

20 | CLINICAL EVALUATION OF BCIs

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4 **P**revious chapters in this book have discussed the technical principles and methods of BCI technology. These
 5 chapters show that, despite their current limitations,
 6 BCIs are fast becoming effective communication and control
 7 devices. However, the rapid growth of this research and its
 8 remarkable progress are still confined almost entirely to the
 9 cosseted environments of a multitude of laboratories through-
 10 out the world. Furthermore, most BCI experiments have been
 11 and continue to be conducted in able-bodied humans or ani-
 12 mals rather than in the severely disabled people for whom this
 13 new technology is primarily intended.

14 Certainly, there are compelling theoretical and practical
 15 reasons for this overwhelming focus on laboratory studies in
 16 normal subjects: labs provide the strictly controlled environ-
 17 ments and expert oversight conducive to the development and
 18 optimization of new technology; and able-bodied populations
 19 are more available and avoid the additional variables intro-
 20 duced by disease and injury that may vary widely across
 21 individuals.

22 Nevertheless, this focus leaves a major research gap that
 23 must be addressed if BCIs are to fulfill their primary purpose
 24 and justify the considerable support that their development
 25 receives from governments and other funding entities. That is,
 26 the BCIs that work well in the laboratory need to be shown to
 27 work well in real life, to provide people with disabilities new
 28 communication and other capabilities that improve their daily
 29 lives.

30 In some ways, this essential task is considerably more com-
 31 plicated and more demanding than the laboratory research that
 32 produces a BCI system. That original research has a single aim:
 33 to design and optimize a BCI that provides reliable and accurate
 34 communication or control in a carefully controlled and closely
 35 monitored laboratory setting. In contrast, research that seeks to
 36 establish the real-life usefulness of a BCI system has four differ-
 37 ent aims. They may be stated as a set of four questions:

- 38 • Can the BCI design be implemented in a form
- 39 suitable for long-term independent use?
- 40 • Who are the people who need the BCI system,
- 41 and can they use it?
- 42 • Can their home environments support their use
- 43 of the BCI, and do they actually use it?
- 44 • Does the BCI improve their lives?

This chapter addresses each of these questions in turn. 45
 It considers the steps involved in answering each and the 46
 potential problems that must be overcome. Since the present 47
 peer-reviewed literature lacks any formal multisubject studies 48
 that address these questions (and indeed has few reports of any 49
 kind that are directly relevant to these questions), the discus- 50
 sion necessarily relies heavily on the authors' experience to 51
 date, which is primarily with a noninvasive EEG P300-based 52
 BCI system (see chapter 12 in this volume). Nevertheless, the 53
 chapter's overall intent is to provide information and insight 54
 that would apply to any effort to take any BCI system out of the 55
 lab and validate its effectiveness in the everyday lives of people 56
 with disabilities. 57

CAN THE BCI DESIGN BE IMPLEMENTED 58 IN A FORM SUITABLE FOR LONG-TERM 59 INDEPENDENT USE? 60

61 For some BCIs, this first question is readily answered in the
 62 negative. For example, the expense, size, and complexity of
 63 fMRI-based or MEG-based BCI systems confine them to labo-
 64 ratory settings, at least for the foreseeable future (Bradshaw
 65 et al. 2001; Buch et al. 2008; Cohen 1972; Kaiser et al. 2005; Lee
 66 et al. 2009; Mellinger et al. 2007; Tecchio et al. 2007; van Gerven
 67 and Jensen 2009). BCIs that rely on implanted devices (e.g.,
 68 electrocortigraphy [ECoG], local field potentials [LFPs], or
 69 single units) have demonstrated impressive capacity both in
 70 animals and in humans. These BCIs face the same safety
 71 requirements as any device for clinical use, and, in addition,
 72 they must demonstrate that they are sufficiently reliable and
 73 effective to warrant human implantation (Donoghue 2008). At
 74 present, BCIs based on EEG (and possibly also those based on
 75 functional near-infrared spectroscopy [fNIRS]) are the best
 76 candidates for independent use (Bauerfeind et al. 2008; Coyle
 77 et al. 2007; Naito et al. 2007). Even so, their transition from the
 78 laboratory to the home, and to long-term everyday use, requires
 79 substantial reconfiguration of their components and consider-
 80 ation of issues that do not generally arise in the laboratory.

81 Any BCI system deployed for independent use must be
 82 safe to operate in the home environment without on-site tech-
 83 nical support. Components should be few, small, portable, and
 84 relatively inexpensive; and the connections between them
 85 should be minimized (e.g., by use of telemetry) and extremely
 86 robust. They must be packaged in sturdy and configurable



Figure 20.1 (A) The current Wadsworth P300-based BCI home system. The components include a laptop computer, an eight-channel EEG amplifier (Guger Technologies,), an electrode cap (Electro-Cap International,), a 20" monitor, and connecting cables. (B) A compact traveling BCI evaluation unit designed for easy setup, breakdown, and storage of all necessary hardware and supplies.

1 housing to provide flexible setup and easy storage and must be
 2 able to withstand potentially rough handling over many
 3 months. Ideally, the amplifiers should be insensitive to the
 4 many sources of electromagnetic noise present in home set-
 5 tings, and the electrodes and their mounting (e.g., for EEG, the
 6 electrode cap) should be capable of functioning safely and
 7 effectively for many hours per day over months without main-
 8 tenance or replacement. The software should be easy to use and
 9 thoroughly tested (i.e., impervious to BCI user or caregiver
 10 error). Before attempting to take a BCI system out of the labo-
 11 ratory, investigators should meet these requirements to the
 12 greatest extent possible. At the same time, they should recog-
 13 nize that further changes are likely to be needed when the BCI
 14 is actually deployed in the home environment. In this regard
 15 the principles of modularity in the software (e.g., Schalk et al.
 16 2004) and in the hardware (e.g., Cincotti et al. 2008) can expe-
 17 ditate the implementation of improvements and upgrades, and
 18 the tackling of unexpected failures. Figure 20–1A shows the
 19 current version of the P300-based BCI home system developed
 20 at the Wadsworth Center of the New York State Department of
 21 Health (Albany, NY); and figure 20–1B shows a compact trav-
 22 eling unit for evaluating this system's suitability for potential
 23 users who are homebound.

24 Figure 20–2A shows the Wadsworth BCI home system in
 25 operation. This system has now been used by seven severely

disabled people in their homes over months and years. It is
 managed by the caregivers in the users' homes, with internet
 oversight from the Wadsworth BCI laboratory and occasional
 home visits by technical personnel from the lab. The foreground
 of figure 20–2A shows the crowded environment of the user's
 room. It is typical of the environments of people with severe
 disabilities.

WHO ARE THE PEOPLE WHO NEED THE BCI, AND CAN THEY USE IT?

