

# 個別診断／試験結果／効能証明書

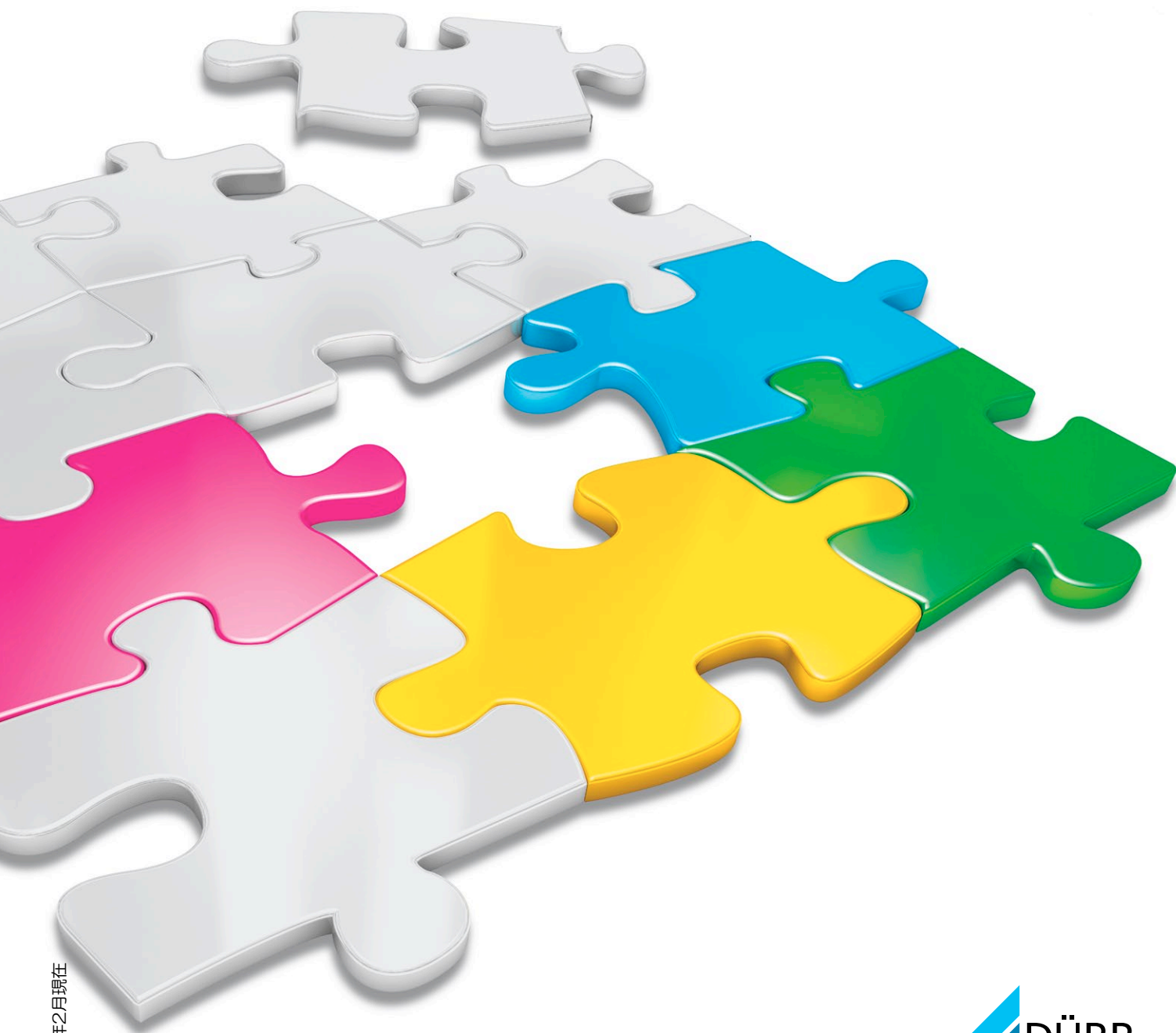
デュールデンタル ハイジーンシステム

MD520 impression disinfection

インプレッション | 印象体・技工物の除菌

ハイゴジェット HYGOJET

印象体・技工物の洗浄除菌システム



# 個別診断／試験結果／効能証明書

## MD520 impression disinfection

### インプレッション | 印象体・技工物の除菌

## ハイゴジェット HYGOJET

### 印象体・技工物の洗浄除菌システム

MD520の菌及び真菌 (C.アルビカンス) への消毒効果検証 .....	1
PD Dr. med. H.-P. Werner 2006/08/14 MD520 Bactericidal and fungicidal (C. albicans) efficacy, Dirty conditions	
MD520の有機物負荷下における菌及び真菌への静菌・消毒効果検証 .....	3
Dr. Holger Brill 2007/07/17 Suitability of MD520 for instrument disinfection	
MD520の汚染状況下における菌及び真菌への表面消毒効果検証 .....	4
Prof. Dr. Med. H. - P. Werner 2005/11/11 MD520 Surface disinfection with mechanical action Bactericidal and fungicidal effectiveness, Dirty conditions	
DGHMガイドラインに準じたMD520の菌及び真菌への静菌・消毒効力の検証 .....	6
Dr. rer. Nat. Holger Brill 2005/03/18 Summary of the tests carried out in accordance with the DGHM-standard methods and expert opinion	
MD520の殺菌効力の検証 .....	7
Dr. rer. Nat. Holger Brill 2006/04/17 Efficacy testing of the disinfectant MD520 according to EN13727	
MD520の殺真菌効力の検証 .....	8
Dr. rer. Nat. Holger Brill 2006/04/17 Efficacy testing of the disinfectant MD520 according to EN13624	
MD520の定量的浮遊試験における殺結核菌効力の検証 .....	9
Dr. med. vet. R. Leimbeck and Dr. rer. nat. W. Groetsch 1994/09/01 On the results of testing the tuberculocidal effectiveness of MD520 in the quantitative suspension test	
MD520の定量的浮遊試験における殺結核菌効力の検証 .....	10
Dr. med. vet. R. Leimbeck 1988/11/17 On the results of testing the tuberculocidal efficacy of MD520 in the quantitative suspension test	
EN14348に準じたMD520の殺結核菌効力の検証 .....	11
Dr. Holger Brill 2006/04/17 Efficacy testing of the disinfectant MD520 according to EN14348	
EN14348に準じたMD520の殺結核菌効力の検証 .....	12
Dr. Holger Brill 2004/10/14 Determination of the tuberculocidal effect of MD520 according to EN14563	
EN14563に準じたMD520の殺結核菌効力の検証 .....	14
Dr. Holger Brill 2007/05/18 Suitability of MD520 for tuberculocidal effect according to EN14563	
MD520の有機物（血液）負荷状況下における使用可能期間の検証 .....	15
Dr. rer. Nat. K.-M. Wolf and Dr. rer. Nat. D. Heermann 2006/11/27 Examination to determine the standing time of MD520 with high organic load (blood)	
MD520のワクシニアウイルス不活性化効力の検証 .....	16
Dr. sc. Agr. J. Wekerle and Prof. Dr. med. vet. D. Strauch 1988/03/10 Testing the activity of the chemical disinfectant MD520 on the enveloped Vaccinia virus	
MD520のC型肝炎ウイルス不活性化効力の検証 .....	17
MikroLab GmbH, Dr. Jochen Steinmann 2001/10/09 BVDV efficacy of MD520	
MD520のアデノウイルス不活性化効力の検証 .....	18
MikroLab GmbH, Dr. Jochen Steinmann 1999/12/10 Adenovirus-efficacy of MD520	
MD520のアデノウイルス不活性化効力の検証 .....	19
MikroLab GmbH, Dr. Jochen Steinmann 2008/12/12 Efficacy of MD520 against FCV in a quantitative suspension test at 20°C	

MD520とハイゴジェット併用時の菌及び真菌(C.アルビカンス)への消毒効果検証 .....	20
Prof. Dr. K. Boessmann 1987/09/07	
Disinfection Performance of Hygojet in combination with MD520	
MD520とハイゴジェット併用時の微生物学的効果の検証 .....	21
Dr. K.-M. Wolf and Dr. D. Heermann 1987/12/11, 1988/11/24	
Microbiological activity of MD520 in combination with the Hygojet	
MD520の浸漬による微生物学的効力の検証 .....	22
MikroLab GmbH, Dr. rer. nat. K.-M. Wolf and Dr. rer. nat. D. Heermann 1995/01/20	
On the result of testing of the microbiological effectiveness of MD520 following immersion disinfection	
MD520のラットへの急性経口毒性試験 .....	23
IBR Forschungs GmbH, Dr. Dr. med. vet. W. Sterner and Dr. med. vet. G. Chibanguza 1988/9	
Acute oral toxicity in Rats	
MD520のハムスターへの粘膜刺激性試験 .....	24
IBR Forschungs GmbH, Dr. med. vet. W.-D. Korn 1989/7/26	
Subacute Cheek-Pouch Mucous Membrane Irritation Test	
様々な印象材料に対するMD520の寸法安定性と石膏体再現性試験 .....	28
Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1989/02/10	
Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials	
MD520の石膏モデルに対する寸法安定性と硬度および表面性状の変化 .....	29
Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1990/04/30	
Changes in Dimensional Stability, Hardness and Surface properties of Plaster Models	
様々な印象材料に対するMD520の寸法安定性と石膏体再現性試験 .....	30
Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1994/11/23	
Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials	
多量の血液存在下におけるMD520の滞留時間の試験結果 .....	31
Dr. rer. Nat. K.-M. Wolf and Dr. nat. D. Heermann 1995/02/22	
On the results of testing the residence time of MD520 in the presence of much blood	
MD520とハイゴジェット併用時の消毒効果 .....	32
Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. K. Boessmann 1987/09/07	
Disinfecting Performance of Duerr Hygojet in combination with MD520	
MD520とハイゴジェット併用時の微生物への効果試験 .....	33
Dr. K.-M. Wolf and Dr. D. Heermann 1988/11/24, 1987/12/11	
Microbiological activity of MD520 in combination with the Hygojet	
MD520とハイゴジェット併用時の印象材料の寸法安定性と石膏体再現性試験 .....	34
Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1989/02/10	
Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials following Disinfection with MD520 in the Hygojet	
MD520とハイゴジェット併用時の石膏モデルの寸法安定性と硬度および表面性状の変化 .....	35
Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1990/04/30	
Changes in Dimensional Stability, Hardness and Surface Properties of Plaster Models	

# MD520の菌及び真菌 (C.アルビカンス) への消毒効果検証

PD Dr. med. H.-P. Werner 2006/08/14

MD520 Bactericidal and fungicidal (C. albicans) efficacy, Dirty conditions

ドイツ応用衛生協会 (DGHM) 基準に従い、汚染状況下における定量的浮遊実験と診療を想定した実使用試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌、C.アルビカンスに対して行った結果、MD520 (100%濃度/未希釈) は2分の作用時間で十分な有効性を示し、以上の試験結果はVAH消毒委員会による消毒プロセスの認証の評価基準を満たしていることが実証された。

PROF. DR. MED. H.-P. WERNER

FACHARZT FÜR HYGIENE UND MIKROBIOLOGIE

c/o HygCen Centrum für Hygiene und  
medizinische Produktsicherheit GmbH

Werksgelände 24

5500 Bischofshofen

Austria

Tel.: +43 (0) 6462 53 19

Fax: +43 (0) 6462 327 53

Prof. Dr. H.-P. Werner c/o HygCen GmbH 5500 Bischofshofen Austria

orochemie Dürr + Pflug GmbH + Co KG

Max-Planck-Straße 27

70806 Kornwestheim

DEUTSCHLAND

2006-08-14

Prof. We

## DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion

Instrument disinfection

Bactericidal and fungicidal (C. albicans) efficacy

Dirty conditions

## EXPERTISE

Having tested the disinfectant **DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion** in accordance with the

"Standard methods of the DGHM\*) for testing of chemical disinfection methods"

(Status: 2001-09-01)

I hereby issue the following evaluation of the results from the test report B 11420e of 2006-08-11:

### Results of the in vitro-test

On the basis of the results of the qualitative suspension tests, the results obtained with the 4 test germs in the following quantitative suspension tests were evaluable.

