ECG signal had a minimal amount of interference, it is recommended that the patient be dressed in a tight T-shirt that will hold the recorder and the patient's cable.**

## 3.4. Patient Information

Once the recording has started, the following information has to be provided to the patient:

1. How to use the events button.
2. Precautions to be taken, including:
   - o do not let the recorder get wet and do not bathe, shower or wash your hair,
   - o do not touch the electrodes or try to unplug the cables from the electrodes,
   - o do not open the recorder or remove the battery or microSDHC card from the recorder,
   - o do not put the recorder closer than 1 meter from mobile phones, television sets or other electronic devices,
   - o do not leave the recorder in close proximity to any heat source, such as heaters.
3. When the patient need to visit the doctor after finishing the ECG signal recording.
4. Confidential of patient data that the recorder contains and that the recorder should therefore be protected.

**A minor who undergoes ECG signal recording needs to be supervised by an adult.**

## 3.5. Finishing the recording

The device switches off automatically 24, 48 hours or after 7 days after the start of the recording. If during the test the battery power falls to a critical level, which entails an imminent loss of data, the recording will be stopped.

In case the test needs to be finished before end of fixed time of recording, you need to wait for the short green flash of the diode signalling that data is saved on the card and only then remove the battery.

The test results saved on the microSDHC card can be read in an microSDHC card reader using the HolCARD 24W software. More details are provided in the HolCARD 24W Operation Manual.

**The AsPEKT 712 recorder supports HolCARD 24W for Series 6, Version 6.60 and higher.**

**The AsPEKT 712 recorder supports HolCARD 24W for Series 8, Version 8.06 and higher.**

# 4. Using the recorder

## 4.1. Replacing the battery

A new high-capacity alkaline battery is recommended to perform a complete, 24-hour or 48-hour test. A new high-capacity Li-Fe battery is recommended to perform a complete, 7-days test. To replace a battery, remove the battery cover located at the back of the recorder by pressing the cover and moving it outwards. Then remove the used battery and put a new one into the open compartment, according to the polarization as indicated inside the compartment. After inserting the battery, the AsPEKT 712 will start working.

**Remove the battery from the recorder if it is used for a longer period of time. It prevents recorder damages caused by a possible leakage of electrolyte.**

**Before starting the recording, insert a new battery into the recorder. Used, expired, improperly stored or low-quality batteries would not allow to make a full test record.**

**Used batteries should be disposed of in a special container.**

## 4.2. MicroSDHC card usage

The recorder supports cards of different manufacturers. An microSDHC card may have the storage capacity between 4 GB and 32 GB. It may happen that low-quality cards will be incompatible with the recorder. This will cause errors in the ECG signal recording and saving unreliable results. If an microSDHC card needs to be added or replaced, contact the recorder's manufacturer or distributor.

**An microSDHC card is a precise element. Do not hit it, crush it or put other objects into the microSDHC card slot.**
**MicroSDHC cards should be stored in the recorder to protect the slot from dirt.**

The microSDHC card connector is located inside the recorder. To properly insert an microSDHC card, remove the battery cover, take out the battery (if it is mounted) and push the card gently into the slot, placing its cut angle at the slot to the right. The card should slide into the slot with its end towards the slot line and, with your finger removed, it should automatically slide out for approximately 1 mm. To remove the microSDHC card, push it into the slot line up to the end and release your finger. The card will automatically slide out for approximately 5 mm, and then it may be removed carefully.

**For the registration of ECG signals, due to various parameters available on the market microSDHC cards, it is recommended to use microSDHC 8 GB of Transcend Company.**

**Do not insert the microSDHC card into the slot using considerable force. In case of resistance, check the position of the inserted card and make sure that there are no foreign elements in the slot.**

**Never remove the card by force. It may damage both the recorder and the SD card. The first thing to do when removing the microSDHC card is to push it inside the slot. Then the card will automatically slide out.**

## 4.3. Starting the recorder

1. After inserting the battery, the recorder for a period of a few seconds test inner circuits and microSDHC card. It is signalled by glowing by a few seconds green diode. Any data on the microSDHC card will be delete.
2. Next, the recorder confirms initiation with a long 1 second green signal of signalling diode and long audible signal, and then it switches into the configuration mode.
3. If the battery level is too low for the device to run properly, this will be communicated with a short orange signal or it will simply fail to start.
4. In case of an unplugged ECG cable or problems with the microSDHC card, the device will signal it with an intermittent sound and a red flashing signal 20 seconds after which the recorder will turn off.

