MELAdoc

The documentation system

```
----------------------------------------
10 MELAG Vacuklav 44-B
----------------------------------------
15 Program:       Universal program
20 Program type: 134°C wrapped 5:00 min
25 Date:          01.11.2005
30 Daily batch:   02 Total: 00368
----------------------------------------
40 Universal program successfully ended
42 =
----------------------------------------
45 Temperature:  135.3  +0.21/-0.39°C
50 Pressure:     2.16  +0.08/-0.22 bar
55 Plateau time: 05 min 00 s
60 Conductivity: 2 µS/cm (226:18.2)
65 Start time:   13:26:39
70 End time:     13:57:39 (31:00 min)
----------------------------------------
80 SN:200344-B1001 BO V2.1
>> never change code in following row <<
0D0000080053028568EA030303E0037531583474
>> Proof of veracity batch log files  <<
----------------------------------------
Step  Time t[m:s] P[mbar] T[°C]
SK11  0:16   0:16   1603   99.2
SK12  0:39   0:23   1284  104.7
SK11  0:52   0:13   1614  107.5
SK12  1:16   0:24   1286  111.4
SK21  1:21   0:05   1624  111.6
SK22  1:45   0:24   1284  116.4
SK21  1:51   0:06   1616  116.2
SK22  2:15   0:24   1281  118.9
SK21  2:21   0:06   1630  118.4
SK22  2:44   0:23   1290  120.0
SF12  3:04   0:20    478  115.9
SF13  3:32   0:28   1622  117.6
SF21  3:40   0:08   1290  118.5
SF22  4:24   0:44    177  109.6
SF23  5:05   0:41   1814  117.6
SF31  5:17   0:12   1287  118.7
SF32  6:01   0:44    195  110.0
SF33  6:44   0:43   1926  118.6
SF41  6:57   0:13   1290  119.6
SF42  7:27   0:30    382  111.3
SF43  7:50   0:23   1737  116.6
SH01  8:34   0:44   2702  129.7
SH02  8:54   0:20   2837  131.6
SS01  9:41   0:47   3075  134.1
SS02 14:41   5:00   3171  135.4
SA00 15:18   0:37   1293  110.7
ST01 19:18   4:00     60   79.2
ST02 21:18   2:00    661   94.8
ST03 25:19   4:01     59   90.7
ST04 26:20   1:01    662   94.6
ST05 30:20   4:00     64   86.8
SB10 30:38   0:18    801   90.7
SB20 30:59   0:21   1001   92.6
SP-E 30:59   0:00   1001   92.6
----------------------------------------
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*I want to have **documented** safety,*
for our patients and for
our medical practice!

Quality - Made in Germany

MELAG

Evidence Based Sterilization

The components of documented instrur

1. Process security

The MELAG autoclaves Vacuklav®, Vacu*quick*®, Euroklav® and Cliniklav®25 are equipped with an advanced monitoring system. This system monitors those parameters that are critical for the success of sterilization: i.e., pressure, temperature and time. High-quality precision sensors provide highly exact measured values.

2. Batch monitoring for Class B

MELA*control*® is a test system conforming to EN 867-5 that serves for batch monitoring and for testing the function of the fractionated pre-vacuum of a Cliniklav®25 or of a "Class B" autoclave. The MELA*control*® unit consists of a test receptacle (the so-called helix) and 250 indicator strips. MELA*control*® simulates and tests the steam penetration of a long, narrow-bore hollow body.

3. Batch documentation

The log printer MELA*print*®42 records the process parameters for the sterilization cycle. This printer can also be connected to the serial interface of older MELAG models that already have a serial interface.
The MELA*win*® software offers an alternative without paper. It is installed on a PC in the doctor's practice: The PC is directly connected to the autoclave (Vacuklav®30-B, 31-B, 23-B, 24-B, Euroklav® and Cliniklav®25) via the serial interface. Instead of sending data to the MELA*print*®42, this configuration automatically transfers all data to the PC in the practice, where it is stored. In addition, this solution allows entry of additional important information: e.g., load details, the name of the operator, etc.

The new premium autoclaves Vacuklav®40-B/41-B/43-B/44-B and Vacu*quick*®13-B/14-B do not need the MELA*win*®-software. They are intended for direct integration into networks in medical practices, via a built-in Ethernet interface. In addition, it is possible to store the logs on a MELA*flash* CF Card. This makes it possible to keep sterilization records without connecting the autoclave to external devices. A card reader acquires the records from the CF Card and transmits this recorded data to the PC. A standard editor then enables display of the records on the PC.
A network adapter is required to connect the MELA*print*®42 logger to a premium autoclave.

ment preparation

MELA*doc* – the system that truly closes a gap

Many doctors' practices document sterilization processes only in a daily log. The MELA*doc* Label Printer facilitates and simplifies batch documentation, and enables tracing the data for a certain batch.

