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Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

ACCEPTED/FILED

JUN 3 - 2014

Federal Communications Commission
Office of the Secretary

In the Matter of)
) ET Docket No. 14-84
Medimetrics Personalized Drug Delivery B. V.)
)
Request for Waiver of Section 15.231(b) of the)
Commission's Rules (Power Limits Breach) to)
Permit the Operation of a Portable Unit as a)
Transmitter (Concerning Very Occasional Short)
Transmission of a Command to an Orally)
Introduced Capsule, Used as a Research Tool in)
the Process of Development of New Drugs)

REQUEST FOR WAIVER

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52 1. Introduction

53 Commercially available Wireless Capsule Endoscopy (CE) systems have rapidly become
54 the procedure of choice for clinical examination of the gastrointestinal tract (Mishkin et al.,
55 2006; Eliakim 2008). These devices only have imaging capabilities and lack any therapeutic
56 potential such as intraluminal delivery of drugs.

57 Controlled delivery of drugs to well defined anatomical and/or functional areas of the
58 gastrointestinal tract are attractive for a wide variety of drugs and diseases.

59 The developments of formulations which provide adequate drug absorption, reproducible
60 bioavailability and/or pharmacokinetic profiles in humans represent a major bottleneck in
61 today's development of orally administered new drugs (Stegemann et al., 2007). By
62 combining diagnostic functionalities to determine anatomical location with the capability to
63 release a drug formulation (either liquid or solid), the IntelliCap® FR system offers the
64 opportunity to rapidly profile new drug candidates and drug formulations to meet patients'
65 needs. Beyond its role in pharmaceutical drug profiling and formulation development, the
66 IntelliCap® FR system offers the potential of therapeutic intervention. Examples include
67 treatment of gastrointestinal diseases such as Crohn's disease or gastrointestinal cancer, as
68 well as therapeutic agents that require high concentrations in the portal system such as
69 insulin, gastrointestinal hormones and chemotherapeutics for malignant liver disease.

70 Traditional ways to address these issues include coatings to protect drugs against
71 degradation by gastric or duodenal contents, modified or extended release preparations,
72 time or pH dependent chemical coatings, and direct duodenal delivery with feeding tubes in
73 percutaneous enterostomies. Several capsule systems have been developed for targeted
74 drug delivery (Sharma 2009). However, lack onboard diagnostic functionalities to control the
75 localization of payload release and therefore require imaging modalities (e.g. scintigraphy)
76 for capsule localization.

77 Medimetrics has developed an intelligent electronic drug delivery device, the IntelliCap®
78 FR system combining *in-vivo* measurement of pH and temperature in the gastrointestinal
79 (GI) tract of humans and larger mammals with a drug formulation release functionality to
80 facilitate delivery of compatible compounds within defined sections of the GI tract.

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82 **2. Device Intended Use Summary**

83 Summarized the IntelliCap® FR product is an oral drug delivery device with *in-vivo*
84 measurement of pH and temperature in the gastrointestinal (GI) tract of humans and larger
85 mammals, in order to facilitate delivery of a compatible compound (in dosage, considered
86 safe and well tolerated) in defined sections of the GI tract as a research tool for premarket
87 drug research. Application as "a research tool" means the product is used within the
88 development path of new pharmaceuticals and does not target the therapeutics market.
89

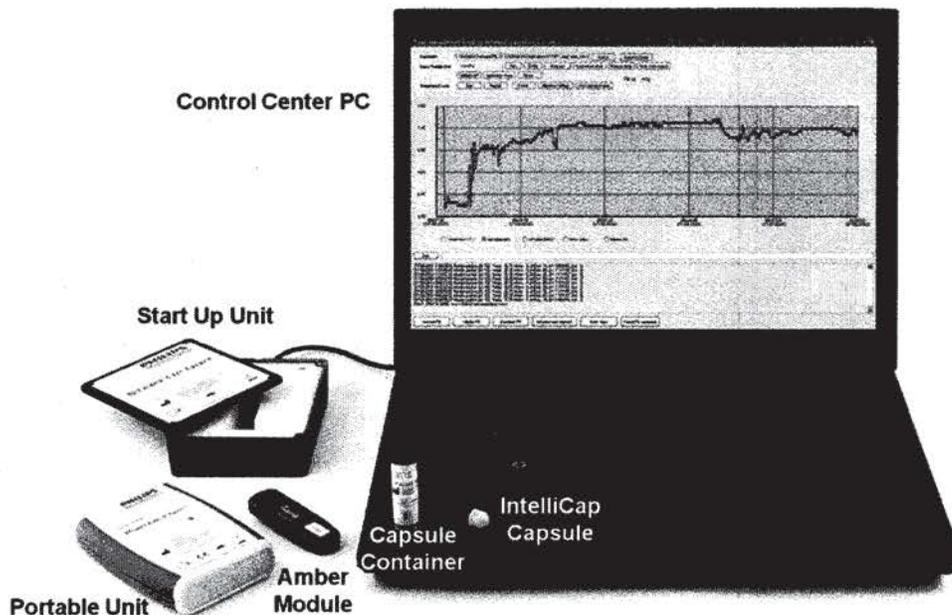
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90 3. Device Description