The quantitative suspension tests were carried out under **dirty conditions** in spread plate technique for germ detections.

**DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion** results in sufficient reductions (5 lg units of test bacteria S. aureus, E. hirae und P. aeruginosa or 4 lg units of C. albicans)

#### under dirty conditions

in 89%	within	15 seconds,
in 75%	within	30 seconds,
in 50%	within	1 minute and
in 10%	within	2 minutes.

Expertise DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion

Page 1 of 2



**Results obtained in tests simulating conditions in practice**

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion** was also in these series tested under **dirty conditions**.

Under **dirty conditions** the product showed sufficient efficacy as

concentrate                      within                      2 minutes

on the test germs *S. aureus*, *E. hirae*, *P. aeruginosa* und *C. albicans*.

**Application recommendations for  
DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion  
for instrument disinfection  
Bactericidal and fungicidal (*C. albicans*) efficacy**

According to the results obtained, **DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion** complies with the

Requirements Specification for the certification of Chemical Disinfection Processes  
by the Chemical Disinfection Commission of VAH

under **dirty conditions** as

concentrate                      within                      2 minutes.



Prof. Dr. med. H.-P. Werner

# MD520の有機物負荷下における菌及び真菌への静菌・消毒効果検証

Dr. Holger Brill 2007/07/17

Suitability of MD520 for instrument disinfection

DGHMのガイドラインに従い、有機物負荷下における試験を行った結果、MD520 (100%濃度/未希釈) は2分の作用時間で十分な有効性を示し、以上の試験結果はVAH消毒委員会による消毒プロセスの認証の評価基準を満たしていることが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE  
PAPENREYE 61, 22453 HAMBURG  
TELEFON 0049-40/557631-0  
TELEFAX 0049-40/557631-11  
EMAIL INFO@BRILLHYGIENE.COM  
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG

Orochemie Dürr + Pflug GmbH & Co. KG  
Max-Planck-Straße 27  
D – 70806 Kornwestheim

Hamburg, 17 July 2007

## Expert's report

### Suitability of *DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* for instrument disinfection

The instrument disinfectant *DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* was tested according to the "DGHM standard methods for testing chemical disinfection procedures", date: 1 September 2001, and evaluated according to the "List of requirements for inclusion of chemical disinfection procedures in the DGHM list of disinfectants", date: 4 February 2002.

According to test report no. L 06/054.2 from Dr. Brill + Partner GmbH, *DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* showed a bacteriostatic and fungistatic as well as bactericidal and fungicidal activity.

*DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* fulfils the DGHM-requirements for listing in the VAH-list under high organic load with the following concentration-time relationship:

100 % 2 minutes.



Dr. Holger Brill

# MD520の汚染状況下における菌及び真菌への表面消毒効果検証

Prof. Dr. Med. H. - P. Werner 2005/11/11

MD520 Surface disinfection with mechanical action Bactericidal and fungicidal effectiveness, Dirty conditions

DGHMのガイドラインに従い、汚染状況下における定量的浮遊実験と診療を想定した実使用試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌、C.アルビカンスに対して行った結果、MD520 (100%濃度/未希釈) は1分の作用時間で十分な有効性を示し、以上の試験結果はVAH消毒委員会による消毒プロセスの認証の評価基準を満たしていることが実証された。

PROF. DR. MED. H.-P. WERNER

FACHARZT FÜR HYGIENE UND MIKROBIOLOGIE

c/o HygCen Centrum für Hygiene und  
medizinische Produktsicherheit GmbH

Werksgelände 24

5500 Bischofshofen

Austria

Tel.: +43 (0) 6462 53 19

Fax: +43 (0) 6462 327 53

Prof. Dr. H.-P. Werner c/o HygCen GmbH 5500 Bischofshofen Austria

orochemie Dürr + Pflug GmbH + Co KG

Max-Planck-Straße 27

70806 Kornwestheim

DEUTSCHLAND

2005-11-11

Prof. We

## DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion

Surface disinfection with mechanical action

Bactericidal and fungicidal (C. albicans) effectiveness

Dirty conditions

## EXPERTISE

Having tested the disinfectant **DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion** in accordance with the

"Standard methods of the DGHM\*) for testing of chemical disinfection methods"

(Status: 2001-09-01)

I hereby issue the following evaluation of the results from the test report of 2005-11-10 B 7758ce:

### Results of the in vitro-test

On the basis of the results of the qualitative suspension tests, the results obtained with the 4 test germs in the following quantitative suspension tests were evaluable.

The quantitative suspension tests were carried out in spread plate technique for germ detections under **dirty conditions**.

**DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion** results in sufficient reductions (5 lg units of test bacteria S. aureus, E. hirae and P. aeruginosa or 4 lg units of C. albicans)

\*) DGHM = German society for Hygiene and Microbiology.

**under dirty conditions**

in 89 %                      within              30 seconds and  
in 75 %                      within              1 minute.

**Results obtained in tests simulating conditions in practice**

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion** was tested in the form of wipe disinfection under **dirty conditions**.

Under **dirty** conditions the concentrate showed sufficient efficacy

the concentrate              within              1 minute

against the test germs **S. aureus**, **E. hirae** and **P. aeruginosa** and **C. ablicans**.

**Application recommendations for  
DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion  
for surface disinfection with mechanical action**

According to the results obtained, **DÜRR SYSTEM-HYGIENE MD 520 Abdruck-** complies with the

Requirements Specification for Certification of Chemical Disinfection Processes by the disinfectant-commission of the VAH<sup>\*)</sup>

under **dirty conditions** with

in concentrate              within              1 minutes.

Prof. Dr. med. H.-P. Werner

<sup>\*)</sup> VAH= Verbund für angewandte Hygiene

# DGHMガイドラインに準じたMD520の菌及び真菌への静菌・消毒効力の検証

Dr. Rer. Nat. Holger Brill 2005/03/18

Summary of the tests carried out in accordance with the DGHM-standard methods and expert opinion

DGHMのガイドラインに従い、菌及び真菌への静菌・消毒効果の検証を行った結果、MD520（100%濃度／未希釈）は有機物汚染状況下で機械的作業によって1分の作用時間で十分な有効性を示すことが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE  
PAPENREYE 61, 22453 HAMBURG  
TELEFON 0049-40/557631-0  
TELEFAX 0049-40/557631-11  
EMAIL INFO@BRILLHYGIENE.COM  
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG

Orochemie Dürr + Pflug GmbH & Co. KG  
Max-Planck-Straße 27  
D – 70806 Kornwestheim

Hamburg, 9 August 2005

## Summary of the tests carried out in accordance with the DGHM-standard methods and expert opinion

The surface disinfectant *DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* was tested in accordance with the “DGHM standard methods for testing chemical disinfection procedures” dated 1 September 2001 and evaluated according to the “List of requirements for inclusion of chemical disinfection procedures in the DGHM list of disinfectants” dated 4 February 2002.

The test preparation proved to be bacteriostatic and fungistatic as well as bactericidal and fungicidal.

The use-recommendation for *DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* for surface disinfection with mechanical action and a high organic load is:

100 % 1 minute



Dr. Holger Brill

# MD520の殺菌効力の検証

Dr. Rer. Nat. Holger Brill 2006/04/17

Efficacy testing of the disinfectant MD520 according to EN13727

EN13727に従い、MD520の消毒効果の検証のため定量的浮遊実験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して行った結果、MD520 (100%濃度/未希釈) は有機物汚染状況下で1分の作用時間で十分な有効性を示すことが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE  
PAPENREYE 61, 22453 HAMBURG  
TELEFON 0049-40/557631-0  
TELEFAX 0049-40/557631-11  
EMAIL INFO@BRILLHYGIENE.COM  
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL - C/O DR. BRILL + PARTNER GMBH - PAPENREYE 61 - 22453 HAMBURG

orochemie Hygiene Präparate GmbH + Co  
Postfach 1630  
D - 70798 Kornwestheim

Hamburg, 17 April 2006

## Expert's report

### Efficacy testing of the disinfectant *DÜRR SYSTEM-HYGIENE MD 520* *ABDRUCKDESINFEKTION* according to EN 13727: 2004 (Phase 2/Step 1)

The disinfectant *DÜRR SYSTEM-HYGIENE MD 520 ABDRUCKDESINFEKTION* was tested and evaluated in accordance with EN 13727: 2004. According to test report no. L 04/252.1 of Dr. Brill + Partner GmbH the test preparation proved to be bactericidal under high organic load.

A sufficient effect within the quantitative suspension test according to EN 13727: 2004 (Phase 2/Step 1) against *Staphylococcus aureus*, *Enterococcus hirae*, and *Pseudomonas aeruginosa* was reached at the following concentration-time relationship under high organic load:

**100 % in 1 minute.**



Dr. Holger Brill

# MD520の殺真菌効力の検証

Dr. Rer. Nat. Holger Brill 2006/04/17

Efficacy testing of the disinfectant MD520 according to EN13624

EN13624に従い、MD520の殺真菌効果の検証のため定量的浮遊実験をカンジダ・アルビカンスに対して行った結果、MD520 (100%濃度/未希釈) は有機物汚染状況下で1分の作用時間で十分な有効性を示すことが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE  
PAPENREYE 61, 22453 HAMBURG  
TELEFON 0049-40/557631-0  
TELEFAX 0049-40/557631-11  
EMAIL INFO@BRILLHYGIENE.COM  
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG

orochemie Hygiene Präparate GmbH + Co  
Postfach 1630  
D - 70798 Kornwestheim

Hamburg, 17 April 2006

## Expert's report

### Efficacy testing of the disinfectant *DÜRR SYSTEM-HYGIENE MD 520* *ABDRUCKDESINFEKTION* according to EN 13624: 2004 (Phase 2/Step 1)

The disinfectant *DÜRR SYSTEM-HYGIENE MD 520 ABDRUCKDESINFEKTION* was tested and evaluated in accordance with EN 13624: 2004. According to test report no. L 04/252.2 of Dr. Brill + Partner GmbH the test preparation proved to be fungicidal under high organic load.

A sufficient effect within the quantitative suspension test according to EN 13624: 2004 (Phase 2/Step 1) against *Candida albicans* was reached at the following concentration-time relationship under high organic load:

100 % in 0.5 minutes.

A sufficient effect within the quantitative suspension test according to EN 13624: 2004 (Phase 2/Step 1) against *Aspergillus niger* was reached at the following concentration-time relationship under high organic load:

100 % in 1 minute.