Present-day BCIs have relatively modest capabilities. Thus, the
 communication and control applications they can provide are
 likely to be of significant value only to people with extremely
 severe disabilities that prevent them from using conventional
 assistive technologies (see chapter 11). Over the past decade a
 number of studies have begun to explore the BCI capacities of
 people severely disabled by disorders such as ALS or high-level
 spinal cord injury (e.g., Bai et al. 2010; Bai et al. 2010; Birbaumer
 et al. 1999; Conradi et al. 2009; Farwell and Donchin 1988;
 Hochberg et al. 2006; Hoffmann et al. 2008; Ikegami et al. 2011;
 Kauhanen et al. 2007; Kennedy and Bakay 1998; Kubler
 et al. 2001; Kubler et al. 2005a; Kubler et al. 2009; McFarland
 et al. 2010; Miner et al. 1998; Mugler et al. 2010; Muller-Putz

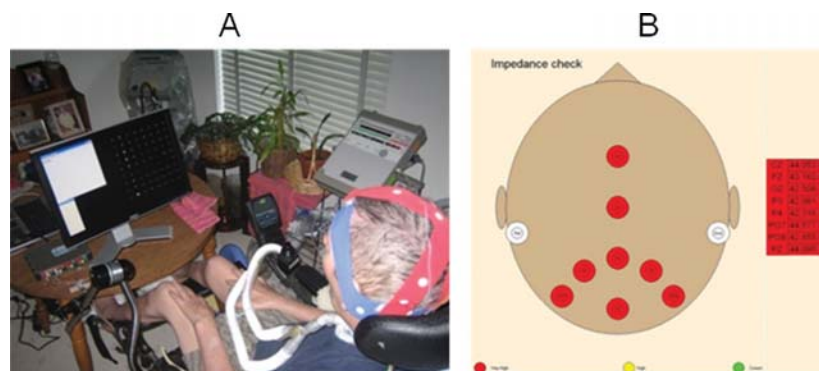


Figure 20.2 (A) A person severely disabled by amyotrophic lateral sclerosis (ALS) using the Wadsworth brain-computer interface (BCI) system in his home. He wears a modified eight-channel electrode cap. (B) Monitor display used by caregiver to check electrode impedance. Red dots are the locations of the eight recording electrodes. When all the locations become green, electrode impedance is sufficiently low, and the caregiver can begin the BCI session.

1 et al. 2005; Nijboer et al. 2008; Pfurtscheller et al. 2000; Piccione
 2 et al. 2006; Pires et al. 2011; Sellers and Donchin 2006;
 3 Sellers et al. 2010; Silvoni et al. 2009; Townsend et al. 2010;).
 4 Although some subjects have been studied in their home envi-
 5 ronments, most of this work has generally consisted only of
 6 limited sessions with the experimenters closely overseeing
 7 BCI operation. Nevertheless, the results to date are encourag-
 8 ing in that they indicate that many people with severe dis-
 9 abilities can use BCIs that could in theory help them in their
 10 daily lives.

11 These individuals are usually home-bound (or institution-
 12 bound) and attended by caregivers 24 hours per day (Albert
 13 et al. 2009). They comprise the target user population for the
 14 BCIs that are available now or likely to be available within the
 15 next decade. How does a BCI researcher find good subjects for
 16 studies testing the effectiveness and utility of BCI home use for
 17 people with severe disabilities? And how does he or she proceed
 18 with these subjects once they are identified?

19 **DEFINING THE POPULATION OF**
 20 **PROSPECTIVE BCI HOME USERS**

21 As in most clinical studies, subjects are selected according to a
 22 specific set of criteria. For the user population described above,
 23 the basic inclusion criteria would be:

- 24 • Little or no useful voluntary muscle control
 25 (e.g., people with late-stage ALS, muscular
 26 dystrophy, severe Guillain-Barré syndrome,
 27 brainstem stroke, severe cerebral palsy,
 28 high-level spinal cord injury, or a variety
 29 of other severe neuromuscular disorders).
 30 (For people with ALS or other progressive
 31 diseases, this criterion might be extended to
 32 include those who have not yet reached this
 33 level of disability but can be expected to do
 34 so eventually.)
- 35 • Conventional assistive (i.e., muscle-based)
 36 communication devices (e.g., eye-gaze systems,
 37 EMG switches) are not adequate for their
 38 needs: they may be entirely unable to use these
 39 devices; their control may be inconsistent or
 40 they may fatigue quickly; they may not like the
 41 devices; or they may desire the additional
 42 communication and control capabilities that a
 43 BCI could provide.
- 44 • Medically stable, with the intent, and a
 45 reasonable expectation, of living for at least one
 46 year. If they have ALS, they have already begun
 47 artificial ventilation or have decided to do so
 48 when it becomes necessary.
- 49 • Able to follow spoken or written directions.
- 50 • Absence of any other impairment that would
 51 prevent BCI usage (e.g., extremely poor vision

- would prevent use of a BCI that uses visual
 stimuli). 52 53
- Stable living environment. 54
- Reliable caregivers (family members and/or
 professionals) possessing or capable of 55
 acquiring basic computer skills and enthusiastic 56
 about supporting the subject’s BCI usage. 57 58
- Subject and caregivers able and willing to 59
 provide informed consent and clearly 60
 enthusiastic about participating in a research 61
 study that may have no lasting direct benefit to 62
 them (Vaughan et al. 2006). 63

Given the wide variety of disorders that can cause severe 64
 motor disability, the complexity of the disabilities they cause, 65
 and other variables associated with these disorders (e.g., medi- 66
 cation, other medical problems), it is often difficult to deter- 67
 mine whether a particular person satisfies these criteria 68
 (Kuebler et al. 2006). For example, aphasia, which occurs in 69
 association with over 25% of strokes, can interfere with the 70
 ability to understand instructions about how to use the BCI 71
 and/or with formulation of messages to be communicated with 72
 it (Pederson et al. 1995; Wade et al. 1986). On the other hand, 73
 a right or left hemianopsia (i.e., loss of the right or left visual 74
 field) produced by stroke would probably not interfere with 75
 BCI use if the screen is positioned in the remaining visual field. 76
 Since many prospective BCI users are older adults with ALS or 77
 strokes, age-related visual impairments (e.g., macular degener- 78
 ation, glaucoma, and cataracts [Streiff 1967]) might also 79
 affect BCI capability. 80