91 3.1 The IntelliCap® FR product system

92 Each IntelliCap® FR product system consists of several components: a capsule, a
93 Portable Unit (PU), a Control Center Unit (comprising the Graphical User Interface) (CCU),
94 and a Start-Up Unit SUU. The components of the IntelliCap® FR product system is displayed
95 in Figure 1. The CCU is a personal computer with software that visualizes data and provides
96 the user interface. The CCU communicates with each capsule via a PU, which is placed in
97 close proximity (within 2 m) to the test subject. Typically the PU is housed in a belt pouch
98 that is placed around the waist of the test subject. The PU relays communication between
99 the IntelliCap® FR capsule and the CCU during operation. Distance between the portable
100 unit and CCU may be up to 100m in open space.



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Figure 1: The IntelliCap® FR system and its components.

119 3.2 Typical Application

120 Typically the IntelliCap® FR product system is employed as a research tool to study the
121 pharmacokinetic properties of a drug. A pharmacokinetic study is typically performed with
122 healthy volunteers. In such a study a pharma development company contracts with
123 Medimetrics for operation of the system. The system is set up and operated by trained
124 Medimetrics personnel who are present at the study site. The study site is typically a
125 commercial research clinic or research hospital. It is a controlled environment with

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126 professional persons guiding and executing the study. Medimetrics task is technical
127 operation of the IntelliCap® FR system and personnel work in conjunction with the clinical
128 study staff. The IntelliCap® FR system is described in the study protocol and the entire study
129 is reviewed and approved by a clinical research oversight committee.

130 The IntelliCap® FR capsule can be programmed to release its drug formulation payload in
131 a single bolus. The localization of the capsule within the gastrointestinal tract is determined
132 by real-time pH readings. The pH profile reflects transit of the IntelliCap® FR capsule from
133 the stomach (pH 1-4) through the pylorus into the duodenum (pH 7-8) and further on through
134 the small intestine, passing the ileocecal valve into the cecum (pH 5-6) and colon. The
135 IntelliCap® FR capsule can be programmed to expel its contents triggered by a change in
136 pH, and/or after a given programmable time, or manually at any time by a command
137 received from the CCU (via the PU). The complete product specification (IntelliCap® FR
138 product User Manual) is provided in the enclosed waiver request supporting documentation.

139 3.3 Communication of Data

140 The IntelliCap® FR capsule and the PU are battery powered devices and are designed in
141 such a way that the operational lifetime of 48-72 hours. In order to have optimal power
142 savings the communication links (Capsule – Portable Unit and Portable Unit – Control
143 Center) are not continuously present. In a normal operational situation the Capsule
144 measures data once every 10 seconds and sends it to the PU, which saves the information
145 and forwards it further to the CCU. Communication from the Control Center to the Capsule is
146 very infrequent. Commands may be sent for example to initiate delivery or change the
147 measurement and reporting interval. Command is also sent to shut-down a capsule after an
148 experiment is finished. Within the normal mode of operation there are only **two commands**
149 issued during the course of an experiment (i.e. within the application lifetime of a capsule):
150 start-delivery and shut-down. In normal mode of operation the PU continuously “listens” for
151 data packets from the capsule, which it further relay to the CCU. If a command is to be sent
152 to the capsule the synchronization takes place upon a data packet received.