Dr. Holger Brill

# MD520の定量的浮遊試験における殺結核菌効力の検証

Dr. med. vet. R. Leimbeck and Dr. rer. nat. W. Groetsch 1994/09/01

On the results of testing the tuberculocidal effectiveness of MD520 in the quantitative suspension test

DGHMのガイドラインに従い、MD520の殺結核菌効果の検証のため定量的浮遊試験をマイコバクテリウム・テラエに対して本液100%濃度/未希釈・75%濃度/1.3倍希釈を1分・2分・5分・10分・15分・30分の作用時間で評価を行った結果、MD520 (75%濃度/1.3倍希釈) は結核菌 (マイコバクテリウム・テラエ) に対して15分および30分の作用時間で十分な有効性を示すことが実証された。

Dr. R. Leimbeck  
c/o Labor L + S GmbH  
Mangelsfeld 4  
D-97708 BAD BOCKLET

September 1, 1994  
No. 07178814

## EXPERTISE

DÜRR SYSTEM-HYGIENE  
Impression Disinfection MD 520

on the results of testing the tuberculocidal effectiveness of MD 520 in the quantitative suspension test

The experiments were conducted according to I/2.3.1 of the DGHM "Guidelines for Testing and Assessing Chemical Disinfecting Methods" and in conformity with the publication of B. van Klingeren and W. Pullen, J. Hospital Disinfection (1987) 10, 292-298, respectively.

Test organism: Mycobacterium terrae ATCC 15755  
Exposure times: 1, 2, 5, 10, 15, 30 minutes  
Test concentrations: 100, 75 %  
Inactivating combination: 3 % Tween 80, 3 % saponin, 0.1 % histidine, 0.1 % cysteine

After treatment, the test batches were diluted in successive 1 : 10 dilution series, and 50 µl each of the dilutions were plated on 7H11 agar medium. After incubation at 37 °C during 21 days, the agar plates that showed no growth were re-inoculated with 100 KBE (colony-forming units) each of Mycobacterium terrae and incubated anew, in order to verify a sufficient inhibition of disinfectant remnants.

### Test Results

The results are given on the enclosed table. They reveal that an inhibition of germ growth on the agar plates (results not shown) was reached by the 75 and 100 % concentration of the slightly diluted test substance. Limit of detection was at 4.30 log KBW /ml, the maximum detectable germ reduction at 3.38 log factors. The maximum detectable germ reduction of 3.38 log factors was safely achieved by the undiluted concentration (100 %) within 5, 10, 15 and 30 minutes. The actual result was achieved by the 75 % concentration within 15 and 30 minutes.

(Dr. med. vet. R. Leimbeck)

(Dr. rer. nat. W. Grötsch)



# MD520の定量的浮遊試験における殺結核菌効力の検証

Dr. med. vet. R. Leimbeck 1988/11/17

On the results of testing the tuberculocidal efficacy of MD520 in the quantitative suspension test

DGHMのガイドラインに従い、MD520の殺結核菌効果の検証のため定量的浮遊試験をマイコバクテリウムに対して本液100%濃度/未希釈・75%濃度/1.3倍希釈・50%濃度/2倍希釈を2.5分・5分・10分・15分・30分の作用時間で評価を行った結果、MD520は結核菌(マイコバクテリウム)に対し10分間(75%濃度/1.3倍希釈) および15分間(50%濃度/2倍希釈)の作業時間で完全に結核菌を不活性化できることが実証された。

LABOR L + S GmbH  
Gesellschaft für Mikrobiologie und biologische Qualitätsprüfung  
Laboratories for Microbiological Quality Examination

Mangelsfeld 4  
Tel.: (09708) 848  
D-8733 Bad Bocklet

November 17, 1988 /S.-

DÜRR SYSTEM-HYGIENE  
MD 520  
Impression Disinfection  
Concentrate

## Expertise

on the results of testing the tuberculocidal efficacy of the chemical disinfectant "DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection" in the **qualitative suspension test**.

The experiments were conducted in accordance with the DGHM "Guidelines for Testing and Evaluating Chemical Disinfection Methods, Section 1 (I/2.2), as of January 01, 1981".

Contact times: 2.5 / 5 / 10 / 15 / 30 minutes  
Test concentrations: 100 / 75 / 50 %  
Test organism: Mycobacterium tuberculosis ATCC 25618  
Inactivating combination: 3.0 % Tween 80  
3.0 % saponin  
0.1 % histidine  
0.1 % cysteine

The test results are shown in the table below.

The 75 % MD 520 solution was able to completely inactivate the test germ within 10 minutes' exposure time, whereas the 50 % solution required 15 minutes' contact time for complete inactivation of Mycobacterium tuberculosis.

**Table:** Tuberculocidal efficacy in the qualitative suspension test after the action of MD 520 (DGHM Guidelines I/2.2)

Test germ Mycobacterium tuberculosis Application concentration of disinfectant %	Contact time (minutes)				
	2.5	5	10	15	30
100	+	+	-	-	-
75	+	+	-	-	-
50	+	+	+	-	-
Control					+

+ = increase of M. tuberculosis  
- = no increase  
WSH = water of standardized hardness

(Dr. med. vet. R. Leimbeck)

# EN14348に準じたMD520の殺結核菌効力の検証

Dr. Holger Brill 2006/04/17

Efficacy testing of the disinfectant MD520 according to EN14348

EN14348に準じて、MD520の殺結核菌効果の検証のため定量的浮遊実験をマイコバクテリウム・テラエに対して高有機物負荷及び低有機物負荷で行った結果、MD520は結核菌（マイコバクテリウム・テラエ）に対し低有機物負荷で15分間（100%濃度/未倍希釈）、高有機物負荷で30分間（100%濃度/未倍希釈）の作業時間で十分な有効性を示すことが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE  
PAPENREYE 61, 22453 HAMBURG  
TELEFON 0049-40/557631-0  
TELEFAX 0049-40/557631-11  
EMAIL INFO@BRILLHYGIENE.COM  
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG

orochemie Hygiene Präparate GmbH + Co  
Postfach 1630  
D - 70798 Kornwestheim

Hamburg, 17 April 2006

## Expert's report

### Efficacy testing of the disinfectant *DÜRR SYSTEM-HYGIENE MD 520* *ABDRUCKDESINFEKTION* according to EN 14348: 2005 (Phase 2/Step 1)

The disinfectant *DÜRR SYSTEM-HYGIENE MD 520 ABDRUCKDESINFEKTION* was tested and evaluated in accordance with EN 14348: 2005. According to test report no. L 04/252 of Dr. Brill + Partner GmbH the test preparation proved to be tuberculocidal under low and high organic load.

A sufficient effect within the quantitative suspension test according to EN 14348: 2005 (Phase 2/Step 1) against *Mycobacterium terrae* was reached at the following concentration-time relationship under low organic load:

**100 % in 15 minutes.**

A sufficient effect within the quantitative suspension test according to EN 14348: 2005 (Phase 2/Step 1) against *Mycobacterium terrae* was reached at the following concentration-time relationship under high organic load:

**100 % in 30 minutes.**



Dr. Holger Brill

# EN14348に準じたMD520の殺結核菌効力の検証

Dr. Holger Brill 2004/10/14

Determination of the tuberculocidal effect of MD520 according to EN14563

EN14563に準じて、MD520の希釈中和法を用いた殺結核菌効果の検証のため、定量的浮遊実験をマイコバクテリウム・テラエに対して行った結果、MD520 (100%濃度/未倍希釈) は結核菌 (マイコバクテリウム・テラエ) に対し低有機物負荷 (0.3%牛アルブミン) 及び高有機物負荷 (0.3%ヒツジ赤血球+0.3%アルブミン) において15分間の作業時間で十分な有効性を示すことが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE  
PAPENREYE 61, 22453 HAMBURG  
TELEFON 0049-40/557631-0  
TELEFAX 0049-40/557631-11  
EMAIL INFO@BRILLHYGIENE.COM  
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG

## Determination of the tuberculocidal effect of

### DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion according to EN 14563: 2001

#### a) Identification of the test laboratory

Dr. Brill + Partner GmbH - Labor für Hygiene und Mikrobiologie, Papenreye 61, 22453 Hamburg; Dr. Holger Brill,  
Margret Becker

#### b) Identification of the sample

- |                                    |   |
|------------------------------------|---|
| - Name of product:                 | DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion                              |
| - Batch number:                    | 50076   |
| - Manufacturer:                    | orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim                          |
| - Date of supply:                  | 18.08.2004  |
| - Storage conditions:              | room temperature and darkness   |
| - Recommended diluent:             | potable drinking water  |
| - Active agents and concentration: | 5.0 g/L glutardialdehyde<br>2.5 g/L alkyl-benzyl-dimethyl-ammonium chloride |

#### c) Test procedure and its validation

- |                   |  |
|-------------------|--|
| - Test procedure: | quantitative carrier test with glass-germ carriers<br>(phase 2/step 2)   |
| - Method:         | dilution-neutralisation method   |
| - Neutraliser:    | 30 g/L polysorbate 80; 30 g/L saponine; 1 g/L histidine;<br>5 g/L sodium-thiosulphate in phosphate buffer (TSH-Nt) |

d) Test conditions

– Period of testing:	24.08.2004 to 21.09.2004
– Product diluent:	sterile, hard water, 300 mg/kg CaCO <sub>3</sub>
– Product test concentrations:	100% volume concentration
– Contact times:	1, 5, 15, 30, 60 minutes
– Appearance of the product and its dilutions:	light-yellow, clear solution
– Test temperature:	20°C ± 1°C
– Load, low:	3 g/L bovine serum albumin
– Load, high:	3 g/L sheep erythrocytes + 3 g/L bovine serum albumin
– Incubation temperature:	36°C ± 1°C
– Identification of the used bacteria strains:	Mycobacterium terrae ATCC 15755

e) Test results

The test results are summarised in table 1 and 2.

f) Conclusions

In accordance with prEN 14563 (2001), batch no. 50076 of the product „DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion“ shows in dilution with hard water under low (3 g/L bovine serum albumin) and high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a tuberculocidal effect against the test germ Mycobacterium terrae. The following concentration-time relationship proved to be sufficiently effective:

100 % 15 minutes

g) Hamburg, 14.10.2004, Dr. Holger Brill



# EN14563に準じたMD520の殺結核菌効力の検証

Dr. Holger Brill 2007/05/18

Suitability of MD520 for tuberculocidal effect according to EN14563

EN14563に準じて、医療領域で使用された器具に対するMD520の化学的殺結核菌効果の検証のため、定量的浸漬実験をマイコバクテリウムに対して有機負荷のない状況で行った結果、MD520 (100%濃度/未倍希釈) は結核菌 (マイコバクテリウム) に対し10分の作業時間で十分な有効性を示すことが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE  
PAPENREYE 61, 22453 HAMBURG  
TELEFON 0049-40/557631-0  
TELEFAX 0049-40/557631-11  
EMAIL INFO@BRILLHYGIENE.COM  
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL - C/O DR. BRILL + PARTNER GMBH - PAPENREYE 61 - 22453 HAMBURG

orochemie Hygiene Präparate GmbH + Co  
Mr Dr. K.-M. Wolf  
PO box 1630  
D - 70798 Kornwestheim

Hamburg, 18 May 2007

## Expert's report

### Suitability of *DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* for instrument disinfection (tuberculocidal effect according to DIN EN 14563:2002)

The disinfectant *DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* was evaluated according to prEN 14563:2002 "Quantitative carrier test for the evaluation of mycobactericidal activity of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2/step 2)".

According to test report no. L 07/032.1 from Dr. Brill + Partner GmbH, *DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* showed a tuberculocidal activity without organic load.

*DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion* fulfils the requirements of the norm (RF  $\geq$  4) by the following concentration-time relation:

100 %      10 minutes.