## 4.4. Configuration mode

The configuration mode is the default mode after switching on the device's power supply:

- for AsPEKT 712 v.2xx which ongoing a maximum of 13 minutes (3 minutes waiting for a call and 10 minutes of wireless connection with ECG preview),
- for AsPEKT 712 v.3xx which ongoing 10 minutes with ECG preview on the recorder display (during this time it is possible to establish a wireless connection with viewing the ECG signal in the computer),

During that period, the recorder verifies the battery level, connection quality of the electrodes and the microSDHC card. This mode enables an assisted connection of electrodes to the patient's body (incomplete contact / electrode disconnection indication) and allows you to preview the ECG signal on the display (AsPEKT v.3xx version) and through the radio link using the following software: HolCARD 24W, AsPEKT Configurator. Once connected, the HolCARD 24W AsPEKT Configurator software will update the date and time in the recorder.

**Before a wireless connection with the recorder is made, please check whether the date and time in the PC are correct.**

In AsPEKT 712 v.2xx version establishing a connection with the computer is only possible for the first 3 minutes after activating the device.

In the version of the AsPEKT 712 v.3xx recorder, it is possible to establish a connection with the computer for the first 10 minutes after switching on the device with Online mode enabled.

After this time, the radio module will be deactivated and the device will start recording automatically. If the battery is discharged, the preview will not be available.

**The configuration procedure with the HolCARD 24W software is described in the HolCARD 24W Operation Manual.**

In the configuration mode, the recorder reports its status with the following signals:

| **Signal control and sound signal** | **Device status** |
|---|---|
| Green blink of a few seconds. | After insert battery to the recorder test of inner circuits and microSDHC card. |
| Green slow blink (every 2 seconds). | Ready to work. |
| Orange slow blink (every 2 seconds). | Battery low, the recorder will not be able to complete a full test.<br>**NOTE!** The signal may not be previewed through the radio link if a weak battery is used. |
| A fast intermittent signal sound and fast red flashing. | Removed ECG cable from the recorder or microSDHC card damaged or removed. After 20 seconds, the recorder will turn off. |
| Short audible signal (every 2 seconds). | Signalling a disconnected electrode/improper electrode conductivity - INOP.<br>Correct the electrodes' attachment, or shave dry if the electrode is applied on bodily hair.<br>The test may not be recorded properly. |

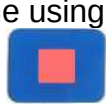
In the AsPEKT 712 v.3xx recorder it is possible to change its configuration using the touch keyboard and view the information on the display. In the menu, the user can choose to view patient data by selecting <Patient info> (after uploading them with the AsPEKT Configurator), changing the recorder settings via the <Settings> option and starting the examination using the <EXAM. START> option. The following parameters can be changed in the recorder:

1. Display mode of ECG signal lead groups.

   o To change the displayed lead groups, use the / keys.

- To set the display of single channels, use the key.

2. Single ECG lead display mode.

   - Changing the displayed leads can be done using the / keys.
   - To set display of channel groups, use the  key.

3. Settings.

   - In this window there is a choice of options:<Exam. type>, <Date and time>, <Online mode>, <Exam mode>, <Language>.

4. Examination type.

   - To select the duration of the examination, select <Settings>, <Exam.type> and with the / keys select the appropriate option: <24 h>, <48 h>, <7 days>, and confirm the selection with the key. After switching on the recorder, the default mode of the examination type is <48 h>.

5. Date and time.

   - To change the date or time, select <Settings> and <Set time> or <Set date> with the / keys, and then enter the configuration menu using the key.
   - To change the time, select the appropriate field in the <Set time> window (hh/mm/ss format) with the / keys and then confirm with the key. The selected field is characterized by yellow arrows. The change of values should be done with the / keys. To exit the <Set time> option and save new settings simultaneously, press the key.
   - To change the date, select the appropriate field in the <Set date> window (dd/mm/yyyy format) with the / keys, and confirm with the

key. The selected field is characterized by yellow arrows. The change of values should be done with the / keys. To exit the <Set date> option and save new settings simultaneously, press the key .