153 The frequency band choice (for communication between the capsule and the PU) has
154 been mostly driven by the capsule sizes (27mmxØ11mm) and its application (intra-
155 corporeal). This means on one side the capsule cannot accommodate an antenna for low
156 frequencies and on the other long frequencies does not propagate through human tissue. In
157 the process of design and development of the capsule two potential bands were considered:
158 MICS-402MHz and ISM-433MHz. Due to the very heavy requirement of LBT for the MICS
159 band the ISM one has been selected. The (capsule) antenna for this band is also not optimal
160 due to the huge size restriction and therefore the power of the PU transmitter (at 433MHz)
161 should be substantial in order any data to be able to reach the capsule through the tissue.

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162 The IntelliCap® FR Portable Unit makes use of two wireless communication links in the
163 frequency bands, known as ISM-433MHz (433.050MHz – 434.790MHz) for communication
164 with the capsule and ISM-2400MHz (2400MHz – 2500MHz) for communication with the
165 CCU.

166 3.4 Band occupation

167 The IntelliCap® FR Portable Unit uses the ISM-433MHz (433.050 - 434.790 MHz) band
168 for sending data on five (5) discrete channels with center frequencies of:

169 433.200 MHz

170 433.550 MHz

171 433.900 MHz

172 434.250 MHz

173 434.600 MHz

174 The data to be transmitted contains a five (5) bytes command for a specific action that is
175 to be performed by the capsule, like “shut-down”, “advance to next segment”, “actuator ON”
176 and “actuator OFF”. Under “Normal” use of operation only the “advance to next segment”
177 and “shut-down” commands are transmitted (via the Portable Unit) to the capsule.

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179 IntelliCap® FR Product System Compliance to the Federal Communications
180 Commission's Rules

181 3.5 Capsule Compliance

182 The capsule has been tested and found fully compliant with respect to the limits for a
183 class B device, pursuant to Part 15 of the FCC Rules (Conformity Certificate, issued and
184 delivered by Telefication B.V., under number 13218660/AA/00; FCC ID: YDVINTELLICAP-
185 CI). A copy of the certificate is provided in the enclosed waiver request supporting
186 documentation.

187

188 3.6 Portable Unit Compliance

189 The IntelliCap® FR Portable Unit has been tested and found fully compliant with respect
190 to the limits if applied as a receiver in the ISM-433MHz. Additionally the PU has been tested
191 and found fully compliant with respect to the limits if applied as a transceiver in the ISM-
192 2400MHz band. A copy of the compliance test report is provided in the enclosed waiver
193 request supporting documentation.

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195 4. Request for Power Waiver Argumentation

196 In order to send a command to the IntelliCap® FR capsule the Portable Unit has to
197 transmit a data stream with sufficient power. The signal power required is in the range of up
198 to 1.3 mW (measured @ 3m distance). In that context the required PU signal emission
199 power exceeds the limits stated under FCC Part 15, Subpart C rule part 15.231(b).

200 Therefore herewith, I, the undersigned Ventzeslav Jordanov, would like to request a
201 "power" waiver of Section 15.231(b) of the Commission's Rules (Power Limits Breach) to
202 permit the operation of the IntelliCap® FR Portable Unit in the ISM-433MHz band,
203 concerning a very occasional transmission of a command to an orally introduced drug
204 delivery capsule, based on the following argumentation:

- 205 1) The IntelliCap® FR Portable Unit is to be used as a transmitter in a **controlled**
206 **environment only** (i. e. commercial research clinic or research hospital), where
207 the possibility of interference with other (authorized) users is highly unlikely; The
208 Portable Unit is used as a **receiver only outside of the controlled environment**
209 (and as one it fully applies with the FCC norms and regulations).
- 210 2) Data is sent during a **very short transmission** – 10.5 ms (5 bytes transmitted)
- 211 3) In normal mode of operation the data transmission is to take place **not more than**
212 **five (5) data packets** within the application lifetime of the product (72 hours); data
213 transmissions are irregular and can be initiated only manual (NON periodic
214 transmissions)

215 Considering the argumentation above, the operation of the IntelliCap® FR Portable Unit
216 pursuant to the requested waiver is highly unlikely to cause harmful interference to the other
217 band authorized users, which to the best of my knowledge are listed below:

- 218 ✓ Remote Control Door Openers: based on argumentation points 2) the band
219 occupation by the IntelliCap® FR Portable Unit transmission is too short, and
220 therefore it will not match any door openers code, which in its simplest form contains
221 at least 8 bytes of data
- 222 ✓ Licensed Amateur Radio Users: based on argumentation points 2) the band
223 occupation by the IntelliCap® FR Portable Unit transmission is too short to have any
224 influence on the amateur radio users; furthermore based on argumentation points 1)
225 it is highly unlikely that any application of amateur radio will take place in close
226 vicinity of hospitals and/or clinic research centers.
- 227 ✓ Federal Government Radar Systems: based on argumentation points 1) it is highly
228 unlikely that the band occupation by the IntelliCap® FR Portable Unit transmission will
229 cause any interference to the Federal Government Radar Systems since the
230 controlled environment locations (i.e. hospitals and/or clinic research centers) are

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231 located within or around urban areas which are outside the 40km zone to the
232 following sites:

- 233 ○ Beale Air Force Base
- 234 ○ Cape Cod Air Force Base
- 235 ○ Clear Air Force Base
- 236 ○ Cavalier Air Force Base
- 237 ○ Eglin Air Force Base

238 ✓ RFID for Identification of Shipping Containers: based on argumentation points 1) it is
239 highly unlikely that the band occupation by the IntelliCap® FR Portable Unit
240 transmission will cause any interference to the RFID tags since these are not used,
241 to the best of my knowledge, within hospitals and/or clinic research centers.
242

243 5. Conclusive statement

244 Considering the argumentation provided above no harmful interference is foreseen with
245 other band authorized users by the extremely occasional application of the IntelliCap® FR
246 Portable Unit as a transmitter and thus it will be consistent with the underlying purpose of the
247 Part 15 technical rules.
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257 I, Ventzeslav Iordanov, do hereby state that the facts set forth therein are true and correct
258 to the best of my knowledge.
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Ventzeslav Iordanov
Principal System Architect
Director Quality Assurance & Regulatory Affairs

March 19, 2014

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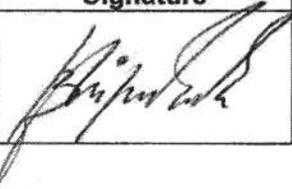
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Hans Zou	Director Applications Medimetrics	15 Jan 2014	
Christoph Wanke	Clinical/Customer Program Leader Medimetrics	15 Jan 2014	
Klaas Kerkhof	Director Industrialization and Manufacturing Medimetrics	JAN-15-2014	

10
11

Name Approver	Function Approver	Approval date	Signature
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Name Author	Function Author	Date	Signature
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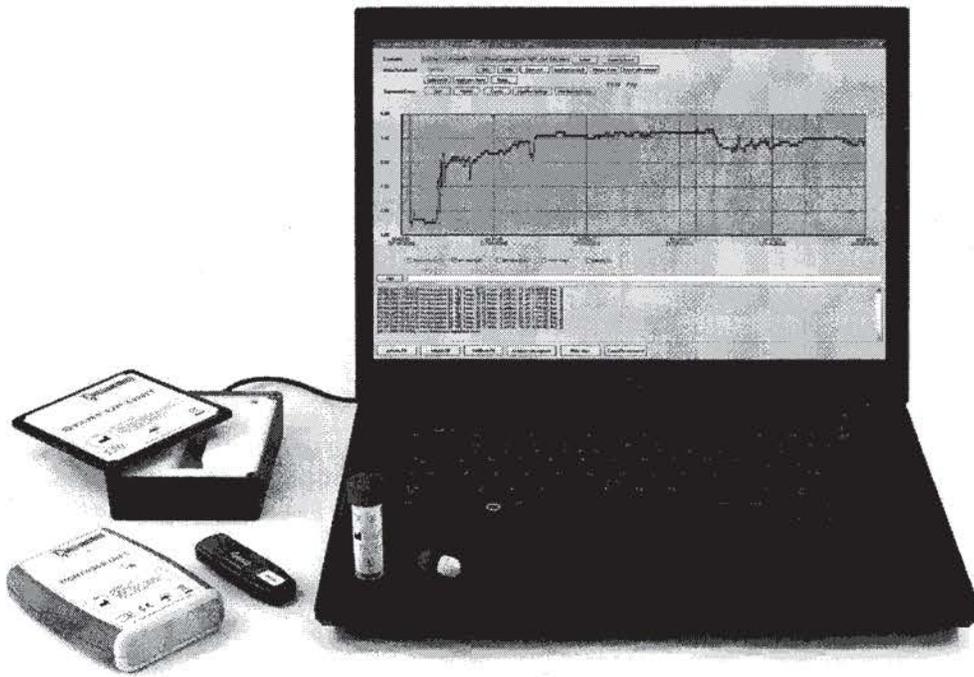
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IntelliCap® FR User Manual