Appropriate assessment questions (e.g., can the person 81
 read text on a screen?) or a standard measure of visual acuity 82
 (e.g., Snellen test [Tucker and Charman 1975]) may evaluate 83
 this visual issue. Another relevant factor includes current medi- 84
 cations (e.g., sedatives) that may interfere with brain function 85
 or affect the EEG (Towler et al. 1962). Cognitive impairments 86
 (which occur in up to 40% of people with ALS [Woolley et al. 87
 2010; Volpato et al. 2010]) and depression may also interfere 88
 with BCI use. Although the recent literature indicates that 89
 people with advanced ALS generally rate their quality of life as 90
 quite high, moderate depression is often present (Gauthier 91
 et al. 2007; Chio et al. 2004; Robbins et al. 2001; Simmons et al. 92
 2006; Kubler et al. 2005b). As in other therapeutic endeavors 93
 (Kirchhoff and Kehl 2007) (as well as in most life endeavors), 94
 mood can affect motivation and play a significant role in BCI 95
 effectiveness (Kleih et al. 2010). 96

97 **RECRUITING PARTICIPANTS FOR BCI**
 98 **HOME-USER STUDIES**

Subject recruitment is a key part of any clinical study and often 99
 presents significant difficulties (e.g., Bedlack et al. 2010). 100
 Recruiting and retaining individuals who have entered the late 101
 stages of a progressive neurological disease can be particularly 102
 challenging (Shields et al. 2010). Hospitals, regional clinics, 103

1 and medical specialists are traditional sources of subject refer- 55
 2 als. However, many potential BCI home users no longer attend 56
 3 a clinic regularly or participate in routine rehabilitation ser- 57
 4 vices, and they may not be under the continuing care of medi- 58
 5 cal specialists. On the other hand, many of these individuals 59
 6 are enrolled in programs that provide assistive technology 60
 7 (AT) for seating, mobility, and communication needs (Cotterell 61
 8 2008). Thus, subject recruitment is often accomplished by con- 62
 9 tacting speech/language pathologists and/or physical thera- 63
 10 pists. Home-care physicians, rehabilitation hospitals, visiting 64
 11 nurse services, and hospice providers can also be sources of 65
 12 potential BCI home users. Local school districts frequently
 13 have information on programs that serve people with extreme
 14 physical challenges. Finally, certain registries of patient popu-
 15 lations can be useful in recruiting a clinical study cohort (e.g.,
 16 the national registry of veterans with ALS developed by the
 17 Veterans Administration, National ALS Registry Home Page;
 18 Allen et al. 2008; Lancet Neurology Editorial 2009]). Such reg-
 19 istries can expand the number of potential contacts well beyond
 20 the immediate geographic region. Registries vary in the cur-
 21 rency of their information and in the steps required to use
 22 them in subject recruitment (e.g., Registry board approval,
 23 local IRB oversight).

24 Whether a particular individual meets the inclusion crite- 68
 25 ria defined above can normally be determined from interviews 69
 26 with caregivers, medical personnel, and/or family members. 70
 27 Thus, in most instances, people who do not meet the criteria 71
 28 can be identified and excluded without actually testing them 72
 29 with the BCI. This can substantially reduce the time and effort 73
 30 the research group invests in testing people who do not turn 74
 31 out to be appropriate for the study. It may also substantially 75
 32 reduce the possibility that exclusion might greatly disappoint a 76
 33 prospective subject. 77

34 OBTAINING INFORMED CONSENT

35 The extremely disabled people who could benefit from current 78
 36 BCIs generally lack understandable speech. In many cases their 79
 37 communication depends entirely on subtle movements of the 80
 38 face, especially small movements of the eyes (Neumann and 81
 39 Kubler 2003). Thus, it may be difficult to obtain the subject's 82
 40 informed consent for participation in a BCI study. Nevertheless, 83
 41 individuals who retain a clear capacity to control such simple 84
 42 movements and to thereby communicate (e.g., via a letterboard 85
 43 held by a caregiver) can provide informed consent, although 86
 44 the process may require considerable time and effort for all 87
 45 concerned. Furthermore, for studies that are found to pose no 88
 46 significant risk (e.g., most noninvasive BCI studies), subjects 89
 47 may participate by providing *informed assent* (Black et al. 90
 48 2010). Informed assent requires only that they be able to answer 91
 49 yes/no questions. Unlike informed consent, it does not require 92
 50 that they be able to ask questions. 93

51 For people in whom the capacity to provide informed con- 94
 52 sent (or assent) is uncertain, many locales have established 95
 53 procedures for permitting close relatives to act on behalf of 96
 54 an incapacitated person to provide informed consent for 97

participation in a clinical trial. Although such surrogate 55
 approvals may be relatively straightforward for noninvasive 56
 minimal-risk BCI systems, they become more problematic for 57
 invasive BCI systems, which may entail significant risks 58
 (including possible discomfort) (see discussion in chapter 24). 59
 For people with progressive diseases such as ALS, informed 60
 consent may be obtained (and BCI use might be initiated) 61
 during earlier stages of the disease when adequate communi- 62
 cation capacity is still present. (Early BCI use may also facili- 63
 tate the transition to extensive BCI use when conventional 64
 communication is no longer possible.) 65

66 DETERMINING WHETHER A POTENTIAL 67 68 STUDY SUBJECT CAN USE THE BCI

69 For each person who has met the inclusion criteria and pro- 70
 71 vided informed consent (or assent), the next step is an evalua- 71
 72 tion of his or her ability to use the BCI. This evaluation 72
 73 represents a Go/No-Go decision for participation in the clini- 73
 74 cal study. In work to date by the Wadsworth BCI research 74
 75 group using a P300-based BCI, this evaluation has consisted of 75
 76 two or three 1–2 hour sessions. During each of these sessions 76
 77 the subject performs a cued letter-selection task referred to as 77
 78 copy spelling (Birbaumer et al. 1999). The goal is to collect suf- 78
 79 ficient data to parameterize the BCI so that henceforth the user 79
 80 can then it to communicate intent (e.g., to spell freely, select 80
 81 icons, etc.). In most cases, as few as 21 copy-spelling selections 81
 82 (i.e., trials) are sufficient to parameterize the system (McCane 82
 83 et al. 2009). With the standard 6×6 P300 matrix (for which 83
 84 chance accuracy is 2.8%), accuracy of $>70\%$ is generally consid- 84
 85 ered adequate for effective communication (Sellers et al. 2006). 85

86 McCane et al. (2009) used interviews to identify 25 people 86
 87 with ALS who appeared to be good candidates for use of a 87
 88 P300-based BCI. In subsequent testing with the BCI system, 17 88
 89 of the 25 candidates (68%) achieved the requisite accuracy of 89
 90 $>70\%$ and were thus judged able to use the BCI. It is worth 90
 91 noting here that there was no correlation between the subjects' 91
 92 BCI accuracy and their disability level as measured with the 92
 93 ALS functional rating scale. For the remaining eight people 93
 94 accuracy was $<40\%$. Seven of these people had visual problems 94
 95 (e.g., ptosis, nystagmus, diplopia) that interfered with BCI use. 95
 96 (Such problems are common in people with late-stage ALS 96
 97 [Mizutani et al. 1990; Pinto and de Carvalho 2008]). These 97
 98 data further emphasize the importance of gathering relevant 98
 99 information prior to BCI testing. 99

