

RIGEL
Total Power. Total Trust.

Introduction to IEC 60601 And IEC 62353 Clarity or Confusion?

Oslo, Norway
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By John Backes
In association with AkuMED

RIGEL
Total Power. Total Trust.

Format

- § Introduction
- § Markets
- § IEC 60601
- § IEC 62353
- § Considerations
- § Recommendations

RIGEL
Total Power. Total Trust.

Rigel Medical

- § Seaward Group (UK) including Clare Instruments, Cropico and Seaward Electronic.
- § Offices in UK and Florida
- § Specialised in the design, development and manufacturing of electrical test equipment.
- § First IEC 601 Electrical Safety Analyser in the 1970's

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Rigel Medical



Rigel 8001
Rigel 233



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Electrical current

- § Closed circuit (ie Live to Earth)
- § Source of Energy
- § Stimulate cells (nerves and muscles)
- § Excess can cause burns in tissue
- § Involuntary Muscle Contraction (Tetanus)
- § Paralyse Respiratory system (heart / lungs)
- § Cause of Ventricular Fibrillation
- § Life saver – Defibrillation – reset heart
- § AC / DC have different effects

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| | |
|-------|--------------------------------|
| 6A | Heart defibrillation |
| 1A | Severe Burns |
| | Heart clamps - no fibrillation |
| 200mA | Severe Risk of Macroshock |
| 100mA | Ventricular Fibrillation |
| | Breathing problems |
| | Muscular paralysis |
| 10mA | Let go threshold |
| | Mild sensation |
| 1mA | Perception of shock |
| | Severe Risk of MicroShock |
| | Ventricular Fibrillation |
| 100uA | |
| 10uA | Risk of Microshock |
| 0uA | Safe |

Howard M. Hochberg, 1971

Importance?



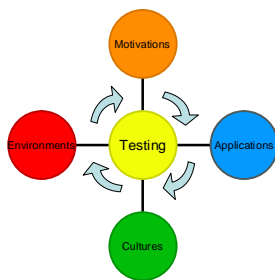
- § Current of 10uA (too small to perceived), can have serious affects on the cardiac rhythm.
- § Patients can be weakened, connected to ME Equipment for a period of time and even anaesthetised.
- § Famous quote:
"If something can go wrong, it will go wrong"

Market sectors



- § Hospitals (public & private)
- § Medical Manufacturers (R&D & Manufacturing)
- § Contract Service (3rd Party & Manufacturers)
- § MOD (Field Hospitals)
- § Education
- § Test Authorities

Testing Needs



IEC 60601-1



- § Design and Type-Test standard (Mandatory)
- § Electrical and Mechanical Safety and Compliance of **Medical Electronic Equipment**
- § Ensure Safety of Patient / User and Environment

ME Definition




- § Treatment, Monitoring or Diagnoses of patients,
- § Single mains connection
- § Physical or electrical contact
- § Transfers energy to or from the patient or
- § Detects such energy transfer to or from the patient.




ME Class




- ⊕ § ME class 1 (Protection relying on fault currents to Earth)
- § ME class 2 (Double Insulated, protection relying on additional insulation)

ME Type




 § Type B - Earth Referenced
 § Type BF – Non Cardiac. Patient Circuit Floating type.
 § Type CF – Cardiac. Patient Circuit Floating type.

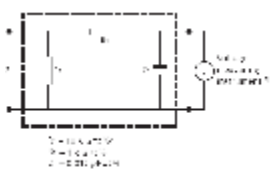
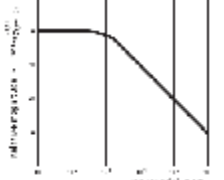
Variants