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112 **1. General Information**

113 This user manual describes the constituent components and basic
114 operation of the IntelliCap[®] FR Drug Delivery and Monitoring System,
115 alternatively referred to as the IntelliCap[®] FR System. Detailed
116 procedures to execute individual operations are described in the GUI
117 Manual [Ref.1]

118 *Trademarks*

119

- 120 • IntelliCap[®] is a registered trademark of Medimetrics Personalized
121 Drug Delivery B.V. in the United States and Europe
- 122 • Microsoft Windows[®] is a trademark of Microsoft Corporation
- 123 • Core2 is a trademark of Intel

124

125 The IntelliCap[®] FR System is manufactured by Medimetrics
126 Personalized Drug Delivery B.V.

127

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129 High Tech Campus 10 (HTC10.208)
130 5656 AE Eindhoven
131 The Netherlands
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133 Telephone: +31 (0)6 11 316 951

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134 **2. Software License Agreement**

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136 Carefully read this SOFTWARE LICENCE AGREEMENT before continuing.
137 By opening/using the Software you accept and agree to comply with the
138 terms and conditions of this Agreement. If you do not agree with these
139 terms and conditions, contact Medimetrics for directions on how to return
140 your software package.

141 *Software Licence Agreement*

- 142 1. Software: As used herein SOFTWARE shall mean the IntelliCap® FR
143 Data viewing software supplied with and designed for use with
144 IntelliCap® FR System products.
- 145 2. Grant of License: Medimetrics grants you the right to use its software,
146 which may include "online" or "electronic" documents.
- 147 3. Upgrades: If the SOFTWARE is an upgrade, the same GRANT OF
148 LICENCE rules apply as if the SOFTWARE were an original installation.
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155 you may either (a) make one copy of the SOFTWARE solely for backup
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159 SOFTWARE after obtaining written permission exclusively from
160 Medimetrics.
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164 terms of the AGREEMENT. You may not reverse engineer, decompile,
165 disassemble, or otherwise reduce the SOFTWARE to a human-
166 perceivable form, nor permit anyone else to do so. You may not modify,
167 distribute or create derivate works based upon the SOFTWARE in whole
168 or in part without the written permission of Medimetrics.

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169 3. Intended Use

170 The IntelliCap® FR system is an in-vivo measurement system of pH and
171 temperature in the gastrointestinal (GI) tract of humans and mammals, in
172 order to facilitate delivery of a compatible compound in sections of GI
173 tract, as a tool for premarket drug research.

174 The IntelliCap® FR system is used as a tool for premarket drug
175 research. The IntelliCap® FR system is to be operated by trained
176 personnel. All persons using or operating the equipment shall receive
177 instruction and training from a member of Medimetrics. This manual
178 serves as a reference for operation, technical information, and
179 standardization of procedures.

180 4. Contraindications

181 THE INTELICAP® FR CAPSULE IS AN INDIGESTIBLE CAPSULE-SHAPED
182 OBJECT.

183 FURTHER AS THE SYSTEM OPERATES WITH WIRELESS RF
184 COMMUNICATION THE POSSIBILITY FOR INTERFERENCE WITH
185 IMPLANTED ELECTRO-MEDICAL DEVICES SHOULD BE AVOIDED, SINCE
186 THERE IS A CHANCE FOR AN ALTERED (UNDESIRE) FUNCTIONALITY OF
187 THE IMPLANTABLE DEVICE THAT MAY LEAD TO SEVERE INJURIES OR
188 DEATH.