100 The evaluation of a person's capacity to use the BCI may be 100
 101 particularly difficult with people who lack a clearly reliable 101
 102 means of basic communication (e.g., an eyeblink or muscle 102
 103 twitch). If an individual does not have an obvious and rela- 103
 104 tively fast way to ask and answer questions, the only way to 104
 105 know that he or she has understood the instructions is for the 105
 106 person to communicate using the BCI, and this requires and 106
 107 assumes that the BCI itself is working properly. The difficult 107
 108 issue of BCI use by people who lack any muscle-based com- 108
 munication (i.e., are completely locked in) is addressed more 109
 fully in chapters 11 and 19 of this volume. 110

1 CAN THE HOME ENVIRONMENT SUPPORT 2 BCI USE, AND IS THE BCI ACTUALLY 3 USED?

4 ASSESSING THE ENVIRONMENT AND THE 5 CAREGIVERS

6 Successful home use of current BCI systems require a home
7 environment that can support their use. Home environment
8 assessment can be accomplished first by appropriate questions
9 during telephone interviews and then during the initial BCI
10 evaluation sessions. Home assessment includes evaluation of
11 not only the physical environment but also the level of interest
12 and ability of the users and their caregivers. The immediate
13 environments of people with severe disabilities are often
14 crowded with much essential equipment, including ventilators,
15 mechanical beds, and wheelchairs. Thus, the placing of the BCI
16 system and the positioning of the prospective user may be
17 challenging, and significant sources of electrical noise and
18 intermittent artifacts may be present. These factors, the diffi-
19 culties they present, and the prospects for overcoming them
20 can be initially assessed in the first home visits. These visits are
21 also an opportunity to assess, at least in an informal fashion,
22 the technical skills, learning capacities, interest, and motiva-
23 tion of the caregivers who will need to support BCI use.
24 Without capable and motivated caregivers, long-term BCI
25 home usage is not possible (Wilkins et al. 2009).

26 For subjects who have an adequate home environment and
27 are able to use the BCI, the next step is to tell the subject and
28 the caregivers who will support and oversee BCI use about the
29 BCI applications available and about the time, effort, and spe-
30 cific tasks involved in BCI use. This will allow the level of moti-
31 vation of both the subject and the caregivers to be further
32 assessed. If they are motivated, a plan may then be formulated
33 incorporating the purposes for which the user wants to use the
34 BCI. For all users, particularly those who still retain some
35 capacity for conventional (i.e., neuromuscular) communica-
36 tion, this planning step should involve both the user and the
37 caregivers to the greatest extent possible. As described in chap-
38 ters 11 and 19, the participants' involvement is a key factor in
39 the success of testing new and/or old BCI applications. If the
40 subjects and their caregivers are motivated and a good usage
41 plan has been defined, the study can then move on to deter-
42 mine whether the person actually uses the BCI in daily life.

43 INITIATING AND EVALUATING BCI HOME USE

44 Initiation and evaluation of BCI home use includes five primary
45 tasks:

- 46 • Configuring the BCI to satisfy the needs and
47 preferences of the user
- 48 • Placing the BCI in the home
- 49 • Training the subject to use the BCI applications
50 and the caregivers to support BCI use
- 51 • Providing ongoing technical support as needed

- Measuring the extent, nature, and success of 52
BCI usage. 53

CONFIGURING THE BCI FOR THE USER 54

55 Before home use begins, the BCI should be configured for the
56 individual user. For example, in the standard P300-based BCI,
57 the numbers and sizes of the matrix items, as well as their
58 brightness and flash-rate, can generally be adjusted according
59 to the abilities and preferences of the user. Careful attention to
60 each user's abilities and preferences is essential. Although
61 speed is generally considered important in communication, it
62 may or may not be of paramount importance to a user who has
63 little or no remaining useful motor function (Millán et al. 64
2010). For these individuals, the restoration of some measure
65 of independent communication may be more important than
66 speed. They may prefer slower but more accurate output to
67 faster but less accurate output. Indeed, one person severely
68 disabled by ALS who uses a P300-based BCI in his daily life
69 chooses to have a 9-sec pause inserted after each selection and
70 thus communicates at a rate considerably slower than the max-
71 imum rate the BCI could provide (Sellers et al. 2010). When
72 they become available for home use, BCI systems that use audi-
73 tory stimuli or combined visual/auditory stimuli may be most
74 appropriate for people who lack sufficient visual function
75 (Farquhar et al. 2008; Hill 2005; Guo et al. 2010; Hinterberger
76 et al. 2004; Klobassa et al. 2009; Sellers and Donchin 2006;
77 Nijboer et al. 2008; Furdea et al. 2009; Kanoh et al. 2008;
78 Schreuder et al. 2010).

79 BCI applications must also match their users' preferences.
80 Carefully tailoring the application to the individual while
81 working within the constraints of the system design will
82 improve use acceptance and general satisfaction with the BCI.
83 Since motivation is critical in ensuring subject participation,
84 the choice of application is extremely important. For example,
85 people with high spinal-cord injuries who are still able to
86 speak, may not be interested in a BCI application that controls
87 a speech-generating device, but may be very interested in an
88 application that controls a computer mouse.

89 The BCI applications that have been tested thus far in home
90 use are based mainly on selection of icons presented on a com-
91 puter screen, and they often include sequential menu formats.
92 They can provide a number of simple functions, including
93 word processing, e-mail, environmental control, and Internet
94 access (e.g., Sellers et al. 2010). Menu formats and sequences
95 can be configured to match the capacities, needs, and prefer-
96 ences of each user. They can support important functions such
97 as: requests for medical or other care; room temperature and
98 other environmental controls; answering simple questions (in
99 print or with a speech synthesizer); interactions with family
100 members or friends; requests for food or drink; e-mail; word-
101 processing; entertainment; Internet access; and others. Figure
102 20-3 shows an e-mail application that several users of the
103 Wadsworth P300-based BCI home system are now employing
104 to communicate with family and friends.