6. Online mode

   - To configure the Online mode, select <Settings> / <Online mode>, using the / keys, select the desired option <OFF> / <ON>, and confirm with the key.

7. Examination mode

   - To configure the examination mode, select <Settings> / <Exam. mode>, using the / keys, select the desired option <Optimal> / <Extended>, and confirm with the key. After switching on the recorder, the examination mode is Optimal.

8. Language

   - To change language, select <Settings> / <Language>, using the / keys, select the desired option <Polski> / <English>, and confirm with the key.

## 4.5. Test recording mode

In the test recording mode, the recorder registers the ECG trace onto the microSDHC card. The default duration of recording is 48 hours. Changing from the configuration mode to the recording mode is possible by means of:

- pressing and holding the event button for approximately 4 seconds until an audible test start signal is heard;
- in AsPEKT 712 v.2xx waiting 3 minutes without a wireless connection or 10 minutes with ECG preview after wireless connection, the recorder will start recording automatically;
- in AsPEKT 712 v.3xx with ECG preview on display waiting 10 minutes, after which the recorder will start recording automatically;

- starting the recording from the software: HolCARD 24W, AsPEKT Configurator by means of wireless communication. After starting the recording through the appropriate software, the patient's data is sent to the recorder and saved on the microSDHC card.
- In the version of the recorder AsPEKT 712 v.3xx there is an additional possibility to start examination. To do this, enter the menu with the key and with the / keys select <EXAM. START> and confirm with the key. If the process of running the test runs flawlessly, the message <EXAM. START> will appear in the central part of the screen, and then the device will enter the test registration mode.

**Registration an ECG signal for period of 7 days is activating only by wireless communication with use of HolCard 24W and Configuration AsPEKT software and additionally, in the recorder AsPEKT 712 v.3xx, from the on-screen menu.**

**For registration an ECG signal for period of 7 days, due to various parameters available on the market, recommended is using AA battery type Ultimate Lithium of Energizer Company.**

**In the 7-day examination mode, it is recommended to work in Optimal mode, due to the lower power consumption of the recorder (AsPEKT 712 v.3xx).**

In the registration mode, the recorder reports its status with the following signals:

| **Signal control and sound signal** | **Device status** |
|---|---|
| Three short and one long beeps with simultaneous green signal. | Switches from configuration mode to registration mode. |
| Short green flash (every 10 seconds). | Correct registration. |
| Short red flash (every 10 seconds). | Disconnected electrode or weak contact (INOP status). |

During registration the patient may signal two types of events (e.g. malaise, stress, physical effort, sleep etc.) with the events button. When the patient feels any discomforts or wants to signal a particular event, they press the event button. The recorder confirms pressing the button with a green blink of the control and records the time when this happened. The device may save two types of events reported by:

- single press of the button - type A event (for example pain or weakness),

- o two presses of the button - the button should be pressed for the second time within 4 seconds after the first one - type B event (for example start of sleep or manual effort).

The next reported event may only be registered after 5 seconds. Both types of events are read by the HolCARD 24W software when analyzing the test.

If the battery is low during the test, the recorder will turn off.

# 5. Maintenance and technical support

## 5.1. Cleaning the recorder and patient cable

Keep the surface of the AsPEKT 712 recorder clean. Pay special attention to elements that come in contact with the patient's skin. Use a clean, soft, dry cloth to clean the recorder. If necessary, you may use a soft cloth soaked in a mild detergent. Mild, non-aggressive detergents, such as soapy water, can be used to clean the patient cable. The device should be wiped with a soft, moist cloth.

**Do not use aggressive chemicals to clean the device.**
**Do not use substances that could abrade the surface.**
**Cleaning agents should be dissolved before use, as per the recommendations of the preparation's manufacturer.**
**Do not allow the cleaning agent to penetrate into the device.**
**Do not spill any liquids on the device and do not submerge it in any liquids.**
**Do not leave the cleaning agent on the device.**
**Do not expose to contact with colour oil.**

**The recorder should be disinfected after each test.**

Disinfection should be carried out as per the hospital's or medical centre's schedule. The device should be cleaned beforehand. Avoid using alcohol for disinfection, because it leads to hardening of the wires and, as a consequence, damages them.

