

Challenges in the development of standards for condoms

Graham Holloway

Chair: ISO/TC 157 “Mechanical contraceptives”

Scope of ISO/TC 157: “Mechanical contraceptives”

- IUD's
- Diaphragms (rubber, silicone)
- Male condoms (latex rubber, synthetic)
- Female condoms ?
- Tubal occlusion devices ???

- All = medical devices

Male condoms

- Old concept (1400 BC) - users' need for protection
- New interest (quality, new diseases, materials, technology)
- Until relatively recently, little research
- Old-established and new manufacturers
- Old stakeholders: manufacturers, users, test houses
- New stakeholders: consumer orgs, regulators, procurement and social marketing agencies, WHO, sex workers

The challenges: 1

- Fitness for purpose - balancing needs of manufacturers and consumers
- Standard has to facilitate regulation
- Prequalification of suppliers is insufficient:
 - **Lot-by-lot inspection necessary**
 - **Not merely lab testing of finished product**
- Mass-produced, cheap articles, made from natural materials
- Is any level of failure acceptable ?
- What constitutes failure anyway ?

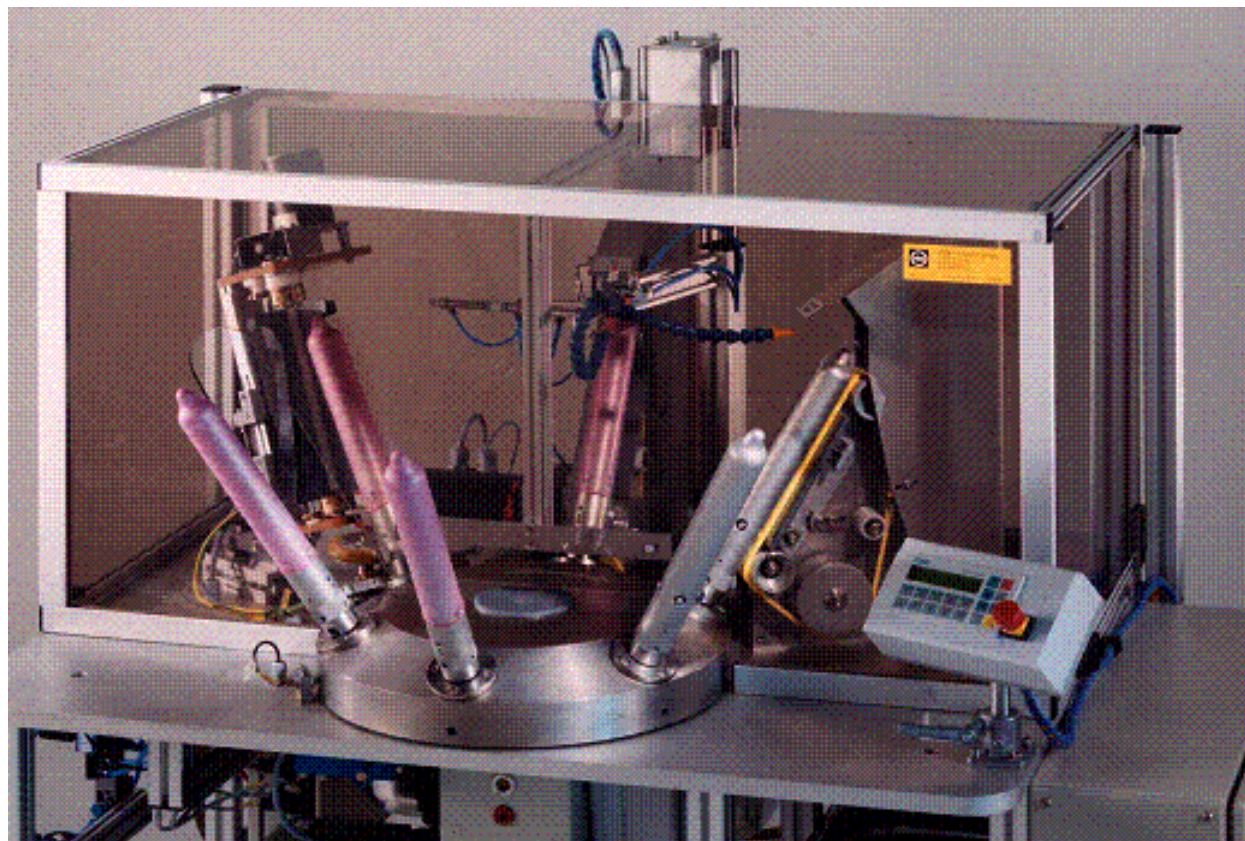
The challenges: 2

- Greatest need is where affordability is least
- Potential users need to be convinced - degree of protection vs impairment of sexual satisfaction
- Research going on on all fronts - how often should the standard be revised ?
- The standard must be used !

Getting technical ...

- Detection of holes (filling with water, electrical conductivity)
- Overall film quality - air burst P, V
- Packaging - air ingress damages latex film
- Shelf life / stability: need for real time data
- Pre-clinical and Clinical investigations
- Effect of additives (spermicides, lubricants)

Dry (final) electrical leak testing



Bank of leak testers



Air burst test



The future ...

- New materials, totally different properties
- New designs, additives, flavours, etc.
- Time and cost of testing becoming a factor
- More data needed on aging, stability
- One standard, accepted and understood by all

Thank you !