105 As discussed in detail in chapter 11, guidelines, standards,
106 and examples abound in the field of AT, and BCI researchers

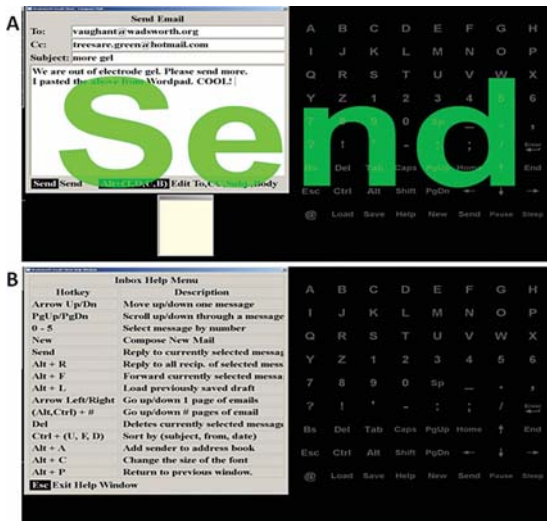


Figure 20.3 The e-mail application for the P300-based Wadsworth BCI home system. (A) On the right is the standard 8 × 9 matrix capable of controlling any Windows-based program that can be operated with a keyboard. On the left is an e-mail that the BCI user has just composed and sent. The green “Send” confirms to the user that the “Send” command has been recognized and executed. The small window below the message is an optional predictive speller feature that can increase writing speed. (B) On the left is the Help Menu, which can be accessed by selecting the word “Help” from the bottom row-fourth column of the matrix (right). This menu lists commands that can be executed through other matrix selections. (See chapter 12 in this volume for full explication of the P300-based BCI methodology used here.)

1 should avail themselves of the extensive technology, experi-
 2 ence, and expertise available in that field. Indeed, BCI home
 3 systems are best viewed as technology that extends the spec-
 4 trum of conventional (i.e., muscle-based) AT technology, and
 5 BCIs will often be most effective when used as new control
 6 interfaces for existing AT devices (chapter 11). BCI clinical
 7 research can benefit from innovations in AT and in other areas
 8 of human-computer interface (HCI) research and develop-
 9 ment (e.g., Cook and Hussey 2002; Cremers et al. 1999). These
 10 can be as straightforward as language-prediction programs
 11 (Ryan et al. 2011) or as novel as the Hex-o-spell (Blankertz
 12 et al. 2007; Williamson et al. 2009).

13 PLACING THE BCI IN THE HOME

14 In the transition from the laboratory to the home, many new
 15 factors that can interfere with BCI use come into play (Sellers
 16 et al. 2003; Sellers and Donchin 2006; Neumann and Kubler
 17 2003). Although the nature of their vulnerabilities varies
 18 with their methodology, all BCIs systems are likely to encoun-
 19 ter a variety of difficulties in making the transition from the
 20 simple, highly controlled laboratory environment to much
 21 more variable, uncontrolled, and demanding home environ-
 22 ments. This is likely to be the case for both noninvasive and
 23 invasive BCIs and for BCIs that use electrical or metabolic sig-
 24 nals. Because most BCI types remain largely confined to the
 25 laboratory, the discussion here necessarily focuses on the prob-
 26 lems encountered by the EEG-based BCIs now being tested in
 27 home use.

Figure 20–2A shows a person with ALS using a P300-based 28
 BCI. It is clear from the figure that, in addition to the BCI 29
 equipment, several other electronic and medical devices 30
 including a ventilator are in very close proximity. The clutter 31
 typical of the immediate home environment of severely dis- 32
 abled people (who are usually in a wheelchair or a bed with 33
 various medical equipment close by) requires that the BCI 34
 system be portable and sufficiently small to fit into this com- 35
 plex environment. The typical home also has other distractions 36
 (e.g., people entering and exiting the room, telephones ringing, 37
 dogs barking, etc.) that may interfere with the attention needed 38
 for BCI usage and that should also be considered in deciding 39
 where to place the BCI. Working together, the user, caregiver, 40
 and investigators should consider the setting(s) in which the 41
 BCI will be used, and decide how the user and the system com- 42
 ponents will best be situated. 43

The typical home has multiple sources of electromagnetic 44
 noise that can degrade the quality of EEG recording. In addi- 45
 tion to generating ongoing 60-Hz (or 50-Hz) line noise, heat- 46
 ing/cooling appliances (e.g., refrigerators) that cycle on and off 47
 and other appliances such as electric garage-door openers can 48
 produce severe transient artifacts. The ventilators essential to 49
 the survival of many prospective BCI users often cause high- 50
 frequency electromagnetic artifacts as well as low-frequency 51
 mechanical (i.e., movement) artifacts (Young and Campbell 52
 1999). Such electromagnetic noise can be reduced by proper 53
 grounding and secure connection of the ground and reference 54
 electrodes and by such maneuvers as suspending the electrode 55
 cables or simply moving them away from the ventilator. Low- 56
 frequency mechanical artifacts caused by head movement with 57
 respiration may be reduced by simple solutions such as putting 58
 additional padding or pillows behind the user’s head or dis- 59
 pensing with the sponge pads sometimes placed under EEG 60
 electrodes. Caregivers and others should be instructed to take 61
 care not to disturb system components or cables once they are 62
 properly placed. Finally, it may be necessary to eliminate 63
 remaining artifacts (e.g., 60-Hz line noise) with filtering meth- 64
 ods (see chapter 7). Furthermore, in addition to addressing 65
 sources of artifacts, it is important to ensure that the electrical 66
 power in the home is sufficiently stable. In some situations, use 67
 of an uninterruptible power supply (UPS) may be necessary. 68

As each home environment is different, the various sources 69
 of interference must be addressed on a case-by-case basis 70
 (Sellers and Donchin 2006). To be suitable for home use, a BCI 71
 system must be robust enough to avoid or accommodate these 72
 problems. Determination of the extent to which a given system 73
 meets this requirement is one of the key goals of a home study 74
 75

Another important part of situating the BCI in the home is 76
 resolving how the daily data on system operation and other 77
 important data (e.g., periodic copy-spelling sessions for adjust- 78
 ing system parameters and/or measuring accuracy) can be 79
 transferred to the investigators remotely. Ideally, this can be 80
 accomplished in an automated fashion through an internet 81
 link. For example, this transfer may use remote desktop control 82
 (Cohen 2004). GoToMyPC® (Citrix Systems) is a service 83
 that provides secure access to remote sites and was used for 84
 transferring BCI data by Sellers et al. (2010). It supports data 85

1 transfer as well as real-time interaction. A separate license is
2 required for each site.

3 **ENSURING SAFETY AND COMFORT**

4 User safety and comfort and caregiver convenience are
5 extremely important and require close and comprehensive
6 attention. Many years of research and use in intensive care
7 units, operating rooms, and emergency rooms show that long-
8 term EEG use is compatible with ventilator technology
9 (Friedman et al. 2009; Phillips et al. 2010; Tantom 2001). BCI
10 clinical researchers must ensure that BCI presence and use
11 does not affect the functioning of other important medical
12 devices. Prior to home installation, each BCI home system, like
13 all medical equipment, should undergo a formal safety evalua-
14 tion by a hospital electronics support group or similar body.