**Only use the generally available specialist disinfectants for medical devices, e.g. BACILLOL, DESCOSEWPT, SEKUSEPT, ALDEWIR, HEXAQUART, BIGUASID, IMPULS, GIGASEPT FF etc.**

**Single-use electrodes are not to be disinfected - after a test these should not be re-used.**

**To confirm the basic functions and safety, operability of the recorder should be periodically controlled (once a year). The inspection is carried out by the manufacturer or an authorized service point and it should include:**
**- visual inspection - checking the legibility and completeness of labels, technical condition of mechanical elements of the recorder, the patient cable - checking for potential damage or dirt,**
**- control of safety parameters - measurements of insulation resistance and leakage currents,**
**- control of functional parameters: power consumption, gain, frequency band.**

**Besides the scheduled (guarantee and post-guarantee) inspections of the recorder (once a year by the manufacturer or an authorized service point), check the recorder, the patient cable on a regular basis before switching the unit on. The inspection should consist in visual checking and assessment for visible cracks. Remove all spotted irregularities with the help of an authorized ASPEL service point.**

The AsPEKT 712 recorder is not appropriate for sterilization.

## 5.2. Environmental protection

When in use the AsPEKT 712 ECG recorder does not create any environmentally hazardous residues, however disposing of a worn recorder or its equipment (e.g. battery) with other waste shall constitute an environmental hazard.

**A worn recorder should be managed properly. It can be done by sending it back to the manufacturer or contacting a company that recycles electronic and electromechanical devices.**

## 5.3. Customer service

To get help with troubleshooting any problems related to the recorder's operation, please contact the ASPEL S.A. department.

## 5.4. How to deal with common problems

| **Problem** | **Solution** |
|---|---|
| The control does not signal any recorder activity. | Check the LR6 (AA) battery polarity and make sure that a new battery was used. |
| Intermittent sound and the control blinks red. | - No microSDHC card or damaged microSDHC card. Replace the microSDHC card.<br>- No connected ECG cable. |
| No ECG signal preview with wireless connection. | -In AsPEKT 712 v.3xx version set the <Online Mode> option to <ON>.<br>- Low battery that does not allow wireless communication. Replace the battery.<br>- Check the distance between the recorder and the computer (this distance should not be more than 10 m).<br>- Check whether there are no obstacles on the transmission pathway (e.g. if the patient is not a source of interference in the transmission pathway).<br>- Reconnect power. After 10 minutes of wireless connection, the recorder interrupts communication. |
| The control blinks orange. | Low battery. Replace the battery. |
| INOP audible signal during configuration. | Verify the connection of electrodes and correct their attachment. |
| No information on events. | Make sure that the patient properly recorded the event information. |

# 6. Electromagnetic compatibility declaration

| **Manufacturer's guidance and declaration – electromagnetic emissions** | | |
|---|---|---|
| The AsPEKT 712 recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the AsPEKT 712 recorder should assure that it is used in such an environment. | | |
| **Emissions measurements** | **Compatibility** | **Electromagnetic environment - guidance** |
| RF emissions<br>EN 55011 / CISPR 11 | Group 1 | The AsPEKT 712 recorder uses RF (radio frequency) energy only for its internal purposes. Therefore its RF emissions are very low and it is not possible for it to cause disturbances in adjacent electronic devices. |
| RF emissions<br>EN 55011 / CISPR 11 | Class B | The AsPEKT 712 recorder is suitable for use in all applications (environments). |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | --- |
| Emission – voltage fluctuations/flicker emissions<br>IEC 61000-3-3 | Not applicable | --- |

