1. Read user guide carefully before commencing work!

2. Application, properties, different types and disposal

   - **Area of application**: Analysis - tool for wipe samples on a single or a group of cytostatic substances\(^1\)

     1) Cytostatic agents belong to the group of CMR drugs (Carcinogenic, mutagenic, toxic to reproduction)

   **Substances which can be analysed:** 5-Fluorouracil, 6-Mercaptopurin, Acemetacine, Azathioprine, Busulfane, 
   Capecitabine, Carboplatin, Carmustine, Chlorambucil, Cisplatin, 
   Clomiphene, Cyclophosphamide, Cytarabine, Etoposide, Flutamide, 
   Gemcitabine, Ifosfamide, Methotrexate, Mitomycine, Oxaliplatin, Tamoxifene, 
   Thalidomide, total platinum.

   Available as single analysis after consultation: Docetaxel and Paclitaxel.

   **Use:** The functionality compared to other substances cannot be guaranteed!
   Analysis of other substances only after consultation with the testing institute IUTA e.V. .
   For single use only!

   **Contents:** The wipe sample set (Item-no.: 4155) contains
   the following (for max. 5 wipe samples in one step):
   - 5x Sample containers, each with 3 folded wipes
   - 1x ca. 40 ml special wipe sampling solution (H20 pH3)
   - 5x Pipette
   - 5x Pair of cytostatic protective gloves
   - 4x Freezer packs (freeze before wipe sampling)
   - 1x Adhesive tape for marking
   - 1x Measuring tape
   - 1x Permanent-marker pen for labelling the container
   - Manufacturer's data and documentation for sending on to the test institute

   Further optional materials (not included):
   Protective gown, safety goggles, if necessary a digital camera for personal documentation of 
   wipe sample surfaces

**Area of application**: The BERNER cytostatic wipe sample set **PharmaMonitor** is used for sampling and analysis of surface 
contaminations when handling CMR-pharmaceuticals (e.g. cytostatics, virustatics).

The analysis and presentation of potential contaminations, reveals errors in the handling of cytostatic substances as well as 
subsequent cleaning procedures so that the work instructions can be adjusted accordingly. Additionally, a validation of the 
cleaning procedures can be achieved with wipe sampling. Suitable surfaces are marked in accordance with the instructions. 
The wipe samples are then taken and sent, along with the required documentation to our business partner, the german 
Institute of Energy and Environmental Technology (IUTA e.V.) for analysis. You will receive the results of the analysis after 
about 4 weeks following receipt of the wipe sample at IUTA.

**Examples for wipe sampling locations during production:**
   - Work surface inside and outside of 
     Preparation (Size: e.g.: 30 cm x 30 cm)
   - Storage areas
   - Transport boxes and transport trolleys
   - Floor in front of the safety cabinet
   - Refrigerator door incl. handling
   - Shrink wrap devices

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\(^{1}\): GB-12 0731 A.doc
Produced: I. Britton; Approved by: G.Maik
Valid from: 10 February 2010
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Examples of wipe samples for transport and during application:

- To check cleaning results after transport damage
- Door handles
- Infusion stand
- Infusion tray
- Treatment chair
- Patient’s bed
- Waste container
- Cleaned surfaces after SpillKit use (e.g. for spilt cytostatics)
- ...

Attention: the total area per wipe sampling point should not exceed 2,500 cm².

Works instructions for carrying out wipe samples: see 2. Document (Description wipe samples).

<table>
<thead>
<tr>
<th>Disposal</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Human</td>
</tr>
<tr>
<td></td>
<td>Risk potential</td>
</tr>
<tr>
<td>CMR drugs</td>
<td>180101</td>
</tr>
</tbody>
</table>

- For Germany: Dispose of the non-contaminated residual materials via the German Green Dot system or as part of the normal household waste!

⇒ "Grüner Punkt" = „Duales System Deutschland GmbH"

4. Queries on the results of the analysis:

You will receive the results of the samples with 4 weeks via e-mail or post. In case of any queries in respect of the analysis, please get in direct touch with:

Institute for Energy and Environmental Technology e.V.
Herrn Dr. Türk
Bilersheimer Straße 60
D-47229 Duisburg
Germany

Tel: +49 (0)2065 / 418 - 179
E-Mail: analysis@iuta.de

5. Quality management system

The Berner quality management system in tested and certified in accordance with DIN EN ISO 9001:2008 by the TÜV Management Service GmbH.
6. Storage and transport requirements

**Wipe sample set:**
- Dark (protect from direct UV- and sunlight)
- Store in a cool (+5 to +40°C) and dry place.
- Freeze ice packs before transport

**Samples:**
- Transport only with frozen ice packs.
- If required the samples -18°Celsius can be frozen for up to 4 days

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7. Date of manufacture
Digit 1-4: year, digit 5+6: month, code 39 readable

8. Expiry date
Digit 1-4: year, digit 5+6: month, code 39 readable

9. LOT - Number
Lot number, Code 39 readable

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10. Copyright and industrial property laws

BERNER INTERNATIONAL GMBH shall not accept liability for any errors / damage arising from the improper use of the wipe sample sets. The contract partner for the customer is BERNER INTERNATIONAL GMBH. The analysis part is subcontracted to the Institute for Energy and Environmental Technology e.V. (IUTA).

The wipe sample set may be subject to technical and production-related changes without prior notice. The German version of this manufacturer’s information is binding.

PharmaMonitor is a registered trademark of the Institute for Energy and Environmental Technology e.V. (IUTA)

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