§ BS / EN 60601
 § AAMI / ES 60601
 § UL 2601
 § AS / NZ 3200
 § CSA C22.2

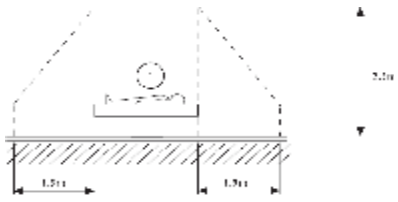
Body Model







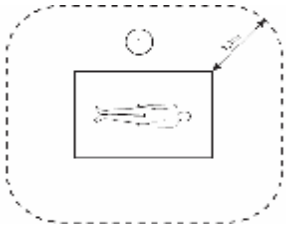
Patient Environment






Patient Environment





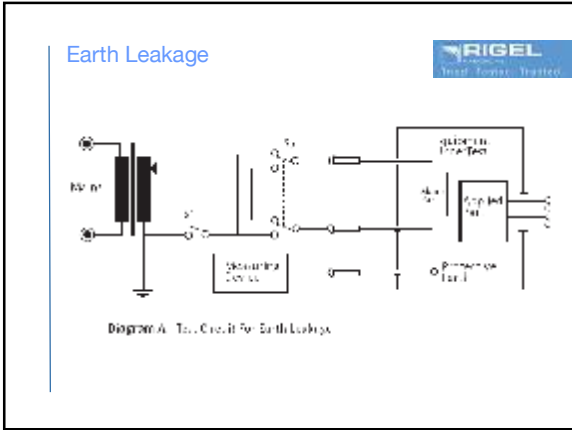
IEC 60601-1 Tests



§ Earthbond Bond Test
 § HIPOT Test (Creepage / Clearance)
 § Leakage Tests (SFC's)

- Earth
- Enclosure / Touch
- Patient (AC / DC)
- Patient Auxiliary (AC / DC)
- Patient type F

 § SIP / SOP SFC



Earth Leakage

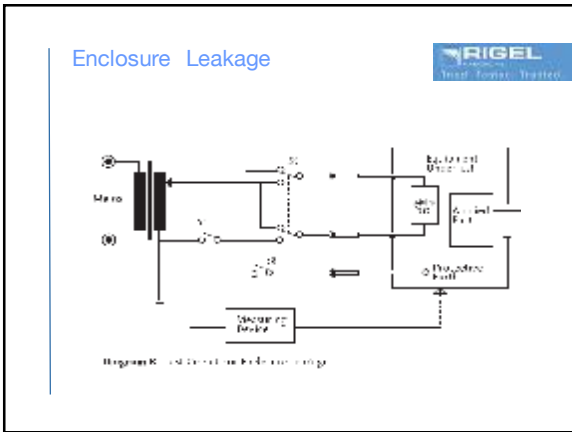
§ Applicable to B / BF / CF (Class 1 only)

§ Conditions

1. Normal Supply
2. Normal Supply, Open Neutral
3. Reversed Supply
4. Reversed Supply, Open Neutral

§ Limits 0.5mA / 1mA (SFC) 2nd edition

§ Limits 5mA / 10mA (SFC) 3rd edition



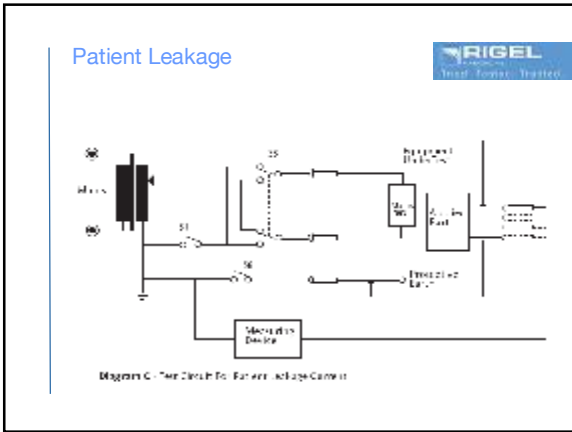
Enclosure leakage

§ Applicable to B / BF / CF

§ Conditions

1. Normal Supply
2. Normal Supply, Open Neutral
3. Normal Supply, Open Earth (Class 1 only)
4. Reversed Supply
5. Reversed Supply, Open Neutral
6. Reversed Supply, Open Earth (Class 1 only)

§ Limits 0.1mA / 0.5mA (SFC)



Patient Leakage

§ Applicable to B / BF / CF

§ Conditions

1. Normal Supply
2. Normal Supply, Open Neutral
3. Normal Supply, Open Earth (Class 1 only)
4. Reversed Supply
5. Reversed Supply, Open Neutral
6. Reversed Supply, Open Earth (Class 1 only)