Dr Holger Brill

# MD520の有機物（血液）負荷状況下における使用可能期間の検証

Dr. rer. Nat. K.-M. Wolf and Dr. rer. Nat. D. Heermann 2006/11/27

Examination to determine the standing time of MD520 with high organic load (blood)

連邦保健局の提案で、消毒液の使用可能期間をDGHMの基準に従い診療条件下に近い2%の血液汚染状況で浸漬試験にて検証された結果、MD520（100%濃度／未希釈）は14日間のテスト期間中、2%及び4%の高有機物負荷にも関わらず試験細菌の黄色ブドウ球菌、腸内連鎖球菌、緑膿菌及び真菌（カンジダ・アルビカンス）に対し十分な効果を示した。以上の結果より、安全性を考慮しても、本品は汚染程度が2%を超えない環境下において最長7日間の使用もしくは50個の印象体への使用が推奨されることが証明された。ただし、0.5%の血液汚染がある場合は効果が保証できない為、本液の使用期間に関わらず液を取り換えることが推奨される。

31.01.2007

WF

## DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection

### Examination to determine the standing time of MD 520 with high organic load (blood)

The time allowed for a disinfectant to stand over several days is gaining ever greater importance because of the increasingly problematic nature of waste disposal and the levels of pollution in waste waters. Prerequisite for the use of disinfectants over several days is a demonstration of the effectiveness under conditions similar to those in practice. In a publication by the Federal Health Department (PETERS, J. and G.SPICHER – Bundesgesundhbl. 34, 262 (1991)), it was proposed that the standing times for disinfectants be investigated under conditions similar to those in practice by polluting the disinfectant with e.g. 2% blood and contaminated test objects.

In order to determine a prolonged standing time, the effectiveness of MD 520 was tested with higher blood contaminations in a modified investigation under conditions similar to those in practice. It was performed in accordance with method 15 of the "DGHM standard methods for testing chemical disinfection procedures, effective 1<sup>st</sup> September 2001".

#### Assessment

As the test results have shown, the effectiveness of a 100% undiluted solution was retained over a test period of 14 days against the test bacteria *Staphylococcus aureus*, *Enterococcus hirae*, *Pseudomonas aeruginosa* as well as the yeast *Candida albicans* in the tests under conditions similar to those in practice in spite of a high organic load of 2% and 4% blood (corresponds to 40 to 80 impressions). The test was a quantitative germ carrier test with high organic load. Pieces of frosted glass were used as germ carriers.

Taking a corresponding safety margin into consideration, a **standing time of max. one week or 50 impressions**, respectively, **of the 100% MD 520 solution** is recommended provided that the contamination by blood does not exceed 2%.

As disinfectants are already soiled to a great extent by a contamination of 0.5% blood, it is recommended to replace the solution earlier on account of its appearance – irrespective of the possibly prolonged standing time.

Dr. rer. nat. K.-M. Wolf

Dr. rer. nat. D. Heermann

# MD520のワクシニアウイルス不活性化効力の検証

Dr. sc. Agr. J. Wekerle and Prof. Dr. med. vet. D. Strauch 1988/03/10

Testing the activity of the chemical disinfectant MD520 on the enveloped Vaccinia virus

連邦保健局及びドイツウイルス疾病管理協会 (DVV) のガイドラインに従い、有機物負荷下 (0.2%牛アルブミンもしくは10%ウシ胎児血清) 及び無負荷の状況下でMD520のエンベロープウイルス不活性化効力を、ワクシニアウイルスを用いて検証した結果、MD520 (100%濃度/未希釈) はワクシニアウイルスに対して30秒の作用時間で十分な不活性化効力を示すことが実証された。

Prof. Dr. D. Strauch  
Ordinarius for Veterinary Hygiene at the University of Hohenheim  
Associate Professor at the University of Stuttgart

Jahnstrasse 32  
Tel.: (07158) 88 36  
D - 7302 Ostfildern 3 (Scharnhausen)

10th March, 1988

DÜRR SYSTEM-HYGIENE  
MD 520  
Impression Disinfection  
Concentrate

## Expertise

on the results of testing the activity of the chemical disinfectant "DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection" on the enveloped Vaccinia virus

The activity of the chemical disinfectant "DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection" on the enveloped Vaccinia virus was tested in accordance with the guidelines of the Federal Health Department and the German Association for the Control of Viral Diseases for testing the efficacy of chemical disinfectants against viruses. The studies were carried out both in the absence and in the presence of a protein load (0.2 % bovine serum albumin or 10 % foetal calf serum).

The chemical disinfectant MD 520 was shown to have an outstanding virucidal activity against the enveloped viral species of Vaccinia. After only half a minute contact time, the infectious titre of this test virus was shown to be reduced to the limits of detection when the preparation was used undiluted. This corresponded to a reduction in titre of  $\Delta$  lg 4.67 - 5.0.

To achieve reliable virucidal activity against Vaccinia viruses (enveloped), the following instructions for use are given:

Disinfectant undiluted  
Contact time half a minute

(Dr. sc. agr. J. Wekerle)

(Prof. Dr. med. vet. D. Strauch)

# MD520のC型肝炎ウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2001/10/09

BVDV efficacy of MD520

MD520のC型肝炎ウイルス不活性化を検証するため、連邦健康管理局 (BGA) 及びドイツウイルス疾病管理協会 (DVV) のガイドラインに従い、定量的浮遊試験を代用ウイルスの牛ウイルス性下痢ウイルス (BVDV) に対して80%濃度/1.25倍希釈の本液を用いて30秒・1分・2分・5分の作用時間で評価を行った結果、MD520(100%濃度/未希釈)は30秒間の作用時間で十分なウイルス不活性化効力を示したことからC型肝炎ウイルス不活性化に有効であることが実証された。

## DR. JOCHEN STEINMANN

Direktor am Landesuntersuchungsamt  
für Chemie, Hygiene und Veterinärmedizin  
Fachbereich Med. Mikrobiologie und Hygiene

D-28205 Bremen  
St.-Jürgen-Straße

Tel.: +49 (0)421 361-6119  
Fax.: +49 (0)421 361-15666  
E-Mail: JSteinmann@lua.bremen.de

2001-10-09  
Dr. St/sbe

Orochemie  
Postfach 16 30  
  
70798 Kornwestheim

BVDV efficacy of DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion

### EXPERT'S INVESTIGATION REPORT

The virucidal efficacy of the disinfectant for impressions DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion from the firm Orochemie against bovine viral diarrhoea virus (BVDV) was investigated by a quantitative suspension test according to the guideline of the Bundesgesundheitsamt (BGA, Federal Board of Health) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV, German Society for the Control of Virus Diseases). BVDV was chosen as a surrogate virus for hepatitis C virus since there is no animal model or tissue culture system for growing this virus. Testing this surrogate virus the possibility is created to give recommendations for the inactivation of HCV by the disinfectant.

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal efficacy if within the recommended exposure period the titre is reduced by 4 logs<sub>10</sub>.

DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion was examined as a 80.0% solution. The exposure times were 0.5, 1.0, 2.0 and 5.0 minutes. Summarizing the results of the experiments it can be recommended to use the disinfectant for impressions DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion for the inactivation of BVDV as follows:

**concentrated 30 seconds**

  
Dr. J. Steinmann



# MD520のアデノウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 1999/12/10

Adenovirus-efficacy of MD520

連邦健康管理局 (BGA) 及びドイツウイルス疾病管理協会 (DVV) のガイドラインに従い、MD520のアデノウイルス2型に対する不活性化効力の定量的浮遊試験を、80%濃度/1.25倍希釈の本液を用いて1分・2分・5分・10分の作用時間で評価を行った結果、MD520(100%濃度/未希釈)は2分間の作用時間で十分なアデノウイルス不活性化効力を示すことが実証された。

## DR. JOCHEN STEINMANN

Landesuntersuchungsamt für Chemie,  
Hygiene und Veterinärmedizin  
Fachbereich Med. Mikrobiologie und Hygiene

D-28205 Bremen  
St.-Jürgen-Straße

Tel.: +49 (0)421 361-6119  
Fax.: +49 (0)421 361-15666

10.12.1999  
Dr. St/sbe

orochemie  
Dürr + Pflug GmbH & Co. KG  
Postfach 16 30

70798 Kornwestheim

adenovirus-efficacy of DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion

### EXPERT'S INVESTIGATION REPORT

The virucidal efficacy of DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion from the firm orochemie/Dürr + Pflug GmbH & Co. KG against adenovirus type 2 strain adenoid 6 was investigated by a quantitative suspension test according to the guideline of the Bundesgesundheitsamt (Federal Board of Health) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Society for the Control of Virus Diseases). In this suspension a disinfectant or a disinfectant solution is considered as having virucidal efficacy if within the recommended exposure period the titre is reduced by  $4 \log_{10}$ .

DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion was examined as a 80.0% solution. The exposure times were 1, 2, 5 and 10 minutes. Summarizing the results of the experiments it can be recommended to use the disinfectant DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion for the inactivation of adenovirus type 2 as follows:

concentrated    2 min.



Dr. J. Steinmann

# MD520のアデノウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2008/12/12

Efficacy of MD520 against FCV in a quantitative suspension test at 20°C

MD520のノロウイルス不活性化効力を検証するため、EN14476に準じて定量的浮遊試験を代用ウイルスのネコカリシウイルス(FCV)に対して本液を10%濃度/10倍希釈・100%濃度/未希釈で20°Cの清浄および汚染状況下で1分・2分・5分・10分の作用時間で評価を行った結果、MD520(100%濃度/未希釈)はネコカリシウイルス(FCV)に対して5分間の作用時間で清浄及び汚染状況下で十分なウイルス不活性化効力を示したことからノロウイルス不活性化に有効であることが実証された。

**DR. JOCHEN STEINMANN**  
Wiss. techn. Leiter der  
MikroLab GmbH

Norderoog 2  
D-28259 Bremen

phone: +49 (421) 27819102  
fax: +49 (421) 2760283  
<http://www.mikrolab-gmbh.de>  
E-Mail: MikroLab.GmbH@t-online.de

MikroLab GmbH, Norderoog 2, D-28259 Bremen

12.12.2008  
Dr. St/BB

orochemie GmbH + Co KG  
Postfach 16 30

D-70798 Kornwestheim

**Efficacy of DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion against FCV in a quantitative suspension test at 20°C following EN 14476:2007-02**

## EXPERT OPINION

This expert opinion is based on the test report O08ML661F dating 12.12.2008.

The virus-inactivating properties of the disinfectant DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion of orochemie GmbH + Co KG against bovine feline Calicivirus (FCV) were investigated by a quantitative suspension test following EN 14476:2007-02 under clean and dirty conditions.

The FCV was chosen as a surrogate for human noroviruses since there is no system for virus replication available. Testing this surrogate virus the possibility is created to give recommendations for inactivation of noroviruses by the disinfectant.

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by  $\geq 4 \log_{10}$  (inactivation  $\geq 99.99\%$ ).

