

"ENERSOL Software is now more secure and provides a higher level of traceability."

*- Jason Shelley,
ENERSOL Programmer*

All ENERSOL software now includes:

- Time stamping*
- User identification and passwords*
- Access levels*
- Electronic signatures*
- CRC 32 checksums*



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ENERSOL Software - Enhanced Security

Enersol's testing and reporting software is now available with powerful security and data audit tracking features. Designed to safeguard data integrity, these features are invaluable for those who need to meet the requirements of FDA 21 CFR Part 11. These new features include user authorisation, electronic signatures, time stamping and checksums. Currently no other similar software on the market provides this level of security.

The requirements of US CFR 21 Chapter 11 on Electronic Records and Electronic Signatures states that records and signatures executed electronically should be equivalent to paper records and hand written signatures.

The regulations say the aim is to permit the widest possible use of electronic technology. It also permits greater traceability with an audit trail including time stamping and sequences of events. Audit trails are important security measures to ensure trustworthiness and the reliability of the records.

Authorisation with user access levels

Enersol has introduced user identification and passwords to all of its software, which limits system access to authorised individuals.

Different levels of access ensure only trained and authorised staff can maintain the electronic system, perform testing or calibration. The users identify themselves with a password and an electronic signature ensures their identity is correctly recorded in the electronic files.

Higher level of traceability with electronic signatures and time-stamping

Electronic signatures are intended to be the equivalent of handwritten signatures, initials, and other general signings. All data and menu choices are recorded and time-stamped in the electronic files with the users electronic signature. This provides a higher level of traceability than any other similar software on the market.

Anti-Tampering using checksums

Checksums provide a level of confidence in detecting file corruption and prevent files from being edited. Checksums also ensure that the data in the file came directly from the testing machine.

Files created by Enersol software are now protected by a CRC 32 checksum.

If you are a user of **ENERSOL** equipment and you require these features please contact **ENERSOL**.

ENERSOL Engineer visits Kyrgyzstan

Senior Engineer, Qing Hua Tan recently returned from a visit to Bishkek, Kyrgyzstan, a small ex-soviet country west of China. Her visit was to a government laboratory with UNFPA support, based in the Kyrgyzstan capital.

Enersol was called upon to repair a condom leaks tester that was purchased from a different manufacturer and to train staff in leaks testing.

The lab reported the leaks tester was faulty from the time of delivery and very difficult to use.

\$8 million in funding for Yulex

Yulex was founded in 1997 with headquarters in California and commercial farms across the south west of the United States,

Yulex holds a licence from the US Department of Agriculture to produce latex from guayule (why-you-lee) according to US Department of Agriculture patented processes.

The Californian natural rubber latex company has just signed a deal with Argonaut Private Equity that has gained Yulex an \$8 million boost in funding.

According to the company, the raised capital in this round has brought the total raised capital to US\$12.5 million.

Thorough clinical tests on guayule, a south western desert shrub, has shown it retains the same qualities of natural latex from the Brazilian rubber tree but is hypoallergenic to health care workers and others sensitive to rubber latex.

It is reported the \$8million in funding will be used to expand the guayule plantation and production plant in Maricopa, California.

HIV Infection Rate drop - Encouraging

Zimbabwe officials have described the fall from 24.6% to 20.1% in the number of adults in Zimbabwe infected with HIV in the last 18 months as very encouraging. They admit the country is still a long way from containing the pandemic.

According to the latest census 1.16 million Zimbabweans in the 15-49 age group are infected with HIV, while 3, 000 people die of AIDS - related illnesses every week. The officials say that if the infection rate had continued at the 2003 level this figure would have been much higher.

ENERSOL Interlaboratory Trials

The Interlaboratory trials of condom and glove testing laboratories as organised by Enersol are a service to testing laboratories and the community in general.

It is intended that the participants compare their own results with the consensus figures (or expected results, for some tests), in conjunction with reading the report. In this way they can identify possible problems with their technique or equipment and take remedial action if necessary. In order to safeguard the anonymity of the labs, they are identified only by a code number. Laboratories in the Enersol trial can compare their own results against up to 75 other laboratories participating in the trial. We have recently learnt that some laboratories are spending up to 4 hours on a test for freedom from holes for the Enersol trial with just 100 samples! Perhaps this is to ensure they find the highest number of holes, but this does not in fact reflect how their work would normally be conducted, nor whether the holes they find would normally be detected using the accepted method. As the aim of standard test methods is to test in an agreed way and try to get reproducible results, over-testing is not productive.