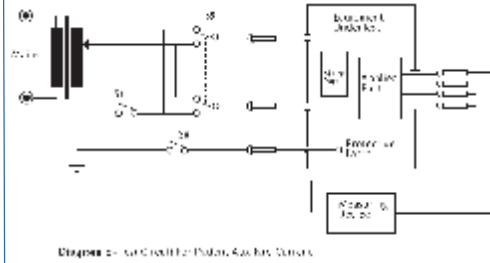
§ AC and DC reading

Patient Leakage



- § Patient Connections shorted within Applied Part for B and BF
- § Patient Connections measured separately within Applied Part for CF
- § Limits B / BF (AC) 0.1mA / 0.5mA (SFC)
- § Limits CF (AC) 0.01mA / 0.05mA (SFC)
- § Limits B/BF/CF (DC) 0.01mA / 0.05mA (SFC)

Patient AUX Leakage



Patient Aux leakage



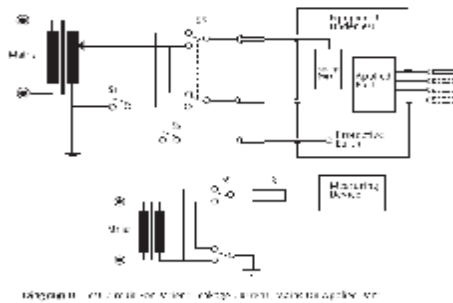
- § Applicable to B / BF / CF
- § Conditions
 1. Normal Supply
 2. Normal Supply, Open Neutral
 3. Normal Supply, Open Earth (Class 1 only)
 4. Reversed Supply
 5. Reversed Supply, Open Neutral
 6. Reversed Supply, Open Earth (Class 1 only)
- § AC and DC reading

Patient Aux Leakage



- § Each Patient Connections to all other Connections shorted within Applied Part
- § Limits B / BF (AC) 0.1mA / 0.5mA (SFC)
- § Limits CF (AC) 0.01mA / 0.05mA (SFC)
- § Limits B/BF/CF (DC) 0.01mA / 0.05mA (SFC)

Patient F-type Leakage



Patient F-Type leakage



- § Applicable to BF & CF only
- § Current Limited to 5mA max at 110% of mains
- § Conditions
 1. Normal Supply, Source Normal
 2. Normal Supply, Source Reversed
 3. Reversed Supply, Source Normal
 4. Reversed Supply, Source Reversed
- § RMS reading

Patient F-Type Leakage



- § Patient Connections shorted within Applied Part for BF
- § Patient Connections measured separately within Applied Part for CF
- § Limits BF (AC) 5mA
- § Limits CF (AC) 0.05mA

Example of Class 1, 10CF



| | | |
|---------------------------|----------------------------------|---------|
| § No of measurements; | | |
| 1. | Earth Leakage | 4 |
| 2. | Enclosure Leakage | 6 |
| 3. | Patient Leakage (6 x 10 x 2) | 120 |
| 4. | Patient Aux Leakage (6 x 10 x 2) | 120 |
| 5. | Patient Type F Leakage(4 x 10) | 40 ± |
| § Total (excl. earthbond) | | 290 !!! |

Example of Class 1, 5BF



| | | |
|---------------------------|---------------------------------|--------|
| § No of measurements; | | |
| 1. | Earth Leakage | 4 |
| 2. | Enclosure Leakage | 6 |
| 3. | Patient Leakage (6 x 1 x 2) | 12 |
| 4. | Patient Aux Leakage (6 x 5 x 2) | 60 |
| 5. | Patient Type F Leakage(4 x 1) | 4 ± |
| § Total (excl. earthbond) | | 86 !!! |

Example of Class 1, 5CF+ 2BF



| | | |
|---------------------------|-----------------------------------|---------|
| § No of measurements; | | |
| 1. | Earth Leakage | 4 |
| 2. | Enclosure Leakage | 6 |
| 3. | Patient Leakage (CF) (6 x 5 x 2) | 60 |
| 4. | Patient Leakage (BF) (6 x 1 x 2) | 12 |
| 5. | Patient Aux Leakage (6 x 7 x 2) | 84 |
| 6. | Patient Type F Leakage(CF)(4 x 5) | 20 |
| 7. | Patient Type F Leakage(BF)(4 x 1) | 4 ± |
| § Total (excl. earthbond) | | 190 !!! |