| **Manufacturer's guidance and declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The AsPEKT 712 recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the AsPEKT 712 recorder should assure that it is used in such an environment. | | | |
| **Immunity testing** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharges (ESD)<br><br>IEC 61000-4-2 | ±8 kV (contact)<br><br>±2 kV, ±4 kV, ±8 kV, ±15 kV (air) | ±8 kV (contact)<br><br>±2 kV, ±4 kV, ±8 kV, ±15 kV (air) | Floors should be made of wood, concrete or ceramic tiles. If floors are covered with a synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient (BURST)<br><br>IEC 61000-4-4 | ±2 kV (power supply lines)<br><br>±1 kV (input/output lines) | Not applicable | --- |
| Surge<br><br>IEC 61000-4-5 | ±1 kV differential mode<br><br>±2 kV common mode | Not applicable | --- |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | <5% $U_T$<br>(>95% dip in $U_T$)<br>for 0.5 cycle and 0º, 45º ,90º ,135º ,180º, 225º, 270º, 315º angle<br><br><5% $U_T$<br>(>95% dip in $U_T$)<br>for 1 cycle and 0º angle<br><br>70% UT<br>(30% dip in $U_T$)<br>for 25 cycles and 0º angle<br><br><5% UT<br>(>95% dip in $U_T$)<br>for 250 cycles and 0º angle | Not applicable | --- |
| Power frequency (50/60 Hz) magnetic field<br><br>IEC 61000-4-8 | 30 A/m<br>(50 Hz / 60 Hz) | 30 A/m<br>(50 Hz / 60 Hz) | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE $U_T$ is the AC mains voltage prior to application of the test level. | | | |

<table>
<tr><th colspan="4">Manufacturer's guidance and declaration – electromagnetic immunity</th></tr>
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<tr><th>Immunity testing</th><th>EN 60601-1-2<br>test level</th><th>Compliance<br>level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td rowspan="2">Conducted RF<br>disturbances<br>EN 61000-4-6</td><td>3 Vrms<br>150 kHz ÷ 80 MHz</td><td>3 Vrms</td><td rowspan="10">Portable RF communication equipment such as mobile phones (including peripheral devices such as antenna cables and external antennas) should be used not closer than 30 cm (12 inches) to any part of the AsPEKT 712 recorder, including cables specified by the manufacturer.<br><br>Constant field strength of the RF transmitters, as determined by local measurement [b], should be less than the compliance level in each frequency range [c].</td></tr>
<tr><td>6 Vrms<br>ISM and amateur radio bands between<br>150 kHz ÷ 80 MHz [a]</td><td>6 Vrms</td></tr>
<tr><td>Radiated RF<br>disturbances<br>EN 61000-4-3</td><td>10 V/m<br>80 MHz ÷ 2,7 GHz</td><td>10 V/m</td></tr>
<tr><td rowspan="7">Fields close to radio equipment<br>EN 61000-4-3</td><td>27 V/m<br>385 MHz</td><td>27 V/m</td></tr>
<tr><td>28 V/m<br>450 MHz</td><td>28 V/m</td></tr>
<tr><td>9 V/m<br>(710, 745, 780) MHz</td><td>9 V/m</td></tr>
<tr><td>28 V/m<br>(810, 870, 930) MHz</td><td>28 V/m</td></tr>
<tr><td>28 V/m<br>(1720, 1845, 1970) MHz</td><td>28 V/m</td></tr>
<tr><td>28 V/m<br>2450 MHz</td><td>28 V/m</td></tr>
<tr><td>9 V/m<br>(5240, 5500, 5785) MHz</td><td>9 V/m</td></tr>
<tr><td colspan="4">[a] The ISM bands (industrial, scientific and medical) between 0,15 MHz ÷ 80 MHz to 6,765 MHz ÷ 6,795 MHz; 13,553 MHz ÷ 13,567 MHz; 26,957 MHz ÷ 27,283 MHz; i 40,66 MHz ÷ 40,70 MHz. Amateur radio bands between 0,15 MHz ÷ 80 MHz to 1,8 MHz ÷ 2,0 MHz; 3,5 MHz ÷ 4,0 MHz; 5,3 MHz ÷ 5,4 MHz; 7 MHz ÷ 7,3 MHz; 10,1 MHz ÷ 10,15 MHz; 14 MHz ÷ 14,2 MHz; 18,07 MHz ÷ 18,17 MHz; 21,0 MHz ÷ 21,4 MHz; 24,89 MHz ÷ 24,99 MHz; 28,0 MHz ÷ 29,7 MHz i 50,0 MHz ÷ 54,0 MHz.<br><br>[b] Field strength of fixed transmitters, such as base stations for radio telephones (cellular/cordless) and land mobile radio, amateur radio, AM and FM radio broadcasting and TV broadcasting cannot be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AsPEKT 712 recorder is used exceeds the applicable RF compliance level, the AsPEKT 712 recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AsPEKT 712 recorder.<br><br>[c] In the frequency range 150 KHz ÷ 80 MHz, field strength should be less than 3 V/m.</td></tr>
</table>