



# International Newsletter

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## New features improve the Enersol Inflation Program

*At Enersol our policy is to continually develop our equipment*

Enersol's latest upgrade to its Inflation Program (version ....2.11) has several new features, including:

1. Improved checksumming security, to make tampering with data very difficult;
2. A more user-friendly report format, enabling users to insert information of their choice in the printed documents; and
3. A new control chart - PCI (Process Capability Index). This innovation was suggested by an Enersol client.

Enersol's Inflation System is the only one that provides a high level of data security.

"We welcome suggestions from our clients and we take them very seriously," said Enersol's Managing Director, Dr John Gerofi.

"They are carefully reviewed before deciding to include them in a program upgrade." Enersol's maintenance clients receive new versions free of charge.

All updates are thoroughly tested on Enersol's in-house machines before release. To manage the amount of checking required, the company limits upgrades to no more than 2 a year.

"If we receive a suggestion that is only relevant to one or two clients, we may offer to quote the price of a customised version of the software as part of our Enersol client service program," said Dr Gerofi.



### Ultra-fast Leaks Tester

ENERSOL's Ultra-fast Electrical Leaks Tester is a convenient and efficient unit. It is compact and extremely rapid to use, has five heads, and can be safely and comfortably operated by one person. It operates on the principle of conductivity. The condom is filled with a conductive solution and is dipped in a bath filled with a similar solution. The condom acts as an insulator separating the two solutions.

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**ENERSOL CONSULTING ENGINEERS** PRODUCTS AND SERVICES FOR TESTING MEDICAL DEVICES

235 Nelson Street Annandale NSW 2038 Australia Tel: +612 9552 1707 Fax: +612 9552 1709 Email: gshelley@enersol.com.au

## Special Report

# Pre- and post-shipment testing

## *A look at the arguments for and against*

By Dr John Gerofi

**B**ulk purchasing of condoms was started by USAID, and later taken up by WHO, UNFPA and social marketers.

After complaints about condoms delivered to some countries, especially in Africa, WHO contracted with PATH to set up condom testing labs in 10 African countries in 1990.

Ultimately, only nine of these labs were ever installed - even though they were offered free of charge - and most failed to function effectively in the long term. But some did work, and in some cases detected poor quality condoms.

When WHO started bulk purchases of condoms for GPA, it decided to have every batch tested before acceptance, a policy taken on by UNFPA and by social marketing organisations like PSI. This process has functioned successfully for many years.

### Quality issues

Most recipient countries accepted condoms bought under these arrangements, and the rate of user complaints appeared to be quite low compared with earlier systems. Of the nine WHO-funded labs in Africa, only two continued to work intensively in the longer term, while another was revived by a social marketing organisation.

Over the last two years, some issues on condom quality have arisen in Africa, and interest in testing condoms received from donors has increased. There are two principal reasons:

1. World Bank policies. In the past, condom procurement was done centrally by a few organisations. When it entered AIDS prevention the Bank offered money directly to individual countries and encouraged them to do their own purchasing. With World Bank funds, some countries may choose to do their own testing as well.
2. Changes to the ISO standard. The 2002 issue of the standard was the first

to stipulate explicitly that condoms must comply until the expiry date. Until then, the situation with condoms already in the distribution chain was unclear. Several authorities were using an approach promoted by PATH, called the CQI, to determine the acceptability of condoms in the distribution chain. The CQI is based on burst volume and is more forgiving than the ISO standard. Some in-country tests revealed condoms which ceased to comply with the standard before their expiry dates. This did not necessarily mean the products were unsafe to use (we actually don't know). In fact, the *a priori* assumption that condoms would meet the standard long after acceptance was never tested before the standard was accepted, and was never previously imposed in hot countries. Not all post-delivery tests were done properly and in some cases condoms which fully complied with the ISO standard were rejected.

More countries are becoming interested in post-shipment testing. The intention in some is to replace pre-delivery testing, in others to augment it.

### Less disruption

Post-shipment testing has some advantages. Because the sample is taken from product that is already in-country, there is no risk of substitution by unscrupulous manufacturers working with corrupt sampling agents. Also, the products have undergone the possible rigours of shipment, and any damage caused by that should be apparent. But there are also drawbacks:

1. It is better for a program to know before a product is shipped whether it is acceptable or not: replacement is much quicker and cheaper when and if it is necessary; there is much less disruption to the distribution schedule; and the manufacturer is responsible for disposing of rejected lots.
2. There are considerably fewer manufacturers than recipient programs:

it is logistically much easier to sample and ship condoms from a manufacturing site than from multiple recipient sites. Many smaller programs supplied by larger NGOs will have their condoms produced simultaneously and these can all be sampled at one time. Post-shipment testing would require, several samplings and courier shipments.