Example of Class 2, 10CF



| | | |
|-----------------------|----------------------------------|---------|
| § No of measurements; | | |
| 1. | Enclosure Leakage | 4 |
| 2. | Patient Leakage (4 x 10 x 2) | 80 |
| 3. | Patient Aux Leakage (4 x 10 x 2) | 80 |
| 4. | Patient Type F Leakage(4 x 10) | 40 ± |
| § Total | | 204 !!! |

Example of Class 2, 5BF



| | | |
|-----------------------|---------------------------------|--------|
| § No of measurements; | | |
| 1. | Enclosure Leakage | 4 |
| 2. | Patient Leakage (4 x 1 x 2) | 8 |
| 3. | Patient Aux Leakage (4 x 5 x 2) | 40 |
| 4. | Patient Type F Leakage (4 x 1) | 4 ± |
| § Total | | 56 !!! |

What do we most
associate with
IEC 60601-1?



Entering IEC 62353

IEC 62353

- § Recurrent Test and Test After Repair
- § Guideline
- § Electrical Safety
- § Visual Inspection, Bonding, Leakage, Insulation
- § Risk Assessment
- § Record keeping
- § Functional Testing

IEC 62353

- § Not Mandatory
- § Not a replacement of IEC 60601-1-1
- § Not a replacement of Local Standard
- § Does not describe Mechanical Safety or
- § Electro Magnetic Compatibility

Parallel to IEC 62353

- § VDE 0751 (Mandatory)
- § AS / NZ 3551 (Mandatory)
- § HEI95 / MDA DB 9801/2006 (Guidelines)
- § IPPEM (Guidelines)
- § NFPA-99 (Type-Test)
- § ES / EN / IEC 60601-1 (Type-Test)

Best practice



- § Experience
- § Recommendations
- § Risk assessment
- § Manufacturers recommendations
- § Reduced IEC 60601-1
- § AC / DC or just AC
- § 1A, 10A, 25A
- § Mains on Applied Parts destructive or not

Visual Inspection



- § Housing – Enclosure
- § Contamination
- § Cabling (supply, Applied Parts etc)
- § Fuse rating
- § Markings and Labelling
- § Integrity of mechanical parts

Bonding

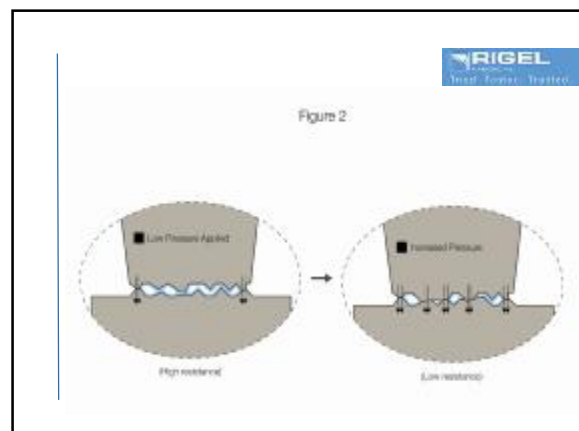
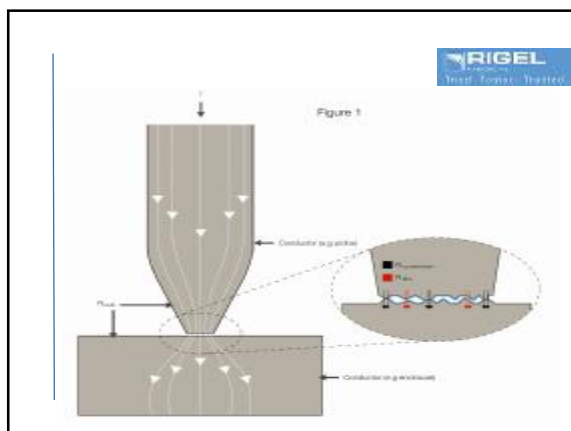