DÜRR SYSTEM-HYGIENE MD 520 Abdruckdesinfektion was examined undiluted and as 10.0 % solution at 20°C under clean and dirty conditions. The exposure times were 1, 2, 5 and 10 minutes. After an exposure time of 5 min virus reduction exceeded 4  $\log_{10}$ -steps. Therefore, a virucidal activity against FCV as surrogate for norovirus was measured as follows:

**clean and dirty conditions    undiluted    5 min**

  
**Dr. J. Steinmann**

# MD520とハイゴジェット併用時の菌及び真菌(C.アルビカンス)への消毒効果検証

Prof. Dr. K. Boessmann 1987/09/07

## Disinfection Performance of Hygojet in combination with MD520

DGHMのガイドラインに従い、MD520とハイゴジェット併用時の黄色ブドウ球菌、腸内連鎖球菌、緑膿菌及び真菌(カンジダ・アルビカンス)に対する消毒効果を検証するため、血液と唾液(ムチン)付着後10分経過したシリコン・ポリエーテルゴム・アルジネート印象材に対し、印象体両面を5秒づつ計10秒間流水下で水洗し、10mlのMD520を8ml(片面4mlづつ)スプレーし10分間作用させた後、10秒間(片面5秒づつ)水洗した。その結果、ハイゴジェットとMD520を併用した以上の工程ですべての印象体は十分な消毒・洗浄効果を示し、シリコンとポリエーテルゴムの菌減少率はアルジネート印象材と比較し高い結果であった。

Prof. Dr. K. Boessmann  
Clinical Center of the Christian Albrecht University Kiel  
Center for Oral & Dental Medicine  
Department for Conservative Dental Medicine

Arnold-Heller-Strasse 16  
Tel.: (0431) 5972818  
D-2300 Kiel

September 07, 1987

DÜRR SYSTEM-HYGIENE  
MD 520  
IMPRESSION DISINFECTION  
Concentrate

### EXPERT REPORT

Disinfecting Performance of DÜRR Hygojet (Instrument for Disinfecting and Cleaning Dental Impressions)  
in combination with DÜRR SYSTEM-HYGIENE MD 520 Dental Impression Disinfection

The Clinical Center was commissioned to study the disinfecting performance of DÜRR Hygojet (instrument for disinfecting and cleaning dental impressions) in combination with DÜRR SYSTEM-HYGIENE MD 520 dental impression disinfection.

The investigation was performed in keeping with the guidelines of the DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie = German Association for Hygiene and Microbiology) "Testing and Evaluation of Chemical Disinfection Procedures" and "Requirements for Entry into the VIIIth List of DGHM" (Hyg. u. Med. 9, 41-46, 1984) under experimental conditions prescribed in detail in the Dtsch. zahnärztl. Zeitschrift 38, 742-748, 1983.

Standardized impressions of A and K condensing silicones, polyether rubber, as well as alginates were contaminated with ATCC cultures of Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans and additionally exposed to blood and mucin, dried for 10 minutes and then disinfected in the above instrument.

The following procedure proved highly suitable:

- Flush with tap water for 10 seconds, each side for about 5 seconds.
- Spray with a total of 10 ml disinfectant MD 520, either side of the impression for about 4 seconds (for a total of 8 seconds).
- Allow disinfectant to act for 10 minutes.
- Rinse (flush both sides of specimen for about 5 seconds, that is, for a total of 10 seconds).

Using the above procedure, reduction factors ranging between 4.51 and 6.35 were obtained. Hence, DÜRR Hygojet (instrument for disinfecting and cleaning dental impressions) used in combination with DÜRR SYSTEM-HYGIENE MD 520 dental impression disinfection is highly suitable for its intended purpose, that is, for disinfecting and cleaning impressions that may be contaminated with bacteria and fungi. Germ reduction is better on silicone and polyether rubber impressions than on alginates.

(Prof. Dr. K. Boessmann)

# MD520とハイゴジェット併用時の微生物学的効果の検証

Dr. K.-M. Wolf and Dr. D. Heermann 1987/12/11, 1988/11/24

Microbiological activity of MD520 in combination with the Hygojet

DGHMのガイドラインに従い、MD520とハイゴジェット併用時の消毒効果を検証するため、診療を想定した状況下で黄色ブドウ球菌、緑膿菌及び真菌(カンジダ・アルビカンス)に汚染した血液と唾液(ムチン)付着後10分経過したアルジネート・シリコン・ポリエーテルゴム・親水コロイド印象材に対し、印象体両面を5秒づつ計10秒間流水下で水洗し、10mlのMD520を8ml(片面4mlづつ)スプレーし10分間作用させた後、10秒間(片面5秒づつ)水洗した。その結果、ハイゴジェットとMD520(100%濃度/未希釈)を併用した以上の工程で、血液と唾液の高負荷状況下にあったすべての検体は10分の作業時間で十分な消毒・洗浄効果を示した。

OROCHEMIE  
Dürr + Pflug GmbH + Co KG  
Research, Development, Technology

Enzstrasse 20  
Tel.: (07154) 6010 / 6030  
D-7014 Kornwestheim

November 24, 1988  
December 11, 1987  
Dr.Wf./Te.

## DÜRR SYSTEM-HYGIENE

### MD 520

Impression Disinfection  
in the DÜRR Hygojet System

## EXPERT REPORT

Microbiological activity of DÜRR SYSTEM-HYGIENE MD 520 Dental Impression Disinfection  
in combination with the DÜRR Hygojet (Instrument for Disinfecting and Cleaning Dental Impressions)

Standardized impressions, namely one alginate (Palgat), two condensing silicones (Permagum, Optosil/Xantopren), one polyether rubber (Impregnum F) and two hydrokolloids (Superbody 500, Rubberloid), contaminated with bacteria (*Staphylococcus aureus*, *Pseudomonas aeruginosa*) and fungi (*Candida albicans*), were tested under practice-related conditions in the DÜRR Hygojet instrument using MD 520 as disinfecting agent.

The investigation was performed in keeping with the guidelines of the DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie = German Association for Hygiene and Microbiology) "Testing and Evaluation of Chemical Disinfection Procedures - Requirements for Entry into the VIIIth List of DGHM as of 01.02.1984" (HYG. + MED. 9, 41 - 46, 1986), as well as under experimental conditions described in detail by BÖSSMANN and FRANZ (DTSCH. ZAHNÄRZTL. ZEITSCHRIFT 38, 742 - 748, 1983).

The beforementioned impression materials, contaminated with the test bacteria and additionally exposed to blood and mucin, were then disinfected and cleaned in the DÜRR Hygojet using the following procedure:

- Flush with tap water for 10 seconds, each side for about 5 seconds
- Spray impression with a total of 10 ml disinfectant MD 520, either side of the impression for about 5 seconds (for a total of about 10 seconds)
- Put impression down and allow disinfectant to act for 10 minutes
- Remove disinfectant by rinsing with water for a total of 10 seconds (flush both sides of specimen for about 5 seconds)

The test results reveal that, by this method, reduction factors ranging between 5.08 and 7.97 with bacteria and between 4.19 and 6.23 with fungi were obtained.

## ASSESSMENT AND APPLICATION RECOMMENDATION

In keeping strictly to the described procedure, the undiluted ready-to-use solution of DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfectant used in combination with the DÜRR Hygojet is highly suitable for disinfecting and cleaning contaminated dental impression materials, even in presence of high loads of blood and mucin. Exposure time to the undiluted disinfection preparation must be 10 minutes.

(Dr. K.-M. Wolf)

(Dr. D. Heermann)

# MD520の浸漬による微生物学的効力の検証

MikroLab GmbH, Dr. rer. nat. K.-M. Wolf and Dr. rer. nat. D. Heermann 1995/01/20

On the result of testing of the microbiological effectiveness of MD520 following immersion disinfection

DGHMのガイドラインに従い、本液の浸漬による消毒効果を検証するため診療を想定した状況下で菌（黄色ブドウ球菌）及び真菌（カンジダ・アルビカンス）、血液と唾液（ムチン）に汚染されたアルジネート・シリコン・ポリエーテルゴム・親水コロイド印象材を未希釈室温のMD520、及び無菌の軟水にそれぞれ5分間浸漬した結果、MD520(100%濃度/未希釈)は血液と唾液の高負荷状況下にあったすべての検体に対し5分の浸漬時間で十分な消毒効果を示すことが証明された。

**OROCHEMIE**  
Dürr + Pflug GmbH + Co KG  
Enzstrasse 20  
D-70806 Kornwestheim  
Tel. (07154) 13 08 - 0

January 20, 1995  
Dr. Wf./Te.

## EXPERTISE

on the results of testing of the microbiological effectiveness of *MD 520*  
following immersion disinfection

**DÜRR SYSTEM-HYGIENE**  
**MD 520**  
**Impression Disinfection**

The microbicidal effectiveness of *MD 520* as a preparation for immersion disinfection was tested with *Staphylococcus aureus* as bacteria species as well as with *Candida albicans* as fungi species under practice-related conditions on two alginates (Palgaflex, Xantalgin select), two silicones (Permagum, Optosil plus/Xantopren), one polyether rubber (Impregum F) and two hydrokolloids (Rubberloid, Surgident).

### 1. Conduct of study

The tests were conducted in conformity with the guidelines for "Testing and Assessing Chemical Disinfecting Methods (as of 12.07.1991" stipulated by the Commission for Disinfectants of the DGHM (= German Society for Hygiene and Microbiology: mhp-Verlag, Wiesbaden 1991) as well as according to Bössmann und Franz (Dtsch. Zahn-ärztl. Zeitschrift 39, 742 - 748, 1983).

The impression materials contaminated with test germs, blood and mucin were placed into a tank containing the undiluted solution of *MD 520*. Test pieces that, following contamination, were placed into the shaking solution without further treatment as well as test pieces that were placed into sterile, completely softened water for 5 minutes, served as control.

### 2. Results of tests under practice-related conditions

As the test results show, bactericidal and fungicidal effectiveness was achieved within 5 minutes.

### 3. Assessment and application recommendation

The undiluted use solution of **DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection** proved by its manner of action that it fulfills the preconditions of a safe immersion disinfection method for contaminated dental impression materials, even in the presence of much blood and mucin.

The undiluted disinfectant *MD 520* requires an action time of 5 minutes.

**Recommended application:**  
**Undiluted solution**  
**for an action period of 5 minutes**

(Dr. rer.nat. K.-M. Wolf)

(Dr. rer.nat. D. Heermann)

# MD520のラットへの急性経口毒性試験

IBR Forschungs GmbH, Dr. Dr. med. vet. W. Sterner and Dr. med. vet. G. Chibanguza 1988/9

Acute oral toxicity in Rats

OECDの理念に従い、MD520の急性経口毒性試験を14日間に渡ってウィスターラット（オス5匹及びメス5匹）に対して行った結果、死亡するラットはおらず、異常な臨床毒性兆候も見られなかった。また、14日後にはすべてのラットにおいて体重増加があった。以上のことから、MD520の急性経口毒性は低いと判定された。

I B R Forschungs GmbH  
(Research Laboratories)

Südkampen Nr. 31  
Tel.: (05166) 50 66  
D-3030 Walsrode 1

September 1988 / ja  
Project No. 1-4-1042-88

DÜRR SYSTEM-HYGIENE  
MD 520  
Impression Disinfection  
Concentrate

## Expertise

on the results of testing the acute oral toxicity in rats in conformity with the OECD Directive 401 (limit test)

### I. TEST OBJECTIVE

The purpose of this study was to determine whether the test product DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfectant gives rise to toxic effects following single oral administration to the rat.

The LD<sub>50</sub> was to be determined over a 14-day follow-up period.

This limit test was conducted in accordance with the "OECD Principles of Good Laboratory Practice" in Testing of Chemicals, OECD (Paris 1982).

### II. SUMMARY

- a) Five male and five female Wistar rats were used for acute oral toxicity testing.