The Enersol Interlaboratory trials were never intended to be used for advertising or self promotion but a condom testing laboratory has made the claim that its interlaboratory trial results show the lowest standard deviations in the test results. The claim appears to be made to enhance the image of both the testing lab and the equipment it produces. The 2004 Enersol condom trial results do not support the claim.

Pioneer Condom Maker At ISO Meeting

Mr. Hermann Richter was a guest at the closing dinner of the ISO TC 157 meeting in Berlin. Mr. Richter's father, Emil, started condom manufacturing in Erfurt, Germany in the 1920s.

The factory in Erfurt was nationalised directly after the second world war by the East German Government. Hermann Richter moved to Sarstedt, near Hannover and began to develop the first automatic latex dipping line in Germany, in cooperation with two English engineers and their company called EMD.

After German re-unification, the Erfurt factory went through a number of changes of ownership and is now Condomi. Mr. Richter also developed (with EMD in Kitzbuehel) a high voltage dry testing machine for condoms in 1959. He formed a company named "Rubion" in Sarstedt in 1960, to produce condoms for the major German condom brands and suppliers. In 1979 the factory was sold to the London Rubber Company.

The production of condoms at LRC Sarstedt was closed in the 1990s and the machinery was transferred to other LRC factories. Then Mr. Richter and his son Klaus and a trading company formed "C.P.R. Produktions- und Vertriebs GmbH" also in Sarstedt.

The style of dipping machine developed by Mr. Richter is compact and easy to install but has relatively low capacity per machine. The design concept is today used by machine manufacturers including SSL (formerly London Rubber), Döka, CPR, and of course Richter Hi-Tech in Malaysia, which is co-owned by Mr. Richter's son, Klaus. Thus this concept accounts for a significant proportion of the condom dipping machines in the world today. Similarly, dry high voltage electronic testing now has at least equal popularity with the older wet testing method. Mr. Hermann Richter still lives near Hannover.

German firm to distribute for Polar Pharma

Polar Pharma India Ltd has just signed a memorandum of understanding with the German based Makro Medien-Dienst (MMD) to distribute its branded condoms in Europe.

The Orissa based Polar Pharma India Ltd has told the Bombay Stock Exchange that MMD will be the exclusive distributor of the company's products in Germany and other neighbouring European markets.



Cabbies may hand out free condoms

Taxi drivers in the Welsh capital of Cardiff may hand out free condoms to clients following a rise in the level of sexually transmitted disease in the country.

Drivers would hand out Trojan condoms to those passengers who request condoms on Thursdays, Fridays and Saturdays after 10.30pm.

A six-week pilot scheme called "Safe Ride Home" in Brighton - where cabbies gave thousands away has been described as a success.

The spokesperson for Trojan, Neale Hunt, said a number of taxi companies across the UK had shown interest in the scheme.

Durex sales grow

Durex condom maker SSL International PLC expects sales for the first half of the financial year to (Sept 30) to have grown 7% in line with its previous forecasts.

The company said it remains on track to make "substantial progress" this year towards its target of doubling 2004 reported operating profits by 2007.

Durex condoms in America and Eastern Europe, and the rollout of its Scholl Party Feet product into Continental Europe have driven the company's increased performance.

The rationalisation of its Scholl footwear range to focus on more profitable products has, as expected, dented sales, the company said in a trading statement. Locally owned brands have also declined slightly, it added.

The remainder of the business, comprising of unbranded condoms, third party brands and third party supply achieved increased sales compared last year.

ISO Condom Committee Meets

By John Gerofi with assistance from Alison Arnot-Bradshaw

ISO TC 157 held a marathon meeting from September 1 to September 9, in Berlin. Nine of the existing working groups (WG's), plus the Chairman's Advisory Group met.

WG 3 (IUDs) was unable to make any progress as a systematic review of IUD efficacy is still underway. The principal matter to be discussed is the proposal to require a target maximum pregnancy rate of 1% instead of the 2% previously required. A presentation was given about the copper levels in the blood of women using TCU380A. It was thought that the study raises more questions than it answers, as it is not known what level of copper can be considered toxic.