15 Furthermore, users and caregivers need to understand that
16 BCIs do not substitute for standard monitoring of the BCI user
17 who has compromised pulmonary functions and thus that
18 ventilator alarms and other safeguards must remain in place
19 (Fludger and Klein 2008). In designing a BCI system and its
20 clinical study, it is also important to eliminate to the greatest
21 extent possible the chance that BCI (or user) malfunctions
22 might compromise safety (see chapter 24). For example, stud-
23 ies that enable independent use of environmental controls
24 should ensure that the BCI cannot produce outputs that could
25 endanger the user (e.g., by setting the room temperature too
26 high). All the tasks that the BCI enables should be structured
27 to prevent their creation of safety hazards.

28 For EEG-based studies, there is an extremely small chance
29 of skin abrasion. This risk depends on the particular sensor cap
30 and gel. The Wadsworth Center BCI research group has used
31 the Electro-Cap International™ cap system for 5000+ hours in
32 the lab, has monitored 1000+ hours of its independent home
33 use, and has not encountered a single incident of such abra-
34 sion. Despite this reassuring experience, researchers and care-
35 givers must remain alert to the possibility, and caregivers
36 should make regular scalp inspection part of their normal BCI
37 routine.

38 **TRAINING THE USER AND THE CAREGIVERS**

39 In the course of the initial BCI evaluations and demonstrations
40 of the available applications, the user typically becomes famil-
41 iar with the basic features of BCI use. Nevertheless, to ensure
42 that difficulties do not arise from simple misunderstandings or
43 inadequate orientation, researchers should provide guided
44 practice and well-documented help menus. The more chal-
45 lenging and complex requirement is training the caregiver to
46 support BCI system use. It is essential to have a logical and
47 complete caregiver training protocol. Caregivers must know
48 how to initiate and oversee effective BCI operation. Since fully
49 asynchronous BCIs are not yet available for home use (see
50 chapter 10), the initiation of BCI usage requires substantial
51 neuromuscular function, and thus it involves a caregiver.

52 The caregiver must learn how to: place the electrode cap on
53 the user so that it is comfortable and properly positioned; add
54 electrode gel; turn the BCI system on; check that all electrodes
55 are recording good EEG signals and fix any that are not; initiate
56 system use; monitor BCI operation; turn the system off; remove

the cap and maintain the cap and electrodes in good working
57 order; recognize technical problems or poor performance and
58 request technical support as needed; ensure that data transfer
59 to the research lab occurs as required; and ensure that periodic
60 brief copy-spelling sessions for checking system parameters
61 and/or measuring performance take place. 62

Typically, the caregiver's training will occupy two or three
63 separate 1-hour sessions and will culminate with the investiga-
64 tor simply watching the caregiver go through the entire BCI
65 usage process (i.e., placing the cap and starting the system,
66 overseeing operation, removing and cleaning the cap), as well
67 as the ancillary processes (e.g., data transfer, copy-spelling
68 session). 69

Neither caregivers, users, nor other clinical personnel are
70 likely to be trained researchers. Therefore, all information,
71 even for routine tasks, should be carefully scripted. Each train-
72 ing objective (e.g., cap placement, skin preparation, gel appli-
73 cation, electrode check, etc.) should be demonstrated and then
74 practiced, with training objectives clearly described and profi-
75 ciency for each task tested separately (Gursky and Ryser 2007).
76 For the caregiver, the required objectives may include some
77 that are seemingly obvious but nonetheless crucial (e.g., con-
78 tinuing to devote his or her attention to the user while follow-
79 ing the instructions on the screen). In addition to initiating
80 and stopping the BCI, the caregiver should also be able to
81 pause and resume BCI operation for essential activities (e.g.,
82 tracheal suction for a user who is on a ventilator [C. Wolf, per-
83 sonal communication, 2011]). 84

Figure 20–2B displays a tool used to train the caregiver and
85 to serve as a reminder that electrode impedances must be
86 below an acceptable level prior to starting the BCI system. 87
88 Eight circles representing the electrodes can be red, yellow, or
89 green. Green indicates acceptable impedance. Yellow or red
90 indicates that the electrode needs further attention (e.g., skin
91 preparation, gel). Other screens provide guidance in placing
92 the cap, and testing the connections between the computer and
93 the amplifier and monitor. As a general rule, caregiver training
94 is most likely to be successful when the complexity of the
95 hardware and software are minimized to the greatest extent
96 possible.

97 **PROVIDING ONGOING TECHNICAL SUPPORT 98 AS NEEDED**

99 Once the BCI is placed in the home, and the user and
100 caregiver(s) are adequately trained, independent daily use can
101 begin. Throughout this use, and particularly in the initial weeks
102 and months, the investigators should closely monitor opera-
103 tion remotely and be readily available to resolve any difficulties
104 that arise. This oversight is essential for gathering the basic
105 data of the study and also for maximizing the likelihood that
106 the BCI will come to serve important purposes in the user's
107 daily life. The system will be used only if it works reliably and
108 with minimal difficulty. Thus, it is crucial, particularly in the
109 early days, for the investigators to respond quickly to any
110 problems that arise, and to be prepared to correct them
111 immediately.

112 Many problems may be resolved remotely, through e-mail
113 or phone discussions with the caregiver, analyses of data sent

1 over the Internet, or real-time audiovisual interactions over
2 the Internet. Others may require home visits, and (rarely)
3 replacement of a system component. It is worthwhile, and
4 might be considered a key aspect of a BCI home-use study, to
5 employ a formal system for documenting problems and the
6 time and effort involved in their solution. Such data are impor-
7 tant in assessing the clinical (and ultimately the financial)
8 practicality of the BCI system.

9 To a significant degree, problems may be reduced by care-
10 ful selection of system components and prophylactic measures
11 aimed at ensuring that they function satisfactorily as long as
12 possible. For example, one of the most widely used EEG caps
13 (ElectroCap, Inc.) has been estimated to have an average life
14 span of 450 hours. This corresponds to 450 diagnostic sessions
15 in a clinical EEG laboratory. However, a home BCI system
16 might be used 5 hr/day, 7 days/week, which is 1820 hr/year
17 (Sellers et al. 2010). Thus, several caps are likely to be needed
18 by an individual home user each year. Careful cleaning and
19 regular cap rotation may extend cap and electrode life span
20 and reduce the incidence of poor BCI performance caused by
21 cap or electrode malfunction. Nevertheless, for a person who
22 uses the BCI many hours per day, caps should be routinely
23 replaced or refurbished every few months, rather than simply
24 changed when they fail.

25 As time passes, and the skills and sophistication of the user
26 and caregiver increase, problems are likely to arise less fre-
27 quently. Nevertheless, it is prudent to continue periodic regu-
28 lar home visits, even if at relatively long intervals. During such
29 visits, the user's physical state and environment may be reas-
30 sessed, applications may be added or upgraded as appropriate,
31 and adjustments may be made in the BCI hardware and
32 configuration.