Clinical-toxicological signs and symptoms were recorded over the entire observation period. All animals, that is, acute deaths as well as those sacrificed at the end of the study, were examined for gross organ changes in the cranial, thoracic and abdominal cavities.

- b) No clinical-toxicological signs and symptoms were detected.

- c) At the end of the 14-day follow-up period, all animals showed normal weight gain compared with baseline.

- d) There were no deaths.  
Post-mortem (14 days post dosing) revealed no abnormalities.

- e) Determination of the LD<sub>50</sub> yielded the following results:

24 hours + 14 days

male and female animals > 5 ml/kg  $\hat{=}$  5,005 mg/kg

- f) Under the GefStoffV (German legislation on dangerous substances) of August 26, 1986 (BGBl = Bundesgesetzblatt /Federal Register of West Germany 1470), page 7, the pertinent EEC Directive, and OECD Directive, the toxicity of the test product following single oral ingestion is above the "less toxic" level.

(Dr. Dr. med. vet. W. Sterner)

(Dr. med. vet. G. Chibanguza)

# MD520のハムスターへの粘膜刺激性試験

IBR Forschungs GmbH, Dr. med. vet. W.-D. Korn 1989/7/26

Subacute Cheek-Pouch Mucous Membrane Irritation Test

DIN規格に従い、MD520の粘膜刺激性試験を7日間に渡ってハムスターに対して行った。歯科材料のPALADON65を用いて左の頬袋にはMD520原液で洗浄したものを、右の頬袋には未洗浄のものをそれぞれ挿入し、クリップにて閉鎖し7日間観察した。1体のハムスターの右側頬袋にわずかな炎症が見られた他、コントロール体、テスト体のそれぞれに病理組織学的試験で上皮浸潤の所見があったが、すべてのハムスターにおいて行動の変化は見られず、正常な体重増加がみられた。以上の結果より、MD520はハムスターの頬袋の粘膜に影響を与えなかったことが証明された。



IBR Forschungs GmbH  
Südkampen Nr. 31, D - 3030 Walsrode 1  
Telefon (0 51 66) 59-0  
Telex 9 24 342 ibr d  
Telefax (0 51 66) 50 26

IBR Forschungs GmbH & Co.  
Bioanalytisches Zentrum KG  
Feodor-Lynen-Straße 5  
D - 3000 Hannover 61  
Telefon (0511) 5 30 04 40  
Telex 9 24 342 ibr d  
Telefax (0511) 5 30 04 41

Issue Date: July 1989 / ja

IBR Project-No.: 2-6-261-89

Subacute Cheek-Pouch  
Mucous Membrane Irritation Test

with

"DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion"

in Syrian Hamsters  
( *Mesocricetus auratum* )

FINAL REPORT

SPONSOR:

Orochemie  
Enzstraße 20

7014 Kornwestheim

**Mucous Membrane Irritation Test**  
**of**  
**"DÜRR SYSTEM-HYGIENE MD 520 Abdruck-Desinfektion"**

**in Syrian Hamsters**

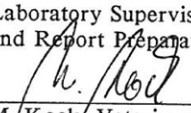
We, the undersigned, hereby declare that the work was performed under our supervision according to the procedures herein described. Symptoms, findings and data recorded in this report, correspond to the results obtained during the performance of this study.

Study Director:




Dr. med.vet. W.-D. Korn  
Principal Scientist  
Department of Toxicology

Laboratory Supervision  
and Report Preparation

  
M. Kock, Veterinarian  
Staff Scientist  
Department of Toxicology

Histopathology:

  
Prof.Dr.med.vet. S. Ueberschär  
Consulting Pathologist

26/07/89



## I. INTRODUCTION

It was the purpose of this study to examine whether the synthetic material PALADON, which had been subject to disinfection with the test article "DÜRR SYSTEM HYGIENE MD 520 Abdruck-Desinfektion" in the DÜRR-Hygojet contained residues of the test article which could induce mucous membrane irritations when applied to the cheek-pouch of hamsters over a period of 7 days.

The study was carried out following the principles of Good Laboratory Practice Regulations (U.S. Federal Register, Friday Sept. 4th, 1987, 21 CFR, Part 58, Final Rule) and was conducted according to DIN V 13 930 Norm 5.2.20.

For the performance of this study, the IBR-protocol, signed and dated on May 22nd and on May 24th, 1989 was valid.

## II. SUMMARY

The synthetic material PALADON 65, left untreated and treated with an undiluted washing solution of "DÜRR SYSTEM HYGIENE MD 520 Abdruck-Desinfektion" was applied to the right and left cheek-pouch, resp. in narcotised syrian chambers. The cheek-pouches were closed by suture clips and the samples remained in place for seven days.

Under the experimental conditions the following result were obtained: All animals showed a normal motor and sensory behaviour during the entire test period. All animals showed a normal gain in body weight.

Macroscopic findings revealed a slight inflammation of the right cheek-pouch around the untreated material PALADON 65 in animal no. 5.

Histopathological examinations disclosed a slight subepithelial infiltration in each one control- and test localisation.

III. CONCLUSION

Under the experimental conditions described, the test article "DÜRR SYSTEM HYGIENE MD 520 Abdruck-Desinfektion" had no topical effect on the mucous membrane of cheek-pouches in Syrian hamsters, which was indicative for an irritating potential of the test substance.

# 様々な印象材料に対するMD520の寸法安定性と石膏体再現性試験

Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1989/02/10  
Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials

DIN規格13909および13913に準じて、9つの印象体（アルジネート3、エラストマー4、親水コロイド2）を用いて、MD520の寸法安定性試験を行った結果、それぞれの印象材の石膏体において寸法変化は見られずその誤差範囲は0.02-0.08%の低い値で、石膏細部の再現性は印象体の薬液消毒の有無による差異はでなかった。試験を行った印象体60%で石膏体表面の硬度がやや低下したが、石膏結晶化はわずかな範囲のみにみられたので、これらの変化は低度 (<10%) に分類された。以上の結果から、MD520は各印象材料の消毒薬として適しており、寸法安定性もしくは石膏細部の再現性の劣化は起きないことが実証された。

Dr. Klaus Ludwig  
Clinical Center of the Christian Albrecht University Kiel  
Center for Dental & Oral Medicine  
- Department for Dental Prosthetics -

Arnold-Heller-Strasse 16  
Tel.: (0431) 5970  
D-2300 Kiel

February 10, 1989

DÜRR SYSTEM-HYGIENE  
MD 520 IMPRESSION DISINFECTION  
Concentrate

## EXPERT REPORT

Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials  
following Disinfection with DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection  
in the DÜRR Hygojet (instrument for disinfecting and cleaning dental impressions)

Nine different dental impression materials, three alginates, four elastomers, and two hydrocolloids, were subjected to a dental impression DÜRR SYSTEM-HYGIENE MD 520 disinfection cycle in the DÜRR Hygojet instrument, and then examined for dimensional stability and gypsum cast tolerance, compared with a control group that was not disinfected.

The disinfection cycle comprises the following steps:

- (a) Spraying of impression with water for 10 seconds;
- (b) Spraying of impression with MD 520 for 10 seconds;
- (c) Spraying of impression with water for 10 seconds after allowing MD 520 to act for 10 minutes.

For dimensional stability testing, impressions were taken of a tapered stainless steel specimen under standardized conditions. Following disinfection, casts were made from these impressions using the same mix of type 4 hard gypsum for these casts and a control group. Deviations in the external dimensions of the gypsum casts were then measured by application of a hollow stainless steel cone of the same dimensions as the test specimen used for taking the impressions.

For testing gypsum cast tolerance, impressions of a test block with standardized grooves in accordance with DIN 13909 and DIN 13913 were taken and compared with the corresponding gypsum casts.

HV1 hardness to Vicker and the accuracy of the test block lines on the casts were determined on all gypsum casts.

Evaluation of measurements yielded the following results:

1. Significant deviations from the dimensions of the impression were noted for the gypsum casts of none of the materials tested. In fact, depending on the impression material, the deviations ranged between 0.02 and 0.08 % and were thus smaller than inaccuracies that may have arisen from the impression itself.
2. Reproducibility of details is equally good on the gypsum casts of all materials, irrespective of whether the impressions were disinfected or not.
3. 60 % of the materials tested resulted in minor decreases in gypsum cast surface hardness following disinfection. Since gypsum crystallization is affected to an only small extent, these changes are classified as minor (< 10 %).

The results of these experiments suggest that the disinfection procedure under study is suitable for and tolerated by common dental impression materials. Deterioration of dimensional stability or of reproducibility of details on the gypsum casts would not be expected.

(Dipl.-Phys. Dr. rer. nat. Klaus Ludwig)

# MD520の石膏モデルに対する寸法安定性と硬度および表面性状の変化

Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1990/04/30  
Changes in Dimensional Stability, Hardness and Surface properties of Plaster Models

DIN規格13913に準じて、5つの異なる作業模型用石膏(タイプⅢ-1、タイプⅣ-4)を用いてMD520の石膏モデルに対する寸法安定性と硬度および表面性状の変化を評価する試験を行った。結果、コントロールグループと比較して大きな差異はでなかったが、水を使用していることによりすべての石膏体において0.01-0.08%のわずかな線形拡張が見られた。また、何もしていない石膏モデルと比較した際、MD520を使用した石膏モデルおよび水のみを使用した石膏モデルの両方に9-22%のわずかな硬度範囲の増加がみられた。今回テストを行った石膏の再現性はMD520の使用有無で差異はでなかった。以上の結果から、MD520は各石膏材料の消毒薬として適しており、寸法安定性もしくは石膏細部の再現性の劣化は起きないことが実証された。

Dr. Klaus Ludwig  
Clinical Center of the Christian Albrecht University Kiel  
Center for Dental & Oral Medicine  
- Department for Dental Prosthetics -

Arnold-Heller-Str. 16  
Tel.: (0431) 5970  
D-2300 Kiel

April 30, 1990

DÜRR SYSTEM-HYGIENE  
MD 520  
Impression Disinfection  
Concentrate

## EXPERT REPORT

Changes in Dimensional Stability, Hardness and Surface Properties of Plaster Models  
following Disinfection with DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection  
in the DÜRR Hygojet (instrument for disinfecting and cleaning dental impressions)

Five different dental gypsums for making working models, one model plaster Type III (DIN 13911) and four model plasters Type IV, were subjected to a dental impression DÜRR SYSTEM-HYGIENE MD 520 disinfection cycle in the DÜRR Hygojet instrument, and then examined for changes in dimensional stability and hardness, compared with a control group that was not disinfected.

The disinfection cycle comprises the following steps:

- (a) Spraying of impression with water for 10 seconds
- (b) Spraying of impression with MD 520 for 10 seconds
- (c) Spraying of impression with water for 10 seconds  
after allowing MD 520 to act for 10 minutes

For dimensional stability testing, impressions were taken of a tapered stainless steel specimen in conjunction with an addition cross-linking polymeric siloxane under standardized conditions, and casts were made from these impressions using the same mix of each type of plaster. A half-open stainless steel external cone was used to measure the occlusal cleft of all plaster casts. Three each of the impressions were then exposed to the disinfection cycle, whereas the rest were treated identically without using the disinfecting agent. Subsequently, the occlusal cleft was measured again by applying the hollow stainless steel cone.

For testing surface deviations of plaster models, six impressions each of a test block in accordance with DIN 13913 were taken and compared with the corresponding plaster casts. Three plaster casts each were exposed to the disinfection cycle, whereas the rest had to undergo the control treatment.