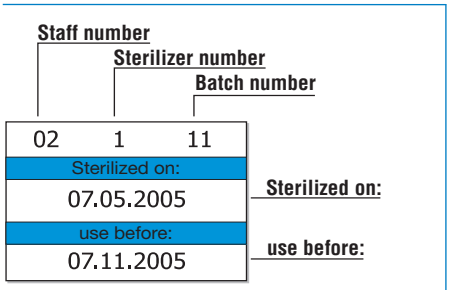
This solution makes it easy to trace back and match up a particular instrument or a certain patient to all essential data from the sterilization process: i.e., the date of sterilization, the batch number, the person providing approval clearance for use of the instruments, the sterilizer that was used, and the sterilization expiration date.

a. Documentation of a batch

The MELA*doc* documentation system prints a label after each sterilization process, and attaches this label to the Sterilization Journal for documentation of the batch.

b. Designation

After sterilization, MELA*doc* affixes a label to designate that the sterilization packaging with the sterilized instruments has in fact been fully satisfactorily processed. This procedure satisfies all the conditions for enabling the operator of the systems to correctly provide approval clearance of a sterilized batch. The MELA*doc* system avoids all the dangers of older systems: e.g., puncture of the packaging by ballpoint pens, or partial dissolving of the plastic packages (with resulting microperforation) by permanent markers



c. For surgical records

MELA*doc* labels are multiple-adhesive. This means that they can be peeled off from the instrument packaging after use, and simply attached to the patient's records.

d. Simple tracing

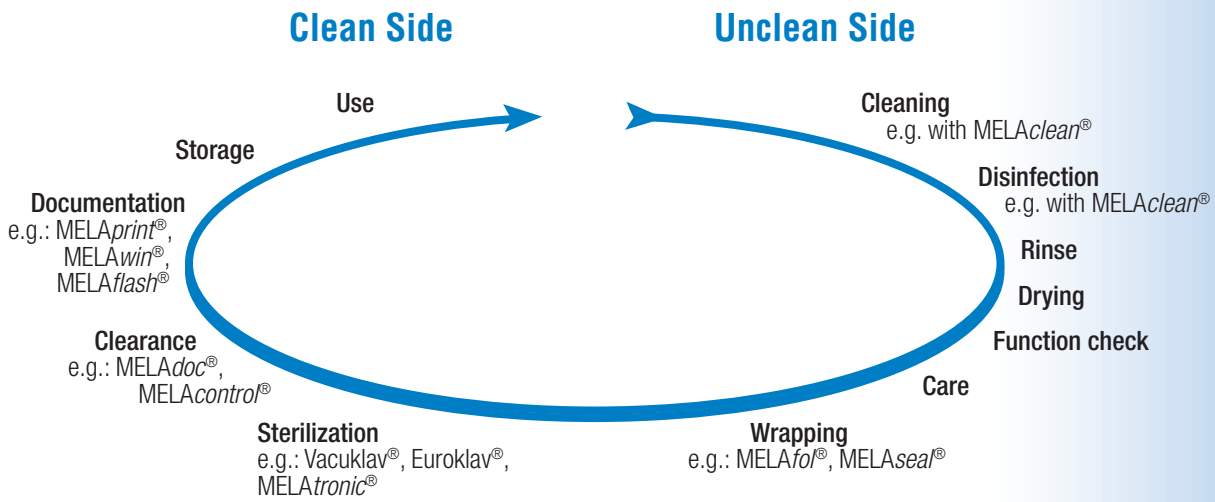
In case that a patient makes a claim for damages for secondary infection, the MELA*doc* labels in the patient's records provide all information on the correct sterilization process for the instruments used. The labels allow tracing the patient's data back to the responsible operator and to the equipment used (sterilizer number). The information on the sterilization data and the batch number enable tracing the process back to the sterilization logs (MELA*print*®42, MELA*flash* CF Card, MELA*win*® etc.). This procedure provides the required proof: that the instruments were properly sterilized.

Is documentation necessary?

In case of litigation

If a patient institutes legal proceedings for recovery of damages against a medical institution, in the belief that he or she had been harmed (for example, after use of non-sterile instruments), long-standing legal interpretation in many legal systems requires that the patient must prove that the attending physician has committed malpractice and has thereby harmed the patient. As a rule, however, the patient will be unable to produce the required evidence: i.e., in most cases he or she will not be able to prove his claims or collect for damages. Jurisprudence in many countries, consequently, has institutionalised the practice of reversal of the burden of proof here. This means that the physician's practice or the medical facility must prove that it has not committed malpractice.

If the attending physician can present a complete and correct record of technically satisfactory preparation of the sterilized instruments, established judicial precedent in many countries includes the ruling that the recorded measures have in fact been carried out, and that no liability exists



Quality and precision for the most exacting in hygienic requirements

More than 50 years ago, MELAG began in Berlin to specialise in manufacture of sterilization equipment. Verification of its great, international success has been the sale of more than 355,000 MELAG units.
Decades of experience, modern computer-aided production in the Berlin plant, employment of highest-quality materials, and experienced and reliable staff – all have made MELAG equipment renowned for quality and convenience.
MELAG corporate philosophy includes systematic specialisation in hygiene and sterilization, in a limited line of products.

With the equipment and accessories it produces for legally stipulated equipment preparation, flawless sterilization, and safe sterile storage of sterilized articles, the entire MELAG staff is proud to have made an essential contribution to the protection of the health of patients and of medical staff.

MELAG

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