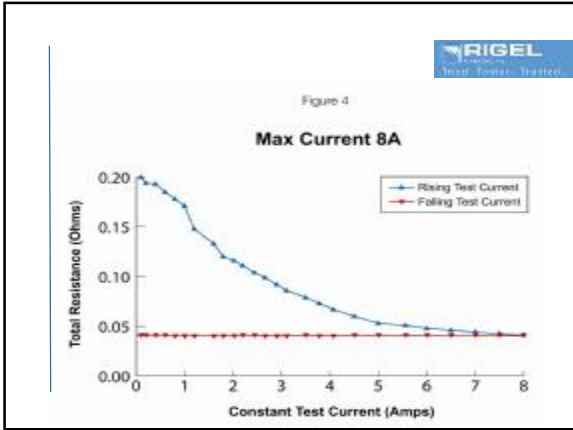
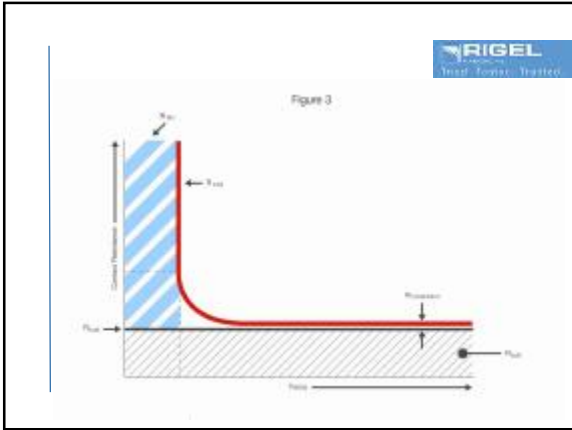
- § Minimum 200mA AC / DC into 500m Ω
- § Reversed Polarity for DC
- § Maximum 24 V o.c. voltage
- § 300m Ω

Considerations



- § High Test Currents (10A or more)
- § Low Test Currents (<8A)
- § Contact Resistance

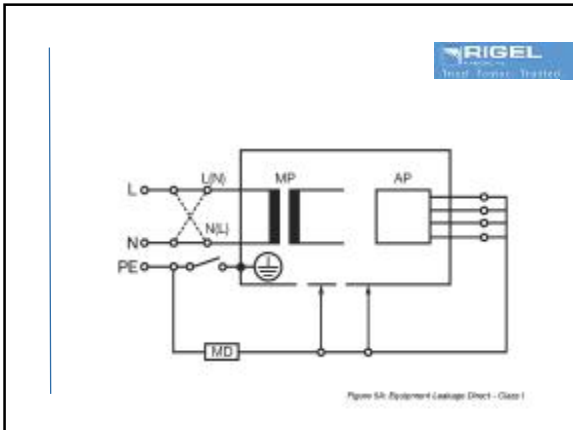




- Insulation**
- § Optional Test
 - § Equipment Breakdown
 - § Mains Parts to Earth / Ground
 - § Applied Parts to Earth / Ground
 - § Applied Parts to Mains (F-type only)
 - § 500VDC

- Leakage**
- § Equipment Leakage
 - § Applied Part Leakage
 - § Different Methods
 - § Common Patient Connections
 - § Total Leakage
 - § Compare

- Equipment Leakage**
- § Total leakage deriving from the AP's, Enclosure and Mains Parts combined to real Earth.
 - § Class I and II.
 - § B, BF and CF equipment.
 - § All Patient Connections / AP's shortened
 - § RMS value.



Considerations

- § Direct Method
- § Differential Method
- § Alternative Method
- § Repeat Failed Tests (individual AP's)
- § Repeat Failed Tests (individual PC's)
- § Compare results (Trends)



Applied Part Leakage

- § Total leakage of Patient Connections (AP) to Earth, (non) conductive parts on the enclosure.
- § Fault condition Mains on Applied Parts.
- § 3.5mA limited @ mains frequency.
- § Floating type (BF & CF), Class I and II.
- § Group Patient Connections of single function.
- § Excluded AP's left floating
- § RMS value

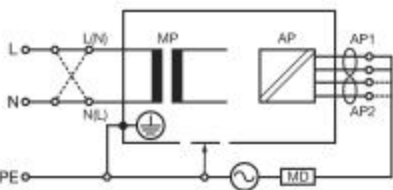


Figure 53. Applied Part Leakage Direct - Class II

Example of Class 1, 10CF

- § No of measurements;

| | |
|-----------------------------------|---|
| 1. Equipment Leakage (Dir / Diff) | 2 |
| 2. Applied Part Leakage (Dir) | 2 |
| § Total (excl. earthbond) | 4 |
- (vs 290 in IEC 60601!!!)



