



by Ron Evans, Datrend Systems Inc.

All About Electrical Safety Testing and Leakage. As a biomed technologist, are we performing excessive electrical leakage testing on medical equipment? When is the last time you found medical equipment with high leakage?

This was a one day seminar held in Moncton, NB.

## In this Article

- [Photos from this session](#)
- [Presentation material Used by Ron Evans](#)
- [Notes from the afternoon discussion session](#)
- [Datrend Products Information](#)
- [Ron's outline of his presentation](#)

## Photos From the Session

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## Presentation Material

Click on the link below to download Ron's material in Power Point format.

[Electrical Safety Testing and Leakage Currents](#)

## Group Discussion

In afternoon those present were broken into groups that discussed electrical safety testing its relevance and what level of documentation is required and of benefit. This was done by

answering a list of questions posed by the organisers. Below are notes from the follow-up session where the groups answers were compared

These notes were recorded by Jeremy Dann

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## **Question 1: Should we be recording leakage values?**

Answers from break out groups

- 1) Yes – good for investigations and trends
- 2) No/Yes couldn't agree
- 3) Pass fail only – no values
- 4) 50% in the group were recording – suggest Pass/Fail is good enough
- 5) 50/50 Split – okay with Pass/Fail only but worried about legal implications
- 6) Data capture depends on Automation – Those capturing it Manually use Pass/fail which is okay
- 7) Yes and No – Pass/Fail only works but keep old data
- 8) No
- 9) Pass and fail

Consensus discussion following – Pass/Fail is all that is truly required.

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## **Question 2: Are we analyzing Leakage Data?**

Answers from Break out groups

- 1) No
- 2) No
- 3) No – don't collect it
- 4) No
- 5) No – only in case of failure
- 6) No

- 7) No
- 8) No
- 9) No

Consensus discussion following – services do not analyze the data they collect.

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### **Question 3: Should we test leakage current. If so to what standard?**

- 1) Yes – to European standard (Not adopted in Canada) - ISO62353
- 2) Yes – because we don't analyze it
- 3) Yes – 60101
- 4) Maybe – after repair and Incoming Inspection
- 5) Yes – we can prevent 1% failure rate – 60101
- 6) Yes - 62353 (**See Note1**)
- 7) Yes
- 8) Yes – to today's most up-to-date Canadian Standard
- 9) Yes

Consensus discussion following – We should test leakage – how and to what standard no consensus

**Note1 – ISO 62353 Medical electrical equipment** – Recurrent test and test after repair of medical electrical equipment.

Standard must be purchased (online options exist) See introductory pages here - [http://webstore.iec.ch/preview/info\\_iec62353%7Bed1.0%7Db.pdf](http://webstore.iec.ch/preview/info_iec62353%7Bed1.0%7Db.pdf)

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### **Question 4: Can we work together in Atlantic Canada and come to consensus on Leakage testing?**

- 1) Yes – it would be a good thing
- 2) Nice idea – won't work
- 3) No – need Canadian consensus

- 4) No – we need external help
- 5) No
- 6) Not Likely – different test equipment in different locations
- 7) No – we should but can't
- 8) No because we are not meeting provincial even
- 9) No

Consensus discussion following – We should, but are unlikely reach a consensus.

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## Datrend Products

In addition to a full featured electrical safety analyzer Datrend Systems Inc. manufactures, carries and supports a specialized line of quality manufactured Biomedical Test Instruments used around the world for Electrical Safety Analysis, Test Automation, Infusion Device Analysis, Defibrillator/Pacer Analysis, Pulse Oximeter Analysis and Patient Simulation.

In a world where Fluke Biomedical has increasingly bought out all the competition it is nice to see a company continue to release innovative products.

Datrend products are available in Canada from Carestream Medical Ltd.

[Click here to visit the Datrend Website](#)

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[Click here to download a scanned copy of a Carestream/Datrend Product Flier](#)

## Presentation Outline

## 1. Standards, Regulations and Leakage Current

- Standards versus Regulations
- CSA versus Health Canada
- Health Canada versus FDA versus IEC
- Why do we do leakage current measurement (from a legal point of view)?
- Perception versus reality
- Canadian Electrical Code
- Provincial Regulations – Department of Public Safety
- Hospital Accreditation

## 2. Safety Standards

- What Standards are relevant
- What Standard to use?
- What are the differences?
- Why are there so many Standards?
- Canada versus USA versus EU and the rest of the world
- Will discuss:
  - C22.2 No 125
  - Risk class 1, 2, 2G and 3
  - Leakage current limits for each risk class
  
- CSA 601 Classification (protection against electrical shock)
  - Class I
  - Class II
  - Internally powered equipment (battery or battery packs)
  - Degree of protection against electrical shock
    - Type B Equipment
    - Type BF Equipment
    - Type CF Equipment
  - Clarify the difference between Medical Device Classification (Health Canada) and Degree of protection from electrical shock (CSA).

**3. Particular leakage Current Tests<sup>20</sup>**

- Why do we do leakage current measurement (from a clinical point of view)?
- What is a safe level of leakage current?
- Types of leakage current: Earth leakage current, Touch/Chassis (Enclosure) leakage current, patient leakage current, patient auxiliary current
- We will discuss:
  - Diagrammatic representations of the different leakage measurements
  - Leakage current measurement conditions (normal conditions and single - fault conditions)
- What are internal leakage measurements and are they necessary? Is this just another name for ground wire or earth leakage?
- Is an open neutral leakage measurement necessary? Why or why not?

**4. Group discussion**

As a biomed technologist, are we performing excessive electrical leakage testing on medical equipment?

**5. Open Q & A session**

{jcomments on}