WG 10 (inflation) discussed ways of including a wider range of sizes in the requirements of the standard. A brand of condoms with 55 sizes has been on the market for about a year, and it is impossible to do the ISO 4074 tests on some of the sizes. WG 10 also re-considered the details of the collar retaining the condoms on the inflation tester, and the effect of temperature on the results of the inflation test.

WG 13 (shelf life) received new data comparing real time and accelerated stability studies. Overall, most studies indicate that tests at 50°C are reasonably predictive of real time trends. Studies at 70°C are relatively poor predictors of real time trends. Relevant parts of the standard will be amended accordingly. There was a proposal to stipulate what is to be done in case of oven failure during testing.

WG 14 (guidance on use of ISO 4074) met, but decided to postpone further work so it could be harmonized with the new edition of ISO 4074. The present version of the guidance document has been accepted for publication.

WG 15 (effect of lubricants and medicines) reviewed data from its previous trial, and decided to base any future test on the tensile test. Further tests will be done in two labs to try to improve the reproducibility of the tests. The aim of the test was confirmed as being for substance manufacturers to test the effect of their product on condoms. The onus is on the manufacturers of the topical products to assess if they are compatible.

WG 17 (synthetic male condoms) discussed comments received on the draft standard that was circulated. There was a resolution to establish a task group within WG17 to draft a proposal for airburst requirements. A new CD will be put together incorporating the comments.

WG 18 (female condoms) is still at an early stage of its work, and a subcommittee is now working on appropriate tests. The structure of the standard is likely to follow the pattern being used for synthetic male condoms by WG 17.

WG19 (Methods for hole detection) was presented with information on the reliability of the electrical test versus the rolled water test and on the sensitivity of the electrical test and a modified electrical test. The previously planned study on improving the electrical test will still go forward. The WG requested a proposal for defining fill levels for condoms on the leaks test from 'They Fit/Condomania'.

WG20 (Clinical trials) is continuing the development of a clinical study guidance document for the evaluation of the slip and break attributes of condoms made from synthetic materials. The study protocol will be based on non-inferiority not superiority. The WG will also begin development of a clinical study guidance document for the evaluation of all of the failure modes of female condoms.

There were two special sessions. The first was from researchers at the University of Indiana, and related to the acceptability, breakage and slippage of "They-Fit" condoms. The second was from Dr White, of SSL, about the breakage of condoms in simulated intercourse.

53rd meeting of TC45 - Rubber Products

The 53rd meeting of TC45 was held in San Francisco from October 24 to 28. Of particular interest to Enersol's clients and friends is the work being done in SC3 (raw materials), and SC4 (products).

SC3/WG2 has been working on a standard for the determination of residual powder on medical gloves, both for powdered and powder-free gloves. This year an interlaboratory testing program was conducted by Enersol in which 13 laboratories participated. The resulting Precision Statement will be included in the draft standard and it will be circulated for voting as FDIS 21171 in 2006.

SC4/WG5 discussed 3 matters of interest. First, changes to the width sizes were discussed at last year's meeting as some manufacturers are having difficulty meeting the tighter requirements of the 2003 version of ISO11193. There was no progress in introducing these changes into the standard during 2005, and it will be circulated as an amendment in 2006.

SC4/WG5 also discussed a new work proposal for general purpose gloves, but the working draft presented to committee members during 2005 required many changes and has been returned to the project leader for redrafting. It will be circulated as CD in 2006.

Finally, Part 2 of ISO11193 (for vinyl gloves) had been circulated during 2005 and was unanimously approved by the member countries. It will be circulated with some editorial corrections as FDIS in 2006.

American majority support birth control & overseas aid

An online poll of 2,242 U.S. adults by Harris Interactive between September 6 and 12, 2005 found that condom use to prevent HIV and other sexually transmitted diseases is supported by 92% of adults, including 93% of Catholics, 82% of born-again Christians, 83% of the "very religious" and 81% of Evangelicals.

It also found that 87% of the public supported sex education in high schools and the funding of international HIV prevention and treatment programs, although only 76% of born-again Christians, 77% of the "very religious" and 72% of Evangelicals supported the former, while 82% of all religious categories supported the latter.