Example of Class 1, 5CF +2BF

- § No of measurements;

| | |
|-----------------------------------|---|
| 1. Equipment Leakage (Dir / Diff) | 2 |
| 2. Applied Part Leakage (Dir) | 4 |
| § Total (excl. earthbond) | 6 |
- (vs 190 in IEC 60601!!!)



Example of Class 1 or 2, 1B

- § No of measurements;

| | |
|-----------------------------------|---|
| 1. Equipment Leakage (Dir / Diff) | 2 |
| § Total (excl. earthbond) | 2 |

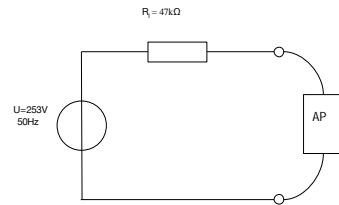


Considerations

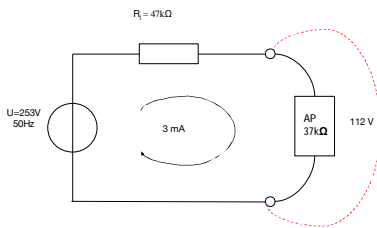
- § Direct Method
- § Alternative Method
- § Touchable Mains Voltage
- § Repeat Failed Tests (individual PC's)
- § Compare results (Trends)



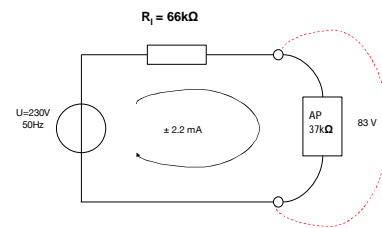
IEC 60601 F-Type



IEC 60601 F-Type



IEC 62353 Applied Part Leakage



IEC 62353 mains compensation

$$(230V / 83V) \times 2.2 \text{ mA} = 6 \text{ mA}$$



60601 vs 62353

Type BF limit = 5mA

Result (60601) 3 mA (PASS)

Result (62353) 6 mA (FAIL)



Methods

- § Direct Method
- § Differential Method
- § Alternative Method

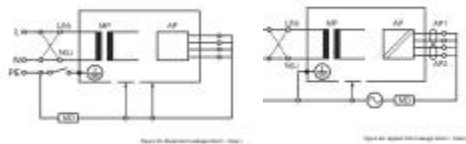


Direct Method

- § True Leakage to Earth through MD
- § Direct comparison IEC 60601-1.
- § AC and DC leakage current.
- § Highest accuracy

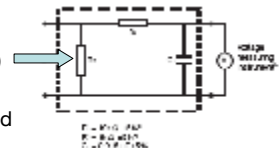


Direct Method



Considerations

- § Ground Interrupted
- § The 1kΩ resistor (MD)
- § Secondary Earth path
- § Polarity of the Live and Neutral
- § TN (Terre – Neutral) system



Differential Method

- § I_{Δ} Phase – Neutral.
- § Total equipment leakage current.
- § Impartial to Secondary Earth connections.
- § Protective Ground Intact. (no 1KΩ)
- § Safer working practice.



Considerations

- § Relatively in-accurate (<100μA).
- § External magnetic fields.
- § High current consumption of the DUT.
- § Limited frequency response <20Hz
- § Polarity Phase – Neutral
- § AC only



Differential method

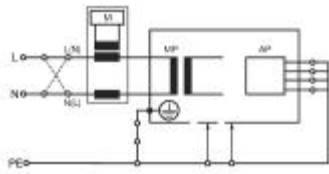


Figure 16 Equipment Leakage (Differential) – IEC 60601

Alternative method

- § Similar to a Dielectric Strength Test
- § Current Limited Mains potential / frequency.
- § Polarity not applicable (P-N short)
- § TN-System not applicable
- § Secondary Earth not applicable
- § Battery powered instrument.
- § Highly repeatable
- § Breakdown of dielectrics

Considerations

- § Current limiting resistor.
- § Measuring voltage is dependent on the test load.
- § Measured leakage current is scaled
- § Equipment is not be activated
- § Not directly comparable with IEC 60601.