33 **MEASURING THE EXTENT, NATURE, AND** 34 **SUCCESS OF BCI USE**

35 The automated transfer of complete data on BCI system opera-
36 tion should allow full quantification of the extent (i.e., days
37 used, hours/day) and nature (i.e., specific applications) of
38 daily BCI use. The measurement of performance, specifically
39 accuracy, is more problematic because, for most routine usage,
40 the actual intention of the user (i.e., the correct BCI output)
41 is not known with certainty. Periodic brief copy-spelling ses-
42 sions in which the system specifies the correct output are the
43 most straightforward solution. Alternatively, or in addition,
44 appropriate analysis programs (designed with appropriate
45 attention to user privacy concerns (see chapter 24) may detect
46 errors (e.g., spelling mistakes in written text) and calculate
47 accuracies.

48 It is also important to monitor other aspects of the user's
49 state and environment for changes that may greatly affect BCI
50 use. Disturbances such as intercurrent illnesses may interrupt
51 the user's normal routine and can greatly reduce BCI use, at
52 least temporarily. Other problems, such as the temporary
53 absence or permanent departure of the caregiver who supports
54 BCI use, and the need to train a replacement, may also reduce
55 BCI use. Fluctuations or progression in the user's basic disease,
56 particularly for users with ALS, may also affect BCI use. For
57 people with ALS, monitoring of this progression may be

accomplished with the revised ALS functional rating scale 58
(ALSFRS R) which provides a succinct measure of disability 59
(Cedarbaum et al. 1999). In addition to standard monitoring 60
of these specific factors that may affect BCI use, caregivers and 61
investigators should be alert to sudden changes in BCI use that 62
might be caused by changes in the user's physical or mental 63
state or in other factors. 64

65 Finally, periodic questionnaire-based interviews of users,
66 caregivers, and family members are useful ancillary tools for
67 identifying system or procedure modifications that might
68 improve BCI performance or usefulness and/or increase user
69 or caregiver satisfaction and convenience.

70 **DOES THE BCI IMPROVE THE USER'S LIFE?**

71 Certainly, the simplest and most obvious measure of BCI use-
72 fulness is the extent to which it is used. No matter how simple
73 and convenient, BCI use requires significant commitment on
74 the part of both the user and the caregiver. Thus, frequent use
75 is probably a good indicator that the user finds it worthwhile.
76 At the same time, for scientific evaluation, the validation of a
77 home BCI system requires more formal and substantive assess-
78 ment of its impact on the lives of its users and their caregivers,
79 as well as on their family and friends.

80 Recent studies indicate that, despite common assumptions,
81 quality of life (QoL) can be quite good in people with severe
82 motor disabilities (e.g., Kubler et al. 2005b; Nygren and
83 Askmark 2006; Chio et al. 2004; Simmons et al. 2006). Indeed,
84 this finding provides much of the impetus for BCI develop-
85 ment. The measures developed for these QoL studies can also
86 be used to evaluate the impact of BCI use.

87 One of the most important considerations in choosing an
88 assessment instrument is its length. To ensure accurate and
89 complete data collection from individuals who may have diffi-
90 culty communicating, any instrument should be relatively
91 brief. One such instrument is the McGill QoL questionnaire,
92 which was designed for individuals with advanced disease
93 (Cohen et al. 1995; Cohen et al. 1996). It is widely used as the
94 basis for other, more elaborate questionnaires, including the
95 Simmons scale designed specifically for ALS (Simmons et al.
96 2006). The McGill questionnaire consists of 17 questions in
97 two parts. Part A consists of one comprehensive question
98 asking the patient for an overall assessment of his/her quality
99 of life (and is itself capable of providing a basic QoL measure).
100 Part B includes 16 questions that cover physical, psychological,
101 existential, and support domains. Answers are indicated on an
102 11-point Likert scale (0–10). Depending on practicality, addi-
103 tional more complex measures might be used to assess QoL in
104 BCI users with severe disabilities (e.g., Chio et al. 2004; Kubler
105 et al. 2007; Kurt 2007; Lulé et al., 2009; Mautz et al. 2010;
106 Simmons et al. 2006).

107 In addition to the impact on the BCI users, comparable
108 measures are available for evaluating BCI impact on others
109 (e.g., caregivers, family members), as well for evaluating others'
110 perceptions of how the BCI is affecting the user. These instru-
111 ments (e.g., The Psychosocial Impact of Assistive Devices Scale
112 [PIADS] [Derosier and Farber 2005; Giesbrecht et al. 2009;
113 Scherer et al. 2010]) may be administered at the beginning of

1 the study and at intervals of some months thereafter. Positive
2 changes in these measures can constitute important evidence
3 for the practical clinical value of a BCI system.

4 BCI efficacy may also be measured in other ways, such as
5 by its ability to permit reductions in caregiver effort, or to
6 increase the productivity of the user. For example, the inde-
7 pendent communication enabled by present-day P300-based
8 BCIs may free the caregiver from serving as a communication
9 partner (and the user from the need to have a partner), or may
10 even help the user to continue productive employment (e.g.,
11 Sellers et al. 2010).

12 DIFFICULT CHALLENGES IN BCI 13 TRANSLATIONAL STUDIES

14 BCI translational studies confront five difficult challenges that
15 arise from the nature of the user population. First, the users are
16 typically extremely disabled and may have progressive diseases.
17 Their highly compromised physical states, medication regi-
18 mens, frequent intercurrent illnesses, and dependence on often
19 transient caregivers mean that many factors unrelated to the
20 BCI system itself may greatly affect its day-to-day usage and
21 distort the data that quantify that use. Furthermore, for people
22 with progressive disease (e.g., ALS, multiple sclerosis), their
23 overall level of function and their need for and ability to use
24 the BCI may change markedly over the course of the study.
25 This may further complicate the task of assessing BCI impact.
26 In the case of ALS particularly, a substantial number of users
27 may die in the course of a long-term study (Murray 2006).

28 The second issue is that it is extremely difficult or even
29 wholly impractical to conduct large-scale fully controlled stud-
30 ies that compare BCIs to conventional assistive technology.
31 The number of appropriate subjects is limited and the partici-
32 pation of each one requires prolonged effort on the part of the
33 investigators. Thus, studies implemented by a single laboratory
34 will generally have small numbers of subjects. Although coordi-
35 nated multicentered studies are a possible method for study-
36 ing many subjects, they require an expensive and demanding
37 second level of organization and oversight to ensure unifor-
38 mity of subject selection, investigator training, and study execu-
39 tion across the multiple sites involved. Furthermore,
40 controlled studies comparing BCI systems with other assistive
41 technology (e.g., eye-gaze systems) introduce further complex-
42 ity in terms of standardization of methods and uniformity of
43 procedures. One potential response to this problem is a study
44 design in which each subject serves as his or her own control
45 (i.e., uses the BCI for 6 months, then an eye-gaze system or
46 nothing for 6 months, etc.) However, such designs are likely to
47 be difficult to justify ethically (much less implement) in
48 extremely disabled users, and they may be essentially impos-
49 sible in users with progressive disorders such as ALS.