189 SUBJECTS WHO ARE UNABLE TO SWALLOW THE CAPSULE OR WHO
190 PRESENT RISK FOR RETENTION OF THE CAPSULE SHOULD BE EXCLUDED
191 FOR USE, SINCE USAGE IN THESE CASES MAY LEAD TO SEVERE
192 INJURIES OR CHIRURGICAL INTERVENTION. IN THE CASE OF DOUBT AT
193 LEAST THE FOLLOWING CONTRAINDICATIONS APPLY:

- 194 • SUBJECTS WITH KNOWN OR SUSPECTED GASTROINTESTINAL STRICTURES,
195 INCLUDING (SUSPECTED) CROHN'S DISEASE;
- 196 • SUBJECTS WITH SWALLOWING DISORDERS;
- 197 • SUBJECTS USING ACID REDUCING MEDICATION;
- 198 • SUBJECTS USING NSAID'S;
- 199 • SUBJECT WITH KNOWN CARDIOPULMONARY OR GASTROINTESTINAL
200 DISORDERS;
- 201 • PREGNANCY OR BREASTFEEDING;
- 202 • SUBJECTS UNDERGOING MRI IMAGING WHILE THE INTELICAP CAPSULE IS
203 PRESENT IN THE BODY.

204 5. Restrictions

205 The dosage of compound(s) loaded into the IntelliCap® FR Capsule
206 should be safe and well tolerated.

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207 **6. IntelliCap[®] FR System Components**

208 **6.1 Control Center PC**

209 The system is primarily controlled and operated from a notebook PC
210 called the Control Center (CC). Software will be pre-installed by
211 Medimetrics personnel who will check the specifications of the commercial
212 notebook PC for compatibility. A notebook PC shall meet the following
213 minimum requirement:

214 CPU 1.6GHz, RAM 2GB, Operation System Microsoft Microsoft Windows
215 7 Professional, Service Pack 1, with Microsoft .NET Framework 3.5
216 installed.

217 *Software*

218 The Data viewing software application is specifically designed to be
219 used with the IntelliCap[®] FR System. Additional information concerning
220 detailed operation of the software may be found in separate
221 documentation not included with this system user manual. Basic
222 operation of the IntelliCap[®] FR System is covered here. With the Data
223 viewing software the user is able to:

- 224 • Initialize an IntelliCap[®] FR capsule with the behavior profile
- 225 • Establish a data communication link with a Portable Unit
- 226 • Activate an IntelliCap[®] FR capsule
- 227 • Enter pH calibration data for a given IntelliCap[®] FR capsule
- 228 • Continuously present the following parameters graphically and/or
229 numerically on screen:
 - 230 - pH Data: ADC reading and calibrated value
 - 231 - Temperature of IntelliCap[®] FR capsule
 - 232 - Battery reading of IntelliCap[®] FR capsule
- 233 • Command an IntelliCap[®] FR capsule to advance to the next
234 program segment
- 235 • Shut down an IntelliCap[®] FR capsule
- 236 • Import experiment data from previous data log files
- 237 • Export experiment data for analysis in external programs

239 **6.2 Start Up Unit**

240 The IntelliCap[®] FR capsules are initialized and activated by a Start-Up
241 Unit (SUU). The SUU is connected to the Control Center PC by a USB

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242 cable. The SUU incorporates a startup coil for inductively coupling energy
243 to an IntelliCap® FR capsule. Upon start up the IntelliCap® FR capsule
244 closes a switch for connection to its internal battery power. The SUU is
245 able to communicate wirelessly to an IntelliCap® FR capsule. This
246 communication link is also used to initialize the capsule. Initialization is
247 the process of programming the capsule with the desired behavior profile.
248 A photograph of a Start-Up Unit is shown in Figure 3.

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Figure 3: Photograph of a Start-Up Unit used to activate and initialize IntelliCap® FR capsules.

Note: Actual labels are discussed in Chapter 21.

277 **6.3 Portable Unit**

278 The Portable Unit (PU) is the main means for communication with an
279 IntelliCap® FR capsule during the execution of an experiment. The PU can
280 communicate with both the IntelliCap® FR capsule and the Control Center.
281 As the communication range of the IntelliCap® FR capsule is limited the
282 Portable Unit must be placed near the test subject. A photograph of a
283 Portable Unit is shown in Figure 4.