Prior to and following the treatment, HV1 hardness to Vicker and the accuracy of the test block grooves on the impressions were determined on all plaster casts.

Evaluation of measurements yielded the following results:

1. No significant deviations in comparison with the control group were noted of any of the cast materials tested. Caused by the H<sub>2</sub>O treatment, however, all test bodies showed slight linear expansions ranging between 0.01 and 0.08 %.
2. Both the disinfected as well as the H<sub>2</sub>O-treated cast surfaces show slight increases in hardness ranging between 9 % and 22 % compared to the untreated plaster casts.
3. In comparison with the control group, reproducibility of the test grooves on the plaster casts of all materials was not visibly impaired following disinfection.

The results of these experiments suggest that the disinfecting procedure under study is suitable for common dental model plaster materials. Relevant deviations in dimensional stability or a deterioration of reproducibility of details on the plaster gypsum casts would not be expected.

(Dipl.-Phys. Dr. rer. nat. Klaus Ludwig)

# 様々な印象材料に対するMD520の寸法安定性と石膏体再現性試験

Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1994/11/23  
Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials

DIN規格13909および13913に準じて、7つの異なる印象材（アルジネート3、エラストマー4、親水コロイド2）をMD520に10分間浸漬消毒し、10分間水道水に浸漬したコントロールグループと比較する寸法安定性試験を行った。また、印象体をMD520で消毒したものとしなかったものの両方を用いて硬石膏（タイプ4）で石膏体を作成し、石膏再現性試験を行った。その結果、印象体の寸法に大きな差異は見られなかった。印象材料によって起こり得る寸法誤差は、印象体自体の不正確さよりも小さいといえる。石膏体の細部再現性はコントロールグループと比較し、目視できる劣化は見られなかった。また、テストを行った印象体57%で石膏体表面の硬度が低下した。2種の材料で12-15%の硬度低下がみられた一方で、その他の2種の材料では4-7%の硬度増加が確認された。特定のアルジネートと石膏に相性の不一致が存在し、試験を行ったアルジネートの一つは、ある石膏と相性が悪くテスト結果はMD520による消毒とは関係がないことが示された。以上の結果より、MD520を用いた浸漬消毒は印象体の消毒に適するものであり、寸法安定性および細部再現性の劣化は起きないことが実証された。

Dr. Klaus Ludwig  
Clinical Center of the Christian Albrecht University Kiel  
Center for Dental & Oral Medicine  
- Department for Dental Prosthetics -

Arnold-Heller-Strasse 16  
Tel.: (0431) 5970  
D-24105 Kiel

November 23, 1994

DÜRR SYSTEM-HYGIENE  
**MD 520**  
IMPRESSION DISINFECTION

## EXPERT REPORT

**Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials Following Immersion Disinfection with DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection**

Seven different dental impression materials (two alginates, four elastomers and one hydrocolloid) were subjected to immersion disinfection with *MD 520* for 10 minutes and then examined for dimensional stability and gypsum cast tolerance, compared with a control group that was not disinfected but was immersed in normal tap water for the same period of 10 minutes.

For dimensional stability testing, impressions were taken of a tapered stainless steel specimen under standardized conditions. Casts were made from the disinfected and non-disinfected impressions using the same mix of type 4 hard gypsum. Deviations in the external dimensions of the conical gypsum casts were then measured by determining the occlusal gap after applying a hollow stainless steel cone of the same dimensions.

The gypsum cast tolerance was tested using the test block according to DIN 13909 and DIN 13913.

After taking impressions of the test block, gypsum casts were made of from the disinfected impressions and from the control group.

HV 1 hardness to Vickers and the accuracy of the test block lines on the casts were determined on all gypsum casts.

Evaluation of the measurements yielded the following results:

1. Significant deviations from the dimensions of the impression are not anticipated for the gypsum casts after immersion disinfection with *MD 520*. In fact, depending on the impression material, the possible deviations are smaller than inaccuracies that may have arisen from the impression itself.
2. Reproducibility of details on the gypsum casts displayed no visible deterioration for the materials tested after disinfection compared with the control groups.
3. The gypsum casts of 57 % of the impression materials tested displayed significant changes in surface hardness. With two of the materials a decrease in hardness of between 12 % and 15 % was observed, while another two materials displayed an increase in hardness of between 4 % and 7 %. An incompatibility existing in certain products between alginates and several gypsum products (type IV) should be noted. One of the alginates displayed an incompatibility in combination with a gypsum product which occurred irrespective of disinfection.

The results of these experiments suggest that immersion disinfection with *MD 520* is suitable for use with common dental impression materials.

Deterioration of dimensional stability or of reproducibility of details on the gypsum casts would not be expected.

(Dipl.-Phys. Dr. rer. nat. Klaus Ludwig)

# 多量の血液存在下におけるMD520の滞留時間の試験結果

Dr. rer. Nat. K.-M. Wolf and Dr. nat. D. Heermann 1995/02/22

On the results of testing the residence time of MD520 in the presence of much blood

DGHMのガイドラインに準じて、多量の血液存在下におけるMD520の滞留時間および効能を40-80個の印象体に対し、100%濃度/未希釈および50%濃度/2倍希釈の本液を用いてテストを行った。その結果、2%および4%の血液負荷下においても、テスト菌である黄色ブドウ球菌、大腸菌、緑膿菌、カンジダアルビカンスに対して試験期間の30日間有効であった。血液負荷下で4%以下の濃度で本液を使用すると7日間もしくは、50個の印象体で滞留時間が実証されたが、ほとんどの場合、100%濃度/未希釈で5分間の使用が推奨される。しかし、血液負荷が0.5%の場合でも消毒液の変色が見られる場合は、早めに液を交換することが推奨される。

## OROCHEMIE

Dürr + Pflug GmbH + Co KG  
(Research, Development, Technology)

Enzstrasse 20  
Tel.: 07154 / 1308 - 0  
D-70806 Kornwestheim

February 22, 1995  
Dr. Wf

## DÜRR SYSTEM-HYGIENE

### MD 520

### Impression disinfection

## Expertise

on the results of testing the residence time of MD 520  
in the presence of much blood

Taking the problems of waste disposal and the increasing pollution load of the waste waters into account, the residence time of disinfectants over a number of days is getting more and more important. Assessing their effectiveness under practice-related conditions is a requirement for the use of disinfectant solutions over several days. For testing the residence time of disinfectants, the German Federal Health Department (BGA) in their bulletin (PETERS, J. and G. SPICHER - Bundesgesundhbl. No. 34, 262 (1991)), recommend tests under practice-related conditions in the presence of for instance 2 % blood and contaminated test objects.

In a modified qualitative suspension test for the determination of an extended residence time, the effectiveness of MD 520 in the presence of a lot of blood was tested in accordance with paragraph I/2.1 of the guidelines for "testing and assessing chemical disinfecting methods" stipulated by the disinfectant commission of DGHM (= The German Society for Hygiene and Microbiology).

## Evaluation

As the results of the qualitative suspension tests show, despite a 2 % and 4 % load of blood - corresponding to 40 to 80 impressions -, the undiluted and 50 % MD 520 use solution remained effective against the test bacteria *Staphylococcus aureus*, *Escherchia coli* and *Pseudomonas aeruginosa* as well as the fungi *Candida albicans* over the total 30 days' duration of the experiment.

Provided that the load of blood in the use solution be not higher than 4 %, a residence time of 7 days or 50 impressions the most can be recommended for the undiluted MD 520 concentration and an action period of 5 minutes.

It must, however, be pointed out that even in the presence of just 0.5 % blood, a disinfectant solution is discoloured to such a high extent that - independent of the possible prolongation of the residence time - an earlier renewal is recommended for optical reasons.

(Dr. rer. nat. K.-M. Wolf)

(Dr. rer. nat. D. Heermann)

# MD520とハイゴジェット併用時の消毒効果

Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. K. Boessmann 1987/09/07  
Disinfecting Performance of Duerr Hygojet in combination with MD520

DGHMのガイドラインに準じて、黄色ブドウ球菌、緑膿菌、カンジダアルビカンスで汚染されたアルジネート、シリコン、ポリエーテルゴムの印象体に血液および唾液を添加し10分間乾燥させた後、水道水で表裏5秒ずつ合計10秒間水洗し、10mlの本液を片面4秒ずつ合計8秒間スプレーした後、10分間放置、その後表裏5秒ずつ合計10秒間水洗し、消毒効果の試験を行った。以上の工程を用いて4.51-6.35の減少係数が得られたことから、細菌および真菌に汚染された印象体の洗浄消毒に、MD520のハイゴジェットでの使用はとて適していることが証明された。病原菌の減少はアルジネートよりもシリコンとポリエーテルゴムの印象材でよく見られた。

Prof. Dr. K. Boessmann  
Clinical Center of the Christian Albrecht University Kiel  
Center for Oral & Dental Medicine  
Department for Conservative Dental Medicine

Arnold-Heller-Strasse 16  
Tel.: (0431) 5972818  
D-2300 Kiel

September 07, 1987

DÜRR SYSTEM-HYGIENE  
MD 520  
IMPRESSION DISINFECTION  
Concentrate

## EXPERT REPORT

Disinfecting Performance of DÜRR Hygojet (Instrument for Disinfecting and Cleaning Dental Impressions)  
in combination with DÜRR SYSTEM-HYGIENE MD 520 Dental Impression Disinfection

The Clinical Center was commissioned to study the disinfecting performance of DÜRR Hygojet (instrument for disinfecting and cleaning dental impressions) in combination with DÜRR SYSTEM-HYGIENE MD 520 dental impression disinfection.

The investigation was performed in keeping with the guidelines of the DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie = German Association for Hygiene and Microbiology) "Testing and Evaluation of Chemical Disinfection Procedures" and "Requirements for Entry into the VIIIth List of DGHM" (Hyg. u. Med. 9, 41-46, 1984) under experimental conditions prescribed in detail in the Dtsch. zahnärztl. Zeitschrift 38, 742-748, 1983.

Standardized impressions of A and K condensing silicones, polyether rubber, as well as alginates were contaminated with ATCC cultures of Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans and additionally exposed to blood and mucin, dried for 10 minutes and then disinfected in the above instrument.

The following procedure proved highly suitable:

- Flush with tap water for 10 seconds, each side for about 5 seconds.
- Spray with a total of 10 ml disinfectant MD 520, either side of the impression for about 4 seconds (for a total of 8 seconds).
- Allow disinfectant to act for 10 minutes.
- Rinse (flush both sides of specimen for about 5 seconds, that is, for a total of 10 seconds).

Using the above procedure, reduction factors ranging between 4.51 and 6.35 were obtained. Hence, DÜRR Hygojet (instrument for disinfecting and cleaning dental impressions) used in combination with DÜRR SYSTEM-HYGIENE MD 520 dental impression disinfection is highly suitable for its intended purpose, that is, for disinfecting and cleaning impressions that may be contaminated with bacteria and fungi. Germ reduction is better on silicone and polyether rubber impressions than on alginates.