Seventy per cent of the public supported the funding of international birth control programs, 66% of Catholics, 53% of born-again Christians and 48% of Evangelicals.

Poll organisers said it was "interesting" that the attitudes of Catholics were generally very similar to those of all adults and, on some issues, very unlike the official position of the Pope and the Church. Your contributions are welcome...

Do you like the new look newsletter? What changes would you like to see? Your contributions are welcome. The ENERSOL International Newsletter is produced by ENERSOL Consulting Engineers as a service to the latex industry. If you have any news or views you would like to contribute please send them to us by e-mail to jgerofi@enersol.com.au or by fax to +61 2 9552 1709

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ENERSOL... Just Visiting

We would like to thank our many visitors with this new feature in our International Newsletters.

Chinese Delegation

In September Enersol was visited by a large delegation of Chinese officials from Population and Family Planning Commissions and Contraceptives Supply Stations from provinces across mainland China.

Their visit to Australia included a meeting with Enersol's Gergaynia Shelley (General Manager), Grace Iskander (Laboratory Manager), Lisa Henretty (Admin/IT) and Xiaoli Yin (Engineering Assistant) to discuss quality testing and Enersol laboratory testing equipment. The meeting included an informative slide show about the importance of condom testing, the quality process and Enersol's products, services and personnel.

Joseph L Morris (top, right)

In August, South African condom importer Joseph Morris from BARR Pharmaceuticals toured Enersol. The purpose of his visit was to see Enersol's laboratory and testing equipment.

Steffen Bodemeier (right)

On a recent tour of Australia, Dr Steffen Bodemeier of CPR Produktions und Vertriebs GmbH Germany visited Enersol and Dr John Gerofi.

CPR have recently acquired a significant interest in the condom production facility of Vulkan in the Czech republic. The condom factory had been split off from other Vulkan activities. CPR plans to consolidate dipping at its Sarsted headquarters, but do testing and packing at the former Vulkan factory.



FDA draft guideline on condom labeling

The USFDA has given interested parties until February 13th 2006 to comment on a draft guidance document for the proposal for labeling of natural rubber latex condoms.

The amended classifications would apply special control guidelines for the labeling of latex condoms, with or without spermicidal lubricant. In conjunction with the general controls for condoms, the FDA believes the controls will provide a reasonable assurance of condom safety and effectiveness. The labeling recommendations reflect a review on the part of the agency, National Institutes for Health (NIH) and Centers for Disease Control and Prevention (CDC). The draft also includes issues requiring special controls related to nonoxynol-9 (n-9).

The proposal is connected to attempts by Senator Coburn to cast doubts on the effectiveness of condoms. The proposed labeling is lengthy, complex and likely to discourage condom use. US condom suppliers should study it carefully and make written submissions to the FDA via the Division of Dockets Management (HFA-305) in Rockville, MD or electronically via <http://www.fda.gov/dockets/ecomments> with docket ID 2004N-0556.

PATH press release...

Experts examine female condom evidence and chart road for the future

Contact: Ellen Cole, ecole@path.org, tel +1 206 285 3500

Seattle, October 14, 2005—The female condom has tremendous potential to improve the health of women, and yet 12 years after it was first introduced, use is still low. Experts from 15 countries convened in Baltimore, MD, September 26 to 29 and agreed on a plan to accelerate access to and use of the female condom in developing countries.

During the three-day Global Consultation on the Female Condom, experts reviewed evidence of the female condom's effectiveness in preventing pregnancy and sexually transmitted infections (STIs) and learned about countries' program experiences. Unpublished data from WHO studies presented at the conference confirm that the female condom is as effective as the male condom in preventing pregnancy, while other data suggest that making female condoms available can reduce HIV and other STIs.

Limited use of male protection in Fiji

A study of family planning in the Fiji Islands shows that there is limited use of male protection methods. According to Women and Men of the Fijis Islands: Gender Statistics and Trends, a publication from USP lecturer Dharma Chandra and government statistician Vasemaca Lewai, only 13% of men used condoms and 0.2% underwent a vasectomy. The authors said that the use of condoms by young people was believed to be increasing as a result of vigorous education campaigns on sexually transmitted infections, including HIV/AIDS.