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306 **Figure 4: Photograph of a Portable Unit used for communication**
307 **between an IntelliCap® FR capsule and the Control Center PC. An**
308 **Amber USB Adapter is used for wireless communication between the**
309 **Control Center PC and a Portable Unit.**

310

311 **Note:** Actual labels are discussed in Chapter 21.



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312 The PU is a relatively small and lightweight unit that may be worn by a
313 test subject on a belt or specially designed holder. The holder may be fit
314 comfortably about the waist of a person and contains a pocket for housing
315 a PU. Data is stored locally on the PU and is additionally relayed to the
316 Control Center for immediate visualization and analysis. Data stored in
317 the PU memory is primarily for redundancy and to collect data when the
318 subject exits the test environment. The data can be downloaded by direct
319 connection via USB cable between the PU and Control Center. This
320 operation is intended to occur after the end of an experiment as the PU
321 cannot receive data from an IntelliCap capsule while downloading data via
322 the wired connection. There are two types of Portable Units that are
323 discussed in details in Chapter 21: Labels.

324 *Amber Module*

325 An Amber Wireless M-Bus USB Adapter AMB8465 operating at 868 MHz
326 (AMB2560 at 2.4 GHz for the US type) is connected to the Control Center
327 PC. The purpose of the Amber module is for low power wireless
328 communication to the Portable Unit. The Portable Unit is configured with a
329 matching module for wireless communication with the Control Center PC.
330 The USB Adapter is a product of Amber Wireless GmbH, Colonge,
331 Germany. The Amber USB Adapter and Control Center PC have been pre-
332 configured for operation with the IntelliCap[®] FR System. A photograph of
333 an Amber USB Adapter is shown in Figure 4 as well.

334

335 **6.4 IntelliCap[®] FR capsule**

336 The purpose of the IntelliCap[®] FR capsule is to measure conditions of
337 its local environment and to deliver the contents of a medication
338 container. The IntelliCap[®] FR capsule is prepared by loading the
339 medication container with the target medication and initializing it with the
340 desired behavior profile. The IntelliCap[®] FR capsule is also calibrated for
341 accuracy of the pH readings. The capsule is activated at a Start-Up Unit
342 and then used for an experiment. The capsule is swallowed by a test
343 subject and passes naturally through the digestive tract. It is excreted. As
344 needed the IntelliCap[®] FR capsule will be recovered after excretion by the
345 test subject. The recovered capsule can be cleaned and observed for
346 properties such as condition of the medication container or post-recovery

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347 calibration of the pH sensor. A photograph of an IntelliCap® FR capsule is
348 shown in Figure 5.

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366 **Figure 5: Photograph of an IntelliCap® FR capsule used for drug**
367 **delivery and monitoring in a test subject.**

368

369 **Note:** Actual labels are discussed in Chapter 21.

370

371 **7. Data security and privacy**

372

373 The IntelliCap® FR System provides a secure repository for your
374 information. The Control Center PC contains an encrypted hard drive and
375 can only be accessed by an authorized user through password entry. The
376 Data viewing Software stores data in a log file and can output data to a
377 formatted Excel file. Collected data relates specifically to an individual test
378 subject. Local laws governing the privacy and handling of data shall be
379 followed. Data files should be noted by subject number only and should
380 never contain direct information on the name or other personal
381 information of the test person.

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8. Warnings

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9. Cautions

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- CLINICAL USE OF THE INTELICAP[®] FR SYSTEM IS RESTRICTED TO TRAINED PERSONNEL, SINCE USAGE BY UNQUALIFIED PERSONNEL MAY LEAD TO SEVERE INJURIES.
- COMPONENTS AND SOFTWARE OF THE INTELICAP SYSTEM ARE OPTIMIZED FOR USE TOGETHER. DO NOT CONNECT OTHER MACHINES, DEVICES TO THE START UP UNIT, PORTABLE UNIT, CONTROL CENTER PC OR ITS ACCESSORIES BECAUSE DAMAGE TO INTELICAP[®] FR SYSTEM, DEVICES, OR SEVERE INJURIES TO THE USER OR THE PATIENT MAY OCCUR.
- NEVER USE THE PORTABLE UNIT ON A PATIENT WHEN CONNECTED TO THE MAINS FOR CHARGING OR ANY OTHER REASON. SERIOUS INJURY TO THE PATIENT MAY OCCUR.
- WHEN HANDLING THE INTELICAP[®] FR CAPSULE THE OPERATOR SHALL PUT ON A FRESH PAIR OF GLOVES. FAILURE TO OBSERVE THIS PROCEDURE RISKS TRANSMISSION OF MICROBIAL CONTAMINANTS TO THE PATIENT WHO SWALLOWS THE INTELICAP[®] FR CAPSULE.