(Prof. Dr. K. Boessmann)

# MD520とハイゴジェット併用時の微生物への効果試験

Dr. K.-M. Wolf and Dr. D. Heermann 1988/11/24, 1987/12/11

Microbiological activity of MD520 in combination with the Hygojet

DGHMのガイドラインおよびBoessmannとFranzによる実験条件に従って、細菌(黄色ブドウ球菌、緑膿菌)および真菌(カンジダアルビカンス)に汚染された4種の印象体(アルジネート1、シリコン2、ポリエーテルゴム1、親水コロイド2)をMD520とハイゴジェットを用いて診療条件下で試験を実施した。試験を行う印象体は細菌及び真菌に汚染された後、さらに血液および唾液を添加し、水道水で表裏5秒ずつ合計10秒間水洗、10mlの本液を片面4秒ずつ合計8秒間スプレーした後、10分間放置、その後表裏5秒ずつ合計10秒間水洗し、消毒効果の試験が行われた。その結果、細菌に対しては5.08-7.97、真菌に対しては4.19-6.23の減少係数が得られたことから、ハイゴジェット内での未希釈のMD520の使用は血液による高負荷状況下および唾液存在下でも汚染された印象体の洗浄消毒にとっても適していることが証明された。その際の作用時間は10分間とする。

OROCHEMIE  
Dürr + Pflug GmbH + Co KG  
Research, Development, Technology

Enzstrasse 20  
Tel.: (07154) 6010 / 6030  
D-7014 Kornwestheim

November 24, 1988  
December 11, 1987  
Dr.Wf./Te.

DÜRR SYSTEM-HYGIENE  
MD 520  
Impression Disinfection  
in the DÜRR Hygojet System

## EXPERT REPORT

Microbiological activity of DÜRR SYSTEM-HYGIENE MD 520 Dental Impression Disinfection  
in combination with the DÜRR Hygojet (Instrument for Disinfecting and Cleaning Dental Impressions)

Standardized impressions, namely one alginate (Palgat), two condensing silicones (Permogum, Optosil/Xantopren), one poly-ether rubber (Impregnum F) and two hydrokolloids (Superbody 500, Rubberloid), contaminated with bacteria (*Staphylococcus aureus*, *Pseudomonas aeruginosa*) and fungi (*Candida albicans*), were tested under practice-related conditions in the DÜRR Hygojet instrument using MD 520 as disinfecting agent.

The investigation was performed in keeping with the guidelines of the DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie = German Association for Hygiene and Microbiology) "Testing and Evaluation of Chemical Disinfection Procedures - Requirements for Entry into the VIIIth List of DGHM as of 01.02.1984" (HYG. + MED. 9, 41 - 46, 1986), as well as under experimental conditions described in detail by BÖSSMANN and FRANZ (DTSCH. ZAHNÄRZTL. ZEITSCHRIFT 38, 742 - 748, 1983).

The beforementioned impression materials, contaminated with the test bacteria and additionally exposed to blood and mucin, were then disinfected and cleaned in the DÜRR Hygojet using the following procedure:

- Flush with tap water for 10 seconds, each side for about 5 seconds
- Spray impression with a total of 10 ml disinfectant MD 520, either side of the impression for about 5 seconds (for a total of about 10 seconds)
- Put impression down and allow disinfectant to act for 10 minutes
- Remove disinfectant by rinsing with water for a total of 10 seconds (flush both sides of specimen for about 5 seconds)

The test results reveal that, by this method, reduction factors ranging between 5.08 and 7.97 with bacteria and between 4.19 and 6.23 with fungi were obtained.

## ASSESSMENT AND APPLICATION RECOMMENDATION

In keeping strictly to the described procedure, the undiluted ready-to-use solution of DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfectant used in combination with the DÜRR Hygojet is highly suitable for disinfecting and cleaning contaminated dental impression materials, even in presence of high loads of blood and mucin. Exposure time to the undiluted disinfection preparation must be 10 minutes.

(Dr. K.-M. Wolf)

(Dr. D. Heermann)



# MD520とハイゴジェット併用時の印象材料の寸法安定性と石膏体再現性試験

Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1989/02/10  
Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials following Disinfection with MD520 in the Hygojet

9つの異なる印象材(アルジネート3、エラストマー4、親水コロイド2)をハイゴジェットとMD520を用いて洗浄消毒を行い、寸法安定性と石膏体再現性をコントロールグループと比較する試験を行った。試験を行う印象体は、ハイゴジェット内で10秒間水洗後、MD520を10秒間噴射、10分後に10秒間水洗を行った。また、印象体をMD520で消毒したものとしなかったものの両方を用いて硬石膏(タイプ4)で石膏体を作成し、DIN13909および13913に準じて石膏再現性試験を行った。結果、印象体の寸法差異は0.02-0.08%と大きな差異は見られず、印象材料によって起こりうる寸法誤差は印象体自体の不正確さよりも小さかった。石膏体の細部再現性は、消毒の有無に関わらずすべての印象体において良く同等であった。また、テストを行った印象体60%で石膏体表面の硬度がわずかに低下したが、石膏の結晶化に影響を与えた範囲は小さく、これらの変化は低度(<10%)に分類された。以上の結果より、ハイゴジェットを用いたMD520の使用は一般的な印象体材料に適しており、寸法安定性および細部再現性の劣化は起きないことが実証された。

Dr. Klaus Ludwig  
Clinical Center of the Christian Albrecht University Kiel  
Center for Dental & Oral Medicine  
- Department for Dental Prosthetics -

Arnold-Heller-Strasse 16  
Tel.: (0431) 5970  
D-2300 Kiel

February 10, 1989

DÜRR SYSTEM-HYGIENE  
MD 520 IMPRESSION DISINFECTION  
Concentrate

## EXPERT REPORT

Dimensional Stability and Gypsum Cast Tolerance of Various Impression Materials following Disinfection with DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection in the DÜRR Hygojet (instrument for disinfecting and cleaning dental impressions)

Nine different dental impression materials, three alginates, four elastomers, and two hydrocolloids, were subjected to a dental impression DÜRR SYSTEM-HYGIENE MD 520 disinfection cycle in the DÜRR Hygojet instrument, and then examined for dimensional stability and gypsum cast tolerance, compared with a control group that was not disinfected.

The disinfection cycle comprises the following steps:

- (a) Spraying of impression with water for 10 seconds;
- (b) Spraying of impression with MD 520 for 10 seconds;
- (c) Spraying of impression with water for 10 seconds after allowing MD 520 to act for 10 minutes.

For dimensional stability testing, impressions were taken of a tapered stainless steel specimen under standardized conditions. Following disinfection, casts were made from these impressions using the same mix of type 4 hard gypsum for these casts and a control group. Deviations in the external dimensions of the gypsum casts were then measured by application of a hollow stainless steel cone of the same dimensions as the test specimen used for taking the impressions.

For testing gypsum cast tolerance, impressions of a test block with standardized grooves in accordance with DIN 13909 and DIN 13913 were taken and compared with the corresponding gypsum casts.

HV1 hardness to Vicker and the accuracy of the test block lines on the casts were determined on all gypsum casts.

Evaluation of measurements yielded the following results:

1. Significant deviations from the dimensions of the impression were noted for the gypsum casts of none of the materials tested. In fact, depending on the impression material, the deviations ranged between 0.02 and 0.08 % and were thus smaller than inaccuracies that may have arisen from the impression itself.
2. Reproducibility of details is equally good on the gypsum casts of all materials, irrespective of whether the impressions were disinfected or not.
3. 60 % of the materials tested resulted in minor decreases in gypsum cast surface hardness following disinfection. Since gypsum crystallization is affected to an only small extent, these changes are classified as minor (< 10 %).

The results of these experiments suggest that the disinfection procedure under study is suitable for and tolerated by common dental impression materials. Deterioration of dimensional stability or of reproducibility of details on the gypsum casts would not be expected.

(Dipl.-Phys. Dr. rer. nat. Klaus Ludwig)

# MD520とハイゴジェット併用時の石膏モデルの寸法安定性と硬度および表面性状の変化

Clinical Center of the Christian Albrecht University Kiel Center for Dental & Oral Medicine, Dr. Klaus Ludwig 1990/04/30  
Changes in Dimensional Stability, Hardness and Surface Properties of Plaster Models

DIN規格13913に準じて、5つの異なる作業模型用石膏（タイプⅢ-1、タイプⅣ-4）を用いて、ハイゴジェット内でMD520を使用し、石膏モデルに対する寸法安定性と硬度および表面性状の変化を評価する試験を行った。コントロールグループと比較して大きな差異はでなかったが、水を使用していることによりすべての石膏体において0.01-0.08%のわずかな線形拡張が見られた。また、何もしていない石膏モデルと比較した際、MD520を使用した石膏モデルおよび水のみを使用した石膏モデルの両方に9-22%のわずかな硬度範囲の増加がみられた。コントロールグループと比較し、今回テストを行った石膏の再現性はMD520の使用有無で差異はでなかった。以上の結果から、MD520は各石膏材料の消毒薬として適しており、寸法安定性もしくは石膏細部の再現性の劣化は起きないことが実証された。

Dr. Klaus Ludwig  
Clinical Center of the Christian Albrecht University Kiel  
Center for Dental & Oral Medicine  
- Department for Dental Prosthetics -

Arnold-Heller-Str. 16  
Tel.: (0431) 5970  
D-2300 Kiel

April 30, 1990

DÜRR SYSTEM-HYGIENE  
MD 520  
Impression Disinfection  
Concentrate

## EXPERT REPORT

Changes in Dimensional Stability, Hardness and Surface Properties of Plaster Models  
following Disinfection with DÜRR SYSTEM-HYGIENE MD 520 Impression Disinfection  
in the DÜRR Hygojet (instrument for disinfecting and cleaning dental impressions)

Five different dental gypsums for making working models, one model plaster Type III (DIN 13911) and four model plasters Type IV, were subjected to a dental impression DÜRR SYSTEM-HYGIENE MD 520 disinfection cycle in the DÜRR Hygojet instrument, and then examined for changes in dimensional stability and hardness, compared with a control group that was not disinfected.

The disinfection cycle comprises the following steps:

- (a) Spraying of impression with water for 10 seconds
- (b) Spraying of impression with MD 520 for 10 seconds
- (c) Spraying of impression with water for 10 seconds  
after allowing MD 520 to act for 10 minutes

For dimensional stability testing, impressions were taken of a tapered stainless steel specimen in conjunction with an addition cross-linking polymeric siloxane under standardized conditions, and casts were made from these impressions using the same mix of each type of plaster. A half-open stainless steel external cone was used to measure the occlusal cleft of all plaster casts. Three each of the impressions were then exposed to the disinfection cycle, whereas the rest were treated identically without using the disinfecting agent. Subsequently, the occlusal cleft was measured again by applying the hollow stainless steel cone.

For testing surface deviations of plaster models, six impressions each of a test block in accordance with DIN 13913 were taken and compared with the corresponding plaster casts. Three plaster casts each were exposed to the disinfection cycle, whereas the rest had to undergo the control treatment.

Prior to and following the treatment, HV1 hardness to Vicker and the accuracy of the test block grooves on the impressions were determined on all plaster casts.

Evaluation of measurements yielded the following results:

1. No significant deviations in comparison with the control group were noted of any of the cast materials tested. Caused by the H<sub>2</sub>O treatment, however, all test bodies showed slight linear expansions ranging between 0.01 and 0.08 %.
2. Both the disinfected as well as the H<sub>2</sub>O-treated cast surfaces show slight increases in hardness ranging between 9 % and 22 % compared to the untreated plaster casts.
3. In comparison with the control group, reproducibility of the test grooves on the plaster casts of all materials was not visibly impaired following disinfection.

The results of these experiments suggest that the disinfecting procedure under study is suitable for common dental model plaster materials. Relevant deviations in dimensional stability or a deterioration of reproducibility of details on the plaster gypsum casts would not be expected.

(Dipl.-Phys. Dr. rer. nat. Klaus Ludwig)