50 The third issue concerns study duration and long-term
51 commitment to the user. In general, formal studies usually
52 specify a time period over which each subject is studied (e.g., 1
53 or 2 years in the case of home BCI use). However, if the BCI is
54 successful, that is, if it substantially improves the user's life,
55 s/he may very understandably want to continue to use it.

Indeed, this is particularly probable for the extremely disabled 56
subjects who are the users of BCI systems now ready for clini- 57
cal testing. Since these BCI systems are relatively inexpensive, 58
simply allowing the user to keep the hardware past the end of 59
the study may not be a major problem. However, the continu- 60
ing need for technical support and supplies (e.g., electrode 61
caps) requires continued funding as well as expertise that may 62
be available only from the laboratory that conducted the study, 63
which means that the laboratory personnel need to be available 64
and able to provide the support. Although this problem will 65
presumably be resolved when BCI systems ultimately become 66
reimbursable medical devices, studies with nonreimbursable 67
systems are currently needed to provide the data that will jus- 68
tify such reimbursement. 69

The issue of commitment is even more complex for sub- 70
jects who have progressive disorders. The BCI may serve them 71
well initially, but as their disease progresses it may become 72
ineffective. The subject, caregivers, or family members may 73
then ask or expect the investigators to modify the system so 74
that it can continue to function effectively. Although the inves- 75
tigators may indeed want to do this, they may lack the requisite 76
resources or expertise. At this point no general solution 77
is apparent for these very difficult situations, and acceptable 78
courses of action must be developed on a case-by-case basis. It 79
behooves the investigators to anticipate these situations as they 80
design BCI studies and to consider how they might respond 81
most effectively (see chapter 24 for further discussion). 82

The fourth issue concerns subjects who may well need a 83
BCI, but who do not qualify for the study or cannot use the 84
BCI system under study. The ad hoc development of new mod- 85
ifications to accommodate a single prospective user (beyond 86
those possible in the existing system or readily implemented, 87
such as covering one eye to prevent diplopia) is likely to divert 88
investigator efforts and resources from the study itself and 89
unlikely to be successful. Furthermore, such modifications 90
may well constitute entirely new research endeavors that 91
require their own IRB reviews and approvals. In general, if a 92
clinical study is to be carried forward to completion and to 93
yield substantive results, the range of possible subject-specific 94
adjustments (e.g., matrix brightness, stimulus rate, etc.) should 95
be defined from the start. Subjects who cannot achieve ade- 96
quate accuracy within this range of adjustments should not be 97
included in the study, painful though it may be to all involved 98
including the investigators. (At the same time, the investigators 99
might still offer substantive help to such individuals as 100
described in chapter 24.) 101

Finally, the need for initial and ongoing technical expertise 102
often prevents the undertaking of BCI clinical studies alto- 103
gether, or limits them to individuals or institutions with sub- 104
stantial resources and very strong commitments to the 105
endeavor. The development of effective translational partner- 106
ships like that undertaken between the BCI research group at 107
the Wadsworth Center and clinicians at the Helen Hayes 108
Rehabilitation Hospital can enable BCI clinical studies. Such 109
partnerships between researchers and clinicians may facilitate 110
and accelerate the translation of BCI systems from the labora- 111
tory to successful long-term home use by those who need 112
them. 113

1 FUTURE IMPROVEMENTS THAT WILL 2 PROMOTE BCI CLINICAL TRANSLATION

3 The practicality and appeal of EEG-based BCI systems for
4 home use should be greatly augmented by the continuing
5 development both of more streamlined hardware and software
6 and of applications that are useful to people with severe dis-
7 abilities (e.g., Cincotti et al. 2008; Münfänger et al. 2010; Sellers
8 et al. 2010). In addition, convenience and comfort can be
9 increased by the development of dry or active electrode sys-
10 tems (e.g., Gargiulo et al. 2010; Popescu et al. 2007; Sellers et al.
11 2009; see also chapter 6). Cosmesis can be improved with more
12 attractive and/or inconspicuous electrode mountings (i.e.,
13 electrode caps that look like ordinary hats or helmets).
14 Although the standard electrode cap with gel application func-
15 tions adequately, gel-free electrodes and more comfortable
16 caps are clearly important to many prospective users. Smaller
17 more robust amplifiers and computers and replacement of
18 wired connections with telemetry should further increase the
19 convenience, cosmesis, portability, and durability of these
20 systems. Decreases in the complexity of the system hardware
21 (e.g., number of electrodes) and software, and increase in
22 reliability, speed, and range of useful applications will also
23 encourage BCI home use.

24 SUMMARY

25 BCIs are fast becoming effective communication and control
26 devices. However, they are still confined almost entirely to the
27 protected environments of a multitude of laboratories through-
28 out the world. This focus leaves a major research gap that must
29 be addressed if BCIs are to fulfill their primary purpose and jus-
30 tify the considerable support their development receives from
31 governments and other funding entities. The BCIs that work well
32 in the laboratory need to be shown to work well in real life and to
33 provide to people with disabilities new communication and
34 capabilities that improve their daily lives. To meet these require-
35 ments, they must be simple to operate, need minimal expert
36 oversight, be usable by people who are extremely disabled, and
37 provide reliable, long-term performance in complex home envi-
38 ronments. Their capacity to satisfy these demanding criteria can
39 only be determined through studies of their long-term perfor-
40 mance in independent daily home use by the people with severe
41 disabilities who constitute their target user population.

42 Once a BCI has proven itself in the laboratory, the transla-
43 tional research that seeks to establish its clinical usefulness
44 must address four questions:

- 45 • Can the BCI be implemented in a form suitable
- 46 for long-term home use?
- 47 • Who needs and can use the BCI?
- 48 • Can her/his home environment support the
- 49 BCI usage and does she/he actually use it?
- 50 • Does the BCI improve his/her life?

This chapter reviews the multiple complex issues involved
in addressing each of these questions. These include: BCI
system robustness, convenience, and portability; subject inclu-
sion criteria; informed consent; the suitability of the home
environment; user and caregiver education and training; user-
specific system configuration and applications; ongoing tech-
nical support; collection of data on amount, type, and success
of BCI usage; complications by intercurrent illness and care-
giver changes; and evaluation of impact on user quality of life.
The chapter also addresses difficult issues particularly relevant
to BCI studies, including disease progression, the practical
limitations on controls and on the size of study populations,
and the issues that may arise when time-limited studies end.

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