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412 **10. Safety**

413

414 Safety features for the IntelliCap® FR System are monitored and
415 controlled by internal hardware and software checks. These features
416 provide an independent mechanism to monitor and react to system faults.
417 Indications of system status are provided both at the Portable Unit and
418 from the Software operating on the Control Center PC.

419 **10.1 Portable Unit Indicators**

420 The Portable Unit has LED indicator lights to monitor status and display
421 to the subject or system operator. The Portable Unit may have the
422 following indications:

- 423 • Power On/Off;
 - 424 - When power is switched on and the Portable Unit operating,
 - 425 the "Power" LED will be will be constantly lit.
 - 426 - When power is switched off, the "Power" LED will be off.

427

428 **WARNING:** NEVER USE THE PORTABLE UNIT ON A PATIENT
429 WHEN CONNECTED TO THE MAINS FOR CHARGING OR ANY
430 OTHER REASON. SERIOUS INJURY TO THE PATIENT MAY
431 OCCUR.

432 **10.2 Control Center Indicators**

433 Software running on the Control Center provides indicator messages to
434 the operator to inform of system status and operation. The following
435 messages should be monitored:

- 436 • Status of Portable Unit
 - 437 The main Data viewing form shows the status of the portable unit in
 - 438 a line in the top grouping see for example Figure 6.
 - 439 - Not Available: Communication with the Portable Unit cannot
 - 440 be established. The operator should check the Portable Unit
 - 441 power status and/or connection of the Amber USB Adaptor
 - 442 and/or settings in the "Configuration" dialog box.
 - 443 - Available: Communication with the Portable Unit is operating
 - 444 normally.
- 445 • Capsule activated message box:
 - 446 - When an IntelliCap® FR is successfully activated at the Start
 - 447 Up Unit, a message box pops up on the screen. The operator
 - 448 should click the "OK" button to dismiss.
 - 449

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450 11. Utilization of IntelliCap® FR system

451

452 The IntelliCap® FR system is used for investigative studies with test
453 subjects. The test subjects are evaluated for inclusion in the study. An
454 attending physician, nurse, or other medical personnel trained in the use
455 of the IntelliCap® FR system directs the subjects for their use and
456 interaction with the IntelliCap® FR system components: the capsule, the
457 portable unit, the belt to hold a PU, and any other ancillary equipment.
458 Additionally the attending medical personnel are assisted by Medimetrics
459 personnel with the set-up and operation of the IntelliCap® FR system. The
460 exact procedures may vary with each study as described in the protocol.
461 Typical actions for use of the system are described below.

- 462 • Medimetrics personnel set up the IntelliCap® FR system in the study
463 environment
- 464 • Medimetrics personnel prepare the capsules for use including
465 initialization, pH-sensor calibration, and activation of capsules
- 466 • A portable unit is prepared by Medimetrics personnel and placed
467 into a belt
- 468 • The belt is given to the test subject for fitting around the abdomen
- 469 • Activated capsules are handed to the attending medical personnel
- 470 • Attending medical personnel provides the capsule to the test subject
- 471 • Test subjects swallow the capsule along with a glass of water
- 472 • Data is recorded at the control center PC
- 473 • The subject remains in a defined area near the control center PC
- 474 • Manual commands may be given from the control center PC to
475 control action of the capsule if called for in the study design
- 476 • Depending on the study design the test subject may be allowed to
477 leave the test area after a certain period of time. While the capsule
478 is still in the body, the belt with portable unit shall still be worn.
- 479 • The subject may remove the belt with portable unit for short
480 periods of time for clothing change, bathing, etc. The belt and
481 portable unit should not be submerged in water or worn in the
482 shower.
- 483 • The belt with portable unit may be removed for sleeping and placed
484 close to the subject's bed
- 485 • The subject shall be requested to recover the capsule from feces
486 after a bowel movement

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