3. Pre-shipment testing keeps sequential batches of product together and facilitates a better appraisal of the overall product quality from each manufacturer

In one case, discovery of a problem with some condoms delivered a couple of years previously has led a country to institute post-shipment testing. But the changes in properties were probably caused largely by the length of storage, and the conditions. To extrapolate from the test results on arrival in-country (maybe after a couple of months in a container) to how they will be after storage and distribution is difficult and outside the scope of standards. It is quite likely that the condoms' burst properties will change even during shipment due to post-vulcanisation, even if the temperature conditions are not extreme. This does not necessarily mean the condoms are unacceptable.

Both pre-shipment and post-shipment testing can work, but it is not clear that the potential benefits of the post-shipment testing regime will be sufficient to outweigh the simplicity of the pre-shipment system.

### Slender benefits

The worst of all worlds would be to do both pre- and post-shipment testing on all batches. In a world of fixed budgets it would reduce the number of condoms available, and the benefits of double testing would be very slender.

Another problem is that post-shipment testing will sometimes fail batches passed at pre-shipment.

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### The Enersol Staff Profile



Lisa Henretty has been with Enersol for over 5 years. Her education was in Environmental Science and she began working in Enersol's Laboratory. Lisa works mostly in Administration, Information Technology and as an assistant to the General Manager and Managing Director - but she can be found just about everywhere at Enersol.

Lisa corresponds with many clients over matters such as Enersol's Interlaboratory Trials and International Newsletters. Lisa will greet you if you ever visit Enersol's Annandale office. You may have spoken with her on the phone as she also runs reception.

Lisa is always cheerful and willing to help. She is now 26 years old and has been a vegetarian since her teens. Lisa has many hobbies from computing and digital photography to keeping many pets! - tropical fish, rabbits, a Chihuahua, guinea pigs, a big furry cat and her next animal adventure is a mini pinscher puppy and bird keeping.

### Automatic condom fitter

AN automatic condom fitter claimed to allow condoms to be put on in a fraction of the time taken manually drew large crowds at the April International Exhibition of Inventions in Geneva. The inventor, Mor Maty Seck, said anyone using his invention, which resembles the wand issued with containers of bubbles sold for children, could fit a condom in one second.

*Speed note:* Hot Rod Condoms, which says it is the first brand to market an applicator condom in the U.S., also claims one second as the time taken to put on a condom with its patented Speedstrip Applicator. Hot Rod Condoms were introduced to the market in 1994.

## Female-controlled microbicide 'in three to four years'

A FEMALE-controlled, vaginal microbicide to prevent HIV infection could be available in three to four years according to the Executive Director of UN, Mr Peter Piot, reportedly told journalists in Geneva recently.

Mr Piot said that conceptually, microbicides were straightforward, "whereas with the vaccine we still don't know where to go," and offered more hope in the "foreseeable future" than an HIV/AIDS vaccine.

He said about 15 microbicides were being tested worldwide, including two human trials in Thailand and the United States.

Microbicides were necessary because "of the increasing feminisation of the HIV/AIDS pandemic, with more than half of new infections worldwide occurring among women."

Mr Piot said that HIV/AIDS prevention programs worldwide were being neglected, partly because they were controversial, and warned of a resulting explosion of new HIV cases.

Although spending on prevention initiatives in developing countries had increased from US\$200 million to more than US\$6 billion in eight years, the "big challenge" lay in obtaining long-term funding commitments from donor countries,

### SSL International back on track

SHARES in SSL International, the condom to orthopaedic sandal maker, rose in April following a positive trading statement one commentator described as the best seen "since the ill-judged merger between London International Group and Seton-Scholl back in 1999."

SSL International said the Durex Pleasuremax condom and the Scholl Party Feet footcare product helped sales growth. It said the company was well on track to meeting its target of doubling operating profit over the three years to March 2007.

Sales of the revamped of the Durex and Scholl brands, including a new gel product, were 4 per cent higher than last year. SSL said the improvement was due to a shift in focus to growing brand contribution by eliminating less profitable styles and investing in new ranges."

### Your contributions 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 fax them to Dr John Gerofi at +612 9552 1709 or email them to [jgerofi@enersol.com.au](mailto:jgerofi@enersol.com.au).