Alternative method

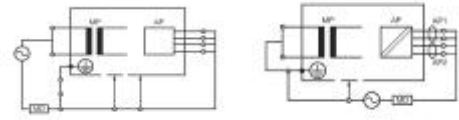


Figure 17 Equipment Leakage (Series) – IEC 60601

Figure 18 Equipment Leakage (Shunt) – IEC 60601

Record Keeping

- § Paper based or Electronic?
- § Structured
- § Protocols
- § Comparing data
- § Trends
- § Scheduling
- § Traceability
- § Peace of Mind

Summary & Considerations

- § Which IEC 62353 methods meet my requirement's
- § Are my Test Instruments compatible?
- § Install Base or New Equipment only?
- § Updating and Communicate Service Procedures / Manuals
- § Is further Training Required?
- § Record Keeping

What can 62353 do for me?



- § Geared-up to meet future trends
- § Follow manufacture's recommended tests
- § Save Time & Money,
- § Increase effectiveness
- § Advocates safe working practise
- § Increases flexibility

What Can Rigel Offer You?



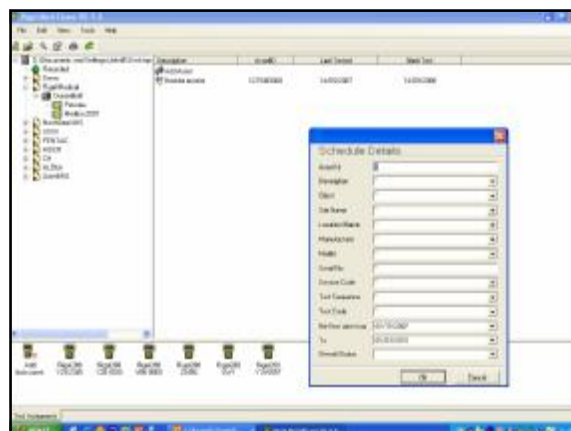
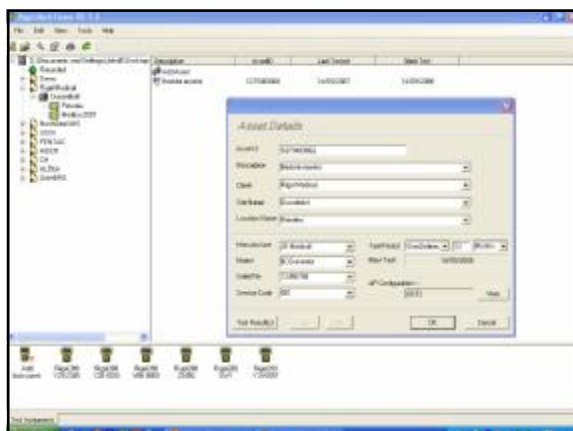
- § Rigel 288 - Hand-Held ESA
- § IEC 60601-1 & IEC 62353
- § 1.7Kg
- § 10 Patient Connections
- § Full / Semi Automatic
- § New Earthbond Technologies.
- § BlueTooth Communication

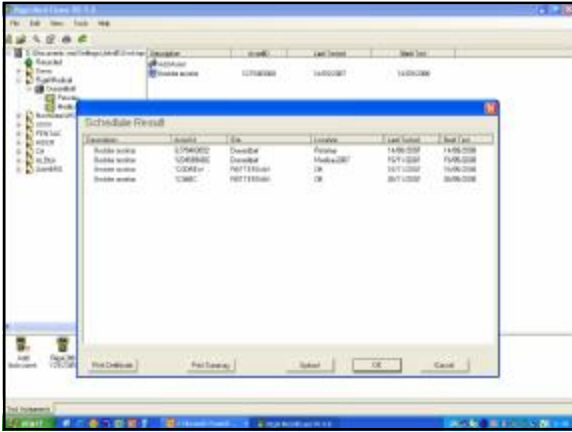


Rigel 288



- § Customer Test Sequences
- § Battery Power
- § PC Up and Download Software
- § Bar code scanning
- § Result printing
- § Barcode pass fail printing







Thank you for your interest

- § Any Questions?
- § Free Booklets Available
- § Demo Rigel 288