Please keep them short and to the point. Every care is taken with the material contained in this newsletter but no responsibility can be taken for its accuracy and it should not be used as technical advice or in formulating decisions.

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## Pre- and post-shipment testing – the case for and against

## High level of approval for Interlab trials

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This could be seen either as evidence that the pre-shipment test was wrong, or that the condoms really had deteriorated in shipment. (There will never be a case where the pre-shipment test fails a batch and the post-shipment test passes it, simply because such batches never reach the second lab - they are not shipped).

In reality, there is always a risk in statistical sampling that a good batch is rejected or that a bad batch is accepted. The more marginal the quality, the more likely this is to happen. Mean burst properties will often be different before and after shipping, and there will be anguish about the cause and meaning.

These unavoidable “disagreements” between labs may be of no significance, but can be used to discredit the pre-shipment test lab.

Though lower than they used to be, complaints about condoms in developing countries still arise. Not all, however, reflect genuine faults. There are, for instance, commercially-motivated complaints by distributors trying to discredit a free or subsidised competitor, or a test lab seeking to generate work for itself and discredit another lab.

There have even been complaints generated by a Government authority as part of a power struggle with another department over who should control condoms.

Another issue is the choice of post-shipment testing lab. Although the original attempts to establish test labs in some African countries in 1990 were

less than successful, there is now much more interest in local labs. In 1990, sovereign autonomy was still the guiding principle and it seemed natural for each country to test and control the quality of its products. Paradoxically, the prevailing wisdom now is for globalisation, harmonisation, certification, accreditation and mutual recognition.

Many countries recognise test certificates from accredited labs, no matter where they are, but moves by some countries to require local post-shipment testing is going against this trend.

The concentration of condom testing has allowed a few large and highly specialised laboratories to develop skills and efficiencies which will be hard to match if the work is fragmented over many smaller labs.

There are also quality issues both inside and outside the standards which require experience and judgment. The risk of a sampling agent becoming corrupt or being duped still exists. So does the risk that a product will be improperly formulated or vulcanised.

But these are not common and may be better dealt with using another approach, like a selective post-shipment testing of occasional lots, in which not all the tests are done and the sample sizes may be smaller. Such a scheme could be designed to add only a couple of percent to the cost of pre-shipment testing.

It is an unfortunate fact that for the present, some form of independent batch-by-batch testing of condoms remains necessary to maintain quality.

A SURVEY designed to increase the efficiency and effectiveness of Enersol's Interlaboratory Trials for condom and glove testing has shown a high general level of client satisfaction.

The review is part of Enersol's ongoing commitment to improving its systems in this area.

As a multi-disciplinary consulting company with particular expertise in the manufacture, testing and distribution of latex products Enersol has been conducting interlaboratory trials for condom testing since the early 1990s and for glove testing since 1988.

The survey included questions relating to sample distribution, distribution of hard copy reports and accreditation of Enersol as a proficiency testing provider.

According to the survey more than 90 per cent of respondents strongly expressed satisfaction with the service provided by Enersol.

Ninety-five per cent said they would recommend the Enersol Interlaboratory Trials to other laboratories.

### Easy to understand

Respondents also showed a high level of satisfaction with the Interlaboratory Trial reports produced by Enersol for both condom and glove trials, and 100 per cent said the statistics used in the reports were easy to understand.

Enersol's managing director, Dr John Gerofi, said that he was happy with the results of the survey.

“The Interlaboratory Trials are extremely valuable to the industry and the process of involving laboratories in different countries calls for an extremely high degree of careful organisation and administration,” he said.

He said that the survey results revealed a number of areas for possible improvement. Suggestions made by respondents would be fully reviewed by Enersol and given every consideration.

## Ultra-fast electrical leaks tester

• From page one If there is a hole in the condom the insulation is broken and an electric current will flow between the solution in the condom and the bath. Results are displayed on a computer monitor and printed on paper and saved on disk. The printed report shows the voltage and the pass/fail status of each condom tested, and also prints a summary for the file. The Enersol software is available in English and Portuguese and can be translated into any language using European characters. A 24-volt transformer ensures operator safety. All five heads operate independently. Condoms that pass are removed from the test head automatically. By the time the operator has loaded and started five heads, the first is ready for the next sample. One operator can test 315 unfoiled condoms in less than 30 minutes. For more information see the Enersol website, [www.enersol.com.au](http://www.enersol.com.au)